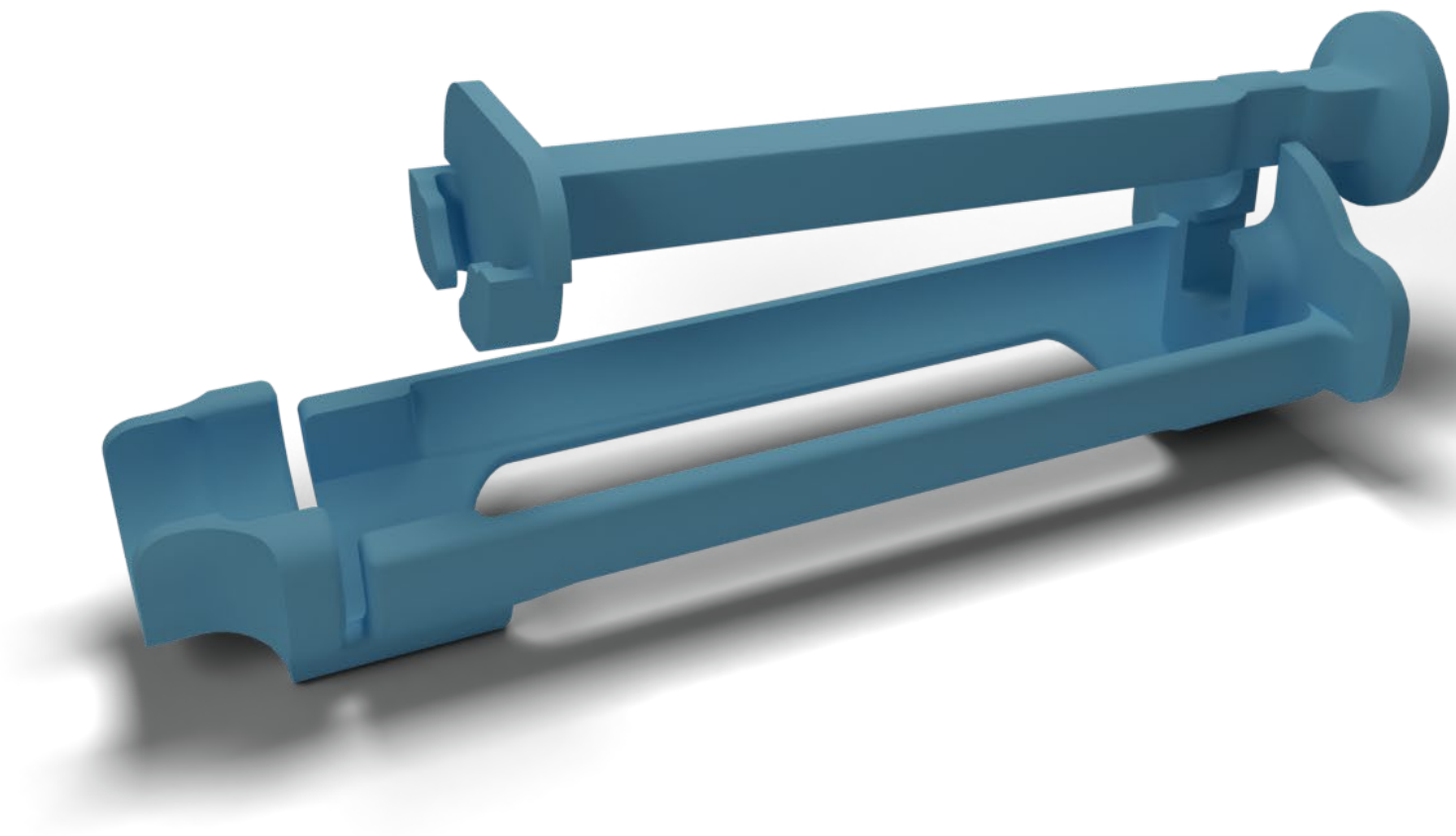
Reprocessing of Syringe Extension Device for Manual Vacuum Aspiration (MVA) procedures in Low Resource Settings in Sub-Saharan Africa:
Effects on material and manufacturing choices.

Master Thesis



Adithyan Senthil Athiban

August 2022

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Effects on material and manufacturing choices.

Master Thesis

Adithyan Senthil Athiban
adithyan.athiban@gmail.com
+31 (0) 619273198

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Master Thesis
MSc Integrated Product Design
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Supervisory team
Dr. ir. Diehl, J.C.
Dr. ir. Paus-Buzink, S.N.

Delft University of Technology
Faculty of Industrial Design Engineering
Landbergstraat 5
2628 CE Delft
The Netherlands

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0.1 Preface

With the conclusion of this Project, I come to the end of my Master's degree in Industrial Design Engineering.

From the start of my course, even from the statement of purpose for my application to this university, I have wanted to work on designing a medical device and this project has given me a taste of what this world looks like. This project has been humbling and motivating, giving me a sense of direction while stripping away a lot of my insecurities, by putting me through struggles to complete it. But I would not have made it this far by myself.

I would like first and foremost to thank JC and Sonja for being such kind, supportive mentors and for helping me complete this project. I would like to thank Karl for being a mentor, sparring partner, and for being very encouraging individual throughout the course of this project.

I would like to extend thanks to Wessel Veenkamp for his help during the material testing phase, and Arun Akella for his motivating words and support. I would also like to thank Stefan van de Geer, for encouraging me in our every passing meeting. And also thank you to my partner for being a pillar of support and for helping me get through this.

I would like to extend my thanks to my roommates, for being the brunt of my ideas and iterations, and also for graciously modelling with all the iterations for pictures.

And finally, I would also like to thank my family and friends for allowing me to lean on them when necessary.

With Gratitude,

Adithyan Senthil Athiban

0.2 Executive Summary

Medical Devices are important tools used for diagnosis, treatment and prevention of diseases, but access to these devices is not equal across the world. The Global South has, although improving, faced consistent struggles with providing equal and accessible healthcare to their population.

This project focused on one such device. There are an estimated 17 million induced abortions and miscarriages in Africa yearly, and about 150,000 of them are in Kenya. Post-abortion care is used to treat these, and Manual Vacuum Aspiration (MVA) is one such procedure. Management of Pain during such procedures is equally important for the care of the patient. Paracervical block is used to inject anesthesia around the cervix to reduce pain and discomfort during the procedure, however, due to lack of accessibility and cost, people sometimes choose to go through the MVA procedure without anesthesia.

The clients have designed Chloe SED, a syringe extension device that tackles this problem, by replacing the need for longer needles which can as much as 70 times more expensive than shorter needles.

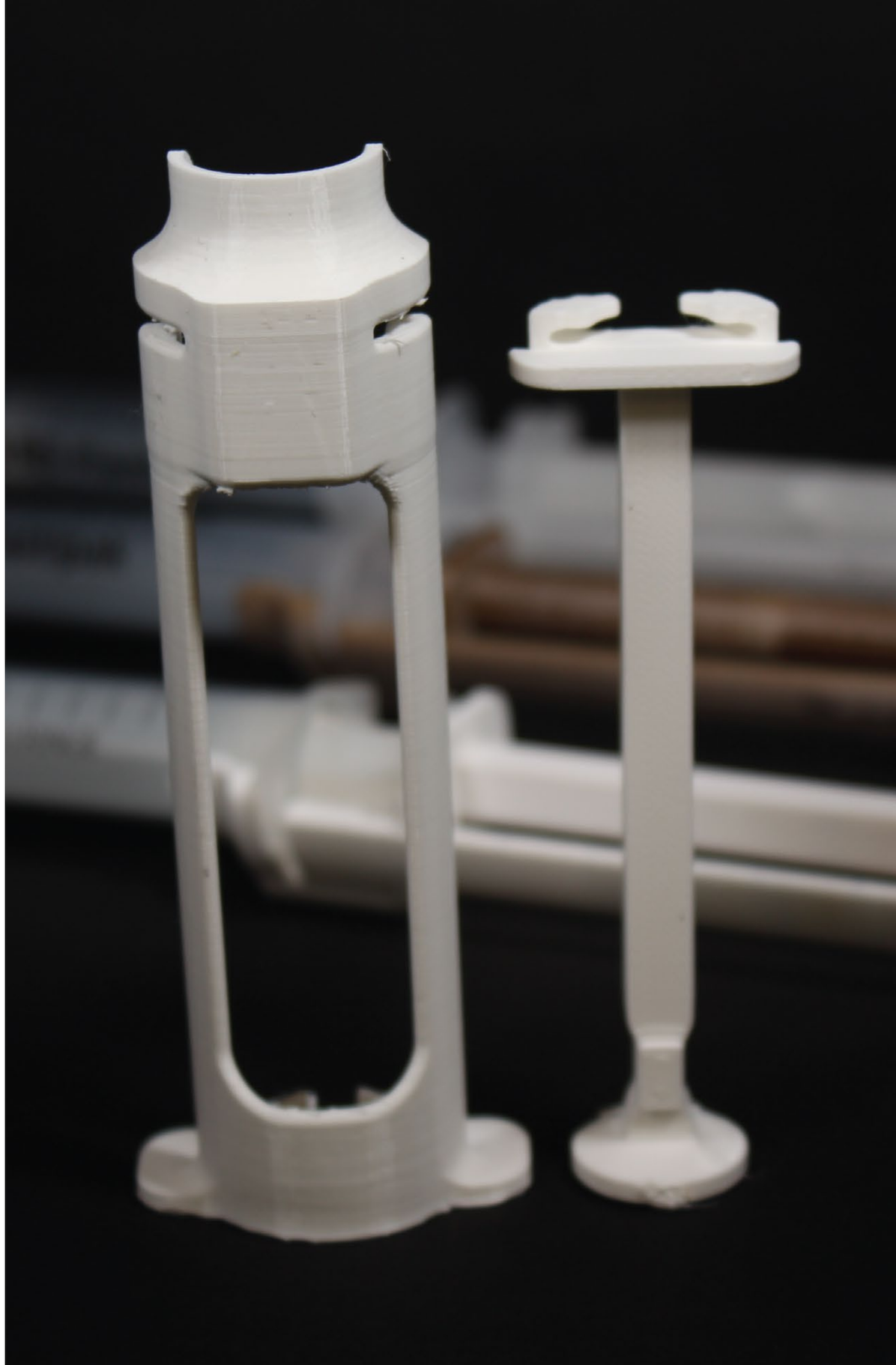
The goal of this project was to understand how medical-grade Chemical Sterilization and High-Level Disinfection (HLD), and usage of the device in context affect the integrity of the device within its expected lifetime, and to suggest material choice, manufacturing method and to recommend design changes for the SED.

The analysis phase resulted in an understanding of the reprocessing method, how the device is used and factors affecting the decision for material choice of a medical device in context. A list of design specifications for the project is generated and drivers established.

After a deeper analysis of the material, two materials were selected, PEEK and PP, to undergo testing. An experiment was developed to understand the impact of reprocessing on the selected materials. Tensile samples and Chloe SED samples were manufactured and tested with 25 cycles of sterilization process as it is done in context. Based on the results from the tests, both materials displayed sufficient characteristics to be used for the manufacture of Chloe SED.

Furthermore, manufacturing methods were explored and injection moulding was recommended as the method of manufacturing. PP was selected because it provides sufficient mechanical and chemical characteristics within the lifecycle of the device and because it was cheaper to source and manufacture. The implications of the results of the research were converted into design directions, the most impactful part was selected, and redesign recommendations were given, taking into account sterilization, use and manufacturing.

As a conclusion for this project, the redesign was tested with the client and proved that it was easier to understand, faster to use and it improved cleanability.



0.3 Table of Contents

Chapter 1

Introduction

1.1 Healthcare

In LMICs, healthcare is provided by public, private providers and mission hospitals (NGOs). Kenya is no different, the majority of Kenya's population receives healthcare services from the public health sector (roughly 50%) and the rest is handled by private, NGOs and mission hospitals. (Access to Health Care Services Has Improved - Report, 2020; Mohiddin & Temmerman, 2020)

Healthcare in Kenya is divided into different levels, and the cases are referred to hospitals of higher level based on the complexity of the case. There are currently 6 levels of care in Kenya (Mariita, 2019).

According to Kenya Health Policy 2014 – 2030, the government aims to make policy changes in line with the constitution of Kenya and global health commitments. One of the changes the policy aims to accomplish is the decentralization of healthcare. In essence, the decentralized system has consolidated service areas into 4 main categories for ease of governance and responsibility.

For the sake of the discussion, we will use the existing levels of hospitals. The levels of the hospitals affect the facilities that are available, so the more complex cases are referred to the hospitals which are on the next tier. A more detailed description of each current tier can be found in Appendix A, pg. 13.

Although maternal healthcare is provided by Lv3 facilities and above, different levels of hospitals follow different procedures. Manual Vacuum Aspiration (MVA) or Electric Vacuum Aspiration (EVA) is performed for almost all procedures of uterine evacuations in Lv6 facilities, and in 8 of 10 cases in Lv5 facilities. (Singh et al., 2013) D&C is more common in Lv4 hospitals and below. Chloe SED will have to be usable in all these contexts.

Level	Hospital
1	Community facilities
2	Health dispensaries
3	Health centers
4	County hospitals
5	County referral hospitals
6	National referral hospitals

Following sterilization protocols involves having to fund procurement and maintenance of devices used for sterilization (such as steam sterilizers). A hospital with more flow of funds, higher level of hospitals, is more likely to have access to such sterilization equipment.

The context of the project, Jaramogi Oginga Odinga Teaching & Referral hospital, is a Lv5 hospital.

1.2 Medical Devices

Medical devices are tools used for health intervention. They are used for the prevention, diagnosis and treatment of diseases, and for patient rehabilitation. However, access to these devices is an ongoing challenge, particularly in low-and-middle-income countries (LMICs). The availability, accessibility and effective use of essential medical devices play an important role in the delivery of quality health services. (World Health Organization, 2012)

Several authors have already indicated gaps in the availability of medical equipment, such as surgical equipment in LMIC) such as Malawi, Sierra Leone, Nigeria, Cameroon, Somalia, and Ethiopia. (Chao et al., 2012; Elkheir et al., 2014; Henry et al., 2012, 2015; Kouo-Ngamby et al., 2015; Oosting et al., 2016; Wong et al., 2014) It is estimated that 38.2% of medical equipment was out of service in developing countries. (Perry & Malkin, 2011) The three main causes were infrastructure, health technology management (HTM), and lack of training. Infrastructure and resource deficiencies include causes such as lack of spare parts, lack of disposables and lack of required accessories (Bekele H., 2008; Erinosho, 1991; Malkin, 2007).

A medical device that is intended for use in an LMIC setting has to be designed with the context of use in mind, or it will suffer from misuse and early disposal. The case study of this project is set in Jaramogi Oginga Odinga Teaching & Referral Hospital, located in Kisumu, Kenya.

Fig.1.1 Donated oxygen concentrators (Howie et al., 2008)

An example of "Mismatch, where oxygen concentrators donated to a hospital in Gambia where the lifespan of donated oxygen concentrators did not exceed 30 minutes (as opposed to 5–7 years in high income countries [HICs]) because of the wrong voltage and frequency to match the electricity network in Gambia, leading to overheating. (Howie et al., 2008)

1.3 Abortion Care

Abortion complications are among the major reasons women seek emergency obstetric care. Post-abortion care (PAC) consists of emergency treatment for complications related to spontaneous or induced abortions, family planning and birth spacing counseling, and provision of family planning methods for the prevention of further mistimed or unplanned pregnancies that may result in repeat induced abortions. (Wikipedia Contributors, 2022)

There are several procedures which can be used for treatment of induced or spontaneous miscarriages. These are broadly classified into medical abortions and surgical abortions. The choice between the two is based on the doctor's recommendation, patient comfort, and duration of pregnancy. (The Different Types of Abortions - Abortion Methods, 2018). The types of abortion procedures are described in Appendix A, pg. 15. The case study is focused on Manual Vacuum Aspiration procedure (MVA).

Vacuum Aspiration

A thin tube connected with a handheld syringe will be inserted into the uterus through the cervix, and vacuum is used to remove the products of conception. This can be done manually, Manual Vacuum Aspiration, or using a mechanical pump, known as Electric Vacuum Aspiration or just Vacuum Aspiration.

This method can be used within 3 to 12 weeks of pregnancy. After the procedure is completed, there may be irregular bleeding for up to 2 weeks. Cramps, similar to those in menstrual cycle, may be present for up to a few days before the uterus recovers.

Fig.1.2 Parts of MVA kit

According to a study done in 2017, there are an estimated 8.168 million miscarriages, and another 8.985 induced abortions in Africa for the year 2017. In Eastern Africa, this number is estimated to be 2.866 million miscarriages and 2.878 million Induced abortions (Jacqueline E., 2018). And within Kenya, an estimated 37,850 miscarriages and 119,912 Induced abortions. (Singh et al., 2013) All of these cases require Post Abortion Care (PAC).

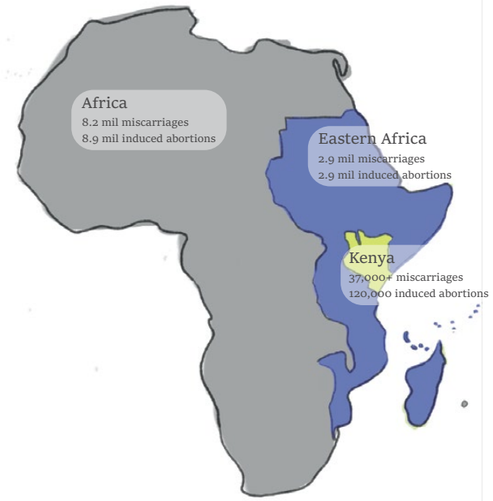


Fig.1.3 Estimated number of abortions in Kenya

According to a study done in 2017, there are an estimated 8.168 million miscarriages, and another 8.985 induced abortions in Africa for the year 2017. In Eastern Africa, this number is estimated to be 2.866 million miscarriages and 2.878 million Induced abortions (Jacqueline E., 2018). And within Kenya, an estimated 37,850 miscarriages and 119,912 Induced abortions. (Singh et al., 2013) All of these cases require Post Abortion Care (PAC).

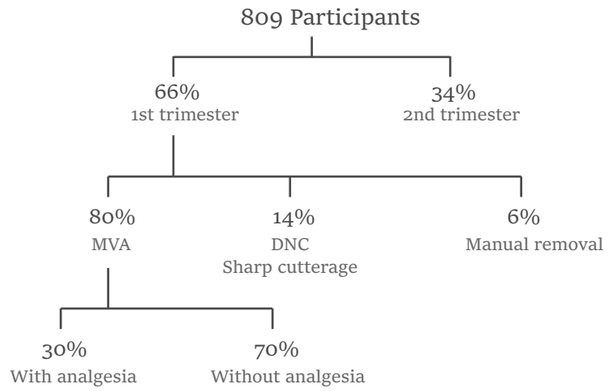


Fig.1.4 Percentage of population without anesthesia (Gebreselassie et al., 2005)

Out of a study conducted with 809 partcipants with abortion complications on a wide range of hospital wards (two Lv6, seven Lv5, and fifty-two Lv4 hospitals), it was discovered that although 52.8% of the sample population underwent MVA procedure, only 30% of the group who went through MVA had access to analgesia.(Gebreselassie et al., 2005)

Using the same estimates, roughly 105,000 women undergo Manual Vacuum Aspiration procedure without anesthesia. The cost and the availability of necessary equipment plays an important role in this lack of access to necessary healthcare.

1.4 MVA Process

Manual Vacuum Aspiration (MVA) is a procedure done within the first trimester of pregnancy that involves suction of the uterine cavity to remove the contents of conception. The procedure is done to treat spontaneous or planned abortions. This process will be defined in more detail in section x.x of this report.

Vacuum aspiration has several advantages to other similar procedures, such as dilation and curettage (D&C). It can be used earlier in a pregnancy and has a lower rate of complications compared to D&C. ('Vacuum Aspiration', 2021) MVA procedure can only be done within the first trimester, 12 weeks of gestation. However, it is the only option available in pregnancies as early as 6 weeks. (C. Johnson, 2021)

Dr. Stephan Gwer was interviewed about the procedure (Appendix x.x) Before the start of the procedure, the patient is seen by the healthcare professional.

The following are the steps followed during a typical MVA procedure, and the pain felt by the patient at each step is recorded on the graph below.

1 Preparation

The patient is made to lie down and the procedure is explained to them.

2 Evaluation of patient

The healthcare professional uses two fingers to examine the vagina to confirm uterine size and position. Personal lubricant is used to ease the insertion of the vaginal speculum.

3 Insertion of speculum

The speculum is inserted sideways and "screwed" in until vertical. It is recommended to warm the speculum before insertion to reduce discomfort due to cold.

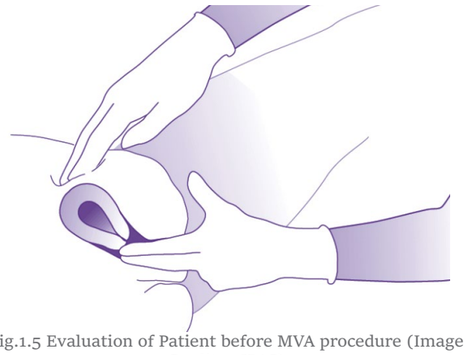


Fig.1.5 Evaluation of Patient before MVA procedure (Image Credits : IPAS)

4 Cleaning the cervix

The cervix is visualized. This procedure may take upto 5 minutes, as difficulty of finding the cervix varies between patients.The cervix is cleaned with a oversized cotton swab and antiseptic solution.

5 Injection on first point

Injection on the first point at 12'o clock (~2cc). The anesthetic acts immediately and numbs the cervix. This is to numb the cervix for grabbing with the tenaculum.

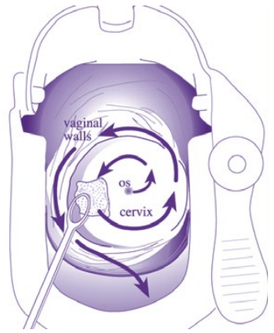


Fig.1.6 Cleaning the Cervix (Image Credits : IPAS)

6 Grabbing cervix

The top of the cervix is pinched with the tenaculum.

7 Injecting in 4 points

Anesthesia is injected in 4 points, 2', 4', 8' and 10'o clock. (~4.5cc each).

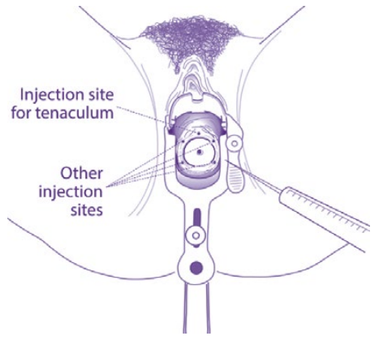


Fig.1.7 Injection sites (Image Credits : IPAS)

8 MVA Procedure

The MVA kit is used to aspirate the uterus. The cannula (tube) is inserted into the cervix and rotated when applying vacuum. The procedure may be repeated once to twice to ensure uterus has been cleaned. if the patient is facing some pain, an extra dose of anesthetic is injected.

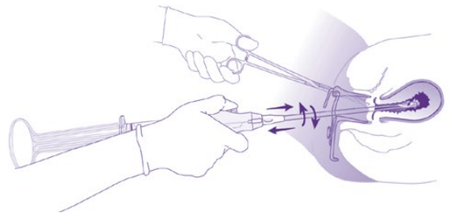


Fig.1.8 Conducting MVA procedure (Image Credits : IPAS)

9 MVA Completion

The contents within the MVA will bemoved into a biohazard contianer and disposed or sent for further testing. The patient may have cramps which will slowly get better.

10 Post-procedure wait

The patient has to wait within the hospital for a minimum of 30 mins to ensure no there were no complications during the procedure (such as tears or rips in the uterus). After this the patient is allowed to go home.

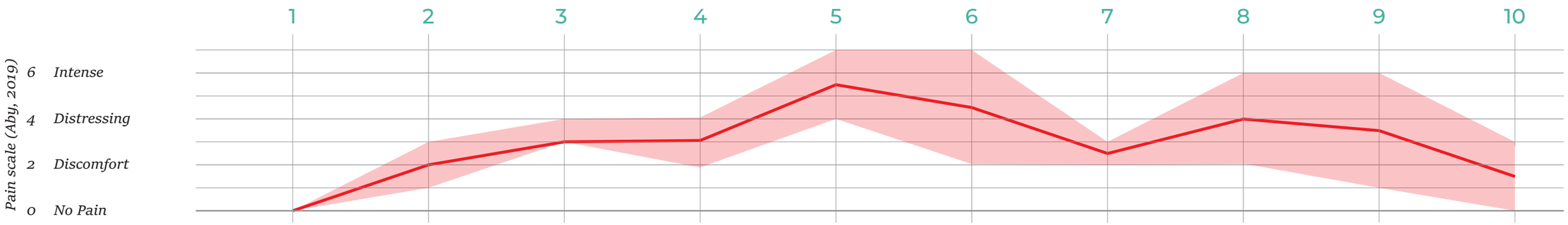


Fig.1.9 Pain scale for patient during MVA procedure

1.5 Pain Management

Management of pain during abortion is a critical aspect of patient care during any PAC procedure (Egziabher et al., 2002; Meckstroth & Mishra, 2009). Research has shown that 20cc of 1% lidocaine solution injected around the cervix has been effective in reducing pain borne by women undergoing MVA for treatment of incomplete abortions (Egziabher et al., 2002)

Paracervical block is used as pain relief for MVA procedure. Before the MVA procedure is done, a local anesthesia needs to be injected around the cervix to alleviate pain (Egziabher et al., 2002). Although paracervical block is painful, it reduces first-trimester abortion pain regardless of gestational age, but the benefit on dilation pain was greater at earlier gestations (Renner et al., 2012).

A paracervical block can be helpful even when performing hysteroscopy, and can be administered to lessen discomfort associated with passage of instruments through the cervix and with the operative procedure in general (Raymond & Lentz, 2022). It is also used as a pain management method during the first stage of labor (McDonald & Noback, 2003).

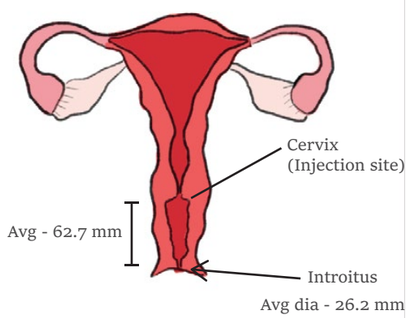


Fig.1.10 Average dimensions of vagina (Barnhart et al., 2006)

The anesthetic is injected non intravenously, at a depth of 3 cm deep, in 2 or 4 points around the entrance to the cervix (Ipas, 2021). According to a study, the mean value of vaginal length is 62.7 mm deep, and mean value of diameter to entry of vagina (introitus) is 26.2 mm (Barnhart et al., 2006). The diameter of an average 10cc syringe is about 17-18mm. When injecting the paracervical block, the cervix is visualized using a vaginal speculum and a tenaculum.

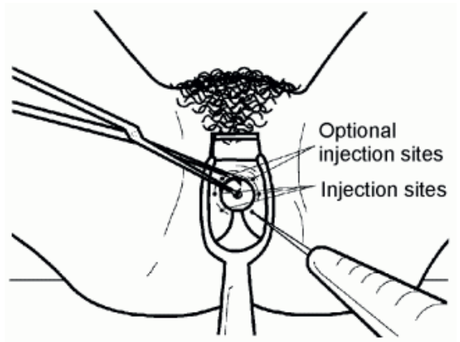


Fig.1.11 Paracervical block injecion sites

Due to the small difference between the opening provided by the vaginal speculum and the size of the syringe, and due to the limited length of the syringe, it becomes difficult to visualize the injection points. Paracervical blocks must be non-intravenous, and an intravenous injection of any local anesthesia can lead to Local Anesthetic Systemic Toxicity (LAST) (Christie et al., 2015), which can lead to complications such as lightheadedness, drowsiness, sensory disturbances, and in more extreme cases lead to muscle twitches and seizures. (Torp et al., 2021)

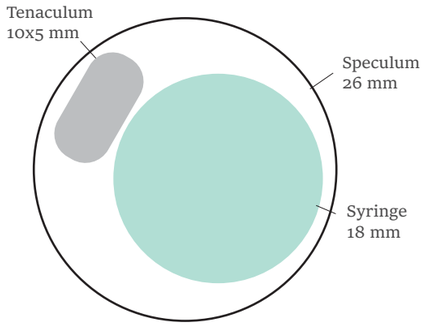


Fig.1.12 Size comparison of tools

In High-income-countries (HICs), where there is access to facilities, spinal needles are used to inject the anesthesia, owing to their long length (~89mm), compared to the commonly used hypodermic needle (30mm). However in Kenya, these spinal needles are not only expensive (upto 170 Ksh; € 1.33) compared to hypodermic needles (2.5 Ksh; € 0.02), but are also not easily available.

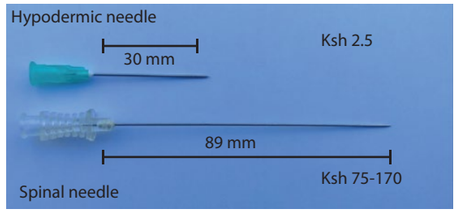


Fig.1.13 Cost comparison of needles

In addition to this, using a hypodermic needle involves reaching into the vagina of the patient for an extended duration of time, which is an uncomfortable experience for both the patient and the doctor.

Due to the high cost and lack of availability, patients either choose to undergo the procedure with hypodermic needle or without anesthesia. (Mutua et al., 2018)

Besides being functional and accessible,

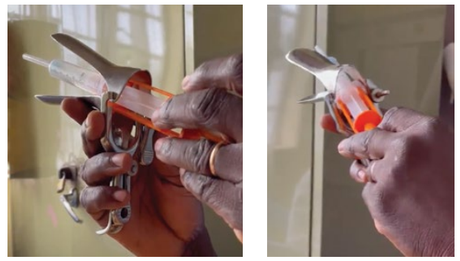


Fig.1.14 Photos taken by Karl during user test of Chloe SED

medical devices in LMIC must also be affordable for use in the context. High cost of maternal healthcare has been proved to be a barrier to approach skilled healthcare. (Borghi et al., 2008) A decision by the Kenyan Government in 2013 made all public maternal care services free for everyone (Pyone et al., 2017) and this has seen a direct increase in usage of maternal healthcare services (Lang'at et al., 2019), but the burden of consumables are still on the patients.

County public hospitals in Kenya have multiple sources of funds, as this provides improved stability of funding. Inadequate funding from any one source is compensated by other sources (Mbau et al., 2018). Medical expenditure in the public healthcare sector in Kenya is majorly funded from 3 sources, namely donors, government funding and Out-of-Pocket (OOP) Payment. In the year 2005-06, an estimated 29.1% is OOP (Mbau et al., 2018). This constitutes a problem as, in 2007, 38% have stated lack of funds as the reason for not seeking medical care (Munge & Briggs, 2014).

There is a high dependence on OOP expenditure (Ministry of Health, Government of Kenya, 2014), and this acts as a barrier to health care in Kenya.

1.6 Clients

The Chloe initiative came together to solve this problem. The team consists of 3 members, Dr. Aparna Ramanathan, Karl Heinz Samenjo (PhD), and Dr. Stephen Gwer. The team is working to innovate in this field and make things more inexpensive and therefore more accessible to the populace in Kenya.

Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH) situated in Kisumu city, Kenya, is the hospital where this device will be field tested.

Dr. Aparna Ramanathan

Co-inventor of the syringe extension and Assistant Professor in the Department of Obstetrics and Gynecology at the University of Illinois at Chicago.

Dr. Stephen Gwer

Medical Doctor - Maseno University Kenya.

Karl Heinz Samenjo

Co-inventor - Researcher at Healthcare for All
- Industrial Design Engineering TU Delft

Fig.1.15 Clients introduction

The solution that the clients have developed to solve this problem and increase access to pain medication is Chloe SED. Chloe Syringe-Extension-Device is a simple device that works by providing an extra 10cm reach to the syringe, thereby allowing the use of hypodermic needles instead of spinal needles. The device is explored further in the next chapter (Chapter 1.7).

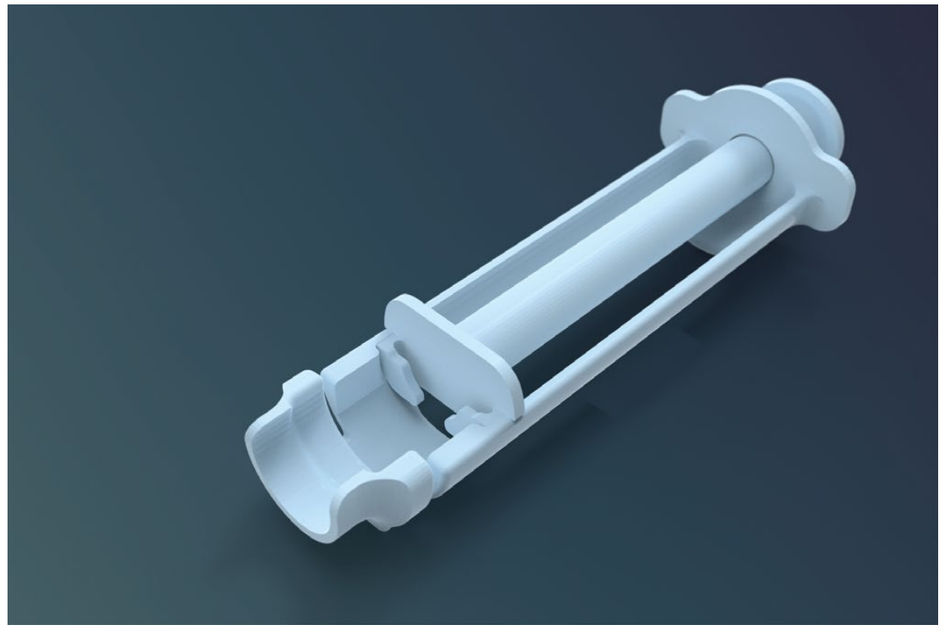


Fig.1.15 Current design of Chloe SED

1.7 Current Solution

The solution that the clients have developed to solve this problem and increase access to pain medication is Chloe SED. Chloe Syringe-Extension-Device is a simple device that works by providing an extra 10cm reach to the syringe, thereby allowing the use of hypodermic needles instead of spinal needles.

The design for Chloe SED has gone through two iterations so far. The first iteration was a basic proof of concept that was prototyped using 3D printing, as shown in Fig. 1.16. This prototype was used to collect user feedback from doctors and nurses with experience in doing the MVA procedure.

Fig.1.16 Proof of concept for Chloe SED

At this stage TUDelft started being involved in the desing process. The devices went through a few iterations, as shown below in Fig.x. The focus of this stage of the design process was to understand the user feedback from the previosu iteration and to make the design user friendly and cleanable. The current state of the design is shown in Fig. 1.18.

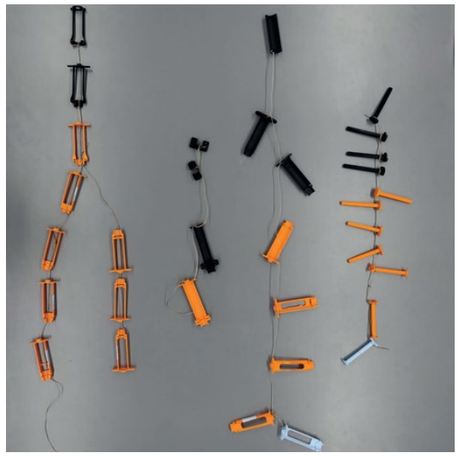


Fig.1.17 Iteration of Chloe SED

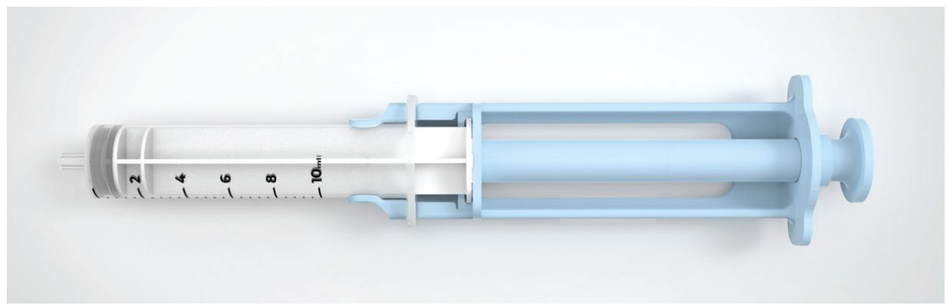


Fig.1.18 Current iteration of Chloe SED

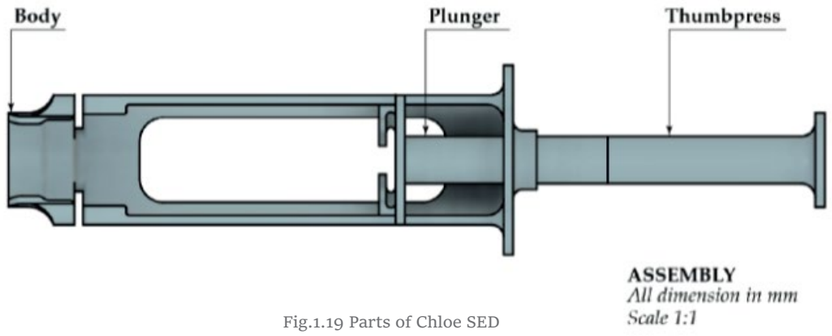


Fig.1.19 Parts of Chloe SED

Chloe SED is a syringe extension device. Consisting of a simple design, it is used to extend the reach of the syringe. It consists of 3 components, the plunger, thumbpress and the body, as shown in Fig. 1.19.

When connected to the syringe, it increases the reach of the syringe, by 10cm, as shown in Fig. 1.20.

Due to the extended reach of the syringe, a hypodermic needle can be used instead of the spinal needle, thereby directly decreasing the cost of the procedure, by at least Ksh 72.5 upto Ksh 168 (based on the availability of spinal needles) per procedure done. The product journey is explored in the next page.

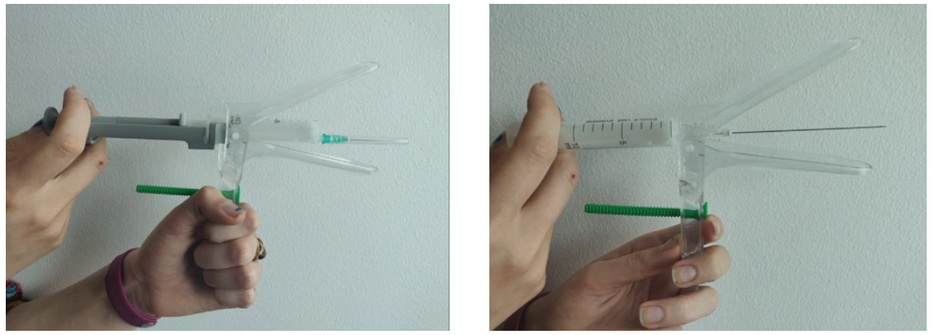
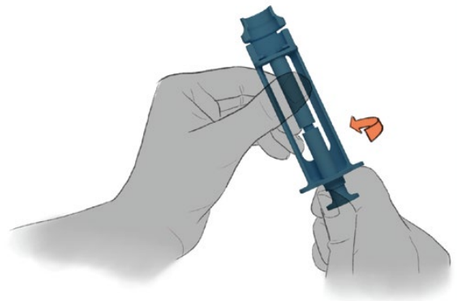
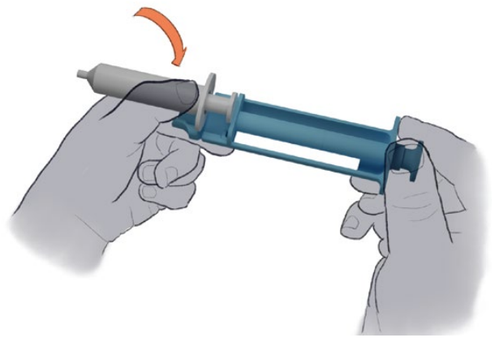


Fig.1.20 Comparsion of Chloe SED; left - Chloe SED and syringe with hypodermic needle; right - Syringe with spinal needle

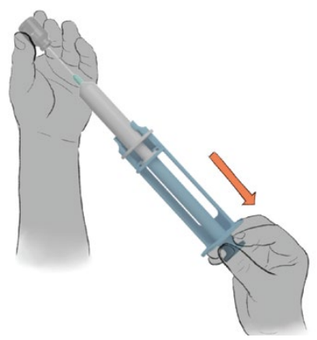
1.8 Product Journey



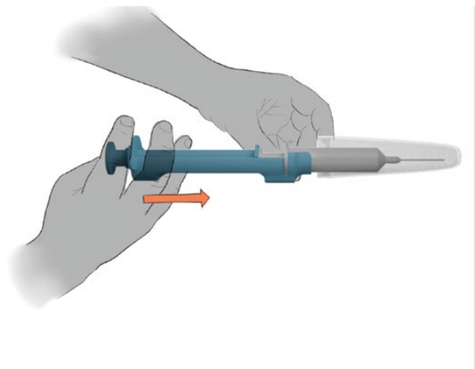
The Chloe SED is assembled.



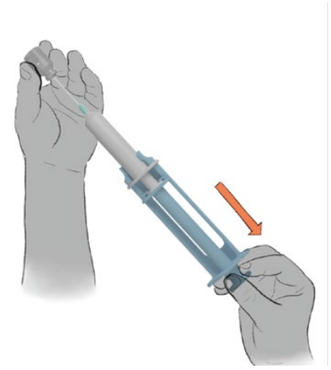
The Chloe SED is attached to the syringe. The needle is attached after this to avoid injury.



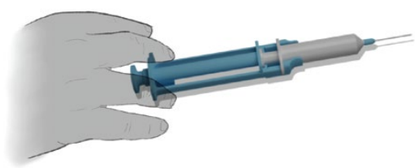
Paracervical block is prepared. 10cc of 1% lidocaine is withdrawn into syringe.



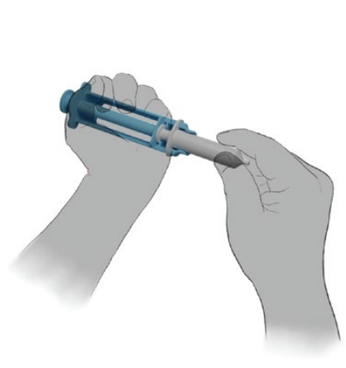
Injections are given in the sites. Once the syringe is empty it is removed to withdraw more lidocaine.



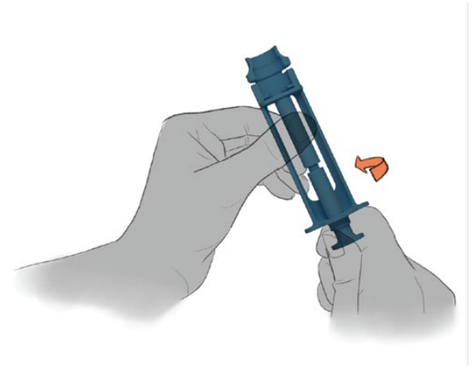
Another 10 cc of 1% lidocaine is withdrawn, and injected in the remaining points.



The syringe along with needle and Chloe SED is placed on the worktable. It is not dismantled, incase more anesthesia is needed.



Once the procedure is completed, the assembly is dismantled, separating the syringe and needle from Chloe SED.



The Chloe SED is disassembled to it's 3 components. and reprocessed.

Fig.1.21 Product journey of using Chloe SED

1.9 Proposed Direction

So far, Chloe SED has been designed and iterated based on user feedback and usage. But for the product to become market ready, a few more questions need to be answered. The immediate next stage of the project is to take a decision on the material and manufacturing choice. There are several factors that come into play when making the decision.

A medical device can undergo wear and tear through its utilization and sterilization procedure. The device has to handle both of these for enough cycles to be profitable to use it.

The cost of manufacturing and using the device for a certain number of cycles has to be cheaper than the alternative, which is using a spinal needle.

In addition to this, as this is introducing a new device to the market, there is an impact on the environment, due to its manufacturing, usage and sterilization. That'll have to be taken into account.

The goal of this project will on making a decision on the material and manufacturing choice for the product. The scope of the project is to understand the sterilization and usage to reach the goal. Environmental factors are not withing the scope of the porject.

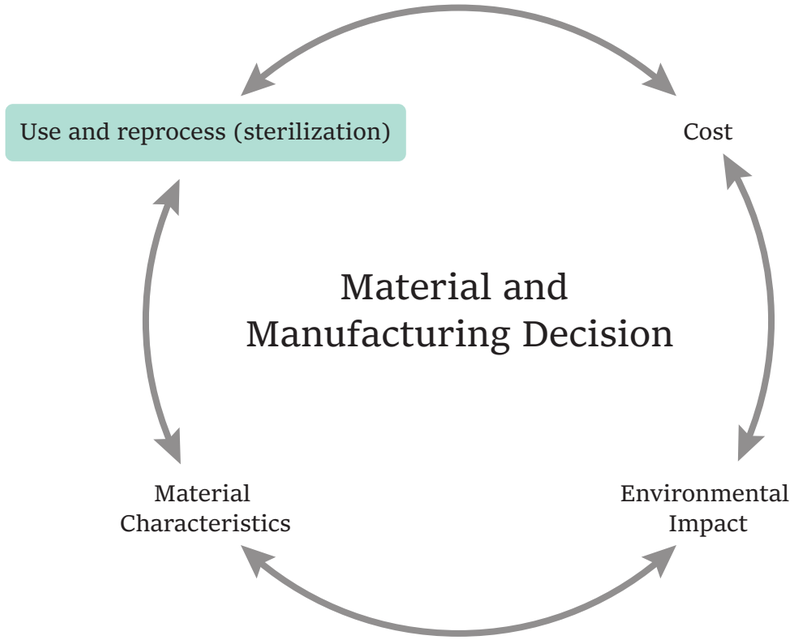


Fig.1.22 Scope for the project

Chapter 2
Understanding the Assignment

2.1 Stakeholders

The stakeholders of the project were analysed and scored based on their Interest vs Influence over the product.

1 Clients

The clients want to solve the problem and create a device that can be sold for profit. They make the final decisions on the design, cost and distribution of the product.

2 Patients

The patient needs the device to be accessible and at a lower cost than the current alternative. The patient has minimal to no influence on the procedure itself.

3 Healthcare workers

They want to provide speedy, affordable and quality healthcare. They influence the ease of use and operation of the design

4 Reprocessing Staff

They want to be able to reprocess the device easily/quickly without complex tasks. They influence the form, material and manufacturing method of the device.

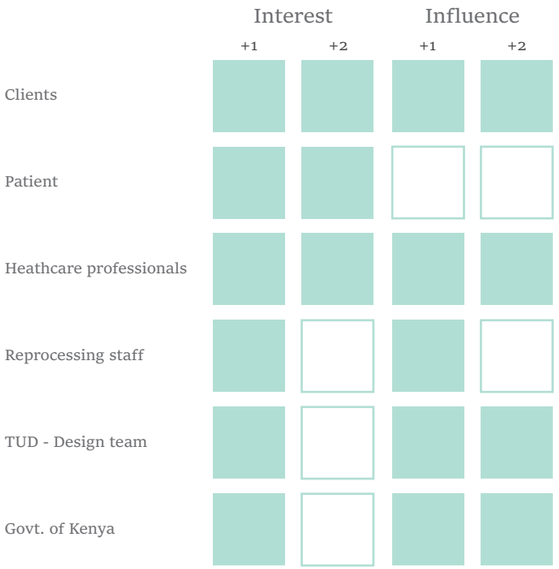
5 TUD / Design team

The design team wants to deliver a good solution to the problem that fits into the context of use. They influence the complete design process.

6 Government of Kenya

The government and relevant bodies within the government want to ensure the quality of the device that is entering the local market. They approve the device to be used in the country.

This was converted into a 2v2 chart to understand the stakeholders.



2.2 Assignment

Currently, Chloe SED is a syringe extender that allows doctors to have an extra reach when using a hypodermic needle as a replacement for a spinal needle. However, this is still a conceptual design, and cannot be taken exactly as is into production. There are factors to be considered within the context of use in Kenya, medical best practices and usability to take this concept and develop it into a complete product that can go into production. This is the starting point for this project.

The primary objective was to understand how medical-grade Chemical Sterilization and High-Level Disinfection (HLD), and usage of the device in context affect the integrity of the device within its expected lifetime, and to suggest material choice, manufacturing method and recommend design changes for the SED.

Fig.2.2 Stakeholder chart

2.3 Design Challenge

"How do we select the right material and manufacturing procedure for Chloe SED to fit into the current usage and reprocessing procedures as done in practice, and be more affordable than the current alternative, within the context of Kisumu, Kenya."

2.4 Specifications

This section provides an overview of the needs and wants of the product from the client.

1 Accessibility

It should be possible to locally manufacture the device. Possible to source the material and manufacturing method within Kenya or nearby.
The device should be easy to obtain in the market.
It should also be easy to store the device in current hospital settings.

2 Usability

Using the device should not cause any additional discomfort to the healthcare providers and the patients.

The device should be reprocessable across Level 4 through Level 6 hospitals in Kenya.
The device should be easy to adopt into the existing process. This means that there should be a low barrier to entry with respect to training for use of the device.

The device has to last at least as long as the MVA kit.

3 Cost

The device should be affordable to use across Level 4 through Level 6 hospitals in Kenya.

4 Regulations

The device has to be compliant with local regulations, and should not face any issues going through the regulations to be approved.

Table.2.1 Design specifications

Environment	*What kind of environmental influences does the product need to withstand during production, transport and use (tempertature, vibrations, moisture, etc)? What effects of the product to the environment should be avoided?*	The product must be able to handle medical grade cleaning agents used in chemical sterilization, namely 2% Glutaraldehyde and 0.5% Chlorine solution The material selected must be biocompatible and non-toxic to patients
Environment	*What requirements result from observing, understanding, handling, operating (etc) the product ?*	Training and handling of the device must be faster and easier compared to the previous iteration
Target Product cost	*Target Product Cost : What is a realistic price for the product , considering similar products? What margin does it need to deliver?*	Each use cycle of the product must not cost more than 1.5 eur (184 ksh)
Life in Service	*With what intensity will the product be used and how long should it last? Is maintenance necessary and possible? What parts need to be accessible?*	The product must be able to handle daily use, cleaning and reprocessing for a minimum of 25 cycles
Safety	*Should specific precautions be taken with regards to the safety of users and non-users?*	The device should have a smooth form, and must be easy to handle.

Chapter 3

Material Exploration

3.1 Reprocessing

Understanding Medical Devices

According to the medical device classification by WHO (See Appendix x.x, pg x), Chloe SED fits into the definition of a medical device as it helps in control of conception.

Medical devices are classified based on their criticality and associated risk of using the device. For CE, there are 4 classifications, Class I, IIa, IIb and III. The regulations become increasingly strict for devices of higher class. (Classification Of Medical Devices And Their Routes To CE Marking, n.d.)

The Chloe SED fits under the Class IIA, as the highest classification of the system that it is a part of is IIA.

During surgeries, there is contact between the surgical tools, other medical devices, and the patient. This contact happens at different levels, namely critical, semi-critical and non-critical. This can cause transfer of pathogens from one patient to the next, via the equipment being used, possibly leading to Healthcare Associated Infections (HAI). To prevent this, medical equipment are either disposed of after single use or reprocessed between uses to decrease risk of pathogen transfer.

Based on discussions with the client and contextual study, Chloe SED has to be a Reusable medical device. (See Appendix A, pg 27).

Reprocessing

It is a step by step process of cleaning and disinfecting or sterilizing of medical devices (FDA, 2019), whereas sterilization is the process of destroying all microorganisms on the surface of a medical device. (CDC, 2019)

There are several reprocessing procedures available, based on the material being sterilized and it's capacity to handle steam, moisture and temperature

There are a variety of sterilization techniques available in a modern day hospital setting (Appendix x.x), out of which only 2 are commonly available in the hospital in context, namely Liquid chemical sterilization and Steam sterilization.

After use, the medical devices go through a cleaning and decontamination process. Following this, the device goes through a sterilization process, and it is recommended to either immediately use or package the device in a sterile environment. Once this is done, it is safe to use for 7 days until the device is non-sterile.

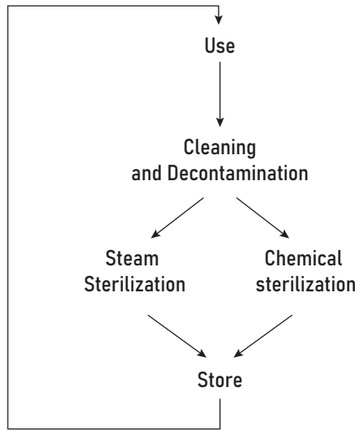


Fig.3.1 Use cycle of a medical device

Steam sterilization is nontoxic, inexpensive (Adler et al., 1998), rapidly microbicidal. It is the most widely used and the most dependable. It is done using an autoclave, where each item is exposed to direct steam contact at the required temperature and pressure for the specified time.

Fig.3.2 Autoclaves available in Jaramogi Oginga Odinga Teaching & Referral hospital (Image credits: Karl)

Fig.3.3 Sterilization bath used in in Jaramogi Oginga Odinga Teaching & Referral hospital (Image credits: Karl)

Liquid chemical sterilization is a procedure used to sterilize devices which are made out of materials that are not heat resistant. It is a two part procedure, first the device is cleaned with a chemical, and second the device is rinsed with running water to remove any chemical residue. This procedure is only recommended for devices that cannot be steam sterilized or are incompatible with other sterilization methods (FDA, 2018)

The process of sterilization for each method are explored in Appendix A, pgs 5-10.

3.2 Material Study

Several factors impact the choice of material for a medical device. The device will have to handle multiple cycles of reprocessing and use cycles before its end of life.

Material choice for medical devices is based on a few characteristics (Sastri, 2013), namely:

- Material characterization
- Sterilization resistance
- Chemical and lipid resistance
- Extractables and leachables characterization
- Biocompatibility and hemocompatibility
- Shelf life and stability

In the exploration to identify which material is most suitable for this use case, the first and most high-level investigation is into the four most commonly used types of materials for medical devices, metals, glass and ceramics and plastics.

1 Metals

Various surgical instruments have been made from several metals for thousands of years. (Fraker & Ruff, 1977; Williams, 1973) Medical devices are often manufactured from metals such as stainless steel, alloys of cobalt, titanium and titanium-based alloys, tantalum, zirconium and platinum.

Advancements over the years in annealing, forging, thermochemical processing and heat treatments have improved the strength and durability of medical device applications (Pilliar, 1991). Similarly, biocompatibility issues have been overcome by advancements in alloying and coating techniques, and these allow metals to continue being used in several applications. (ASM International & Davis, 2003).

Advantages

Manufacturing medical devices from metals ensure they are robust and precise, and when alloyed or coated appropriately, can be made corrosion-resistant and easily reprocessable.

Disadvantages

Metal corrosion, if it occurs, can severely affect the device's performance, integrity, and biocompatibility, and inadvertently using a corroded device could harm the patient. (Bundy, 1994). The cost of processing metal devices is usually higher than plastics since they need to be passivated, coated, or treated to prevent their corrosion when in contact with tissues, organs, and bodily fluids.

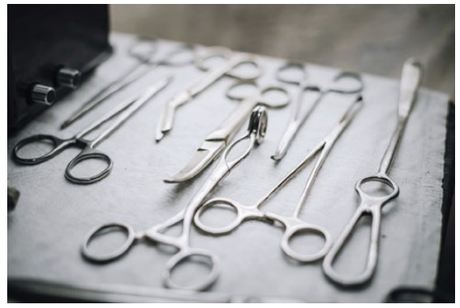


Fig.3.4 Metal medical devices (Image Credit: Getty images)

2 Glasses and Ceramics

A ceramic is defined as an inorganic crystalline solid material that is formed when inorganic, nonmetallic materials are heated to high temperatures to create strong heat-resistant materials. Typically, ceramics, when used in medical devices, are typically found in orthopaedics, and in bone and dental implants. (Vallet-Regí, 2001).

Glasses are defined as amorphous solid materials that have a lot of structural disorders. Most glasses contain silica (SiO_2) as their main component.

Advantages

Ceramics have a range of favourable properties including chemical resistance, biocompatibility, bioactivity, high stiffness and dimensional stability, high levels of hardness, high thermal stability, and excellent wear resistance.
Glasses are strong, biocompatible and can be found in applications such as artificial middle ear bone implants (Ducheyne, 1987).

Disadvantages

Most ceramics and glasses have poor mechanical properties and are brittle (Richerson & Lee, 2018), thus restricting their applications to non-load-bearing implants, lest devices that will be used on patients undergo mechanical stresses and break during use.

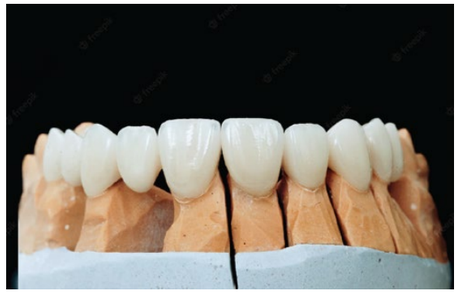


Fig.3.5 Ceramic dental implants (Image Credit: freepik.com)

3 Plastics

Plastics are synthetic high-molecular-weight materials that can be molded or formed into a wide range of parts and products ranging from coatings, fibres, films, and solid particles. There are thousands of different kinds of plastics which are broadly classified based on their physical properties, synthesis, resistance and reactions to substances and processes, or their manufacturing method. (‘Plastic’, 2022)

Advantages

Plastics provide several advantages over other materials. They have the highest level of design and manufacturing flexibility and can take on almost any form that is required. They have the best performance-to-weight ratio, in addition to being inexpensive and easy to mass-produce. (Sastri, 2013)

Disadvantages

Plastics however do have their disadvantages. Some plastics have poor mechanical properties and thermal resistance, and they are sensitive to aging (heat and humidity), but the plastics which do have good properties are more expensive. Within the US alone, healthcare facilities produce more than 5 million tons of waste each year. (Waste | Practice Greenhealth, 2022) of which at least 25% are plastics (Can Medical Care Exist without Plastic?, 2019), which are often disposed of in landfills rather than recycled. (McGain et al., 2008)

Fig.3.6 Plastic medical devices (Image Credit: Shutterstock)

3.3 Material Type Selection

Taking the Design Specifications (see page 22) into consideration, plastics are currently the best choice for manufacturing medical devices. In addition to this, plastics have a wide range of desirable attributes for the re-design of Chloe SED.

Table 3.1 Desirability of plastics

Advantages	Design	Design flexibility	Plastics can be molded into a variety of shapes and dimensions. This allows the complex form of Chloe SED to be manufactured.
		Bondability	Plastics can be joined or bonded to other plastics or metals during manufacture using adhesives, heat and other techniques. It is possible to manufacture Chloe SED using different plastics or metals and bond them.
	Medical	Biocompatibility	Many plastics are inherently biocompatible or can be made biocompatible using additives.
		Nonallergic - Mildew and fungal resistance	Plastics with a smooth finish do not allow bacteria to lodge in spaces. This combined with water resistance reduces microbial growth. This however is not applicable if the surface is porous, for example, in the case of 3D printed parts.
		Sterilization	Different types of plastics are resistant to different types of sterilization methods. Choice of material will have to be made based on the type of sterilization method that is being used.
	Material Properties	Lightweight	Plastics weigh half as much as aluminium, which is a light metal used for medical applications. They are easier to handle and cheaper to transport.
		Water-resistance	Some plastics are water-resistant and this is a desirable property for Chloe SED.
		Chemical and lipid resistance	Different plastics react differently with chemicals and lipids, and the right material can be selected based on the chemicals that will be present in the context of use. Chloe SED will have to be resistant to chemical sterilization.
		Mass producibility	Plastics can be produced in the millions with high precision and at a cheap cost (per unit). This is relevant because Chloe SED will have to be mass produced for use.
		Ease of processability	Plastics have lower working temperatures compared to metals, glass (1500-3000°C) and ceramics (2000-3000°C). The manufacture of metals also involves several steps of post-processing, such as heat treatment and annealing to improve the quality and longevity of the products.
Disadvantages	Material Properties	Poor mechanical resistance	Many plastics have poor mechanical resistance, especially compared to metals. They can soften and can form mechanical creep (deformation with time). The material selected for Chloe SED must have a moderate factor of safety for mechanical forces during use.
		Poor thermal resistance	Most commonly used plastics do not have high-temperature resistance. Chloe SED must be able to handle temperatures during sterilziation.
		Sensitive to aging (heat, light, humidity and air/gasses)	Some plastics degrade quickly when exposed to high heat and/or humidity. This comes into play when deciding the material for Chloe SED.

3.4 Plastics Classification

Plastics are classified into 3 major classes: Thermoplastics, thermosets and elastomers. There are other minor classifications that will not be explored here due to their lack of widespread availability on the consumer market, ruling them out as good materials for low-cost manufacture.

For the use case of Chloe SED, elastomers are not a good choice because of the material's physical flexibility; the device needs to be rigid for this application. The device will have to be made out of thermoplastics or thermosets, both of which are compared in Table 3.2 ('Elastomer', 2022; Sastri, 2013)

Thermoplastics, in general, have higher chemical resistance and hydrolytic stability, making them easier to reprocess when compared to a device made using thermoset plastics. Although thermosets have some good characteristics such as better heat resistance and lower mechanical creep, this is not necessary for Chloe SED applications. Thermoplastics are also easier to manufacture and post-process. *Overall, for the use case of Chloe SED, thermoplastics is a better choice.*

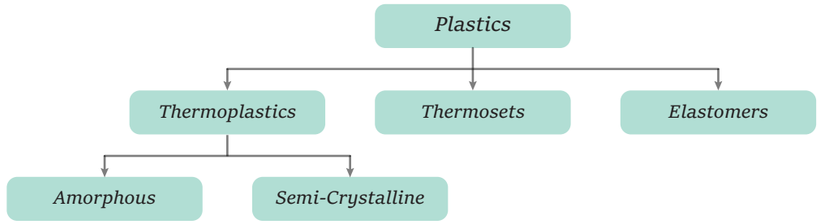


Fig.3.7 Classification of Plastics

Table 3.2 Comparison between Thermoplastics and Thermosets

Property	*Defintion*	*Thermoplastics*	*Thermosets*
Material hardness		Soft	Rigid
Optics/visual	Appearance	Clear	Opaque
Processing	Difficulty of manufacturing process	Easier to process	Difficult to process
Processing temperature	Temperature of manufacturing process	Higher temperature	Lower temperature
Scrap generated	Amount of material waste (scrap) generated during manufacturing	Low	High
Material cost	Initial material cost	Higher	Lower
Total part cost	Part manufacturing cost	Lower	Higher
Flow	Flow of material during manufacturing	High	Low
Electrical properties		Insulator	Conductive
Impact strength		Higher	Lower
Heat resistance	Resistance to temperature	Lower	Higher
Mechanical creep	Deflection under constant load over long periods of time	Higher	Lower

3.5 Material Selection

An important point to note ahead of selecting a material to be used in Chloe SED is that intended use cases range from Level 4 to Level 6 hospitals. While autoclaving is typically the preferred method of reprocessing at large, urban hospitals, smaller, rural hospitals rely on chemical sterilization and High-Level Disinfection. In order to avoid either kind of hospital needing to compromise on existing processes for reprocessing, Chloe SED needs to be reprocessable by both autoclaving and chemical sterilization, and so both factors were considered during the material selection process. The material properties that play a role in deciding these factors are Chemical resistance and hydrolytic stability.

Each factor was graded on a scale of 1 - 4, where:
1 - Poor
2 - Fair
3 - Good
4 - Excellent

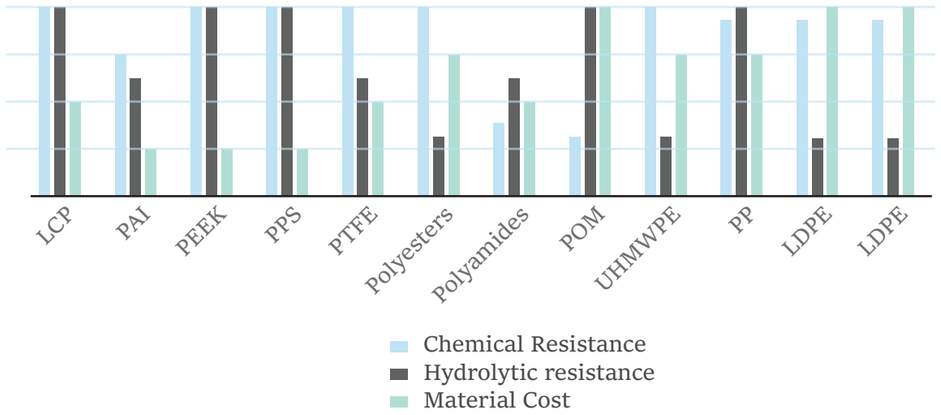


Fig.3.8 Material comparison

Comparing the performance of each material in the context of a medical device reprocessable by chemical and steam sterilization, the standout materials are LCP, PEEK, PPS and PP. In the following paragraphs, the four materials will be explored further to select the optimal option(s).

1 LCP

Although presenting excellent properties with regards to chemical and heat resistance, it is a difficult material to work with regard to manufacturing (Liquid Crystal Polymer | Chemeurope.Com, 2022; 'Liquid-Crystal Polymer', 2022). It forms poor weld lines, and it was only recently explored with 3D printing as a manufacturing method (Researchers Develop Way to 3D Print with Liquid-Crystal Polymers | Sci-News.Com, 2018). For this reason, *LCP cannot be a suitable material for manufacture at this time.*

2 PPS

PPS offers excellent properties for use as a medical device, including properties such as excellent strength, high heat and chemical resistance. The material does have limitations, such as its brittleness and tendency to warp (PPS Injection Molding | Polyphenylene Sulfide Engineered Plastic, n.d.) It also requires annealing (130°C for 2-3 hours) once 3D printed to achieve optimal physical and chemical properties. (PPS Injection Molding | Polyphenylene Sulfide Engineered Plastic, n.d.) All factors considered, *PPS does not appear to be a viable option for manufacturing Chloe SED by any means.*

3 PEEK

PEEK offers excellent mechanical, thermal and chemical properties, and is preferred for injection moulding. PEEK can be autoclaved for 800+ cycles. Though it is a very popular injection moulding plastic, it can be difficult to work with. Moulding of PEEK happens at very high temperatures (370°-450°C) and the machinery will have to be able to handle that temperature. (Injection Molding PEEK Resin | PEEK Injection Molding, n.d.) PEEK is also an expensive plastic.

If it can be proved that PEEK can handle sterilization with glutaraldehyde, then it is a suitable material for Chloe SED.

4 PP

PP is a great commodity plastic that provides good strength for use in the context of Chloe SED. It is also easily injection mouldable, and is commonly used for medical devices. PP has good resistance to Glutaraldehyde, and a limited number of autoclave cycles (~25 cycles). The limitations of PP are that is difficult to 3D print and can cause warping, making it difficult to ensure equal quality in prints. It is also a very cheap and easily available material.

If Injection moulding is an option, PP is a great choice for manufacturing Chloe SED.

Out of all the options available among semi-crystalline thermoplastics, PEEK and PP are currently the best choices.

PEEK is expensive compared to the alternatives, but it also lasts a longer number of cycles, which will be explored experimentally.

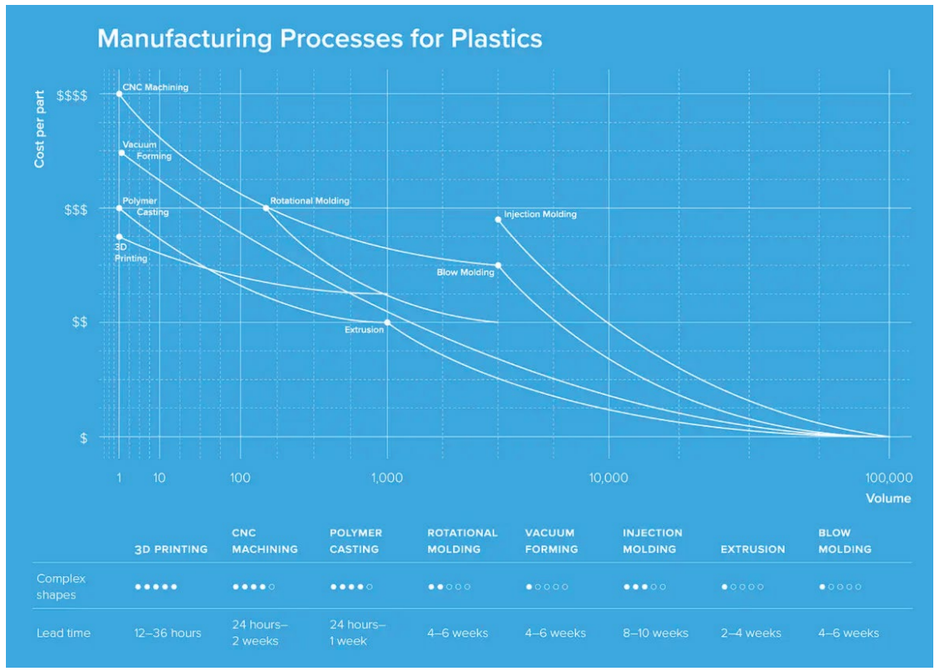
If injection moulding is the method of manufacturing, PP is the better choice.

3.6 Manufacturing

The manufacturing choice for thermoplastics is made based on the following characteristics: form, volume/cost, lead time and material choice (Formlabs, 2022). The following are some of the methods available to manufacture plastics:

- 3D Printing
- CNC Machining
- Rotational Molding
- Vacuum Forming
- Injection Molding
- Blow Molding

A description of these methods can be found in the Appendix A, pg 21.



	3D PRINTING	CNC MACHINING	POLYMER CASTING	ROTATIONAL MOLDING	VACUUM FORMING	INJECTION MOLDING	EXTRUSION	BLOW MOLDING
Complex shapes	●●●●●	●●●●○	●●●●○	●●○○○	●○○○○	●●●○○	●○○○○	●○○○○
Lead time	12–36 hours	24 hours–2 weeks	24 hours–1 week	4–6 weeks	4–6 weeks	8–10 weeks	2–4 weeks	4–6 weeks

Fig.3.9 Manufacturing process comparison for Plastics (Image credit: Formlabs, 2022)

Chloe SED needs to be a solid part, rejecting all the manufacturing procedures applicable for hollow products (rotational moulding, vacuum forming, blow moulding). It also has a complex form to be manufactured, so extrusion is not a viable method. This leaves CNC machining, Injection moulding and 3D printing. CNC machining has high costs and is applicable in the case of low tolerance and high accuracy products, so it can be rejected.

Out of all the discussed manufacturing methods, the procedures that are relevant to the manufacture of Chloe SED are 3D printing and Injection Molding. The important factors are compared below.

Table 3.3 Comparison between characteristics of 3D printing and Injection Moudling

	Property	*3D printing*	*Injection Molding*
Form	Possible complexity of the product	High	Moderate to high
Lead time	Duration between producing CAD models to starting production	Less than 24 hours	2-4 months
Cycle time	Duration of production for each unit	Several hours, based on part size	Seconds
Setup cost	Investment required to set up the manufacturing process	Low	High
Cost per part	Cost of producing a single unit	Moderately high	Very low
Volume	Maximum or minimum number of units to be produced for mfg method to be viable	<1000 parts	5000+ parts

Conclusion:

The differences between 3D printing and Injection molding comes down to the volume of parts, setup cost and cost per part. At this stage of the project, the client had stated a production volume of 1000 units, so 3D printing was decided as the method of manufacturing.

3.7 Material Degradation

A medical device being used degrades over time due to several reasons (Medical Device Polymers, 2013), such as use, storage and reprocessing methods. Based on the material and manufacturing choice, even a small amount of water absorbed can cause material degradation at higher temperatures.

Use

The product does not go through rough wear and tear during use. The use case is generally slow movement with most of the friction between components focussed on one area as shown in Fig. 1.21., pg. 13.

Storage

Storage plays a role in the degradation of medical device material. The availability of facilities for proper storage of medical devices varies between HICs and LMICs. Raised temperatures and humidity speeds up the aging process (Micom Laboratories, 2022). This is not within the scope of the project.

Fig.3.10 Sterilization storage (Image credits: Spacesaver)


Fig.3.11 Storage of sterilized medical devices, Kenya (Image credits: Karl Heinz)

Reprocessing

As discussed in Chpater x.x (page x.), reprocessing plays a major role in affecting the number of use cycles of the device. In the hospital for this case study, two types of reprocessing procedures are commonly used, Steam sterilization and Chemical sterilization. Although PEEK is known to resist Steam sterilization (Kumar et al., 2018), its resistance to Glutaraldehyde and the overall sterilization process is unknown.

For the scope of this project, it would be good to explore the effect of reprocessing on the material.

For a material to be a good choice for Chloe SED, it must be able to handle a minimum of 25 cycles of use and reprocessing. The number of cycles is taken to be 25 as this is comparable to the recommended number of use cycles for MVA syringe (MVA Calculator, 2022). For testing the material against chemical reactions, an experiment is developed.

Chapter 4

Material Testing

4.1 Research Aim

The objective of the study is to understand how reprocessing by means of High-level disinfection (HLD) or Chemical sterilization, affects the mechanical strength and product integrity of a reusable 3D-printed syringe extension device (SED) used for administering paracervical analgesia during MVA.

The reprocessing procedure as done in context has been explored in Appendix A, pgs 5 and 9. For the chemical resistance of the material, the procedure of Chemical Sterilization and High-Level Disinfection (HLD), as described in Fig. 4.1. The experiment was conducted on PEEK and PP.

Method

Two tests were performed to understand how reprocessing by means of Chemical sterilization or high-level disinfection (HLD), affects the mechanical strength and product integrity of a reusable 3-D printed syringe extension device (SED) used for administering paracervical analgesia during MVA.

To test for the mechanical strength of the SED after reprocessing, an ASTM D638 tensile test was performed on 3-D printed PEEK and PP samples, before and after 25 cycles of reprocessing procedures.

To test for product integrity of Chloe SED after reprocessing, a weight difference analysis, functionality test, and visual inspections for any deformation were carried out.

Weight difference analysis was to measure retention of chemicals and material degradation in the SED after chemical HLD and sterilization.

The SED was assembled, used and disassembled, including syringe assembly and disassembly, after each cycle of sterilization. Video recordings were made.

Visual inspection through observation of individual parts and assembly of the SED after chemical HLD and sterilization to check for any physical deformation. Pictures were taken.

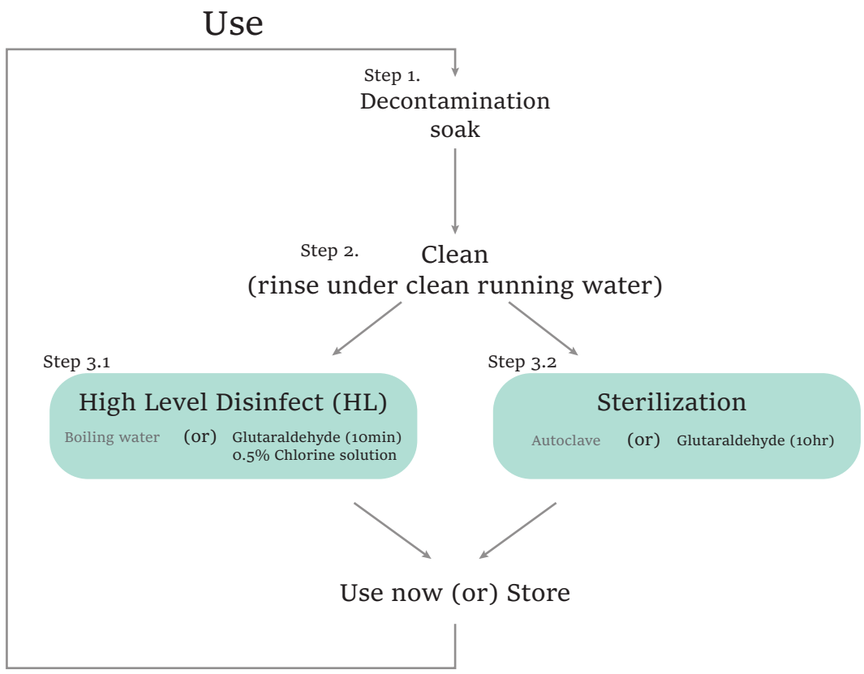


Fig.4.1 Reprocessing procedure

Tensile samples

Three sets of tensile samples of the same print quality were created for each material. A total of 6 sets of tensile samples were printed. The printing was outsourced to Roboze (roboze.com), a manufacturing company that specialized in 3D printing. Each set consists of 5 samples. Each set underwent a different treatment. The sample design matched the specifications listed in the ASTM D638 standard and was modeled to be 3mm thick and 165mm long. The samples were printed on edge. The samples were weighed using a Kern ABT 320-4M weight scale.

- SET 1 samples were left untreated and served as a control group. This set was labeled as the Control group (C).
- SET 2 of the tensile samples underwent 25 cycles of reprocessing through Chemical sterilization as in Fig. 4.1 and steps 1, 2, and 3.2 of the reprocessing procedure. This set was labeled as Sterilization (S).
- SET 3 of the tensile samples underwent 25 cycles of reprocessing through HLD as in Fig. 4.1 and step 1, 2, and 3.1 of the reprocessing procedure. This set was labeled as High Level Disinfection (HLD).

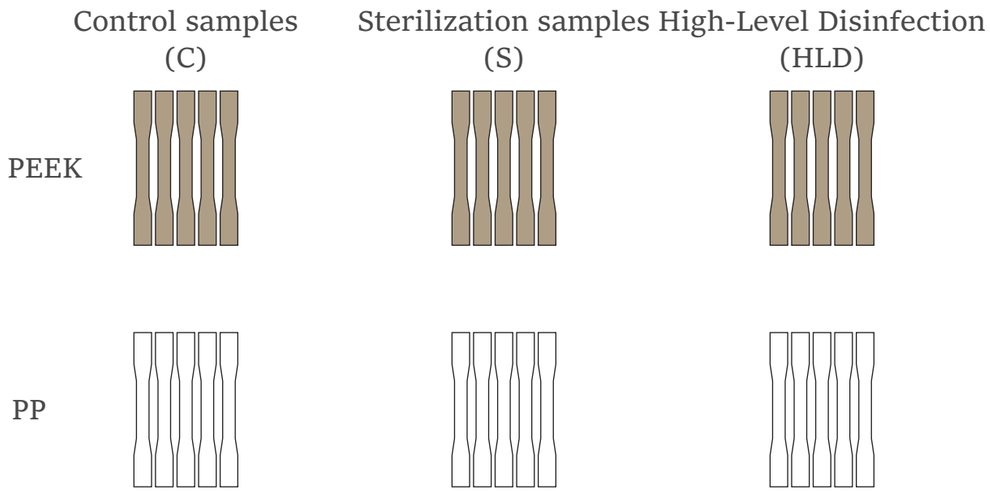


Fig.4.2 Dogbone samples

Chloe SED Samples

Three sets of Chloe SED samples of the same print quality were created for each material. A total of 6 sets of Chloe SED samples were printed. The printing was outsourced to Roboze (roboze.com) the same as for the tensile samples. Each set consists of 1 unit of Chloe SED, consisting of 3 parts, body, plunger and thumbpress. Each set underwent a different treatment.

- SET 1 samples were left untreated and served as a control group. This set was labeled as the Control group (C).
- SET 2 of the tensile samples underwent 25 cycles of reprocessing through Chemical sterilization as in Fig. 4.1 and steps 1, 2, and 3.2 of the reprocessing procedure. This set was labeled as Sterilization (S).
- SET 3 of the tensile samples underwent 25 cycles of reprocessing through HLD as in Fig. 4.1 and step 1, 2, and 3.1 of the reprocessing procedure. This set was labeled as High Level Disinfection (HLD).

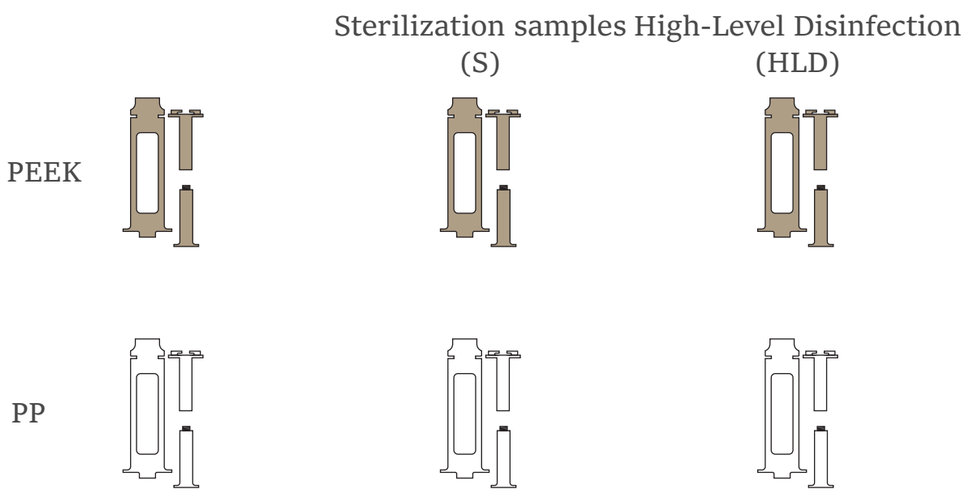


Fig.4.3 Chloe SED samples

Product Integrity Testing

At the start of each reprocessing cycle, the SED was assembled, used and disassembled, including syringe assembly and disassembly. This process was recorded. The samples were weighed during each cycle of sterilization.

4.2 Results

A total of 30 samples were printed and tested, 15 of PEEK and 15 of PP. Due to an error with the test setup, PEEK control sample 1 was removed, which represents 3.3% of the total number of printed samples. After sample removal, a total of 29 measurements were obtained.

Sample Weights

Weight data were collected twice every cycle for 25 cycles. The graphs for the individual increase in weight, and absolute increase in weight are presented in Appendix D.

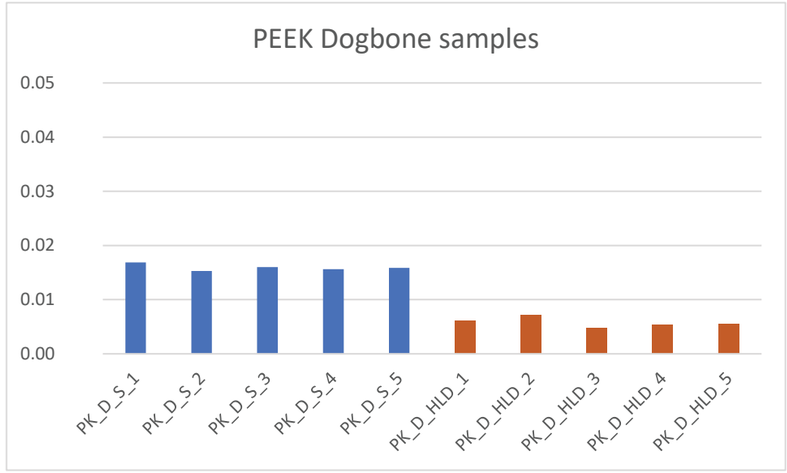


Fig.4.4 Graph of difference in weight from the last cycle the original weight, PEEK Dogbone

For the dogbone samples, sterilization samples have a larger increase in weight as compared to HLD samples. HLD samples have roughly half the increase in weight as compared to Sterilization samples.

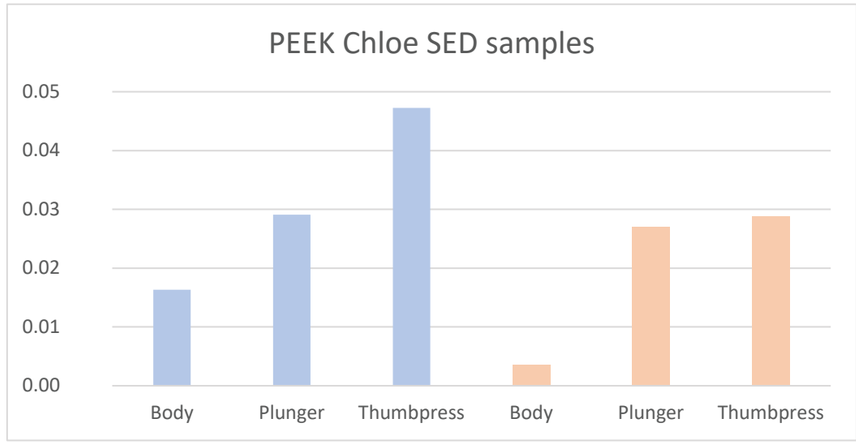


Fig.4.5 Graph of difference in weight from the last cycle the original weight, PEEK Chloe SED

4.2 Results

For Chloe SED samples, the increase in weight of Body is comparable to that of Dogbone samples.

The plunger has double the increase in weight when compared to Body or dogbone samples. HLD Plunger has a similar weight increase when compared to Sterilization plunger.

Sterilization Thumbpress has the highest increase in weight among all the PEEK samples. HLD Thumbpress has roughly half the increase in weight when compared to sterilization thumbpress.

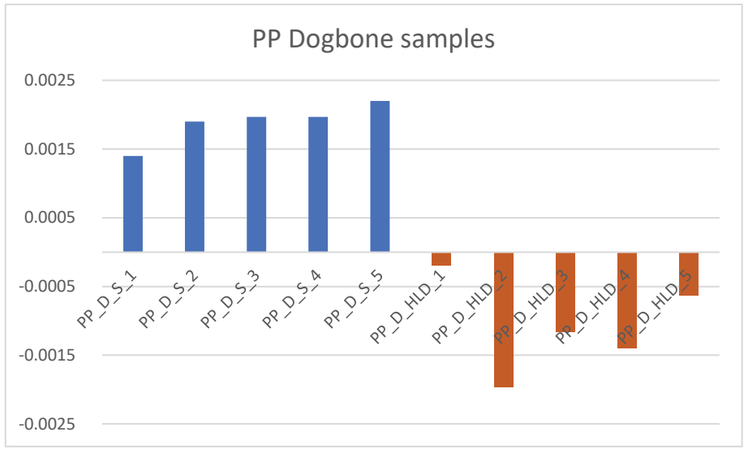


Fig.4.6 Graph of difference in weight from the last cycle to the original weight, PP Dogbone

Change in weight of PP samples is one order smaller than PEEK samples. PP samples have slightly more varying weights when compared to PEEK.

All PP HLD samples show a drop in weight. The dogbone samples have a large variation in the drop in weight.

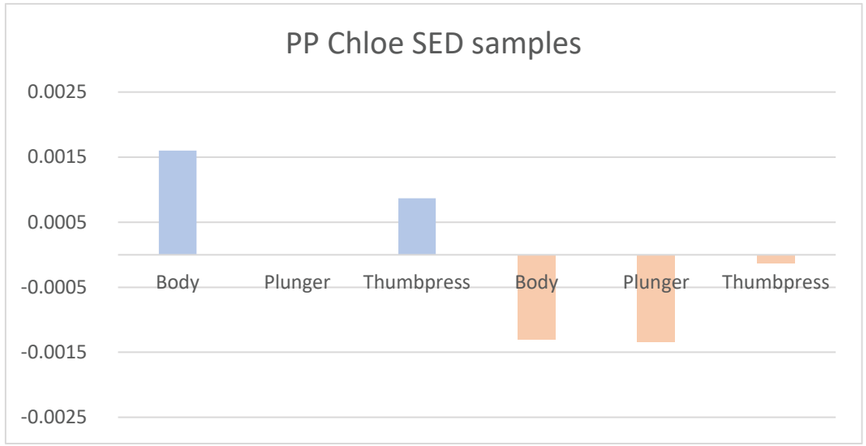


Fig.4.7 Graph of difference in weight from the last cycle the original weight, PP Chloe SED

Tensile Strength

The mean strength of PEEK undergoing chemical sterilization and HLD shows a decrease of 0.36% and an increase 1.4% respectively, and for PP undergoing chemical sterilization and HLD can increase by 0.39% and decrease by 2.36% respectively.

Table 4.1 Tensile strength of samples

	Property	*Tensile Strength - Avg (min-max) (N)*
PP	Control	825.68 (794.62 - 851.13)
	Sterilization	828.98 (801.51 - 871.63)
	HIgh Level Disinfection	806.18 (782.42 - 831.15)
PEEK	Control	3707.46 (3394.65 - 3837.21)
	Sterilization	3693.98 (3324.55 - 4003.88)
	HIgh Level Disinfection	3759.73 (3470.47 - 3856.24)

Limitations

The study took place in a controlled environment, with consistent temperature and humidity throughout the course of the experiment, which is not comparable to the ambient conditions of the case study. Elevated temperatures and humidity increase the pace of aging of materials. (Micom Laboratories, 2022). It was not possible to assess the effect of individual chemicals or water absorption. The nature of the manufacturing method, 3D printing, inherently causes some variation in the prints. This affects the weight change due to variation in the roughness of the surfaces, which in turn affects the absorption. A recommendation for any future experiment would be to produce a larger number of samples to test with.

4.3 Discussion

In this study, dogbones of PEEK and PP material went through 25 cycles of Chemical sterilization and High-Level Disinfection. All PEEK samples and PP Sterilization samples showed an increase in weight, where PP HLD samples showed a decrease in weight.Both increases and decreases were found for tensile strength, with a maximum increase of 1.4% and a maximum decrease of 2.36%.

Weight Increase

For PEEK, the weight increase of Chloe SED body is similar to dogbone samples. This is due to the consistent and smooth surface of the Chloe SED body. It is easy to clean and dry with tissues/sterile gauze.

The SED plunger and thumbpress show higher changes in weight compared to the body and dogbone samples. This can be attributed to the complexity in form, and the external and internal screw threads. The increased surface area could allow for higher chemical retention, as it is difficult to ensure the parts' cleanliness and ensure complete dryness at the end of the procedure. Furthermore, the ragged edges and uneven surface of the plunger could contribute to the change in weight.

Tensile Testing

The impact on mean strength of PEEK and PP after reprocessing by chemical sterilization and HLD are outlined here in Table 4.3.

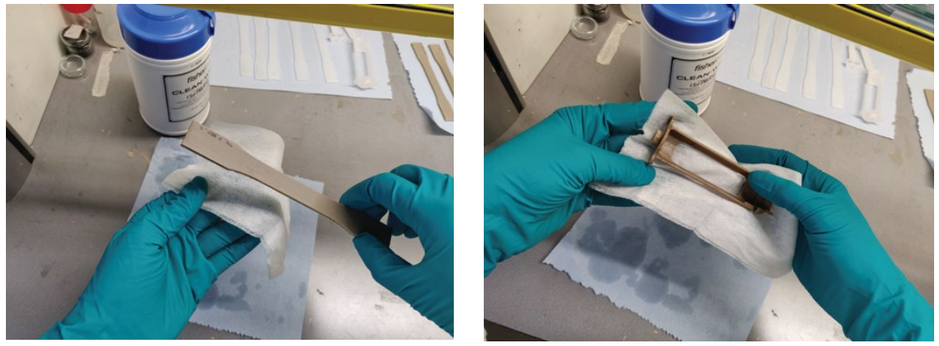


Fig.4.8 Drying of Dogbone Chloe SED body sample

Table 4.3 Impact of reprocessing on mean strength of samples

	Chemical Sterilization	*HLD*
PP	0.39% increase	2.36% decrease
PEEK	0.36% decrease	1.4% increase

There does not seem to be a consistent logical explanation for the varying increase and decrease of tensile strength of the samples undergoing chemical sterilization or HLD. As the environmental factors and procedures were kept consistent for all the samples, the reason could be attributed to different drying rates between the samples. To understand this phenomenon deeper, more stringent control with regard to the drying rate of the samples could be implemented and studied. However, these devices are built to operate only within the elastic region, and these forces are not encountered within actual use cases.

Fracture During Tensile Testing

The pattern of necking for PP samples remained the same during the start of the tensile tests but progressed quickly for chemically treated samples. The fracture formation for the chemically treated samples was ragged and there was a separation between fibres of the 3D printed sample.

The trend of necking and breaks for PEEK samples remained consistent. The majority of the breaks were in the grip section of the sample. This can be attributed to the slow necking and change in the distribution of forces.

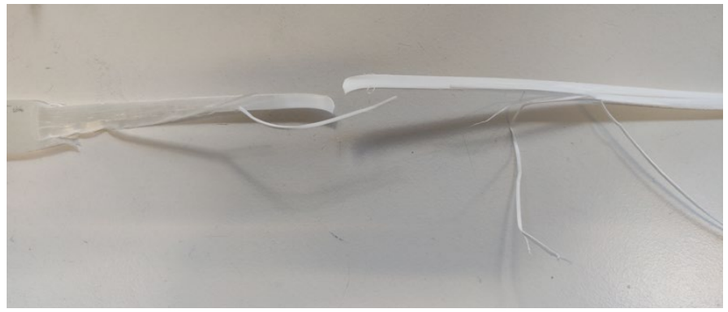


Fig.4.9 Fracture of Chemically treated PP samples

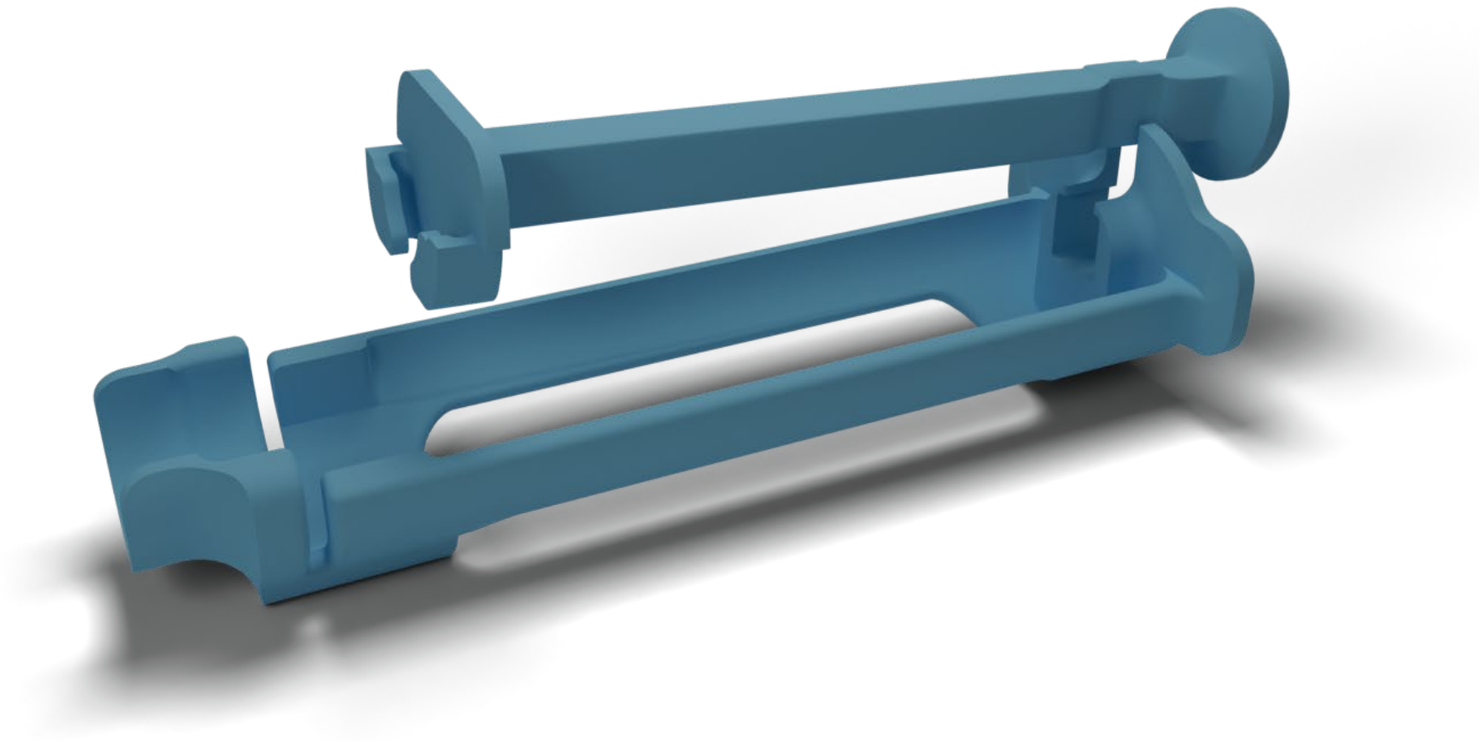
Fig.4.10 From left
a) Fractre of Chemically treated PEEK samples
b) Necking of PEEK sample
c) Progression of necking in the grip area of PEEK sample

4.4 Conclusion

In this study, it was shown that the median strength of PEEK undergoing chemical sterilization and HLD can change by 0.36% and 1.4% respectively, and for PP undergoing chemical sterilization and HLD can change by 0.39% and 2.36% respectively. It is safe to say the materials can used to manufacture a medical device and work safely for a minimum of 25 cycles, when considered from a sterilization perspective. Considering this, PP would be a better option for Chloe SED, if injection moulding is decided as the manufacturing choice. Within 25 cycles, it provides the same characteristics while being cheaper compared to PEEK.

Chapter 5

Re-Design



5.1 Implications on Design

In this section, the results from the tests are presented in relation to their implications on the design of Chloe SED.

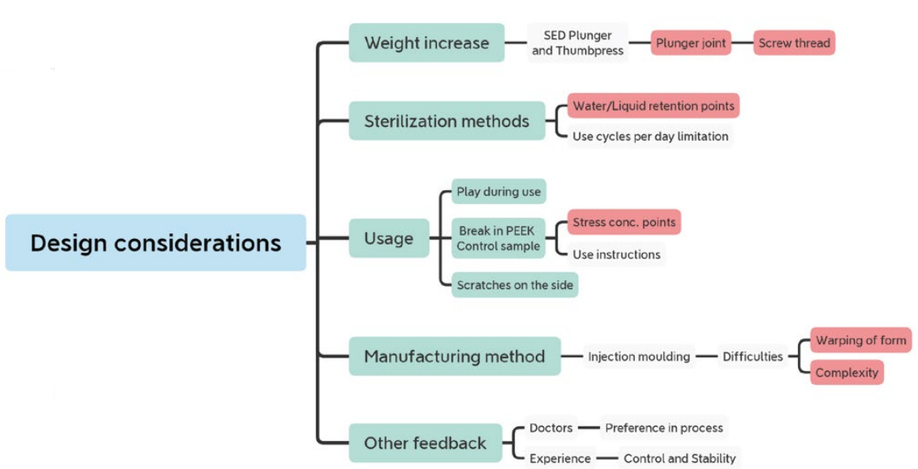


Fig.5.1 Design considerations for Chloe SED

Weight Increase

Contact with chemicals and water impact plastics by causing chain cleavage of the polymers and loss of molecular weight (Medical Device Polymers, 2013), causing chemical retention and loss of product integrity. This further causes changes to the weight of the device.

As discussed before, the SED plunger and thumbpress show higher changes in weight compared to the body and dogbone samples. This is caused by the screw threads and plunger joint.

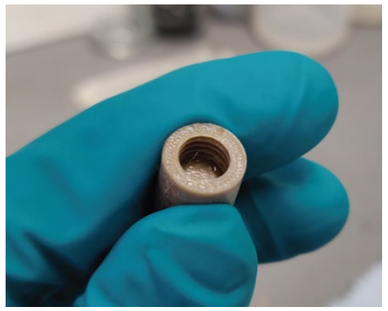


Fig.5.2 Water retention in screw thread

Sterilization Methods

Complex surfaces, such as the screw thread and plunger shape, cause an increase in surface area that is difficult to clean. This may cause chemical retention, and could be a potential source for pathogen or chemical transfer and must be avoided.

The sterilization method also puts a limit on the number of uses possible for a Chloe SED unit. The hospital facility under study at Kisumu, Kenya, is open from 9 am - 6 pm, a total of 9 hours. From hospital records, the number of MVA abortion cases per day is roughly 8.

If the device is being reprocessed using chemical sterilization, it can only be used one time per day, as the end-to-end process of chemical sterilization can take up to 12 hours excluding time for air drying. If HLD is used, there's 30 minute processing period with the SED having to be dried twice. In this case, the SED can be used up to 2-3 times per day.

For a normal working day, a minimum of 8 Chloe SED units is necessary for optimal operation at a Level 5 hospital. This number will vary based on the level and location of the healthcare facility. This will need an increase in the number of units to be manufactured.

The original decision by the client to manufacture 1000 units was made under the assumption that 1 hospital will need only 1 Chloe SED device. But now, at least 8000 units will have to be manufactured to be used in all MVA procedures across Kenya. Because of this increase in the number of units being manufactured, injection moulding is also a manufacturing method that may be considered.

Usage

There exists some play between parts of the Chloe SED during assembly and disassembly. The impact of this play on the usage of Chloe SED is minimal. During testing, this was solved by holding the part down using fingers, this will have to be communicated through the instructions to use the device.

The PEEK_Chloe SED_Control Sample broke during the second use cycle.

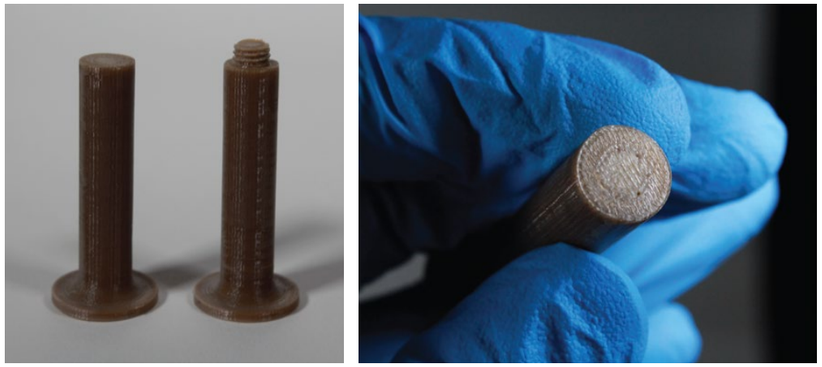


Fig.5.3 Break of PEEK control sample

The break is due to flexural bending at the joint, due to forces during the assembly of the unit. (Fig. 5.4)

This was avoided in other components by reducing play, gripping with the plunger and keeping the lower end in the circular slot of the SED body. This arrests the degrees of freedom and allows for more control of the parts during the assembly. This will have to be conveyed through the instruction manual.

The Chloe SED samples developed scratches during testing. This is unavoidable and part of the use.

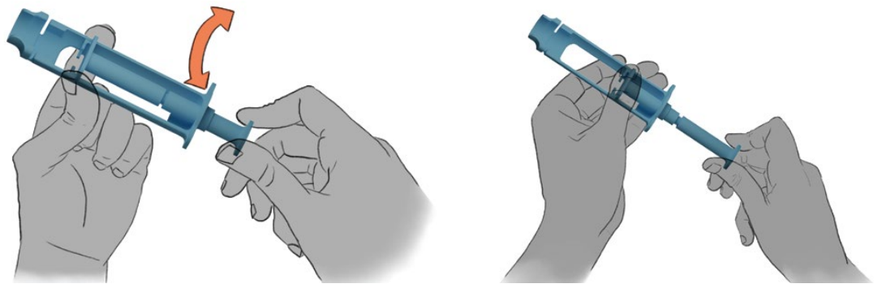


Fig.5.4 From left a) Bending forces that caused the break of PEEK sample b) Thumb grip used to prevent break of samples

Injection Moulding

Injection moulding is now a reasonable method of manufacturing. As discussed earlier in this chapter, at least 8000 units will have to be manufactured to be used in all MVA procedures across Kenya. For this volume of production, Injection moulding is a cheaper and faster method of manufacturing. But the decision to switch to injection moulding as a manufacturing method brings its own set of challenges.

Attention has to be given to the design to prevent warping during manufacturing. Complex form, such as the internal screw thread, will increase the complexity and hence the cost of the mould.

Other Feedback

During the initial interview with Dr. Stephen Gwer, he mentioned having a variation in the preference for the procedure of using Chloe SED.

The initial assumption was, due to the healthcare professionals being used the feel of using the syringe for withdrawing anesthesia, they do not prefer to use the Chloe SED during this process, i.e. they preferred method a. To validate this assumption, the client was interviewed regarding the usage. According to clinical trials ongoing in Kenya, the healthcare professionals got used to method b. This was used as usage method for the re-design of Chloe SED.

From personal experience with injection of anesthesia, stability and rate of injection are important. The feeling of expanding skin/-flesh when injecting anesthesia can be painful and uncomfortable, so the anesthesia is injected slowly, giving the body time to expand.

Because of this, mechanical play during injecting the lidocaine must be kept to a minimum. The surface of the Chloe SED which is sliding should be kept consistent, and ideally close to the feeling of using a syringe. The static friction must be comparable to that of using a syringe, and sliding friction and static friction must be close to each other to allow easy control of the rate of injection while preventing sudden jerks and backlash.

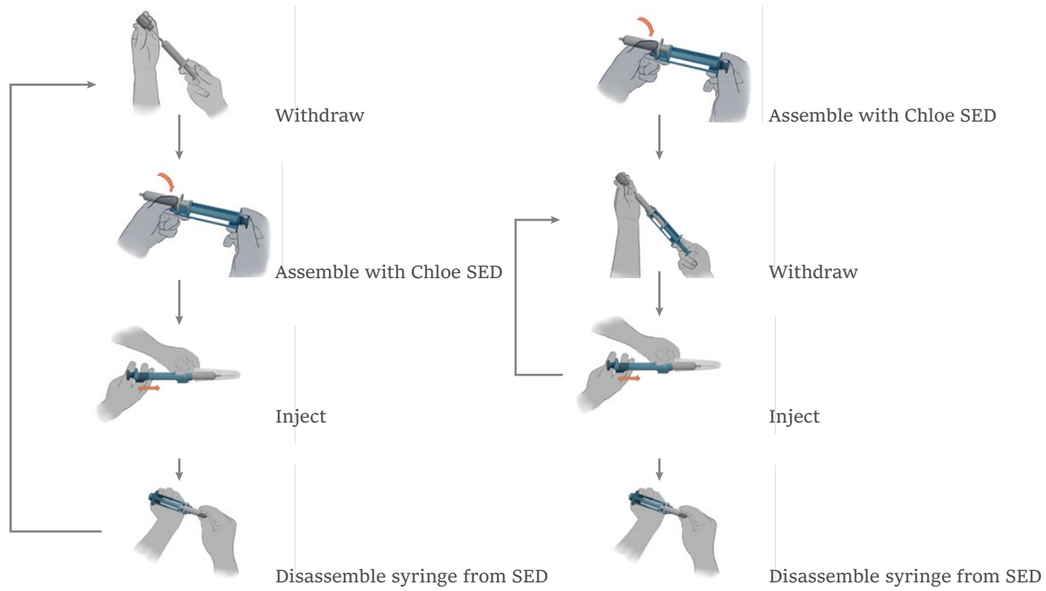


Fig.5.5 Usage methods for Chloe SED

5.2 Redesign Directions

The break is due to flexural bending at the joint, due to forces during the assembly of the unit. (Fig. x.x)

This was avoided in other components by reducing play, gripping with the plunger and keeping the lower end in the circular slot of the SED body. This arrests the degrees of freedom and allows for more control of the parts during the assembly. This will have to be conveyed through the instruction manual.

The Chloe SED samples developed scratches during testing. This is unavoidable and part of the use.

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Attention has to be given to the design to prevent warping during manufacturing. Complex form, such as the internal screw thread, will increase the complexity and hence the cost of the mould.

Joint

The joint has the highest impact in the design and use so far. The screw thread contributes to higher change in weight of device due to sterilization, weight absorption, possible break during use and increased complexity of manufacturing.

Plunger

The plunger is the second part that needs to be changed. The form causes high surface area which is hard to manufacture using 3D printing, and removing the supports causes.

Shrinkage

In PP Chloe SED samples, the slot for the syringe undergoes bending because of reprocessing and drying. This could be prevented by adding more material/ribs to the SED.

Surface

The surface of PP Chloe SED is jagged due to the nature of 3D printing. This causes jagged motion during injection and must be avoided. However, this issue will not exist when the device is injection moulded.

Play During Use

Play during use of the Chloe SED exists but it does not cause issues with use during the early stages of use of the product. After discussion with the client, this was left for a future iteration of the product based on results from on site testing.

Due to the timeframe for the redesign, the joint was decided as the focus. With the above conditions, a brainstorming session was conducted.

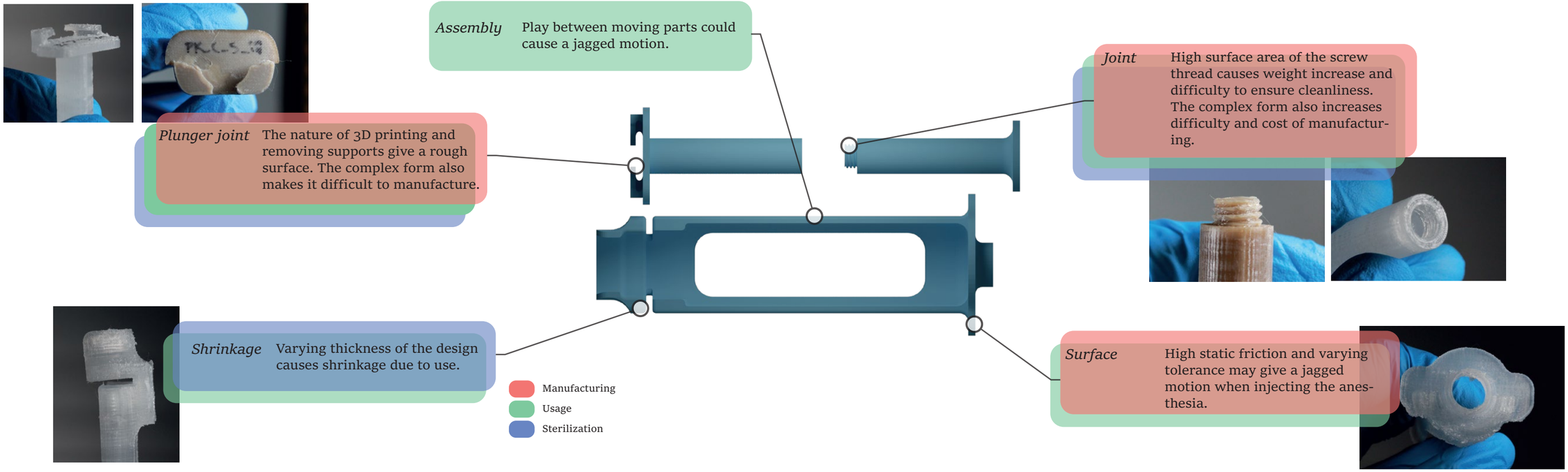


Fig.5.6 Redesign directions

5.4 Concept Generation

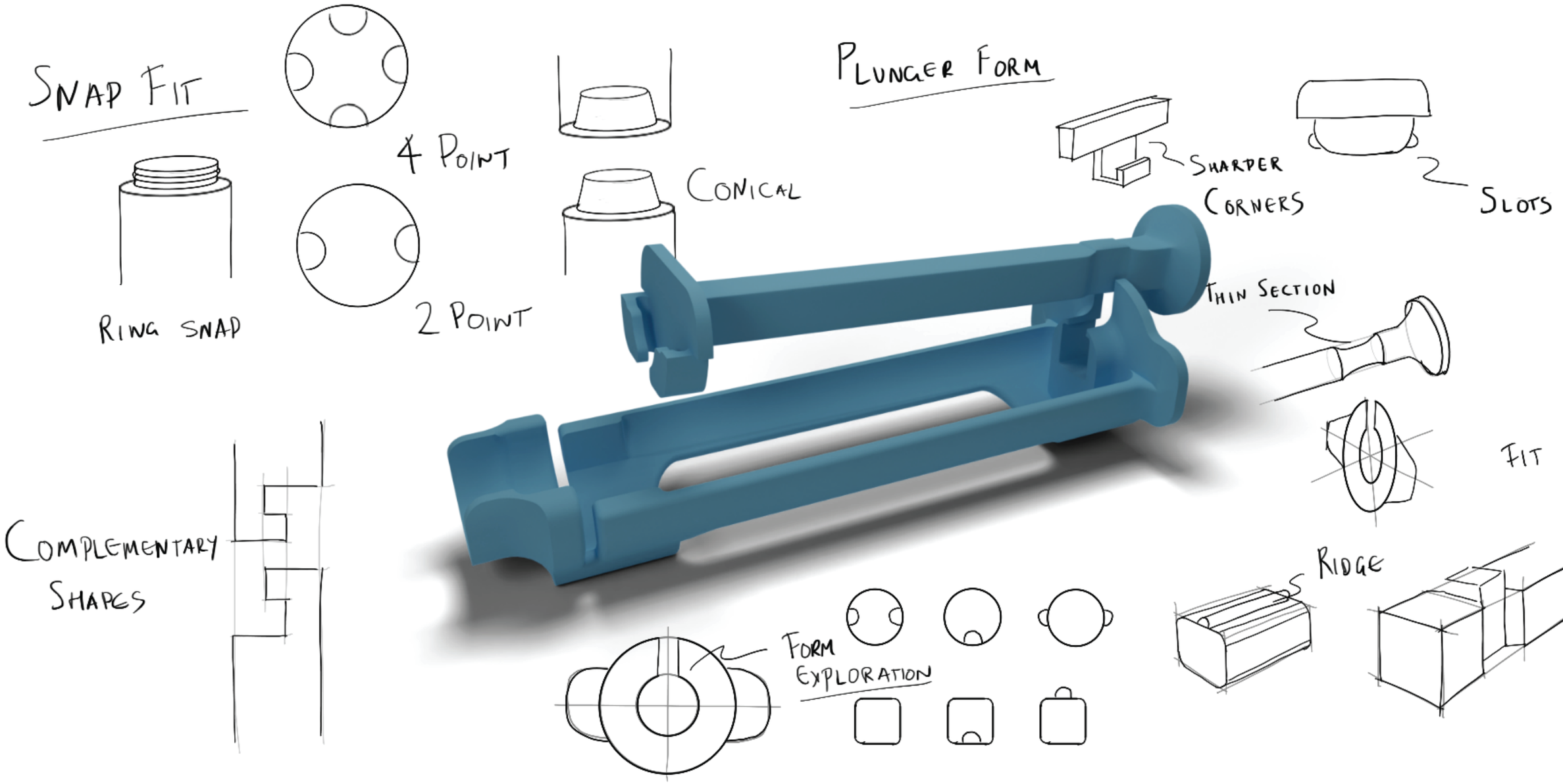


Fig.5.9 Concept generation

5.3 Final Design

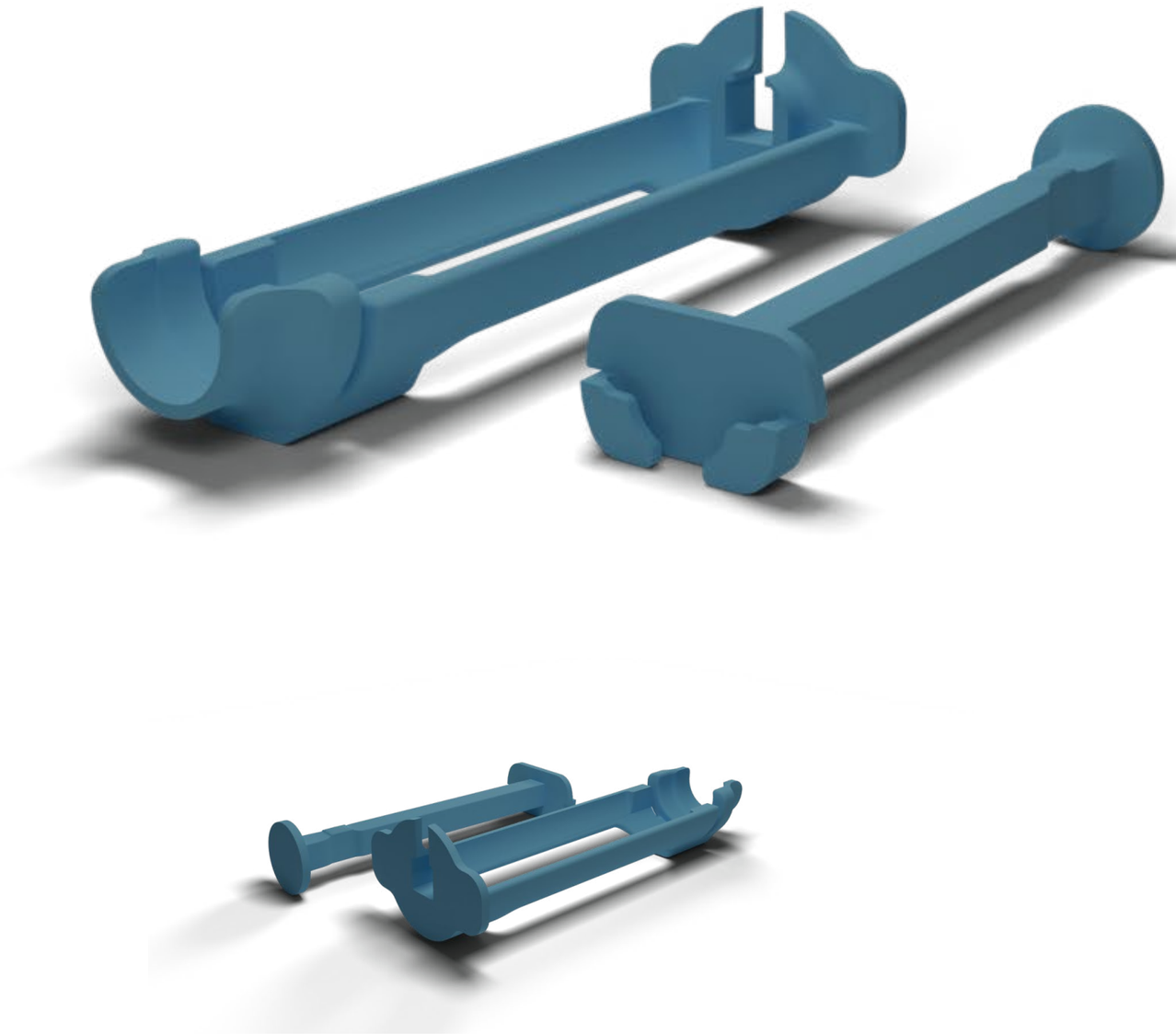


Fig.5.7 a) and b)Perspective views

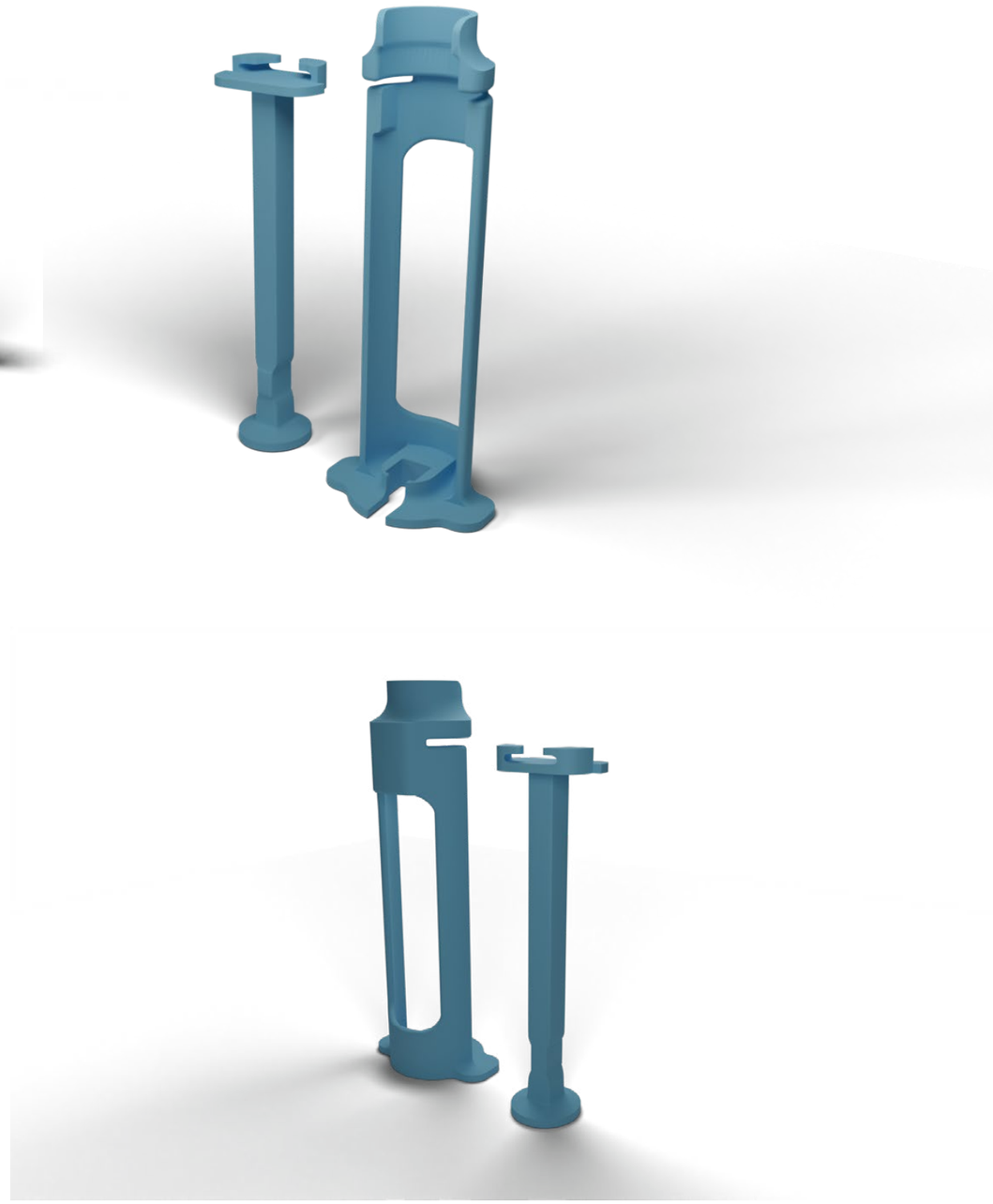


Fig.5.8 a) and b) Front and back views

5.5 Features

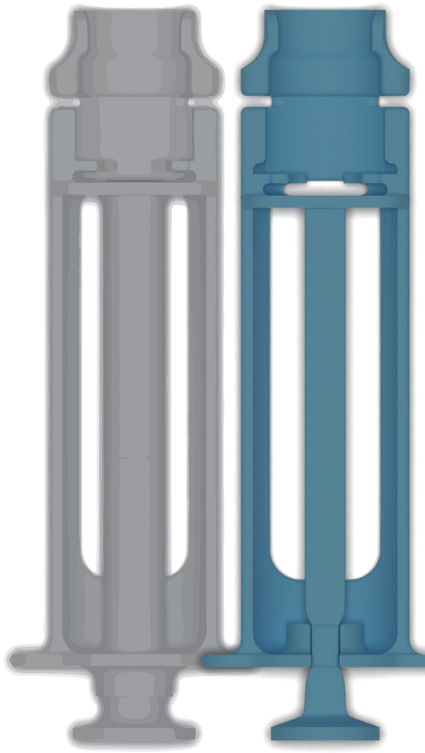


Fig.5.10 Overview of design changes

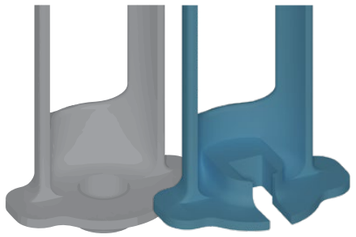


Fig.5.11 Design changes in the base

Material was added behind the slot to allow ease of removal of parts during manufacturing. The slot was inverted to the inside to allow space for the insertion of the plunger, while keeping the dimensions of the product the same.

The plunger was merged into one part, instead of the plunger + thumbpress. A thin section with a ridge was added to allow and control the insertion of the plunger into the body.

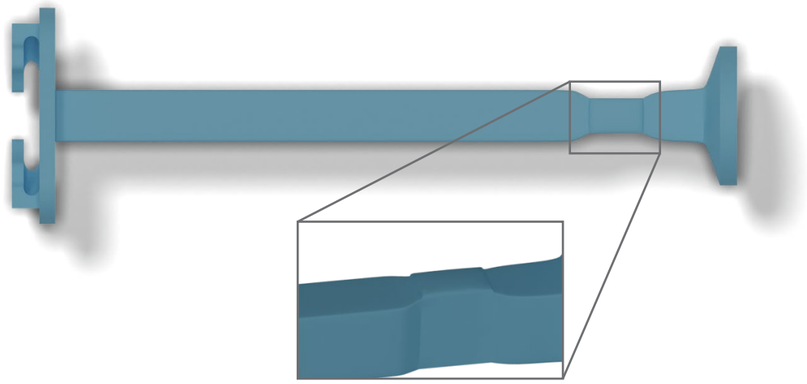


Fig.5.12 Overview of Plunger and ridge

Fig.5.13 Square slot

The hole for the assembly of plunger and body was made from a circle into a square hole with rounded edged. The square shape limits the roatation of the plunger while allowing smooth movement.

Material was removed to create the slot for inserting the Plunger.

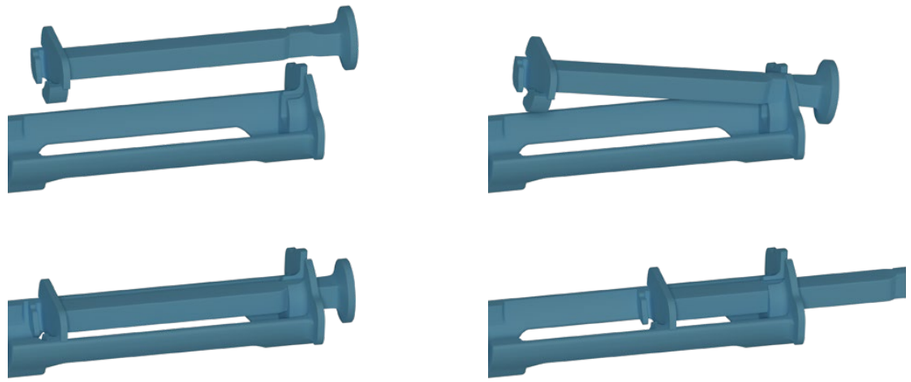
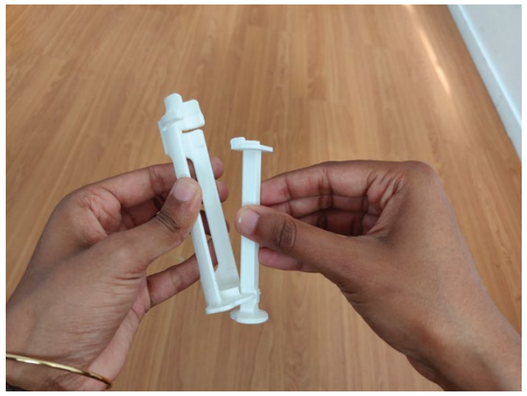


Fig.5.15 Inserting the Plunger

5.6 Usage



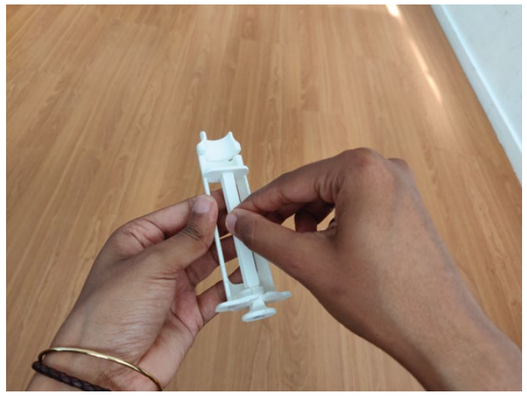


Fig. From left to right
a) The Chloe SED before assembly
b) and c) Inserting the plunger

The redesign form of Chloe SED has an improved assembly process. The thin section of the plunger of the SED fits into the slot provided in the body. Once inserted, it can be push/pulled within the slot.

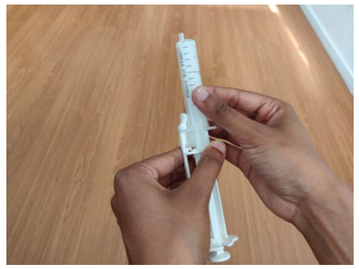
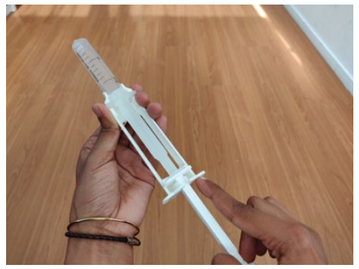


Fig. Assembly the syringe to the SED

The syringe assembly has been kept the same as existing method. The syring is inserted into the body and plunger of the SED.



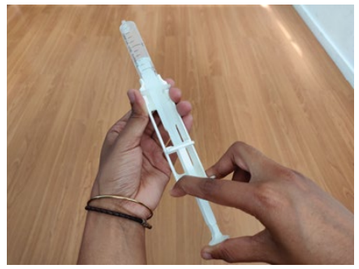
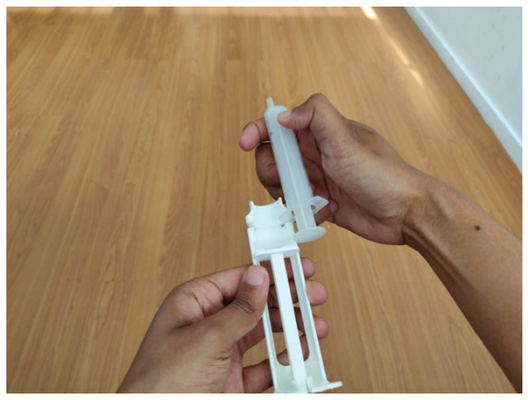
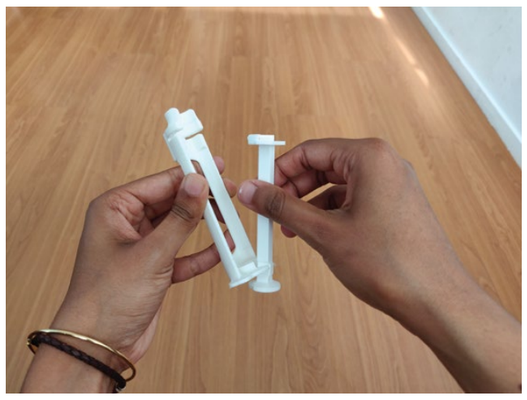


Fig. From left to right
a) Motion for withdrawing the anesthesia
b) Motion for injecting the anesthesia

The withdrawing and injecting motion has been kept the same as existing design. The rotation and mechanical play between the plunger and the body has been noticeably lesser than current design.





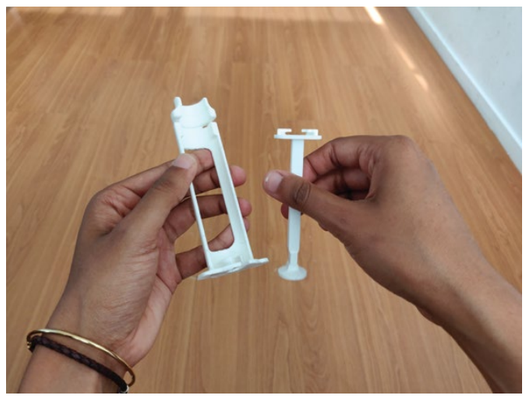


Fig. From left to right
a) Disassembling the Syringe from SED
b) Disassembling the plunger and body of the SED

Disassembly of the Chloe SED has been redesigned. The syringe is first “twisted out” in the same way as the current method. This then allows room for the Plunger to removed

5.7 Client Feedback

The client was given the old and new versions of Chloe SED in that order, and asked to fill in a feedback form, followed by a discussion on the new aspects of the device. The feedback is summarized as follows.

The assembly and disassembly of the SED is easier to figure out.
The assembly between the plunger and body of the SED feels sturdier for the new design compared to the old one.
The assembly between the syringe and the SED does not feel any different.
The rotation along the axis, and mechanical play between plunger and body is less noticeable after the redesign.
The client also noted that it was easier to figure out the assembly and disassembly of the redesign, and that it also took a shorter amount of time to do the actual assembly and disassembly.
The ease of withdrawing anesthesia into the syringe remained the same.
Since the parts of the SED are now bigger and fewer in number, it is a lot easier to keep track of and harder to misplace.
The SED looks equally easy to clean, rinse, and dry for both the versions, but the client acknowledged that the device was easier to clean because of the removal of the screw joint.

The questions and responses for the client feedback can be found in Appendix A, pg. 27.

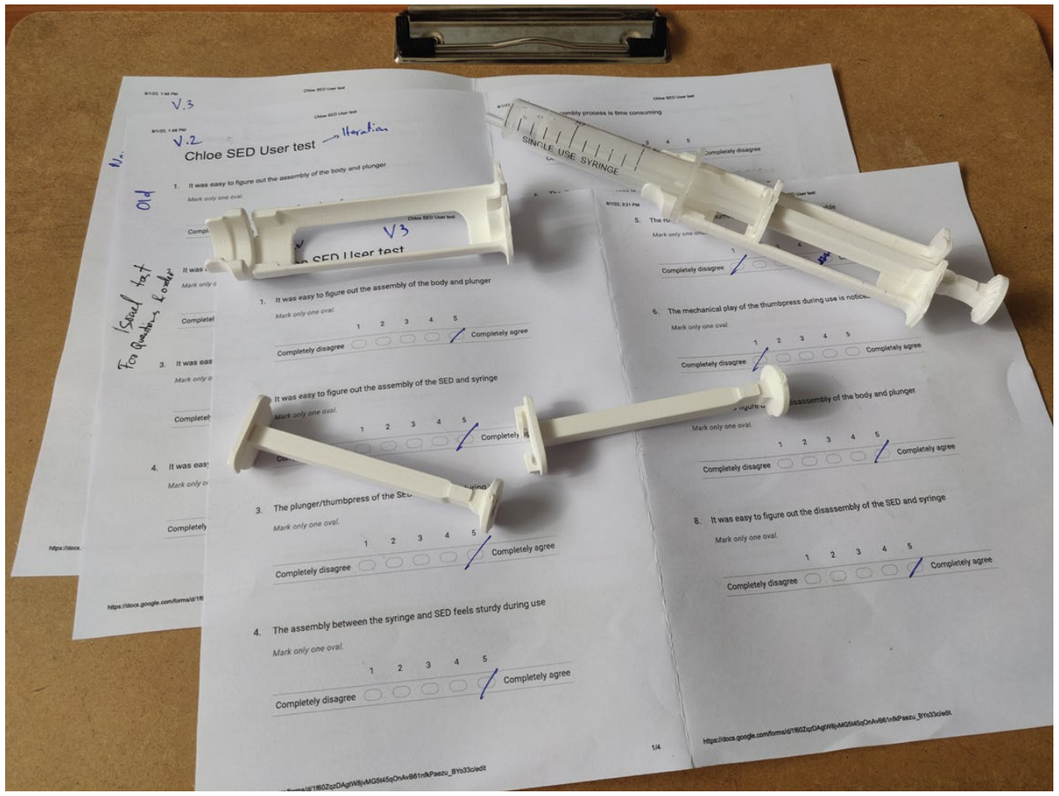


Fig. Discussion with Client

Chapter 6
Conclusion

6.1 Evaluation

The design recommendations is evaluated based on the List of Requirements that were generated suring the Analysis phase.

Legend

✓ Requirement was satisfied

– Requirement was not satisfied

✗ Requirement was nearly satisfied, more work is needed.

✓	The product must be able to handle medical grade cleaning agents used in chemical sterilization, namely 2% Glutaraldehyde and 0.5% Chlorine solution	The product must be able to handle medical grade cleaning agents used in chemical sterilization, namely 2% Glutaralde-hyde and 0.5% Chlorine solution
✓	The material selected must be biocompatible and non-toxic to patients	The material selected must be biocompatible and non-toxic to patients
✓	Training and handling of the device must be faster and easier compared to the previous iteration	Training and handling of the device must be faster and easier compared to the previous iteration
–	Each use cycle of the product must not cost more than 1.5 eur (184 ksh)	Each use cycle of the product must not cost more than 1.5 eur (184 ksh)
✓	The product must be able to handle daily use, cleaning and reprocessing for a minimum of 25 cycles	The product must be able to handle daily use, cleaning and reprocessing for a minimum of 25 cycles
✓	The device should have a smooth form, and must be easy to handle.	The device should have a smooth form, and must be easy to handle.

6.2 Conclusion

Based on client feedback and discussions, the advantages of the redesign are discussed below. The redesign was looked at from 3 perspectives:

Manufacturing

With the current design considerations in mind, Injection moulded PP is the best material and method for manufacturing. If > 5000 units of the device is Injection moulded, it is possible the cost of each use cycle below 1.5 euros.

The complexity of the mould design is reduced as the screw threads have been removed. This makes the mould cheaper to manufacture, and the injection moulding easier, faster and cheaper.

Use

The material selected, PP, is non-toxic and safe to use. The device can handle atleast 25 cycles of use and sterilization, as it was proved experimentally.

The redesign was proved to be easier to understand and faster to assemble and disassemble. It also has a smooth continuous form which is easy to handle, clean and dry.

The number of parts of the SED has been reduced from 3 parts to 2. This means lesser parts to work with. One of the issues the previous iterations of the project tackled was the size of the parts. With the parts of the SED being too small there was a chance for it to be misplaced during use and reprocessing. With the redesign, the overall sizes of each part are bigger, so there is a lesser chance to misplace the parts.

Sterilization

The sterilization process in context was studied. The product was tested for 25 cycles of this procedure.
The redesign, when manufactured using injection moulding provides a smooth form and surface. The SED is now easier to sterilize, rinse and dry.

In addition to this, a summary of the factors affecting decision for medical device is summarized below.

Number of use cycles of any material is directly impacted by:
- Use case; Gentle or rough use, mechanical wear and tear.
- Environment; Storage and environmental conditions.
- Sterilization conditions; elaborated below.
- Standard number of use cycles for material; Max number of use cycles for material (m) under best conditions.

Sterilization conditions is impacted by,
- Adherence; Adherence to regulations of the sterilization methods, availability to technicians etc.
- Method of sterilization; effect of method (chemical ster., steam ster., ionisation etc.)
- Material resistance; Resistance of material to selected method of sterilization.
- Mismatch; Effect of improper sterilization. Impoperly sterilizing a material may increase it’s lifetime, but will not ensuresafe and sterile environment for patient.

6.3 Recommendations

With the conclusion of this project, there are some steps that need to be done after this. The recommendations are as follows.

Design

Now that a decision for the material and manufacturing method has been made, the next stage would be to develop a mould for manufacturing the device using injection moulding. The dimensions of the device will have to be looked at with respect to material and Injection moulding.

Material

Cyclic olefin copolymer (COC) is a potential material for manufacturing Chloe SED in the future. It comparable mechanical and chemical properties to PEEK while being cheaper. This option was not explored during the course of this project as it is still a relatively new material, and providing proof that the device works in the medical context would require rigorous testing.

Packaging

The packaging of the medical device is an important feature of the product. It contains all the necessary labels, which has to comply with regulations, and some devices are steam sterilized after packaging and before sale. This should be one of the next stages that is looked into before market introduction.

Maximum number of uses

Although it was proved that the device functions as normal within 25 use cycles, it would be interesting to look at the maximum number of uses with just mechanical wear and tear. A tester could be developed for this.

Study of videos, images and tensile tests.

A wealth of information was generation through the videos, images and tensile tests. All of these were handed over to the client. These could be useful to explore to further to understand the long term effects of sterilization on the materials tested.

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