Design of an in situ laparoscope lens tip cleaner to ensure clear and constant vision

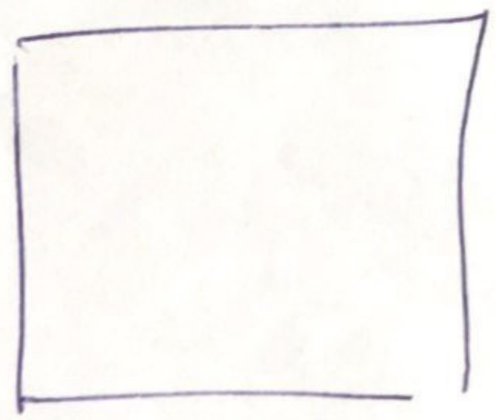
Master thesis appendix , 2019
Sonali Patel

Appendix C

A4 printouts used for interviews.

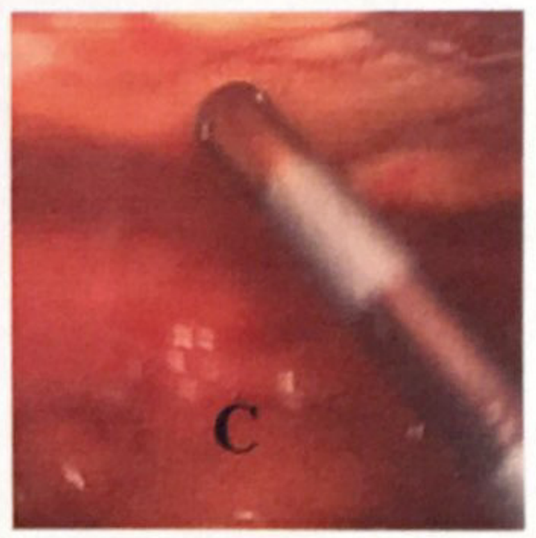
[1] Laparoscopic procedure

[2] Contaminated laparoscope tip

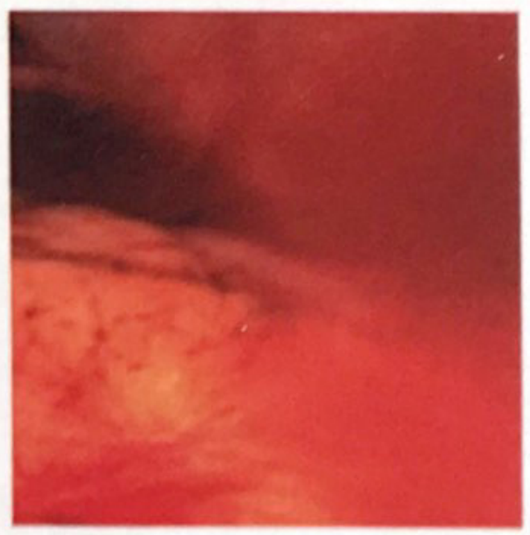


condensation.

Views with contamination:



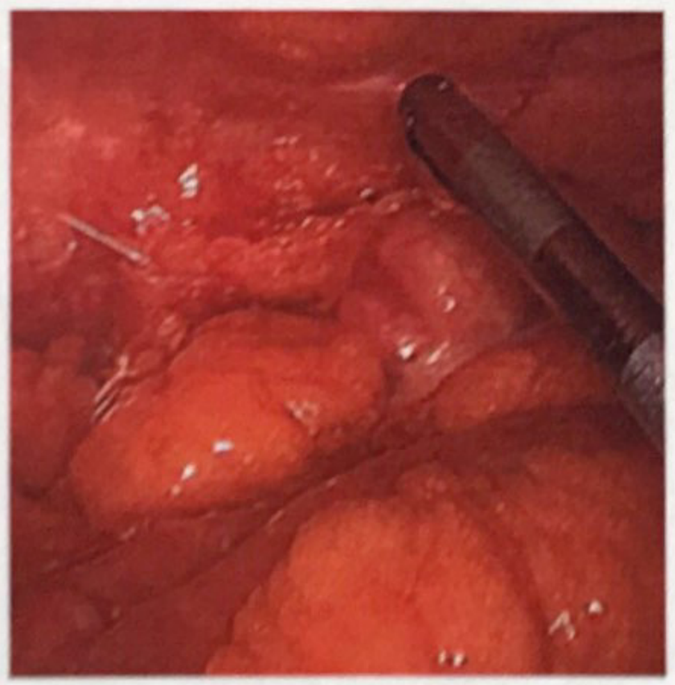
Fogging
[1]



Smudging (fat/tissue)
[2]

View blocked due to blood
[2]

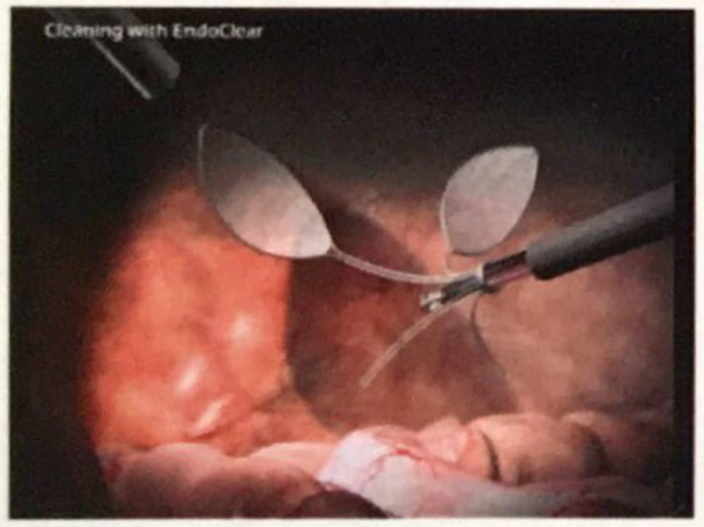
View without contamination:

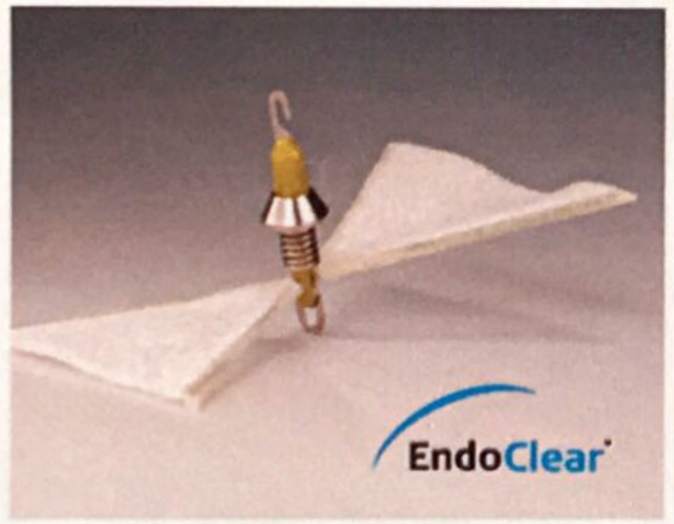


[1]

Defogging solution

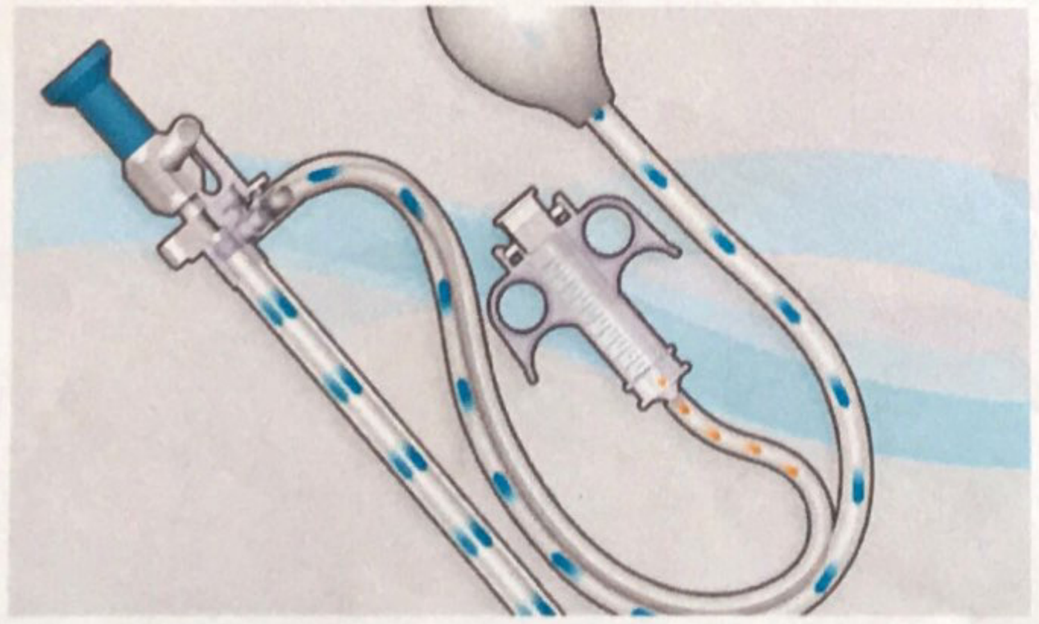
Irrigation based system by Karl Storz -
Clearvision II

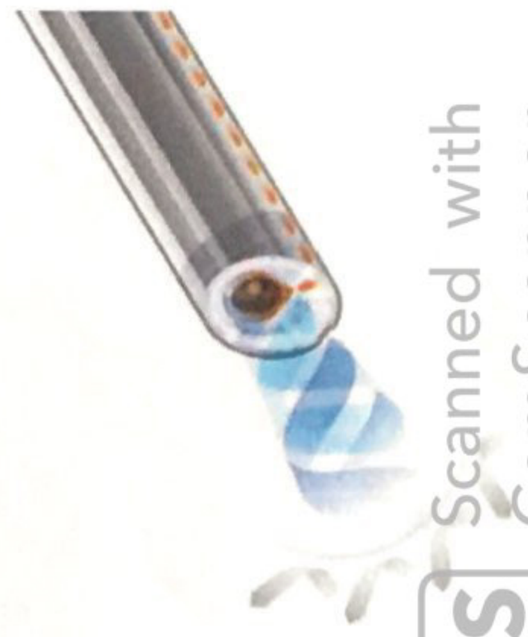




Endoclear

Fluid inflow and irrigation based -Floshield

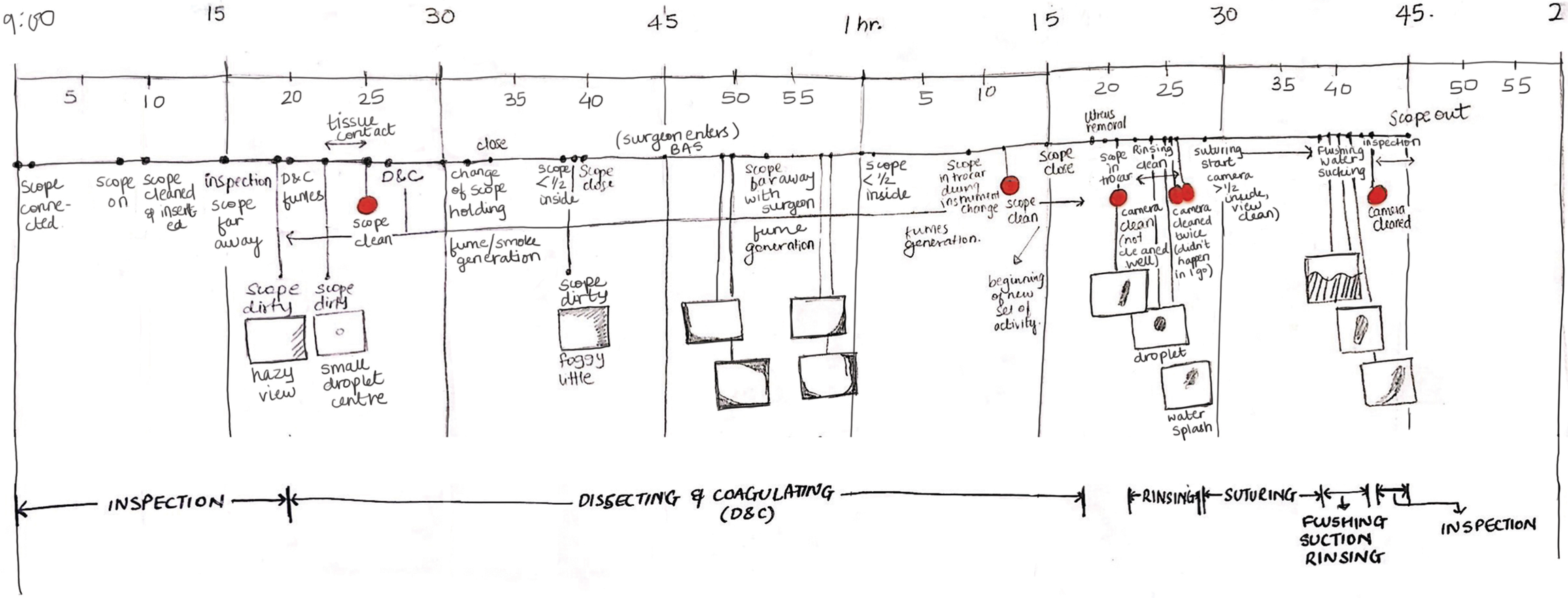




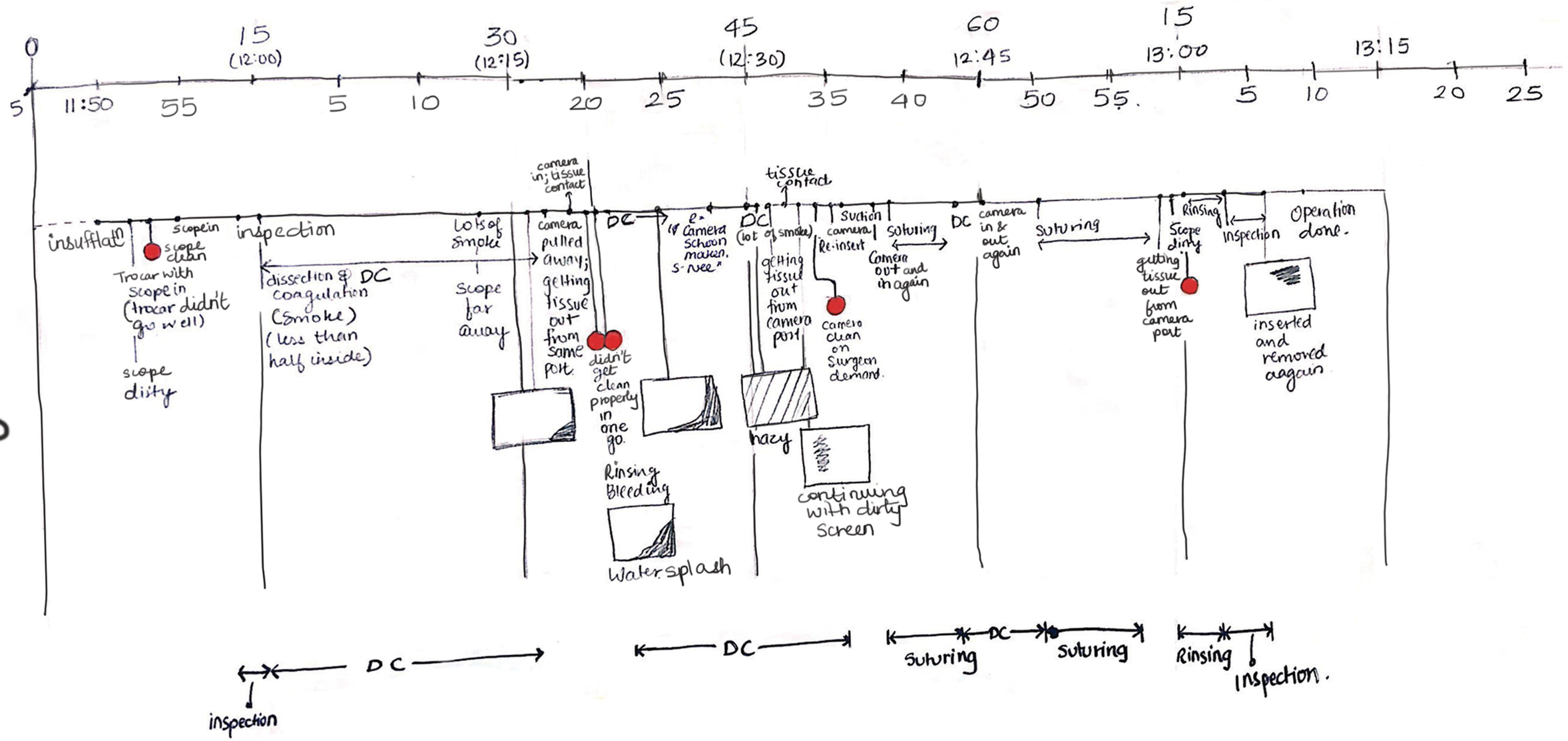
Appendix F

Timelines of the observed surgeries.

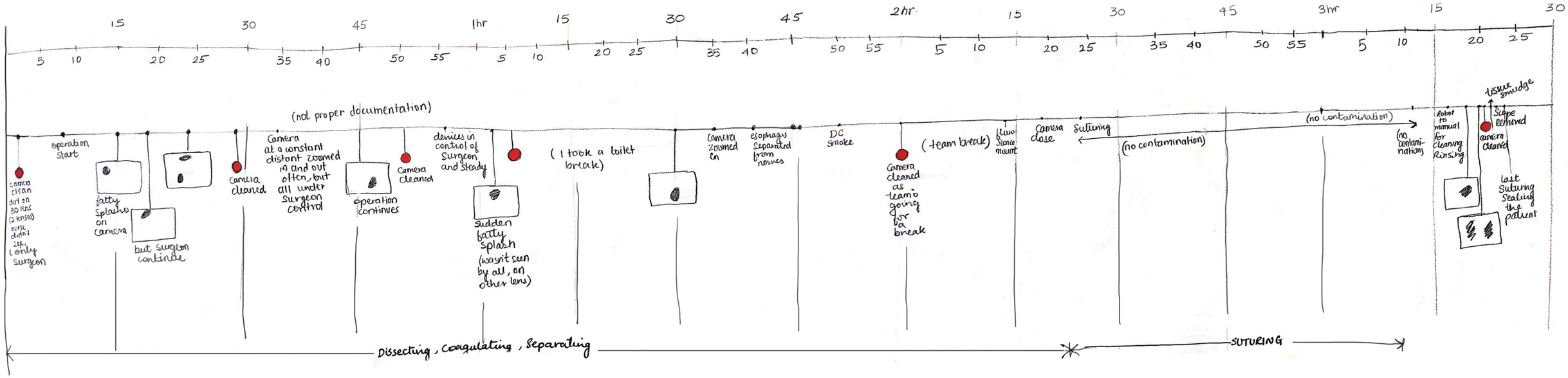
Surgery 1


9:00
15
30
45
1 hr.
15
30
45.
2 hrs.
5
10
20
25
35
40
50
55
5
10
20
25
35
40
50
55
tissue contact
close
(surgeon enters) BAS
Ureus removal
Scope out
scope connected
scope on
scope cleaned & inserted
inspection scope far away
D&C fumes
D&C
scope clean
change of scope holding
scope < ½ inside
Scope close
scope bar away with surgeon
scope < ½ inside
Scope in trocar during instrument change
scope clean
scope close
scope in trocar
Rinsing clean
suturing start
camera > ½ inside, view clean)
Flushing Water sucking
inspection
camera cleared
camera clean (not cleaned well)
camera cleaned twice (didn't happen in 1st go)
scope dirty
scope dirty
hazy view
small droplet centre
fume/smoke generation
scope dirty
foggy little
fume generation
fumes generation.
beginning of new set of activity.
droplet
water splash
INSPECTION
DISSECTING & COAGULATING (D&C)
RINSING
SUTURING
FLUSHING SUCTION RINSING
INSPECTION

Surgery 2


0
15
(12:00)
30
(12:15)
45
(12:30)
60
12:45
15
13:00
13:15
5
11:50
55
5
10
20
25
35
40
50
55
5
10
20
25
insufflation
scope in
scope clean
Trocar with scope in (trocar didn't go well)
scope dirty
inspection
dissection & coagulation (Smoke) (less than half inside)
DC
Lots of smoke
scope far away
camera in; tissue contact
camera pulled away; getting tissue out from same port
didn't get clean properly in one go.
Rinsing
Bleeding
Water splash
DC
"Camera schwein machen, s-vee"
DC
(lot of smoke)
tissue contact
getting tissue out from camera port
camera Re-insert
camera clean on Surgeon demand
Suction
Suturing
Camera out and in again
hazy
continuing with dirty screen
DC
camera in & out again
Suturing
Rinsing
Scope dirty
getting tissue out from camera port
Rinsing
Inspection
Operation done.
inserted and removed again
DC
inspection
DC
DC
Suturing
DC
Suturing
Rinsing
Inspection.

Surgery 3


15
30
45
1hr
15
30
45
2hr
15
30
45
3hr
15
30
5 10 20 25 35 40 50 55 5 10 20 25 35 40 50 55 5 10 20 25
(not proper documentation)
(no contamination)
Tissue smudge
camera clean dirt on 3D lens (2 lenses) nurse didn't see (only surgeon
operation start
fatty splashes on camera
but surgeon continue
camera cleaned
Camera at a constant distant zoomed in and out often, but all under Surgeon control
operation continues
Camera cleaned
devices in control of Surgeon and steady
sudden fatty splash (wasn't seen by all, on other lens)
(I took a toilet break)
Camera zoomed in
esophagus separated from nerves
DC smoke
Camera cleaned as team's going for a break
(team break)
fluo-Scene mount
Camera close
Suturing
(no contamination)
(no contamination)
Robot to manual for cleaning Rinsing
Scope removed
camera cleaned
Last Suturing Sealing the patient
Dissecting, Coagulating, Separating
SUTURING

Appendix G

Collages of images for analyzing laparoscope holding style and its analysis.

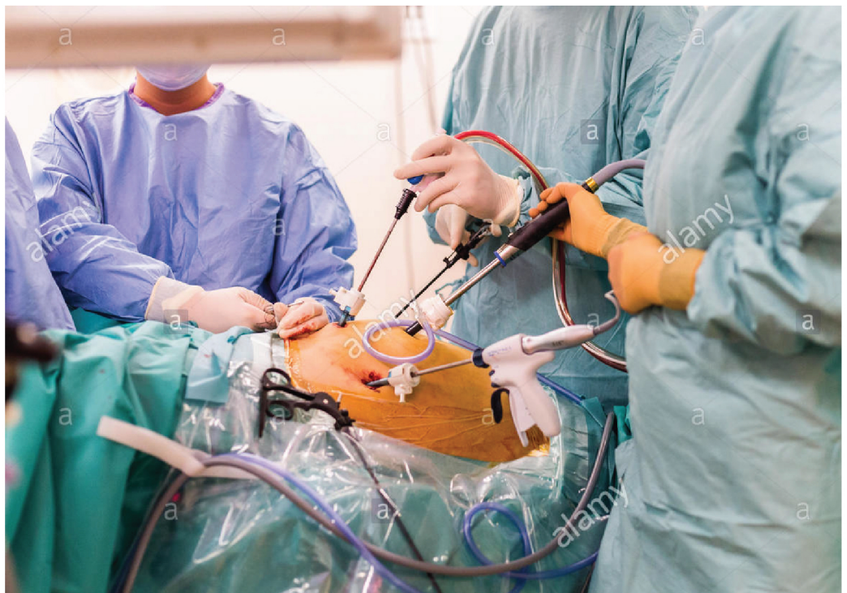
- Hands crossing
- Holding teh scope close to eyepiece
- Around hald working length available

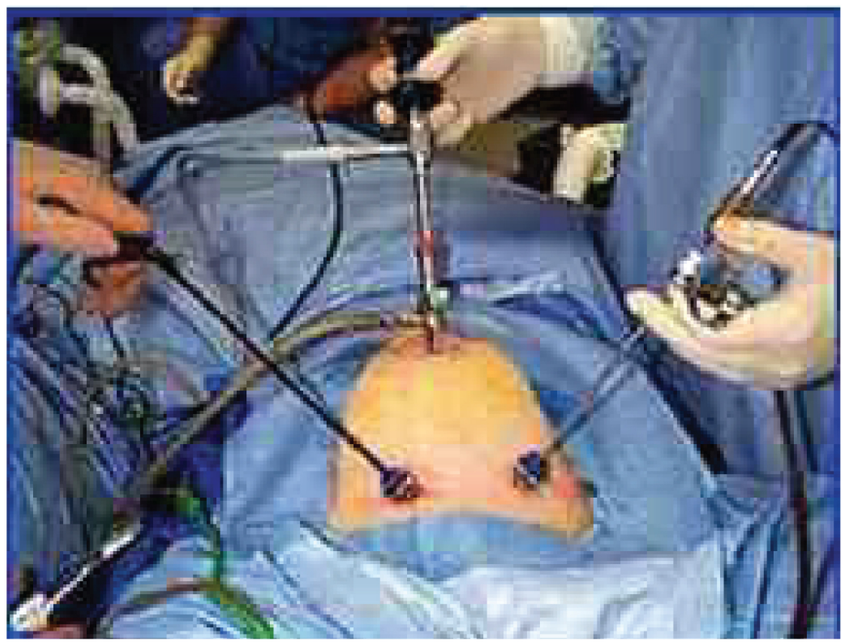
- Light cord present
- Insufflation cord present
- Holding the scope at the back
- Light cable facing the top
- More than half working length available

- Holding the scope with two hands.
- Does not have light cord

- Holding the scope through camera module
- Light cable facing bottom

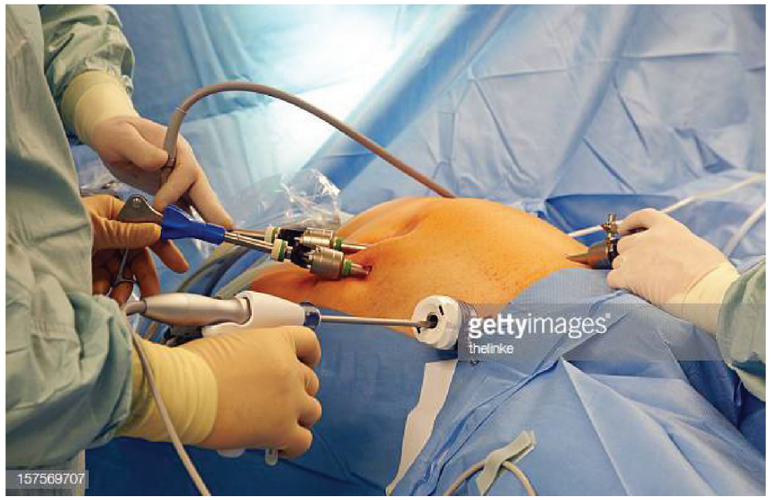
- Looks like endoeye
- Insufflation cord present
- No light cord
- Holding the scope at the end near the cord
- Half working length available





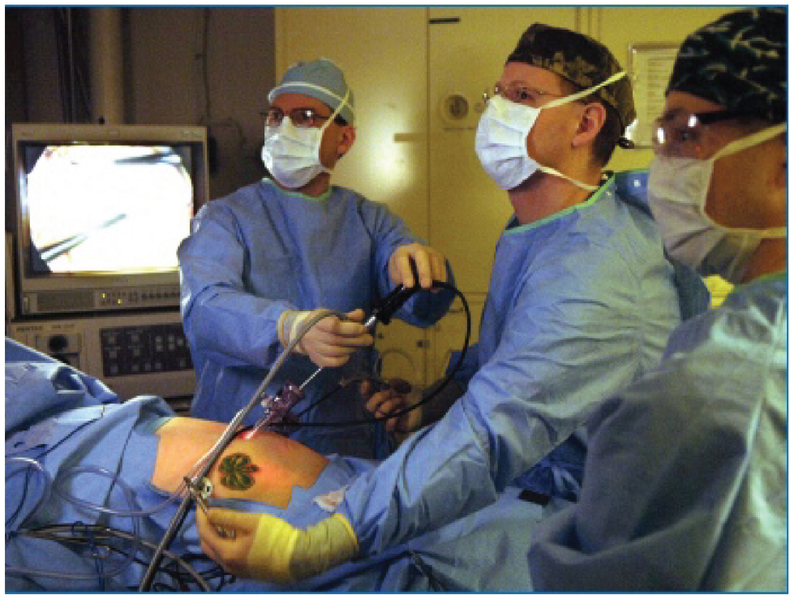
- Different kind of grip
- Insufflation gas tube present
- Light cable facing on side
- Half working length available

- Holding the light cord as well while holding the scope, Light cable facing top
- less than half working length available



-Holding at the camera module through plastic wraps
- around half working length available

- Holding the camera module
- Light cable present facing on the top
- less than half working length available



- Light cord being held with another hand to avoid interference.
- Holding the scope at the back on the camera module

- Holding at the camera module
- More than half working length available
- one port surgery

- Holding the scope at the end with the camera module
- Holding through plastic cover
- More than half working lengthavailable

- Light cable towards side
- Hands crossed and scope being held from the camera cord
- Different grip due the round nature of the camera module

- Light cord facing the top
- scope being held at the camera module and through plastic cover
- Less than half of the scope inside the trocar

- Holding the scope from behind the surgeon
- Holding the light cable with a finger, to not interfere
- different grip of holding as camera module is different.

- Scope being held with two hands
- scope held through plastic cover
- Light cable facing the top
- Around half of the scope inside the trocar.

Appendix H

Ergonomic analysis of the collages.

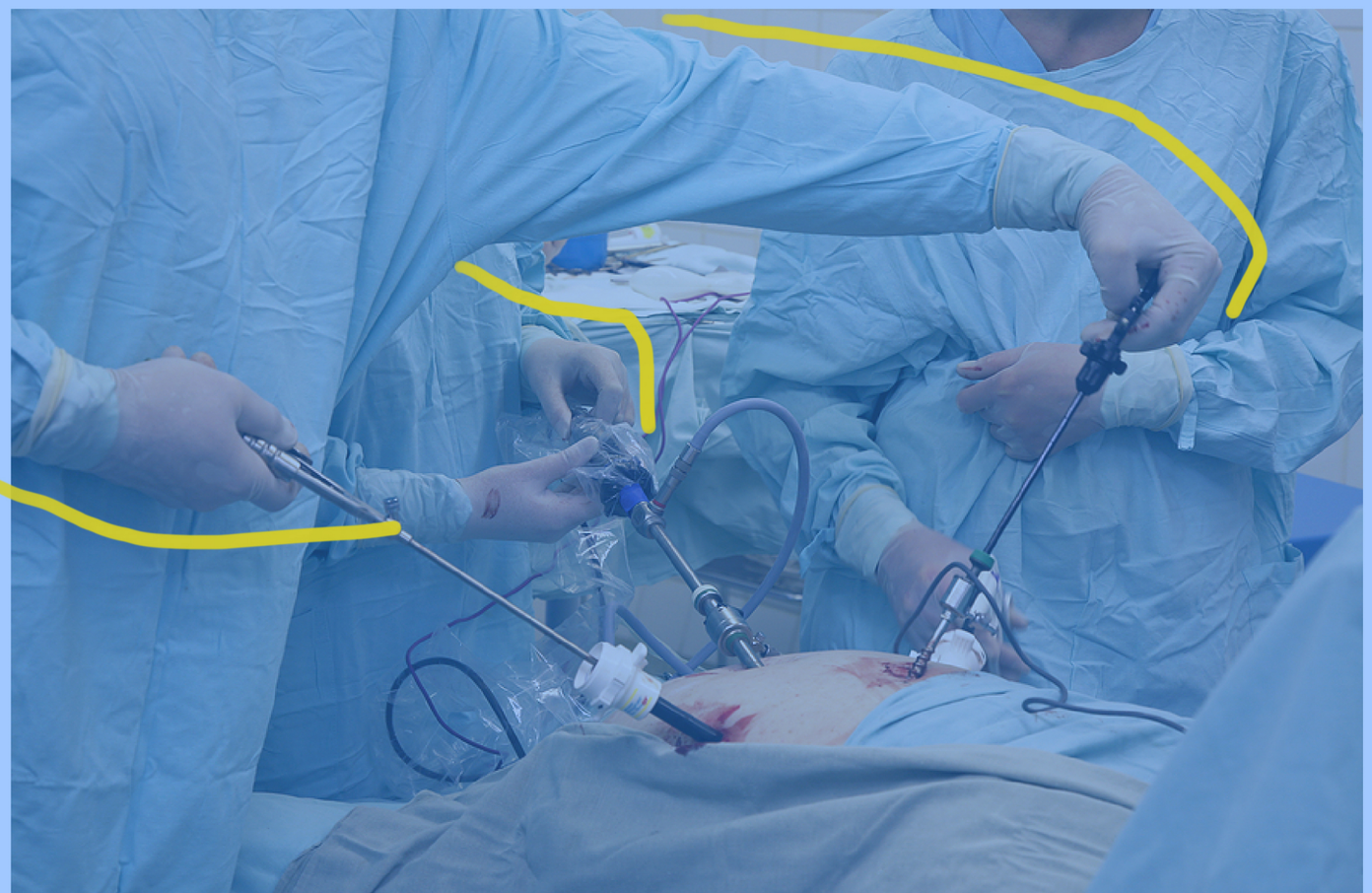
- Holding the scope at the end with the camera module
- Holding through plastic cover
- More than half working lengthavailable

- Light cable towards side
- Hands crossed and scope being held from the camera cord
- Different grip due the round nature of the camera module

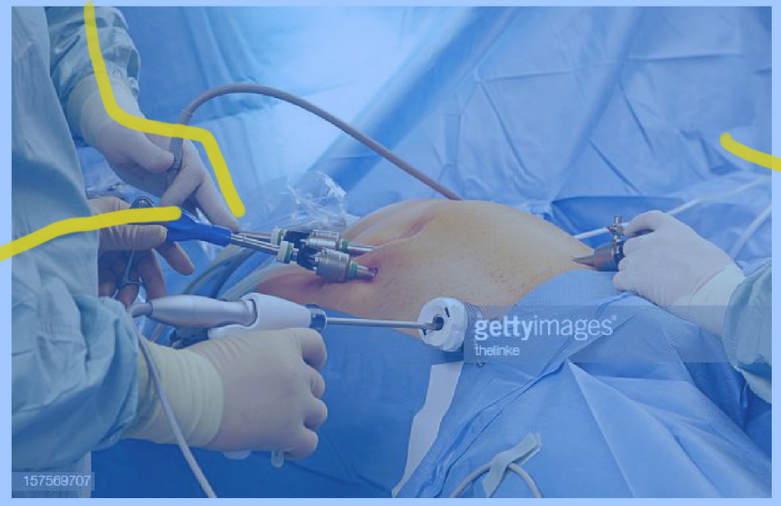
- Light cord facing the top
- scope being held at the camera module and through plastic cover
- Less than half of the scope inside the trocar

- Holding the scope from behind the surgeon
- Holding the light cable with a finger, to not interfere
- different grip of holding as camera module is different.

- Scope being held with two hands
- scope held through plastic cover
- Light cable facing the top
- Around half of the scope inside the trocar.

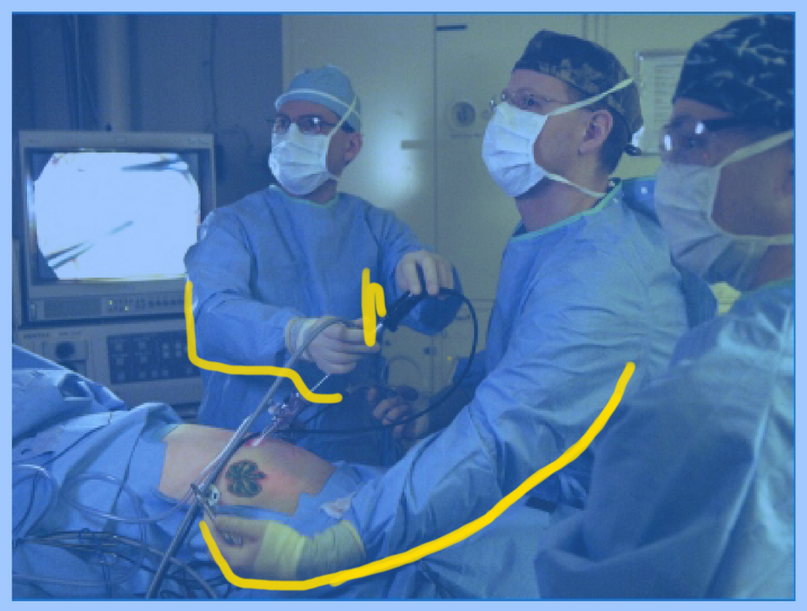


- Holding the light cord as well while holding the scope, Light cable facing top
- less than half working length available



-Holding at the camera module through plastic wraps
- around half working length available

- Holding the camera module
- Light cable present facing on the top
- less than half working length available



- Light cord being held with another hand to avoid interference.
- Holding the scope at the back on the camera module

- Holding at the camera module
- More than half working length available
- one port surgery

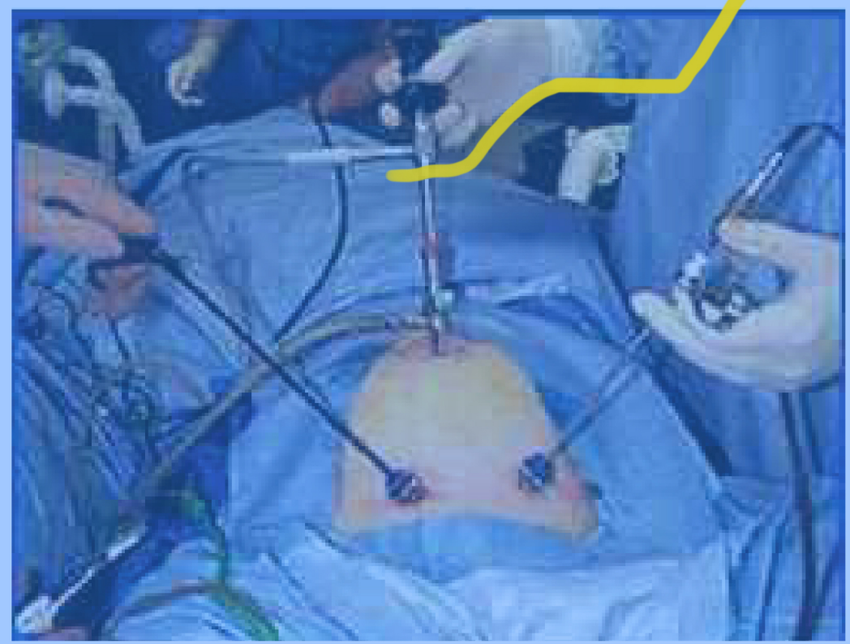
- Hands crossing
- Holding teh scope close to eyepiece
- Around hald working length available

- Light cord present
- Insufflation cord present
- Holding the scope at the back
- Light cable facing the top
- More than half working length available

- Holding the scope with two hands.
- Does not have light cord

- Holding the scope through camera module
- Light cable facing bottom

- Looks like endoeye
- Insufflation cord present
- No light cord
- Holding the scope at the end near the cord
- Half working length available



- Different kind of grip
- Insufflation gas tube present
- Light cable facing on side
- Half working length available

Appendix I

Documentation of existing solutions

Analysis of existing solutions

Companies in the field of laparoscope lens cleaning were recognized from literature and internet and are analyzed for their features, positives, negatives and current news.

Through this exercise, information on previous attempts will be learned. What can be leveraged, what should be avoided and also possible hurdles companies are facing in realizing this technology. As these companies are functioning in the commercial market, they would have patents and hence it is decided to analyze the companies functioning rather than patents filed as there are numerous patents filed with many claims and going through them would not reveal any useful information at this point for the design process. However, analysis of company would provide valuable insights into this device market and how after research and patents, commercializing challenges are realized.

Following are the companies and their products listed for this analysis:

1) Cipher Surgical - OpClear
2) Floshield
3) Instaclear, Olympus
4) Endoscrub, Medtronic
5) ClearCam
6) Advanced laparoscopic care Kit
7) Clearify, medtronic
8) LaparoVue
9) ClearVision, Karl Storz
10) Endopath Excel trocar, Jhonson and Jhonson
11) Endosheath, Cogentix Medical

The information on all companies and their products will be collected. This information will be analysed and categorised into parameters. Then these parameters can be compared across products to deduce insights from.

The factors to keep in mind while collecting information -

- How it works?
- What all is required?
- Sterilizable or disposable?
- Cost?
- Compatible to?
- In situ or outside?
- Contaminants removed

The criteria against which to compare the solutions –

- Power supply required
- Disposables required
- System peripherals
- Effort required to setup
- Cost
- Method of cleaning
- Current status
- Good takeaways and pitfalls

1 Cipher Surgical

Founded: 05/2010
Location: Coventry, England
Website: https://www.ciphersurgical.com/
Operating status: Active
Product name: OpClear
Product image:

Product Information:

OpClear is an in situ solution for removing contamination from the laparoscope lens. It aims to clear the lens of all kinds of contamination such as fogging, soiling from blood, fluid, and smears. The product works on the fluid inflow and irrigation method. The cleaning is done on demand triggered via a footswitch. The lens is washed clean with a combination of Co2 and saline. It defogs without any assistance with its demist function.

The setup of the device as mentioned on the website:
"Position the control unit on or near the visualization stack, connect it to a power supply and attach the gas hose provided to the theatre gas supply or gas bottle. Before use fill a small reservoir on the OpClear® disposable tube with 10ml of saline and attach the sheath to the laparoscope. Then attach OpClear® to the control unit."

The system consists of –

- OpClear disposable sheath and tube set
- OPClear control unit
- Filter
- Saline reservoir
- Footswitch

It is compatible with the majority of rigid laparoscopes and accommodates 0 degree and 30 degrees. On the website, it shows only for 10mm laparoscopes and in various lengths. The sheaths and tubes are disposable, for the rest of the components, it's not mentioned on the website. Cost of the device is unknown as well.

News:
CadmenBoss created the enclosure design for OpClear for Cipher Surgical.
Quoted as said by Andrew Newall, Managing Director of Cipher Surgical
"Andrew also explains why the main competitor to the OpClear® – Floshield has now gone out of business. Cipher Surgical believe this was because the Floshield device didn't work well enough and didn't sell much as a result. This is all good news for Cipher Surgical, who received their safety CE last year and has had positive feedback from surgeons trialling the device."

The first generation OpClear had a CO_2 jet for cleaning the contamination. The second generation has a saline solution to wash away stubborn material and in the third generation, they aim to cater to more sizes of endoscopes.

References:

Revolutionary surgical device sees Science Park company grow | University of Warwick Science Park. (n.d.). Retrieved April 19, 2019, from https://www.warwicksciencepark.co.uk/news/revolutionary-surgical-device-sees-science-park-company-grow/

Case closed: winning enclosure design for hospital devices - Med-Tech Innovation | Latest news for the medical device industry. (n.d.). Retrieved April 19, 2019, from https://www.med-technews.com/med-tech-innovation-expo-news/case-closed-winning-enclosure-design-for-hospital-devices/

OpClear – OpClear. (n.d.). Retrieved April 19, 2019, from https://www.ciphersurgical.com/

Cipher Surgical Competitors, Revenue and Employees - Owler Company Profile. (n.d.). Retrieved April 19, 2019, from https://www.owler.com/company/ciphersurgical

Alternative finance | #CODEInvested success story Cipher Surgical. (n.d.). Retrieved April 19, 2019, from https://www.codeinvesting.com/codeinvested-update-cipher-surgical/

2 Minimally Invasive Devices, Inc.

Founded: 2007
Location: Columbus, Ohio
Operating Status: Active
Website: http://floshield.com/
Product name: FloShield Air and FloShield Plus

Product image:

Product Information:
FloShield is an in situ laparoscope cleaning device to remove debris and contamination on the lens. It is based on fluid inflow and irrigation method for cleaning. The fluid inflow is continuous and uses a part of the insufflation gas. The sheath has microchannels which vary the speed of the flow and thus resulting in a vortex of the gas at the tip. This vortex acts as a barrier for the debris and fogging to happen on the lens. FloShield Air and FloShield Plus are two solutions provided. FloShield Air uses only vortex barrier technology, while FloShield Plus also allows for use of Flo X a biosurfactant to wash the lens off in situ on demand.

It is a fully disposable system. It is compatible with major brands of laparoscopes like Storz, Olympus, Stryker, and Wolf, for 5mm and 10mm laparoscopes, with angles of degrees – 0, 30 and 45. It also provides a solution for robotic surgery (da Vinci).

The system includes –
FloShield Air: sheath, air tube set, trocar vent
FloShield Plus: sheath, tube set, trocar vent and two syringes of Flo-X surfactant.

It doesn't require power as it uses gas from the existing supply. Syringe action is done manually by the operator. They say 2ml liquid would be required for each wash. They also recommend blowing the balloon to give a gush of air to remove adhering liquid or contaminant. The sheath is fixed on the endoscope. The tube set is connected to the insufflation supply. For the devices to work constant supply of CO2 is required throughout the surgery and hence its dependant on it. Its says the following on its website –
"FloShield diverts a portion of the CO_2 gas from the insufflator in order to create the Vortex Barrier at the distal tip of the laparoscope. To maintain a constant fog free and debris free lens, it is critical to provide a consistent nonstop flow of CO_2 gas and this requires the insufflator to be in an "ON" mode throughout the entire surgical case. By

placing the Trocar Vent on a trocar and turning the stopcock on, this will ensure that FloShield's Vortex Barrier Technology will provide visual clarity throughout the entire case."

Floshield Air is said to be 50$.("FloShield-maker Minimally Invasive Devices closes $11.7M Series C round - Columbus Business First," n.d.)

News:
"The company anticipates a full market release of FloShield PLUS including the Flo-X laparoscopic cleaning agent during the first quarter of 2012."("MID (Minimally Invasive Devices) Inc. | Aequitas-Medical," n.d.)

They Claim the following –("Minimally Invasive Devices, Inc. Announces Release of FloShield™ PLUS," n.d.)
FloShield Plus replaces - Anti-fogging solutions, Anti-fog "lens care kits", Heated tubing, Scope warmers, Covidien Crearify TM and Hot water/thermos

FloShield Air & Plus can be used for:
General surgery/Gynaecology/Oncology/Bariatric/Urology/Cardio-thoracic surgery and for transplants.

References :

FloShield | Superior Laparoscopic Vision. (n.d.). Retrieved April 19, 2019, from http://floshield.com/

FloShield-maker Minimally Invasive Devices closes $11.7M Series C round - Columbus Business First. (n.d.). Retrieved April 19, 2019, from https://www.bizjournals.com/columbus/news/2015/03/06/floshield-maker-going-global-as-it-raises-another.html

MID (Minimally Invasive Devices) Inc. | Aequitas-Medical. (n.d.). Retrieved April 19, 2019, from http://www.aequitas-medical.be/en/mid-minimally-invasive-devices-inc

Minimally Invasive Devices, Inc. Announces Release of FloShield™ PLUS. (n.d.). Retrieved April 19, 2019, from https://www.prnewswire.com/news-releases/minimally-invasive-devices-inc-announces-release-of-floshield-plus-132051198.html

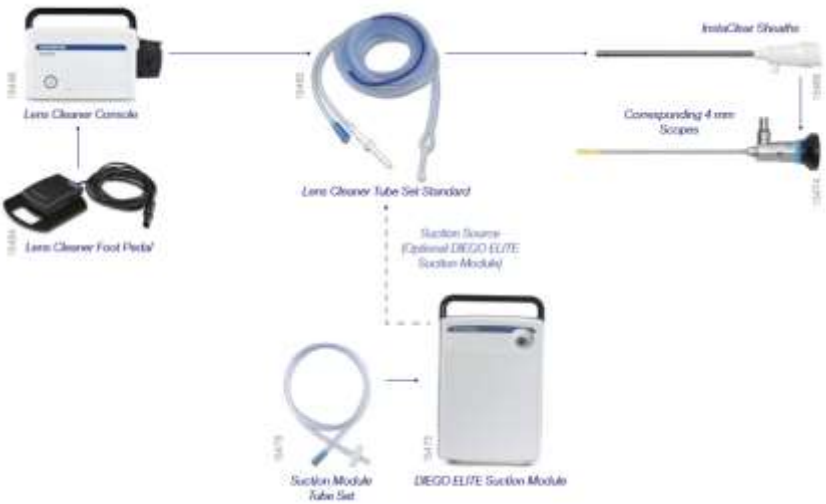
3. Olympus

Founded: 1919
Location: Tokyo
Website: https://www.olympus-europa.com/medical/en/Products-and-Solutions/Products/Product/InstaClear.html
Operating status : Active
Product name: InstaClear

Product image:

Product Information:
InstaClear is an in situ sinuscope cleaning device. So it's used for ear, nose, throat, and neurosurgery. Its uses suction and irrigation as its cleaning method. It is compatible with all the 4mm Olympus Sinuscopes and Storz sinuscopes. And also for various angles. It requires power for its functioning. It is activated via a foot switch.
The system consists of:

- Lens Cleaner Console (the main control unit)
- Lens cleaner foot pedal
- Tube set
- InstaClear Sheaths
- Diego Elite Suction Module
- Suction module tube set



It needs to be set up with a suction module. This suction module also they have recommended. The process to set up the device is: The power cable from the console is plugged in, the foot pedal is attached to the console, the

sheath is put on the endoscope. The tube set is then attached to the sheath. The irrigation and suction are then set up. The system is then ready to use.

News:

This is used in UMC, but only in the ENT department. They used to rely on Endoeye tip heating system which was stopped. And Dr. Helma Grabenstein keeps asking them when will it come back as it helps.

References:

InstaClear Lens Cleaning System - All medical specialities - Olympus Medical Systems. (n.d.). Retrieved April 19, 2019, from https://www.olympus-europa.com/medical/en/Products-and-Solutions/Products/InstaClear-Lens-Cleaning-System.html

4 Medtronic

Founded: 1949
Location: Minneapolis Minnesota
Website: https://www.medtronic.com/us-en/healthcare-professionals/products/ear-nose-throat/sleep-disordered-breathing/inferior-turbinate-blades/related-products.html
Operating status : Active
Product name: Endo Scrub

Product image:

Product information:

Endoscrub is an in situ lens cleaning system for ENT surgeons. It works with irrigation method. It provides high power burst of irrigation to flush out the debris. The EndoScrub system is integrated with their power console system. So it requires power. It is triggered through a foot switch. It says its compatible with broad range of endoscopes and by multiple manufacturers but details are not mentioned. The cost of the product is also not mentioned. No information could be found on its reprocessing methods, setting up procedure, parts required.

It needs it's the console designed my Medtronic as the software of endoscrub works on that. That console manages many other functions. So need for Medtronic compatible devices and instruments is needed.

It requires:

Sheaths, its console and tubing set.

References:

ENT Surgery Products From Medtronic. (n.d.). Retrieved April 19, 2019, from https://www.medtronic.com/us-en/healthcare-professionals/products/ear-nose-throat/powered-ent-instruments/powered-ent-instruments/related-products.html#tab4

5 Medtronic

Founded: 1949
Location: Minneapolis Minnesota
Website: https://www.medtronic.com/us-en/healthcare-professionals/products/ear-nose-throat/sleep-disordered-breathing/inferior-turbinate-blades/related-products.html
Operating status: Active
Product name: Clearify™ Visualization System
Product image:

Product Information:

Clearify is a non in situ solution for cleaning the laparoscope lens. It is essentially a defogging and warming system. Once the laparoscope is inserted in Clearify, it defogs, cleans, protects and maintains the white balance of the scope. the lens. The kit consists of:

- Clearify™ system's hub contains its anti-fogging solution reservoir, white balancer, cleaning pad, and a reducer compatible with all laparoscopes (5 mm to 12 mm)
- Two 6” x 8” x-ray detectable micro pads are included
- The included X-ray detectable Trocar Wipe® has two tips: one for 5 mm trocars, and one for 8-12 mm trocars

The trocar wipe, wipes the debris and fluid which has been pulled in the trocar due to either capillary action or force etc. Many a times soiled trocars are a reason for contaminated lens.

It is a onetime use system and has to be disposed fully. It needs to be activated 5 minutes before the surgery by pressing the On button. It is battery powered. This warms the surfactant liquid to the needed temperature. When all connections are being made, the scope is inserted and kept in to pre heat it. During the operation, Clearify unit is stuck at a convenient place in the sterile field. In the case of contamination, the laparoscope is inserted in Clearify for 5 seconds, after removal its wiped for excess liquid. In the meanwhile, the trocar wipe is used to clean the trocar. And then the cleaned lens is re inserted in the patient.

It accommodates scopes from 5mm up to 12.5 mm. It costs around 35$ a piece. [2]

News:

Clearify was initially D-help a product by NewWave surgical. This was sold to Covidien and the product them became Clearify Visualization system. Covidien was later acquired by Medtronic. [3][4]

References:

[1] Visualization Solutions | Medtronic. (n.d.). Retrieved April 19, 2019, from https://www.medtronic.com/covidien/en-us/products/trocars-access/visualization-solutions.html#clearify-visualization-system

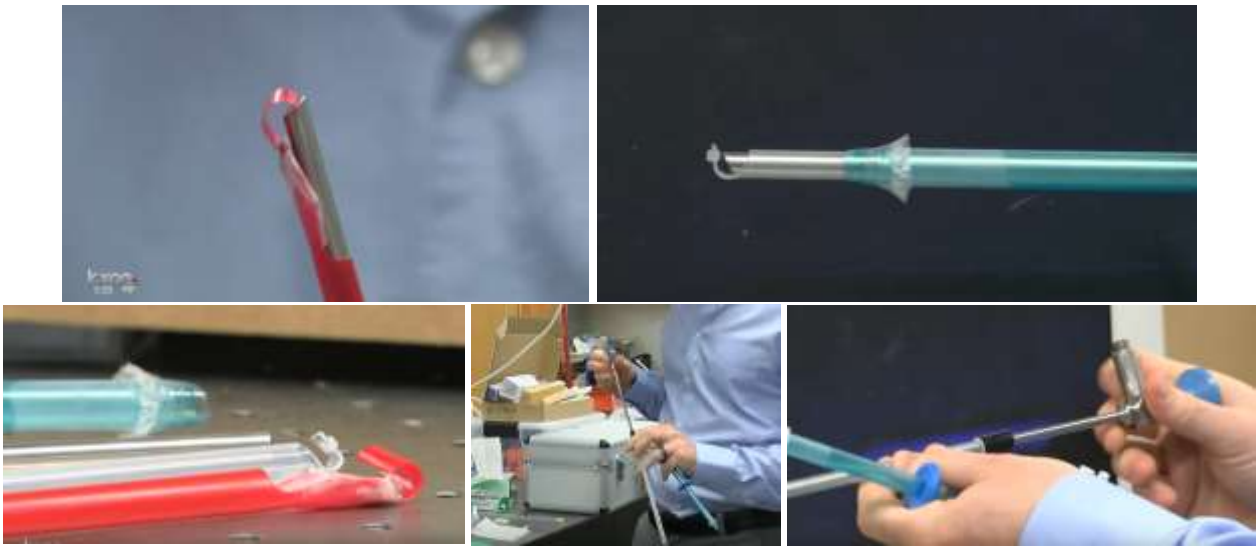
[2] Covidien AutoSuture, 21-345-SD, Covidien Clearify Visualization System (No Box) - eSutures. (n.d.). Retrieved April 19, 2019, from https://www.esutures.com/product/3-short-dated/30-covidien-autosuture/645-accessories/46308338-covidien-clearify-visualization-system-no-box-21-345-SD/

[3] Fast-Growing New Wave Surgical Sold To Covidien. (n.d.). Retrieved April 19, 2019, from https://www.meddeviceonline.com/doc/fast-growing-new-wave-surgical-sold-to-covidien-0001

[4] Press Release | Newsroom | Medtronic | Medtronic to Acquire Covidien for $42.9 billion in Cash and Stock. (n.d.). Retrieved April 19, 2019, from http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004310

6 ClearCam Inc.

Founded: 2018
Location: Southern US
Website: https://www.clearcam-med.com/
Operating status: Active
Product name: ClearCam
Product image:



Product information:

ClearCam is a start-up spin-off from the UT Austin Research group. The solution uses a mechanical wiping method for cleaning the laparoscope lens. The solution is inspired from a simple slurpy straw. They describe the solution as drinking straw with a scoop at the end.

It is a polymer sleeve which goes on the laparoscope. “The ClearCam device’s laparoscope cleaner uses a special geometrically-altered polymer that can be controlled externally to remove unwanted material from the camera’s lens. Surgeons can actuate the cleaner by opening the polymer tip and scraping unwanted materials from the lens, according to the researchers, all without scratching the lens.” [3]

Seems like a disposable sheath. No data on funding, processing, material, working procedure, setup procedure can be found.

News:

A comment on the article shows the exact problem of budding start-ups in these domains focused on a single technology and investors.

“A prime example of the disconnect between the industry and the investing communities. Cleaning scopes during surgery has been around for over 20 yrs and currently, there are product solutions available. However, the issue is the “issue” of scope cleaning during surgery is not major problem w all the robotic applications. The positive takeaway is these young men have learned a lot of excellent experience at a very young age which will help guide them for years.” [3]

Its yet in development with a lot of funding received from various sources. It’s a quite recent development in this field. to come. They have applied for a patent for this technology. Now they are moving towards commercializing the technology.

Here also a typical approach from technology side can be seen. Where research groups are working towards entrepreneurship. So focus always changes from technology after a point to business strategy.

Reference:

[1] ClearCam. (n.d.). Retrieved April 20, 2019, from https://www.clearcam-med.com/

[2] ClearCam | Crunchbase. (n.d.). Retrieved April 20, 2019, from https://www.crunchbase.com/organization/clearcam

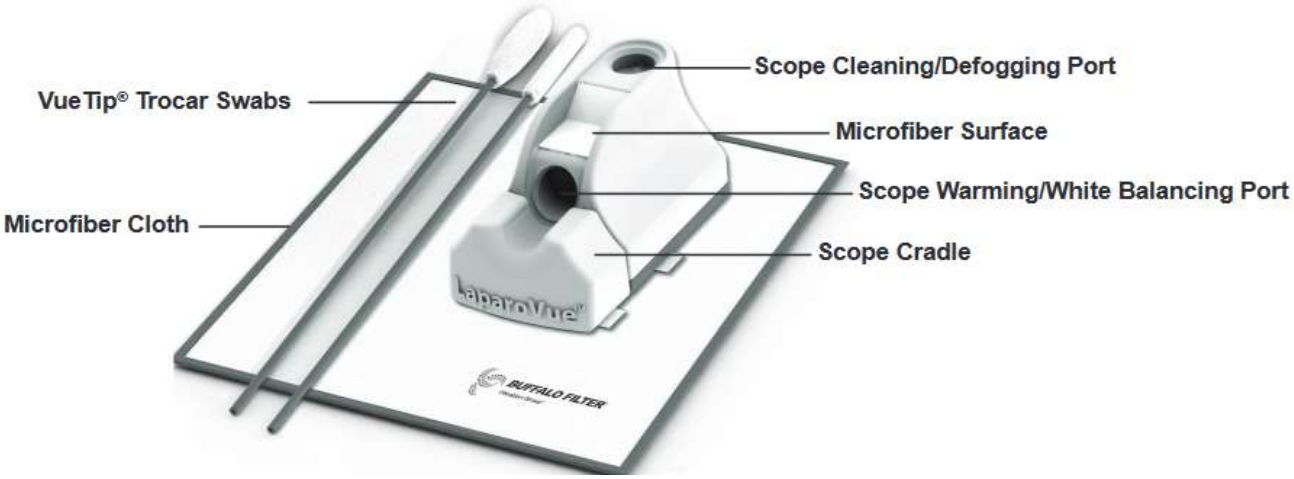
[3] How a Slurpee straw inspired a smudge-free laparoscope | Medical Design and Outsourcing. (n.d.). Retrieved April 20, 2019, from https://www.medicaldesignandoutsourcing.com/how-a-slurpee-straw-inspired-a-smudge-free-laparoscope/#comment-68075

[4] University of Texas at Austin. (2018). *Slurpee Straw Surgery on Vimeo*. Retrieved from https://vimeo.com/277158392

7 Conmed

Founded: 1970
Location: East Coast, Northeastern US
Website: https://www.buffalofilter.com/products/laparoscopic-solutions/laparoscopic-robotic-visibility-solutions/
Operating status: Active
Product name: LaparoVue® Visibility System
Product image:

Product information:
LaparoVue is a not an in situ laparoscope cleaning device. It is based on defogging, and warming method. It aims to clean, defog, warm and white balance the scope during the surgery. It consists of the following components: The microfiber cloth, the trocar wiping swabs, the main unit for inserting the scopes. The main unit has two ports. One port allows for warming/white balancing and other allows for cleaning/defogging. The main unit has a cradle attached in the front which can be detached. It helps to support the scope while its inserted. The whole system can be stuck in a sterile area. It supports a variety of scope dimensions. The system is single use and has to be completely disposed of.



The LaparoVue unit has to be activated by removing the slip sheet at the bottom. This starts the LED lights and starts warming the liquid. The ports can be punctured using the rear end of the Vuetip trocar swabs. The cradle is detached and the unit is ready to use. The scope has to be pre-warmed before the operation.

The cost of the system is not found.

News:

Conmend acquired Buffalo Filter. LaparoVue is an initial product of Buffalo filter.

References:

Buffalo Filter :: Laparoscopic/Robotic Visibility Solutions. (n.d.). Retrieved April 20, 2019, from https://www.buffalofilter.com/products/laparoscopic-solutions/laparoscopic-robotic-visibility-solutions/

CONMED | Crunchbase. (n.d.). Retrieved April 20, 2019, from https://www.crunchbase.com/organization/conmed#section-overview

BUSINESS WIRE. (2019). CONMED Completes Acquisition of Buffalo Filter LLC | Business Wire. Retrieved April 20, 2019, from https://www.businesswire.com/news/home/20190211005585/en/CONMED-Completes-Acquisition-Buffalo-Filter-LLC

8 Karl Storz

Founded: 1975
Location: Europe
Website: https://www.karlstorz.com/nl/en/index.htm?target=
Operating status: Active
Product name: Clearvision II
Product image:

Product Information:
Clearvision II is an in situ lens cleaning device. It is based on suction and irrigation method. It aims to remove all kinds of debris from the lens such as blood, tissue residue through pulsative rinsing. It is activated via a foot pedal. When the pedal is released a negative function is performed resulting negative pressure and thus remaining liquid in sheaths is extracted. It aims to have no intervention cleaning. When the pedal is pressed halfway spurts of rinsing fluid comes out as long as the pedal is pressed. When its fully pressed, continuous rinsing is activated.
The system comprises:

- The main unit having the pump function
- A foot pedal
- irrigation sheaths.
- Tube set
- Holder to hold it on the scopoe

They say the sheaths are reusable. It required a specific holder to assemble on the scope.

On eBay, the Clearvision set costs 4499.99$. It is compatible with the Hopkins telescope, which is Karl Storz's own telescope. It can aacomodate 2.7mm to 4mm diameter and various angles of the scope.

News:

No specific updates can be found.

References:

Welcome to the world of endoscopy | KARL STORZ Endoskope | Netherlands. (n.d.). Retrieved April 21, 2019, from https://www.karlstorz.com/nl/en/index.htm?target=

Karl Storz | Crunchbase. (n.d.). Retrieved April 21, 2019, from https://www.crunchbase.com/organization/karl-storz

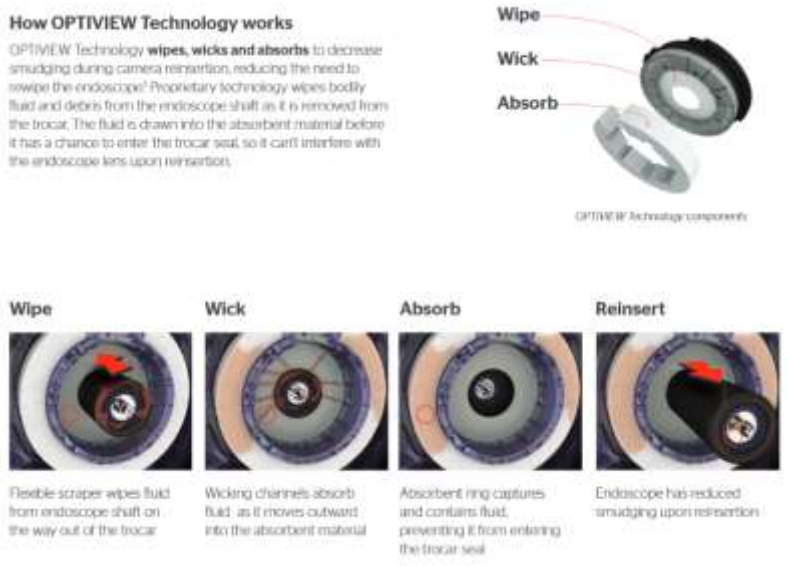
Karl Storz 40334101 ClearVision II Set for sale online | eBay. (n.d.). Retrieved April 21, 2019, from https://www.ebay.com/p/Karl-Storz-40334101-ClearVision-II-Set/599830549

9 Ethicon by Johnson & johnson

Founded: 1886
Location: US
Website: https://www.ethicon.com/na/products/access/trocars/endopath-xcel-trocars-optiview-technology
Operating status: Active
Product name: Endopath Xcel Trocar
Product image:

Product Information:

Endopath excel trocar is a semi in situ solution to prevent the scope from re-soiling upon insertion back into the patient. The body of the scope gets dirty along with the lens. When pulling the scope out of the trocar to clean it, this contamination then gets applied in the interior of the trocar. While putting the clean scope in, the soiling from the trocar re applies on the scope. This solution uses an Optiview technology to avoid this.



This technology wipes, wicks and absorbs the soiling when the scope is being taken out. It is compatible for 5mm,8mm, 11mm and 12mm scopes. No information can be found on its cost and reprocessing methods. The cleaning of the lens has to be still done with traditional wiping methods. However, this Optiview technology gives some positive insights on removal of debris on the body which also lead to contamination of lens.

News:

No current relevant news can be found.

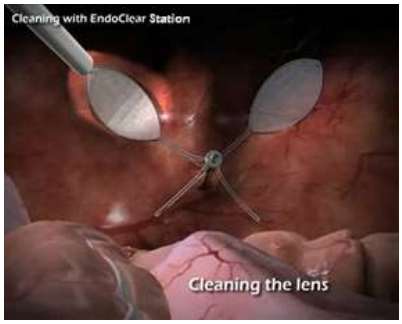
References:

Johnson & Johnson | Crunchbase. (n.d.). Retrieved April 21, 2019, from https://www.crunchbase.com/organization/johnson-johnson#section-overview

ENDOPATH XCEL® Trocars with OPTIVIEW® Technology | Ethicon. (n.d.). Retrieved April 21, 2019, from https://www.ethicon.com/na/products/access/trocars/endopath-xcel-trocars-optiview-technology

10 Virtual Ports

Founded: 2006
Location: Israel
Website: http://www.virtual-ports.com/endoclear.asp
Operating status: Active
Product name: EndoClear
Product image:

Product information:
EndoClear is an in situ laparoscope lens cleaning solution. It uses brushing and wiping as the method for cleaning. It is a stand-alone product which can be anchored using a MicroAnchoring™ Technology in the abdominal cavity. When the laparoscope lens becomes contaminated the surgeon can wipe the lens over the fan like material.
It is a disposable system.
Information on cost price, usage and procedure could not be found.

News: No specific news can be found.

References:

Virtual Ports. (n.d.). Retrieved April 22, 2019, from http://www.virtual-ports.com/endoclear.asp

Virtual Ports | Crunchbase. (n.d.). Retrieved April 22, 2019, from https://www.crunchbase.com/organization/virtual-ports

Appendix L

Discussion with Assi. Prof. Murali Ghatkesar

Discussion

Name: Murali Ghatkesar

Position: Assistant Professor Micro and Nano engineering

Department: 3ME

Place: 3ME, TU Delft

Time: 12:00

Date: 29-04-2019

Aim: The aim of this discussion was to gain more understanding on the material technology; Whether its possible to fabricate it, is it viable for my application, for me to understand if I am going the right way and is it wise to pursue it ahead or I should start looking at something else. Decision check early on in the design process.

Summary:

I gave a brief background of myself and my project and approach of material driven for solving this problem. I showed the two shortlisted research papers on hydrophobic materials. Out of the two he said the one on "Optically transparent super-hydrophobic thin film fabricated by reusable polyurethane-acrylate (PUA) mold" was the closest to my application and need.

There are two ways of a surface becoming hydrophobic, chemical alteration or physical alteration of the surface. Chemical approach is effective, fast but not so robust and physical alterations are slow to achieve but robust for use. Hence the physical approach is to have a surface with nano structures which can hold the molecule of the liquid and not let it touch the underlying surface.

These nanostructures should be capable of holding the molecules with the lowest surface tension. In this way it can already tackle molecules of higher surface tension. Also these structures should be smaller than the wavelength of visible light for refraction to not happen from the optical fibres.

To create such nano structures, he suggested to grow an artificial diamond on a wafer. TU delft has these facilities. This diamond wafers could help achieve the required nano structures. Once this mould is ready, then the process mentioned in the research paper can be followed, by using PDSM layer over the diamond wafer to create negatives of its nano structures. When separated, thin film could be achieved.

Theoretically he says from physics point of view this is possible for the application I have, however it has to be proved. The real challenge is having not only hydrophobic but also oleo phobic at the same time.

Some basic numbers will be initially needed which are:

- All the possible diameters to cater
- Working length
- Temperature of the tip
- Transparency

The facilities to create such a material is available at 3ME. However, since I am not from this faculty, I will have to undergo training, give my prototyping protocol, take lab manager's permission and also

issues could arise about the IP of such a result, as I would be using their resources, lab, consumables and guidance.

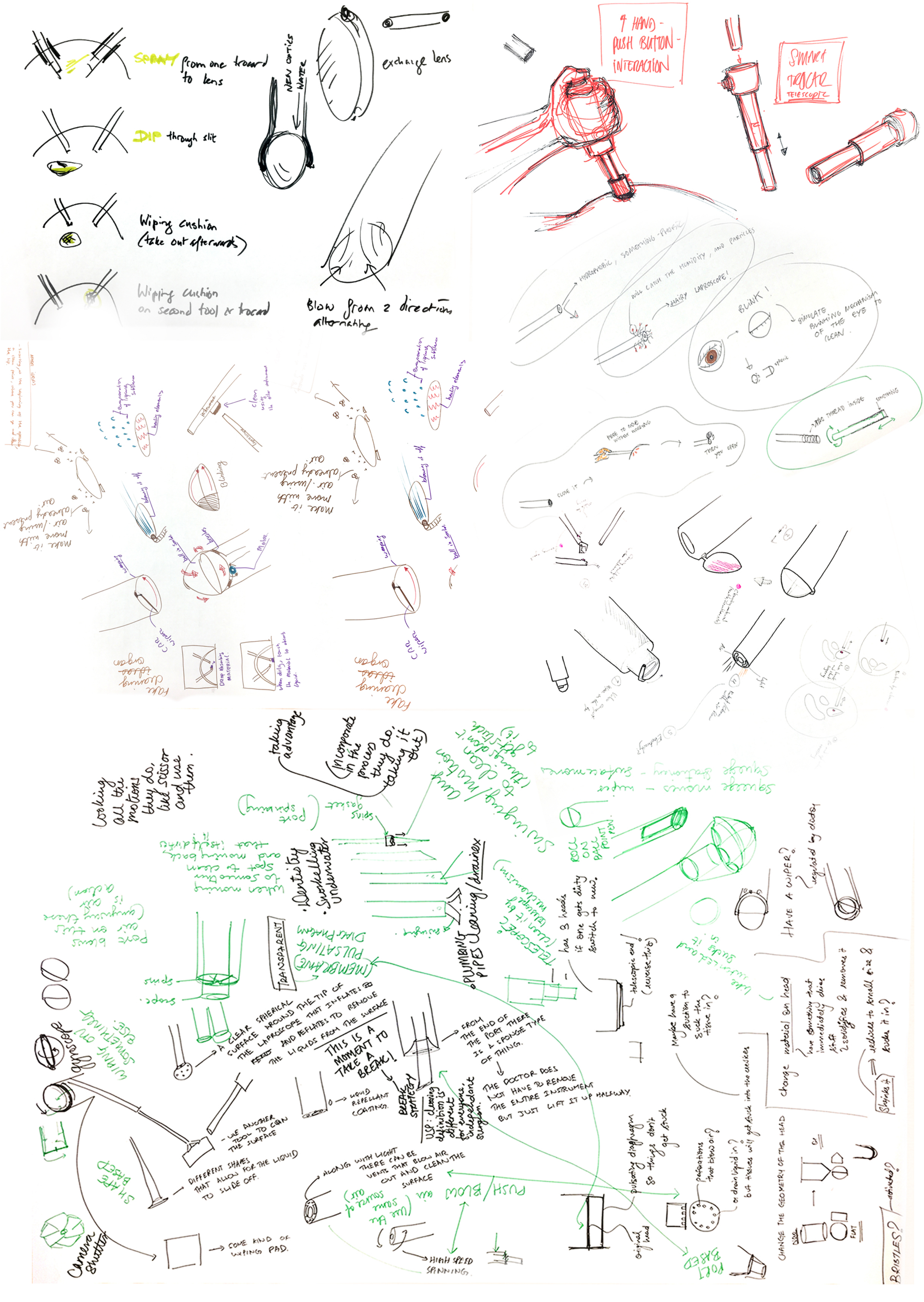
Conclusion:

This path encompasses a whole research question in the field of material science. At this moment to dive deeper in this is not possible. Such a material would definitely have huge benefits. However, even if such a material is possible to get, then there would be problems which could arise by liquid clinging to the sides, or not enough gravity of the liquid to roll of etc. So these aspects need to be kept in mind if this path is chosen.

For now, there are various ways to go ahead. Considering this material as ideal I can see how much I can deflect from the ideal solutions but yet create something viable. May be this level of hydrophobicity is not needed for the current application. May be less level of hydrophobicity can get the work done.

Appendix M

Results of ideation session



SPRAY from one trocard to lens
DIP through slit
Wiping cushion (take out afterwards)
Wiping cushion on second tool or trocard
NEW OPTICS
WATER
exchange lens
Blow from 2 directions alternating
4 HAND - PUSH BUTTON - INTERACTION
SMART TROCAR TELESCOPE
HYDROPHOBIC, SOMETHING - PHOBIC
WILL CATCH THE HUMIDITY, AND PARTICLES
HAIRY LAPROSCOPE!
BLINK!
SIMULATE BLINKING MECHANISM OF THE EYE TO CLEAN.
THREAD INSIDE
Blinking
Make it more with air/using present air
Fake cleaning organ
ROLL ON BALL POINT
HAVE A WIPER?
Looking all the motions they do, like scissor and use them.
taking advantage
(incorporate in the process they do, taking it out)
Identity · Snorkelling Underwater
PLUMBING PIPES cleaning/drainex
TRANSPARENT
PULSATING (MEMBRANE) DIAPHRAGM
TELESCOPE
has 3 heads if one gets dirty switch to new.
telescopic end (reverse this)
A CLEAR SPHERICAL SURFACE AROUND THE TIP OF THE LAPROSCOPE THAT INFLATES AND DEFLATES TO REMOVE THE LIQUIDS FROM THE SURFACE
THIS IS A MOMENT TO TAKE A BREAK!
FROM THE END OF THE PORT THERE IS A SPONGE TYPE OF THING.
THE DOCTOR DOES NOT HAVE TO REMOVE THE ENTIRE INSTRUMENT BUT JUST LIFT IT UP HALFWAY.
LIQUID REPELLANT COATING.
BREAK STRATEGY
USP: cleaning definition is different for everyone, independent surgeon.
USE ANOTHER TOOL TO CLEAN THE SURFACE
DIFFERENT SHAPES THAT ALLOW FOR THE LIQUID TO SLIDE OFF.
ALONG WITH LIGHT THERE CAN BE VENTS THAT BLOW AIR OUT AND CLEAN THE SURFACE
PUSH/BLOW air
HIGH SPEED SPINNING.
SOME KIND OF WIPING PAD.
SHAPE BASED
Camera Shutter
gyroscope
PORT BASED
pulsating diaphragm so things don't get stuck
original head
Maybe have a suction to suck the tissue in?
change material on head
CHANGE THE GEOMETRY OF THE HEAD
BRISTLES?

Appendix N

Tests of ClearX hydrophobic screen protector

TEST

Aim

The aim of this test is to check the capability of Clearex Hydrophobic screen protectors. Through this test following question will be explored:

How well it can repel the impurities and what are the factors surrounding it?

Material

Following material was used in the test setup:

1) 10mm Karl Storz scope 0°
2) 10 mm Karl Storx scope 30°
3) ClearX GoPro Hydrophobic screen protector (Fig. 1)
4) 2 Smartphones - one to capture the view from the laparoscope and another to capture the view at the tip of the scope.
5) Foam holder for scope and smartphone (Fig. 2)
6) A vision checking chart (Fig. 3)
7) A container eg. Beaker or plate
8) Syringe
9) Dropper
10) Water
11) Fake blood

Fig. 1 Clear X GoPro Hydrophobic screen protector

Fig. 2 Foam holder for laparoscope and smartphone, to capture the view from the laparoscope.

Fig. 3 Vision checking chart

Setup

Figures 4a and 4b below show the setup of the tests with 0° and 30° laparoscopes. In each of the test, the laparoscope was fixed in the foam holder. The smartphone had been attached to the foam holder in such a way that the lens of the camera and the eyepiece of the laparoscope aligns to provide a clear view captured by the laparoscope. This setup was further supported with a stand to keep it steady and straight. The vision checking chart was fixed in front of the scope. Figures 5a and 5b show the view captured by the smartphone in the 0° and 30° setups respectively. Another smartphone was placed perpendicular to the setup so as to capture the view at the tip of the scope. This view is shown in figure 6. A container was placed below the tip of the scope to hold the flowing liquid.

Fig. 4a Setup for 0° laparoscope

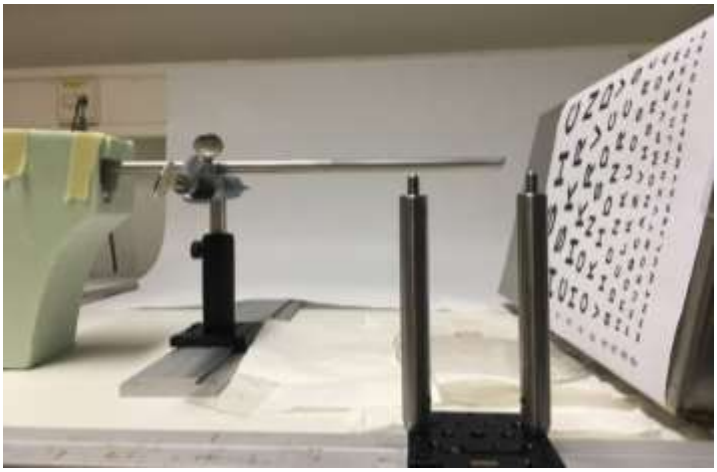


Fig. 4b Setup for 30° laparoscope

Fig. 5a View from the smartphone (0°)

Fig. 5b View from the smartphone (30°)

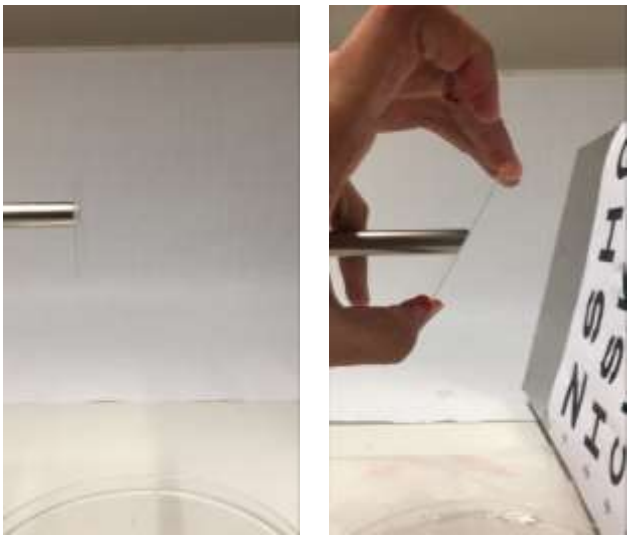


Fig. 6 View from the other smartphone; capturing the activity at the tip of the laparoscope

Method

ClearX Hydrophobic screen protector was held at the tip of the scope. It couldn't be stuck to the tip as the surface area was large and also couldn't be cut into a smaller piece as it cracked since it is glass. So the entire piece was held at the tip as shown in figure 7.

Fig. 7 Holding the protector at the tip

Both the smartphones were set on video recording. The syringe was loaded with water. The water was slowly sprayed on the hydrophobic screen protector from various directions. Later, a dropper was loaded with fake blood and it was applied on the screen from various directions. These two experiments were carried out with 0° and 30° scopes. Figure 8 shows this process.

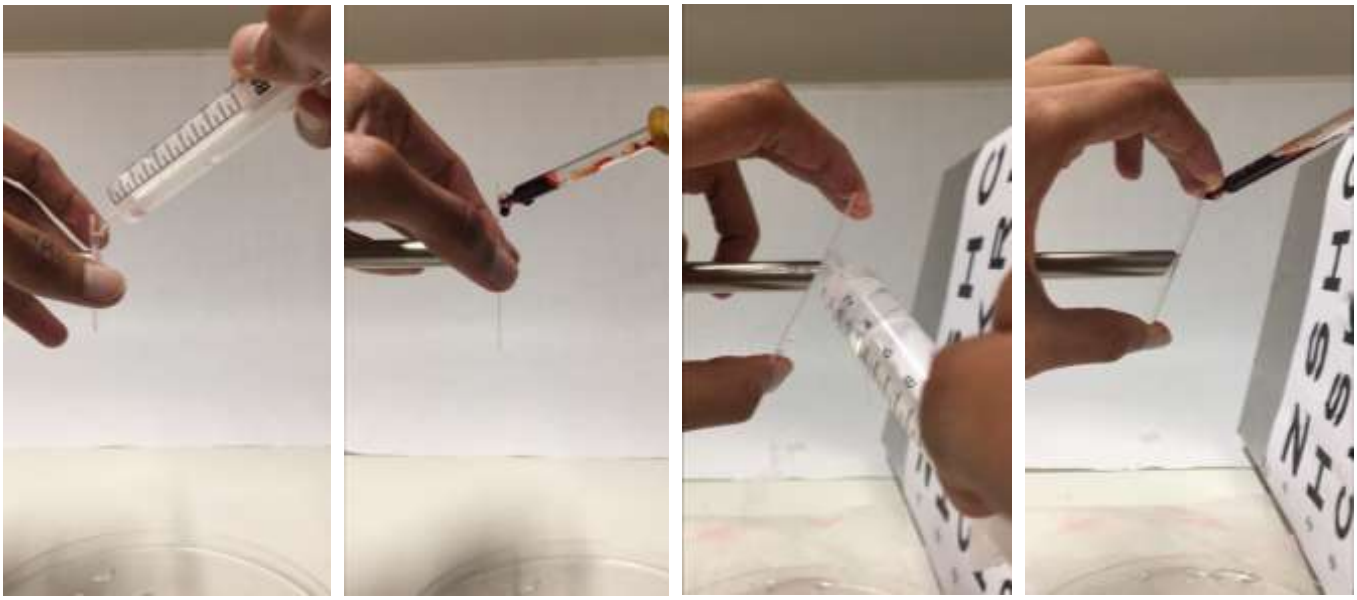


Fig. 8 Water and blood being sprayed on the hydrophobic screen protector at 0° and 30°

Results

The recorded videos were analyzed simultaneously to come down to conclusions.

Fig.9 Droplets on the screen

Fig. 10 Wiping the surface

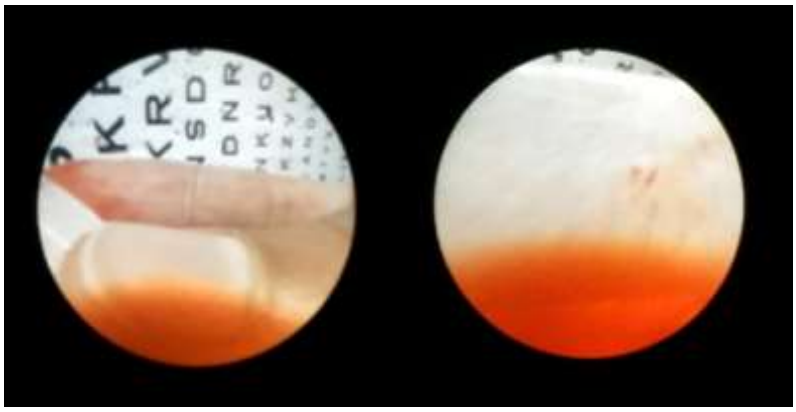


Fig. 11 After wiping the laparoscope lens directly

Following results are obtained after analyzing the videos.

1) When the liquid comes with force, it is repelled by the hydrophobic surface completely. However, when the incoming liquid does not have its own force, the droplets remain on the surface (fig. 9). These droplets are however round in nature, in other words, greater contact angle (fig. 12). Hence it does not completely adhere to the surface of the hydrophobic protector.
2) When a light wipe is given with a sponge sheet on the surface of the hydrophobic protector. The adhering small droplets immediately cling to the sponge and dislodge themselves from the hydrophobic surface (fig. 10).
3) When the liquid is directly applied to the lens tip of the laparoscope, the droplets adhere strongly to the surface (fig.11). Upon wiping using the sponge sheet, the liquid instead of coming off from the surface continues to spread on the surface of the lens (the contact angle decreases further) (fig. 12)

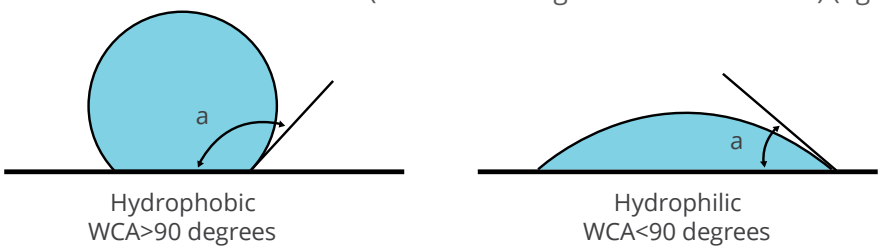


Fig. 12 Water contact angles determining the nature of the surface.

Conclusions

1) The ClearX hydrophobic protector is not completely repellent as small droplets remain on the surface.
2) The ClearX protector eases the wiping process to a great extent as it does not allow the liquid to spread and the droplets continue to remain in round form.
3) This hydrophobic screen protector has to be checked for its biocompatibility. However, a similar protector for medical purposes can be developed.
4) In the future, when such material will have more hydrophobic capabilities, it could be a self-sufficient solution. As it cannot be fully repellent currently, it will have to be augmented with a wiping method in order to achieve a clean surface.

Appendix O

Sketches - ideation round 2

NV1

STORAGE TAPE

PASSING MOVING TAPE

INTERACTION

MECHANICS (easy)

TIP

TEMPERATURE RESIST.

PASSING THROUGH TRICAR

CREASING

FRICTION

DIRTY TAPE SCRAPING BACK

TROCAR ISSUES

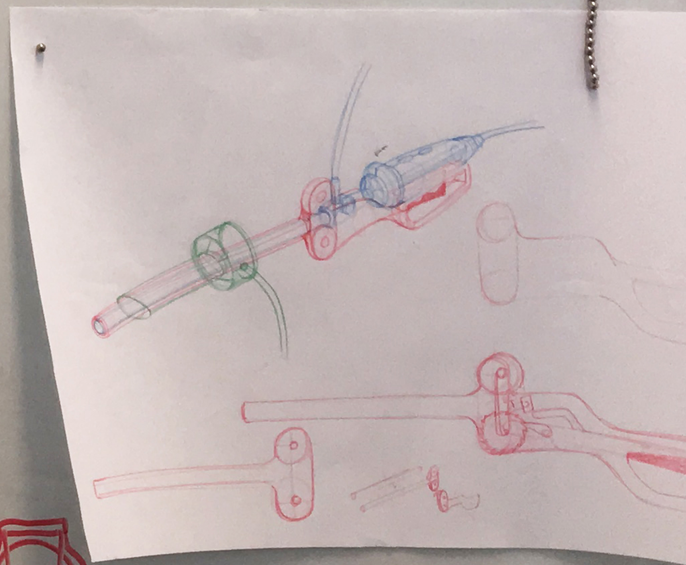
SPACE FOR MOVEMENT

SPACE FOR AIR

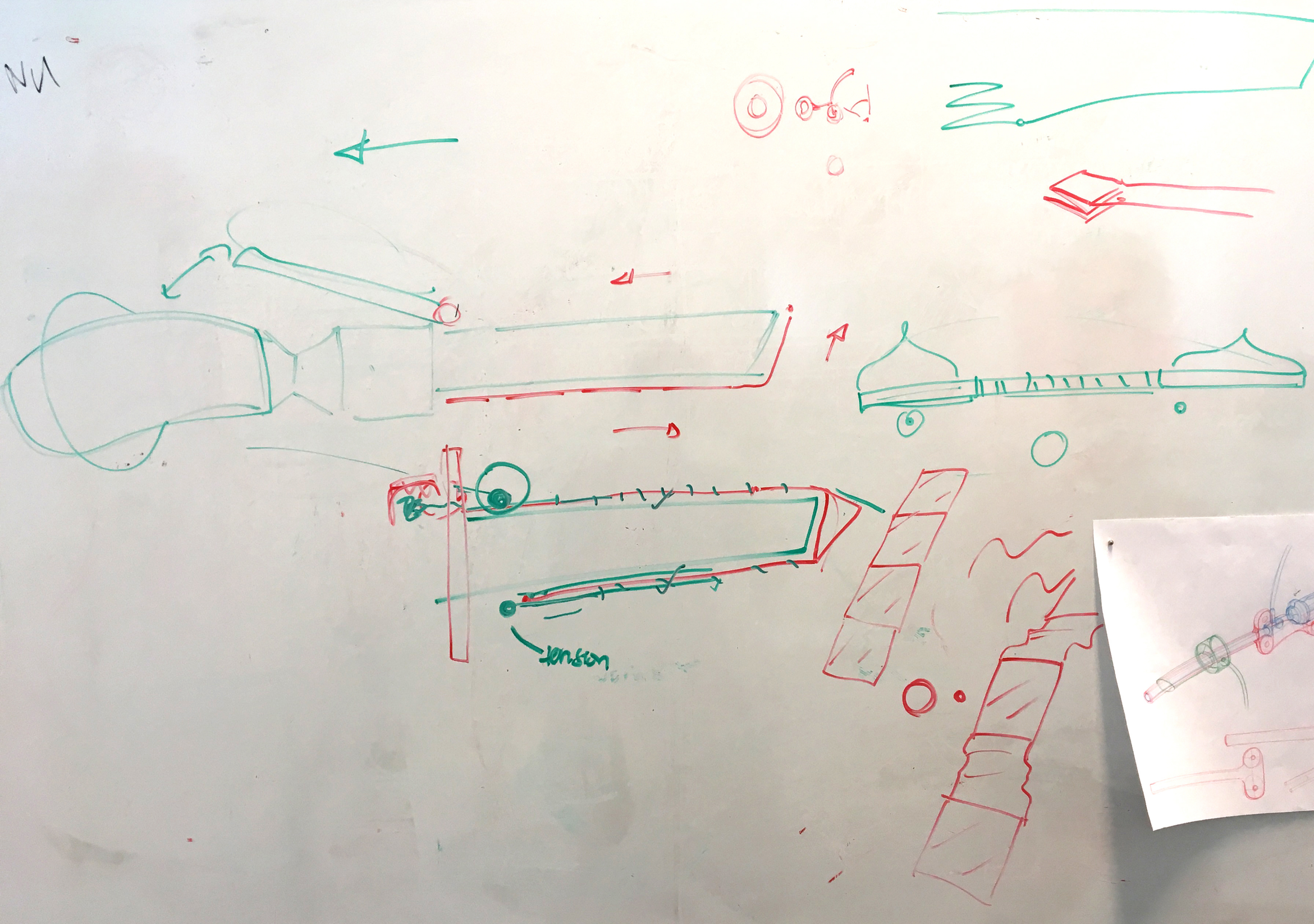
1

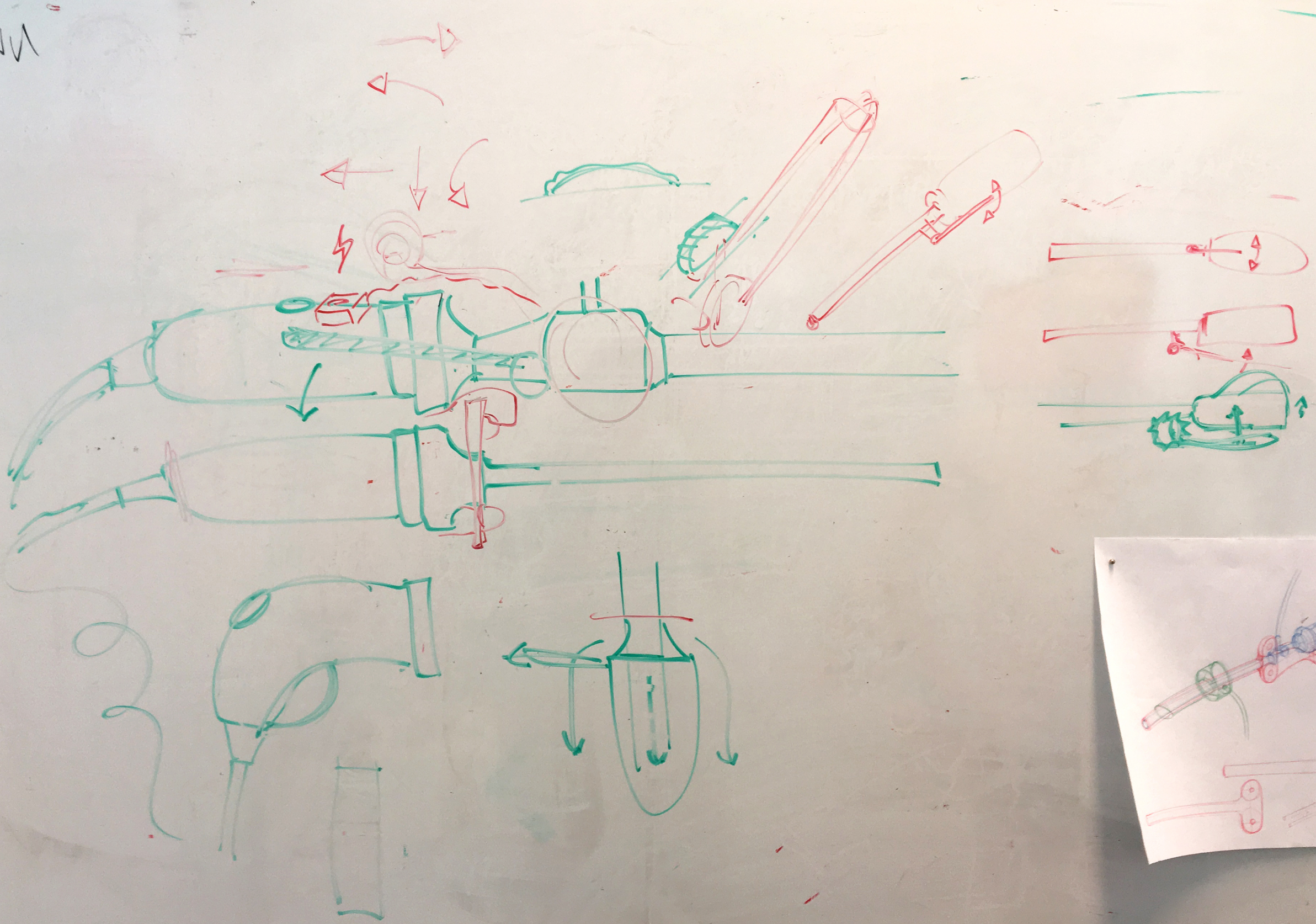
2.

3.



NV1





Appendix P

Test of the stage 1 tip design

Test of stage 1 tip design.

For testing, the 3D printed part was fixed on a stand at an angle to resemble its position while operating, a piece of the tape was passed through it. Water and fake blood were applied on the flat face through a syringe and dropper (fig. 1). Upon soiling the tape was pulled at one end to reveal the fresh piece of tape on the surface. Through this testing behaviour of the liquid on the new tip design was studied. Videos were recorded in the process. It is to be noted that the tape used for this experiment had alternating absorbent and transparent patches.

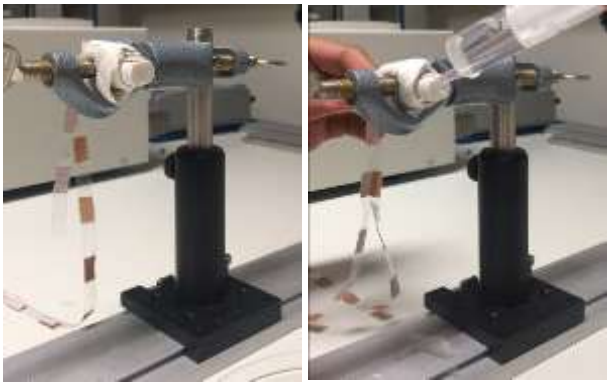


Fig. 1 Setup of the test

Observations

The remaining water droplet at the bottom edge is wiped cleaned and is absorbed by absorbent patch (fig. 2).

Fig. 2 Droplet of water at the edge

Blood is also easily wiped off from the surface and remaining droplets are absorbed by the absorbent patch, thus not spreading back through capillary action (fig. 3)

Fig. 3 Applying blood

When blood was sprayed on the tip instead of applying, the fresh piece of tape on the top also got dirty. And upon moving the tape, it did not go away instantly. The tape had to be moved by many patches. Thus it is essential to cover the fresh tape till it falls over the surface (fig. 4)

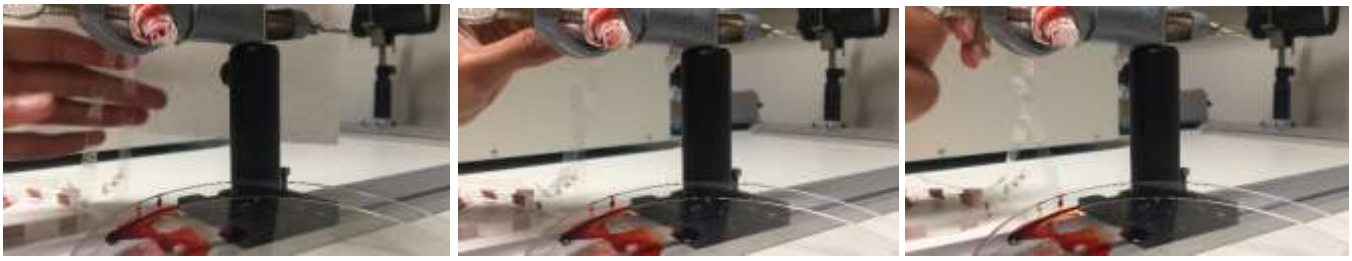


Fig. 4 Fresh tape getting dirty at the top

This test showed that the tape passed very well through the geometry. Few more problems were realized through this test.

When the amount of liquid was more, small droplets cling to bottom surface. They eventually fall off and eventually little bits gets scrapped off on the edge of the outer sheath. Thus for the liquid to not gather near the edge of the tip, the outer sheath can be a bit away from the edge.

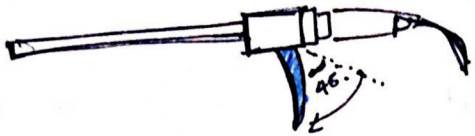
The part of the flat face which was not covered by the tape resulted in the liquid seeping through and getting trapped between the tape and the surface. This was also because the microstructure of the layers of the 3D printed part allowed the liquid to pass through. Here the hydrophobic material could help to not let the liquid spread.

The overall dimensions were still large by 1 mm to fit through the trocar and leave space for the air to pass. This was also the design was 3D printed.

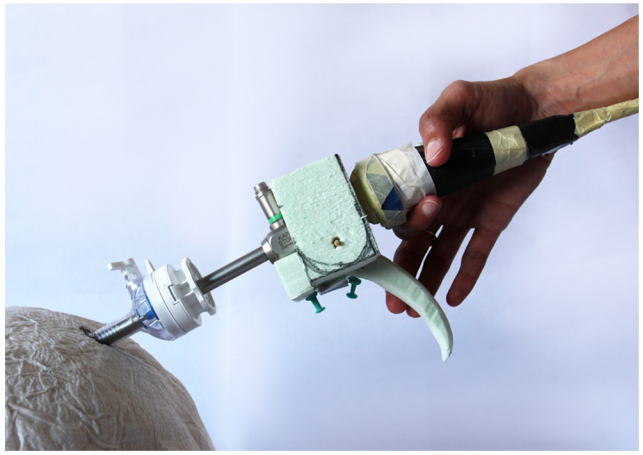
Appendix Q

Trying the trigger designs with the postures from the collages.

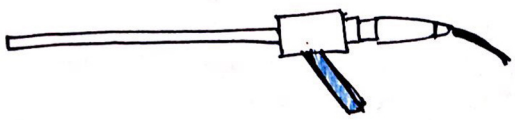
(1)



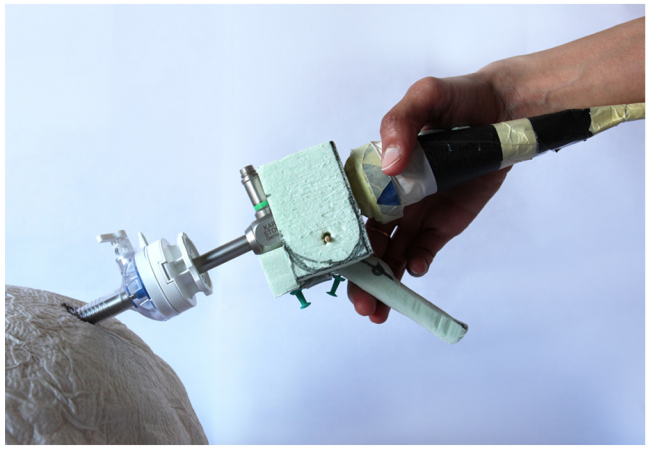
- photo taken.
- all grips tried, difficult to reach with one hand in all positions of holding the scope
- a handle is not in the same plane / axis.
- needs two hands.
- approximately 45° of rotation



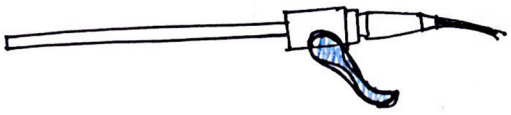
(2)



- photo taken
- all grips tried; the scope will be in air. resting on the trocar during trigger press; hence no support
- the straight handle is better than previous as its more within reach but still doesn't support all holding styles.
- approx 45°.
- I have long fingers so, its possible

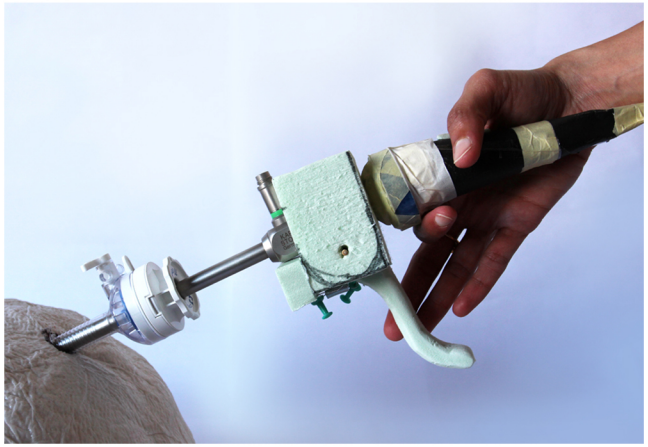


(3)

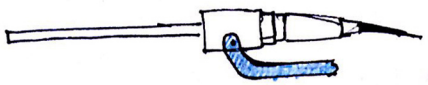


- photo taken
- tried all grips; the end curve of the handle is within reach for many of the positions; still problematic for some
- when ~~held~~ the scope is held and weight is put on trocar, the cha trigger press is a bit easy
- less than 45° movement

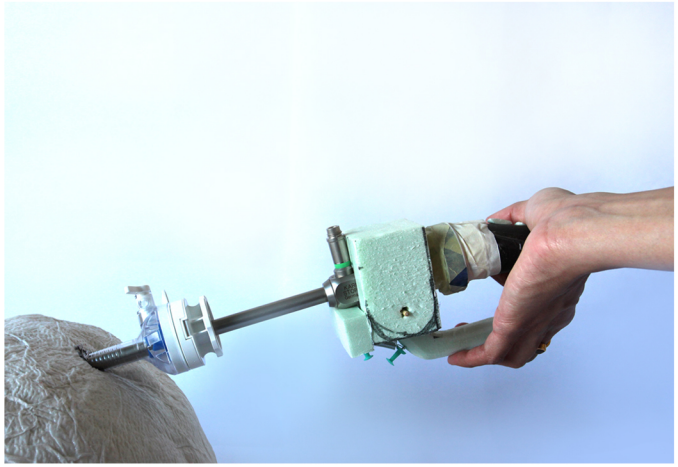
this bump helps to hold up; if shifted more towards the end, will help a lot for fingers to find the handl and anchor on it.



④



- photo taken
- some of the holding styles of ropes are very weird / different; not normal ways of gripping something
- from verticle & horizontal handle exploration; it was clear that most of their ways are non ergonomic. most ergonomic is not their ideal way & solution should follow their ideal way with less learning curve and minimal actions
- handle in same axis as rest makes it more within reach for many positions.
- less than 45°.
- very straight a pump might help to grab and anchor intuitively.



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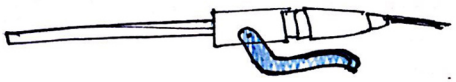
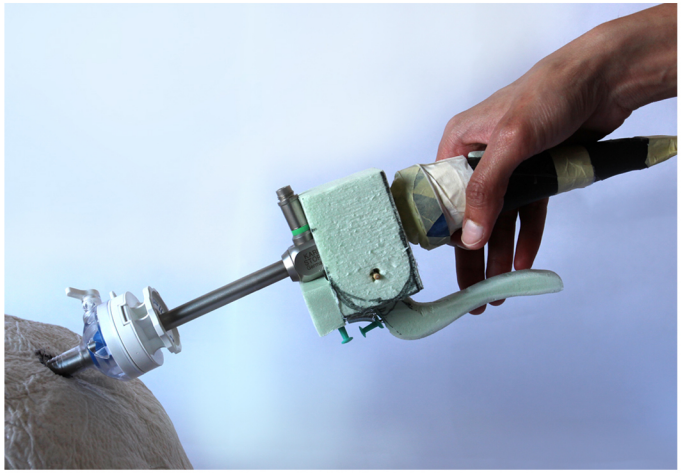


- photo taken
- compination of 4 & 3, it helps to anchor in many holding positions.
- also suits many holding styles
- less than 45°
- can be operatid with pinky
-



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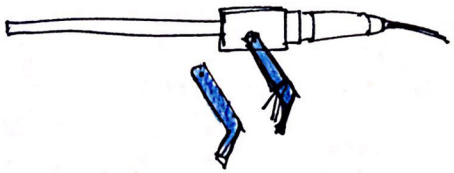
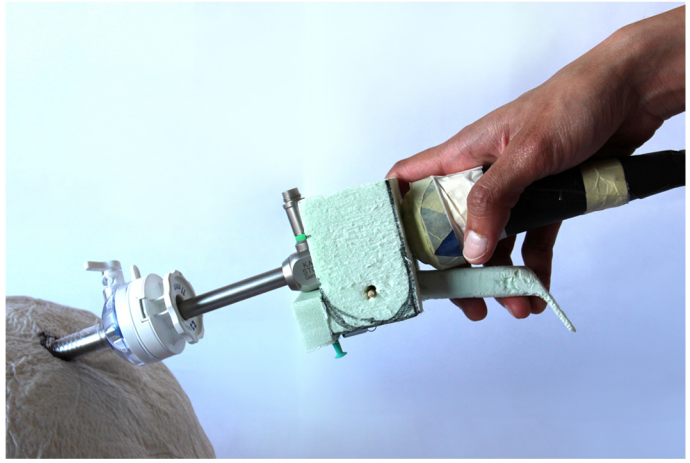
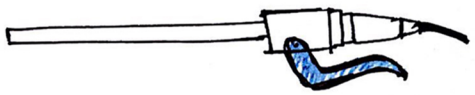


- photo taken
- the sharp and thin bend at the end helps to give good support while anchoring the pinky finger and ring finger
- the reach and operation of use is not that easy and good.
- the angle can be combined with previous design.



(7)



- photo taken
- combination 5 & 6
- works for most positions, easily reachable, helps to anchor and provide support for pinky finger & ring finger
- same axis easy to reach
- less than 45° of movement