Optimising the Design of a Medical Device Intended for Use in Low- and Middle Income Countries

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ABSTRACT

Introduction: Smart Medics Company is a startup from the Delft University of Technology, looking to bring an affordable Video laryngoscope (VL) into hospitals in low-resource regions. This research aims to seek the best suitable transparent material to act as a lens, sealing off a compartment containing an endoscope, as well as, bring forth a design optimisation that will create a waterproof environment for the incorporated electronics and prepare the device for disinfection according to the used disinfection procedures in low-resource regions.
Method: Two approaches have been used to investigate the opportunities. The first approach was by using quantitative research, where glass and polymethylmethacrylate (pmma) were subjected to the disinfection chemicals used in hospitals in low-resource regions. These chemicals included, CIDEX® OPA, Isopropanol and JIK (3.5% active chlorine). This was done in three different experiments, the first experiment was conducted to find the short-term effects of the used chemicals. The second experiment was conducted to see the effect of rinsing with water in between the cycles, and the third experiment revealed the long-term effects of the used chemicals on glass and pmma. Furthermore, prices per material were compared to find the material with the best price-durability ratio.

The second approach was by means of qualitative research. To generate optimisations for the current design of the VL, three methods were used. The first method, a state-of-the-art research combined with a literature search to find solutions that could aid in the process of designing. The second method was the usage of a morphological overview, to generate concepts according to the necessary requirements. Thirdly a Harris profile was created to score the concepts conforming to the context in which the VL will be placed in. Additionally the option to creating a wireless design along with the best method to incorporate the lens into the design were investigated.
Results: Regarding the chemical resistance of both glass and pmma, they both showed to be resistant to the used chemicals. Although pmma showed a form of solvent crazing in the first two experiments, it did not show this in the third experiment, therefore, it is thought that the samples of the first two experiments were contaminated causing this phenomenon. Regarding the price-durability ratio, pmma scores the best as, for the price of one glass lens, 590 pmma lenses could be fabricated.

The qualitative research generated three feasible designs, all three with unique features, in terms of connectivity, power and the disinfection process. The state-of-the-art technology inquiry presented multiple innovative patents that aided during the conceptualisation. The scoring according to the Harris profile revealed the applicability to the desired context. One of the concepts included a wireless design which was evaluated to see how feasible a wireless design would be in this context. This showed that although it was feasible, it would also entail more costs for certification and multiple trade offs are to be made in terms of component selection and thermal management. Lastly, placement of the lens could be during the production phase, as well as, in the post-production phase. The first phase has three options in which the lens could be placed, which bring about multiple disadvantages, such as, higher costs due to more man hours, in addition to, higher costs for the need of multiple mould. The later phase includes the use of a method called ultrasonic welding. This type of fabrication would create a seamless joint between the lens and the VL, which would not only seal the electronics compartment, but it would also ensure that the lens can not come undone, preventing serious harm to the airway during intubation.
Conclusion: In terms of material properties, both glass and pmma are suitable to act as a lens for the VL according to the context it is placed in. However, as glass lenses cost 590 times more than the pmma lenses, this would be the best choice to incorporate into the VL. From the three generated concept designs, the second design was the most desirable as it would not only generate a waterproof design, but it also has the ability to keep its modularity, for both future development as well as optional maintenance in the case that a part breaks down. Although the wireless design is feasible, it is advised to postpone this design. Regarding the insertion of the lens, the preferred choice would be to place it in combination with ultrasonic welding, to create a seamless and waterproof seal for the electronics compartment.

ACKNOWLEDGEMENTS

This thesis is performed as a final part of my Master of science in Biomedical Engineering at the Delft University of Technology. This report presents my scientifically based insights into the creation of a waterproof design intended for use in low-resource countries.

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List of Abbreviations

DFT	Discreet Fourier Transform
LMIC	Low- and Middle-Income Country
MTF	Modulation Transfer function
pc	polycarbonate
pmma	polymethylmethacrylate
pvc	polyvinylchloride
SFR	Spatial Frequency Response
UPS	Uninterruptible Power Supply
VL	Video laryngoscope
WHO	World Health Organisation

1 Introduction

1.1. Background

Researchers of the TU Delft have designed a prototype of a video laryngoscope (VL) for low-resource regions. This prototype is further developed by a start-up named Smart Medics Company, therefore, this research will generate recommendations in regard to the design of the VL.

1.1.1. Intubation

Intubation is the placement of an endotracheal tube, a breathing tube, needed when patients undergo general anaesthesia with muscle relaxation, when they have to be ventilated, or because their airway is obstructed.

An important consideration during some types of surgery is the use of mechanical ventilation. Mechanical ventilation via an endotracheal tube can be indicated when muscle relaxants are used during the operation, to prevent stomach contents from entering the lungs, as well as, to control oxygenation during surgery. Intubation is also a requirement when a patient has serious breathing problems for instance due to a Covid-19 infection [1].

A laryngoscope is an assistive device used to aid with the intubation of a patient. After the patient is asleep, the laryngoscope is inserted into the patient's mouth and by lifting the jaw, the vocal cords are exposed. Once the vocal cords are exposed, the endotracheal tube can be advanced into the upper part of the trachea, creating a pathway for air to flow to- and from the lungs.

Laryngoscopy is thus used for the following:

- Expose the upper part of the larynx and give a clear visual for diagnosing of infections;
- Aid in the insertion of the endotracheal tube;
- Find congestion's in the throat;

In general, laryngoscopes can be categorised in direct- and video laryngoscopes.

Direct laryngoscopy

This type of endoscopy, seen in figure 1.1 is the method that has been used traditionally, and is still common in low-resource settings. "The blade of the laryngoscope is used to retract the tongue and to tilt the larynx for endotracheal intubation" [1]. The advantages of this method are that it gives a three dimensional view of the larynx, the intubation time is less and the blades are in general lower cost than video laryngoscopes [3].

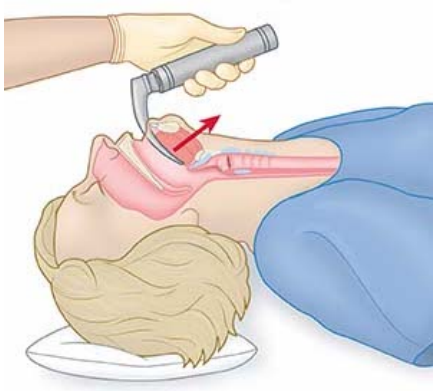


Figure 1.1: Example of the use of direct laryngoscopy [2].

Video laryngoscopy

This method indirectly views the larynx of the patient as seen in figure 1.2 on the right. It uses a small video camera, often depicted as a boro- or endoscope, which then displays the larynx on an external screen. In this research, the term endoscope will be used to reference the used camera. The advantages of this method, are that it gives an enhanced view of the larynx, it causes less stress on the airway and due to the form, it is an easier method for beginners [5, 6]. Recent studies have also shown the importance of the use of video laryngoscopy, in regard to patients with Covid-19. As research has shown that the highest viral load of the virus, SARS-CoV-2, is found in the upper tracheal tract, generating aerosol particles, contamination the personal protective equipment, possibly even, body parts that are exposed, of the medical personnel handling the airway[7]. Due to this, video laryngoscopy is recommended, to minimise the infection risk as the distance between the patient and the anaesthetist is increased [8].

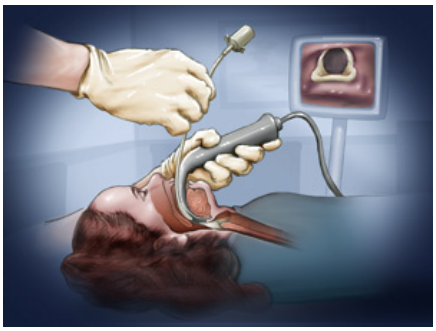


Figure 1.2: Example of the use of a video laryngoscope[4].

1.1.2. Low-Resource settings

In a report on VLs for low-resource settings was written that, VLs are not readily available in LMICs and suggestions were done to combine a USB endoscope with a smartphone. Therefore, a project was started which resulted in the DelftScope, a VL intended for use in LMICs [9].

The design of the VL is broadly finished, however, to incorporate the USB endoscope into the design, the hollow chamber accommodating the electronics will need to be made waterproof. This is necessary as surgical equipment is cleaned by submerging the devices in sterilising liquids. The liquids used in this specific context are: CIDEX® ADS, CIDEX® OPA, Isopropanol, JIK (3.5% active chlorine), soap and/or water [9].

The disinfection procedure is to submerge the instruments in a plastic container filled with one of the above stated liquids for 15 to 30 minutes, however in the desired context, this is often more than a week as the equipment is kept in the containers until it is used again [9, 10].

1.1.3. Current design

The current design of the VL, seen in figure 1.3.1, has two points at which the chemicals could seep through and damage the encapsulated electronics. The first location is seen in figure 1.3.2, this is the opening for the lens. The design of the VL should be made to enclose the lens, such that it could not get loose during operation, as this could cause greater damage to the patient. If the lens were to drop down the throat, into the airway, it could cause bronchial cartilage destruction and fibrosis [11]. Moreover, the lens should seal the opening to the encapsulated electronics in that point. As the lens will cover the endoscope, the material will also need to retain its transparency during the disinfection procedures.

Figure 1.3.3 shows the second place that requires a closure to create a hermetic seal, and make the design waterproof. The current design has a cap with a hole in it to run the endoscope cable through, however this will not make the device waterproof.

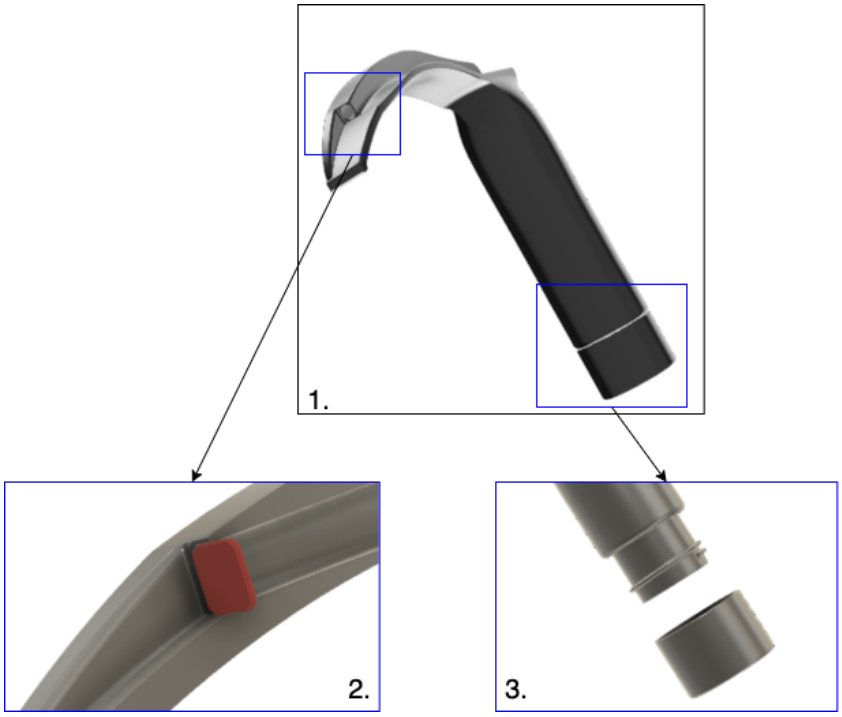


Figure 1.3: The two elements that require a design optimisation to create a hermetic seal. 1. The current design of the VL. 2. Focus on the material properties of the lens. 3. Focus on the design of a hermetic sealable lid.

1.2. Main research question

Due to the disinfection procedure the video laryngoscope will need to be made waterproof, by creating a hermetic enclosure for the electronics, therefore, the main research question is:

"What design modifications are required to create and sustain a hermetic enclosure to incorporate the electronics into the video laryngoscope?"

The lens, will need to be made from a material that will not become dull due to the aggressive chemicals, as well as, seal the compartment to keep the chemicals out. The other opening, the cap, will need to be designed such that the VL could be easily disinfected, according to the disinfection procedures used in LMICs, without causing damage to the encapsulated electronics. This design optimisation will produce a theoretical sealed video laryngoscope, as the production by 3D-printing will not generate a waterproof design and the costs of a mould for injection moulding are too high for trial and error designs.

1.3. Research relevance

The relevance of this research is found in the fact that current western standards for disinfection are not applicable to devices used in low-resource regions [12]. Therefore, the design of medical devices intended for use in these regions should be adjusted to fit into the desired context. Another relevant topic is the fact that the device should be low cost, as it is intended for use in the low-resource regions, meaning the production of the device should also be economical [1, 9].

1.4. Research approach

To answer the main research question, research will have to be conducted by both, experiments as well as design improvements. Therefore, the main question has been split into two parts, seen in figure 1.4. One section is based on the effect of sterilising liquids on the material properties of different transparent materials and the other section is the design of the lid.

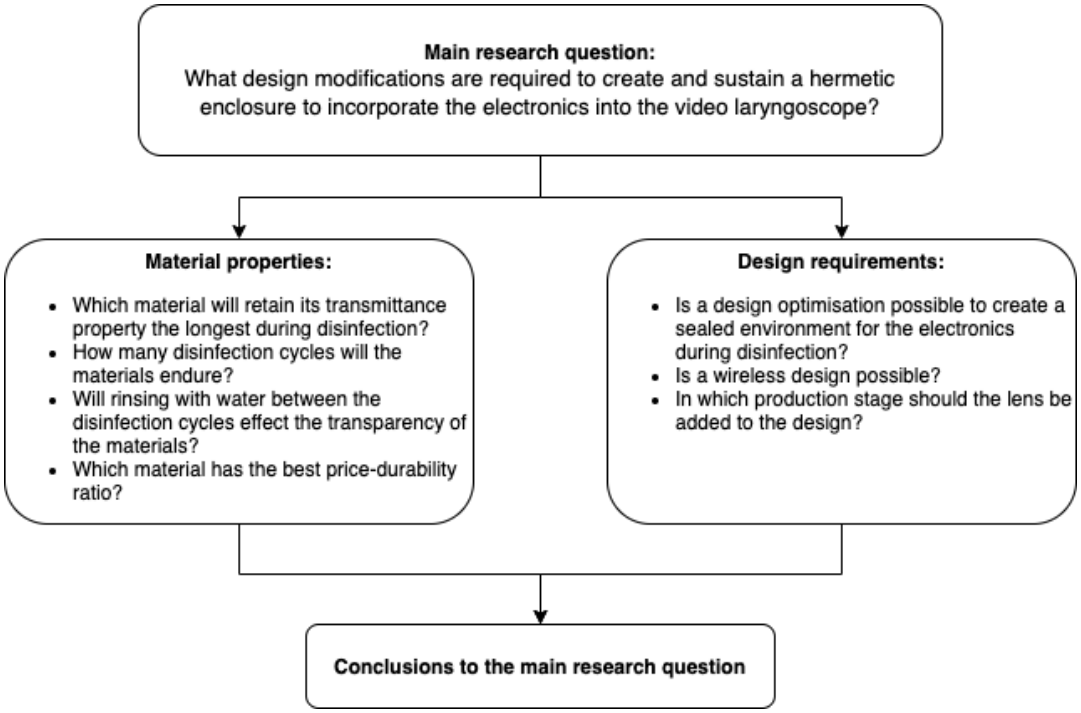


Figure 1.4: Approach to finding conclusions to the main research question.

1.4.1. Material properties

Figure 1.4 shows that the focus for this research lies within the transmittance properties of the transparent materials. The used materials shall be: Glass and pmma. Glass has been chosen as it is assumed to be the most corrosion resistant, transparent and commonly available material [13, 14]. Pmma, also known as Perspex or Acrylic, has been chosen as it is a transparent material that is also commonly available in LMICs, furthermore it is an excellent bio-compatible material, inexpensive and has a high transmittance value [15]. These two materials have been tested to withstand western disinfection cycles, through the use of an autoclave [16]. However, this does not necessarily mean that these materials are resistant to the sterilisation techniques used in LMICs [12].

To analyse the corrosion resistance of each material, the materials will be subjected to three experiments. By placing the samples in a container with the disinfection fluids, a disinfection cycle is simulated. As the liquids will not do significant damage after a single sterilisation cycle, the short-term effects will be analysed in the first experiment, by placing the samples in containers for 17 hours, resembling 50 cycles of 20 minutes. 20 minutes is the standard according to W. Rutala and D. Weber [10].

The second experiment will be done to determine the effect of rinsing with water in between the cycles. To compare these results to the first experiment, this will be repeated 50 times. The third experiment is done to see if the materials are able to withstand the proposed lifetime of the VL, being 2000 disinfection cycles [17]. The effects of the chemicals on the materials will be measured by a method described in ISO 12233:2017. This standard is used to determine the highest obtainable resolution of digital camera's and is therefore, an appropriate method to test the degradation of the lenses [18].

Sherman wrote in a paper, on life cycle assessment of laryngoscopes, that multi-use laryngoscopes have an expected life cycle of 4000 rated uses. However, this is solely for the blade, the inclusion of a fibre optic pipe limits this to 500 uses [19]. As the DelftScope will incorporate an endoscope, and it is designed for durability, the desired lifetime of the VL will be 2000 disinfection cycles [17]. Once the durability of the lenses has been compared, a price-durability comparison should show which material would be the recommended option to use as a lens.

1.4.2. Design requirements

Where the lens isolates the electronics compartment on one side, a design optimisation needs to be done for the screw cap seen in figure 1.3.3. This optimisation will need to be done so that the electronics could be placed and removed without compromising the hermetic environment during disinfection. The optimisations could

add extra features if possible. This could include a wireless design, that transmits a video signal wirelessly and is capable of wireless charging. Or, a design that preserves its modularity, so that it could be upgraded in a later stadium, or if necessary maintenance could take place.

As current techniques make a wireless design possible, the options that need to be taken into account will need to be investigated, to explore the possibilities of a wireless VL [20]. The final step is to solve the question, "in which step of the production should the lens be added?" The available options are to produce the VL as one, or to place the lens during post-production, either through a small opening or during assembly.

All above findings have led to an answer to the main research question, delivering a theoretical hermetic environment for the electronics in the VL.

2

Materials & Methods

2.1. Approach

The aim of this research was to investigate the possibilities of creating a hermetic enclosure to incorporate the electronics into the VL. To do this, both quantitative and qualitative research needed to be done. The material properties were investigated by applying quantitative research methods with an experimental setup and thereby finding a suitable solution for the optical requirement. To find a waterproofing solution for the design of the VL a qualitative study has been done to find the best solution for these requirements.

2.2. Quantitative research

To answer the questions of the material section of the main research question, found in figure 1.4, an experimental setup had been chosen.

2.2.1. Material

Transparent materials

As the experiment is focused on the transmittance property of materials, the materials involved in this experiment, were all transparent and listed below.

1. Glass;
2. Pmma;
3. Polyvinylchloride (pvc) (Excluded due to production restrictions);
4. Polycarbonate (pc) (Excluded due to production restrictions).

Glass was chosen as it is a material that is resistant to all chemicals apart from hydrofluoric acid [21, 22]. It should therefore be the most sustainable solution, in regard to the used disinfection chemicals, compared to the chosen plastics.

The above-mentioned plastics were chosen as they are mass-produced and for this reason, relatively cheap and readily available in LMICs [23]. Furthermore, chemical resistance charts show that these plastics should negligibly be affected by the chemicals used in this research [24]. This implies that although it is insignificant, the clarity of the transparent plastics might be affected by corrosion causing haze and therefore, decreasing the resolution of images obtained through the endoscope.

A known effect of alcohols on pmma is called 'solvent crazing', this occurs when pmma is submerged in alcohols and a stress load is applied [25, 26]. However, during this experiment no stresses were applied and therefore chemical resistance of pmma to isopropanol was assumed.

Due to restrictions in both sample size and post-processing, pc and pvc could, both, not be used for this research. Suppliers would not deliver materials with dimensions smaller than 10-by-10 cm. Which was not a problem for pmma as this could be laser cut, however, pc and pvc were both not suitable for the laser cutting machine. As pc would catch fire and pvc would release chlorine gas, leading to various health risks.

Disinfectants

The chemical liquids in which the materials were submerged were chosen based on the context the VL would be used in. However, some liquids were not acquirable in the Netherlands, for this reason a liquid was either replaced by equivalent chemicals, or, it was disregarded for this research.

1. JIK; 3,5% chlorine, not obtainable, a solution was made by mixing 3.5 parts bleach with one part water.
2. CIDEX® OPA; Fabricated by Johnson & Johnson [27].
3. Isopropanol; Fabricated by Sigma Aldrich [28].
4. Water; Ordinary tap water.
5. CIDEX® ADS; Was not obtainable and no products similar to the active chemical agent glutaraldehyde were found to substitute this disinfection liquid.

As seen above, JIK could be mimicked by using household bleach of 4.5% active chlorine and diluting it to 3.5%. This chemical solution was based on a document provided by the Pacific Public Health Surveillance Network on disinfection and sterilisation in 2001, and the World Health Organisation (WHO) described the protocols for disinfection and sterilisation in 2016 [29, 30].

Sample size

Per chemical a batch of five samples per transparent material was used. For four liquids and a control group this amounts to 20 samples per material per experiment. The second experiment did not contain a batch to submerge in water, thus only required 15 samples per material. The three experiments and a control group of five samples add up to a total of 60 samples per material. Figure 2.1 gives a clear overview of how the samples were branched per experiment and per liquid, including the control group, this was applicable to both glass, as well as, pmma.

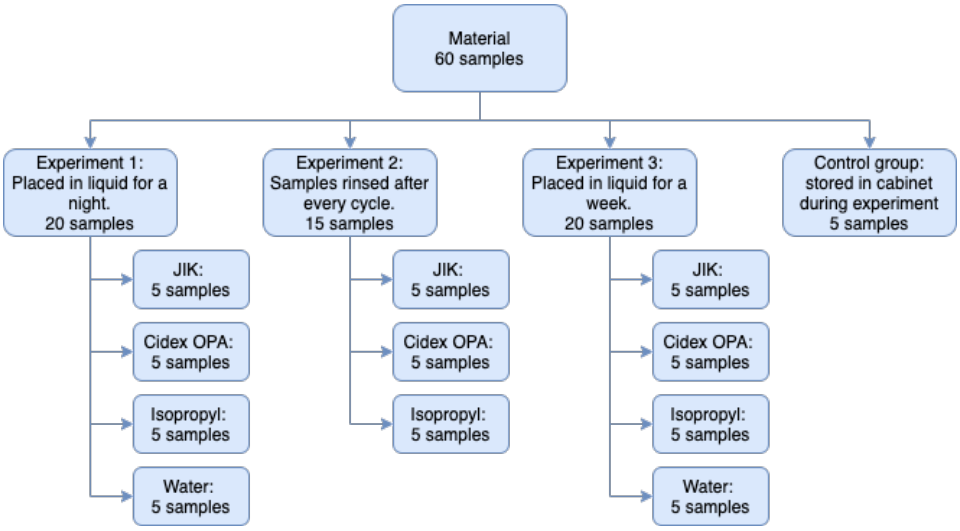


Figure 2.1: A flowchart showing how the samples of both glass and pmma were divided per experiment, including the control group.

Due to constraints in deliveries, the desired size of 5-by-5 mm with a thickness of 2 mm per sample, as used in the VL, could not be ordered. As the smallest sample size available for glass was 18-by-18 mm, this size was used as the standard size to which the pmma lenses will be laser cut.

The thickness of materials varied as there was a limited availability of sheet plastics due to necessary precautions taken because of Covid-19. To find glass samples of this size, and to keep costs low, microscope cover glasses were used as glass samples. The dimensions of these slides were not modifiable, however, for this research, the thickness of 0.15 mm would not be of importance as chemical surface scratching if occurring, would be in the nanometric scale [31]. These dimensional constraints led to the dimensions in the table on the right (table I).

Table I: Overview of the dimensions per material.

Material	Sample dimensions
Glass	18x18x0.15 mm
Pmma	18x18x3 mm

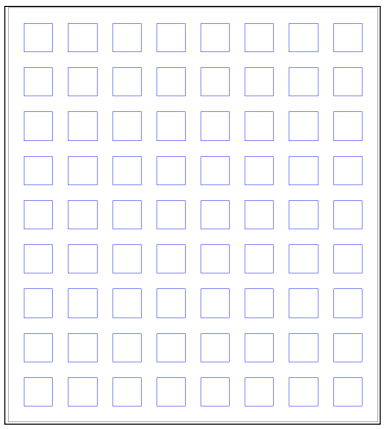
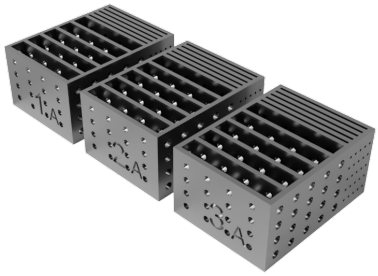


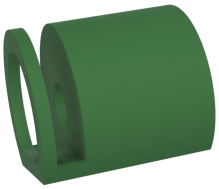
Figure 2.2: An image of the laser cutting profile for the pmma sheet.

The pmma was delivered as a sheet, that needed cutting to acquire the desired dimensions, a laser cutting profile needed to be made. To create a batch group with a random distribution, 72 lenses were laser cut from the sheet. Only 60 lenses were required, however, supplement lenses would be favourable in case extra experiments needed to be performed. These 72 lenses were cut clear from the edge and with a space in between them, so that damage to the edges of the sheet, which might have occurred during shipping, could be ruled out. These laser cut lenses then randomly distributed and placed in sample holders.

To keep track of the different experiments, that were placed in the same containers, per material and per experiment a sample holder was designed, seen in figure 2.3a. These holders could keep five samples of each material and separate them slightly. An open design was created to let the liquids easily flow passed the lenses.



(a) Sample holders for each experiment. A number-letter combination on the front made separation per batch possible. Each holder could carry 5 pmma- and 5 glass lenses. Designed with Autodesk Fusion 360 [32].



(b) A small mount to hold the lenses in place in front of the endoscope during the image capturing. Designed with Autodesk Fusion 360 [32].

Figure 2.3: Designs that facilitated the experiments

2.2.2. Setup

To test the samples consistently after each experimental phase, a mount seen in figure 2.3b was 3d-printed to keep the endoscope in the correct position, with a slot in which the lenses could be placed. Consistency across the different images, acquired through the endoscope, was maintained by creating a setup as seen in figures 2.4, 2.5 and 2.6. In this setup, the endoscope was placed 25 cm away from the image, to allow for a 4:3 ratio image to be acquired. This ratio was necessary as the resolution of the endoscope was 640-by-480 pixels. To acquire calculable data, an image, seen in figure 2.5, is used. This image is used in photography to calculate the maximum obtainable resolution of a camera, standardised by ISO 12233:2014 [18]. The image has 60 slanted edges, at a 5° angle divided over 15 squares. This angle offset has been done to sample the edges in countless different phases, allowing accurate estimation of the Spatial Frequency Response (SFR) [18].

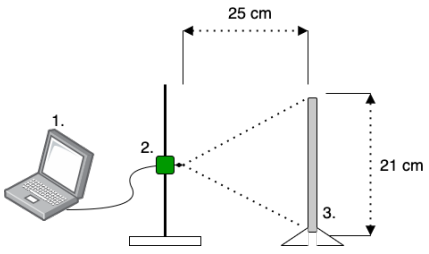


Figure 2.4: Schematic drawing of experimental setup. 1. The computer running the imaging software. 2. The mount that holds the lens in place in front of the endoscope, as seen in figure 2.3b. 3. The screen that holds the test chart seen in figure 2.5.

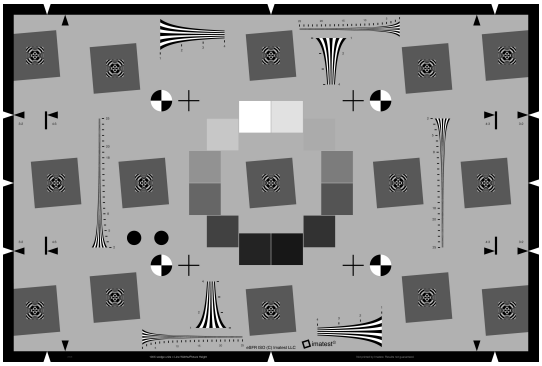


Figure 2.5: ISO 12233 2014 test image used to calculate the resolution of cameras by evaluating the slanted edges of the 15 squares [18].

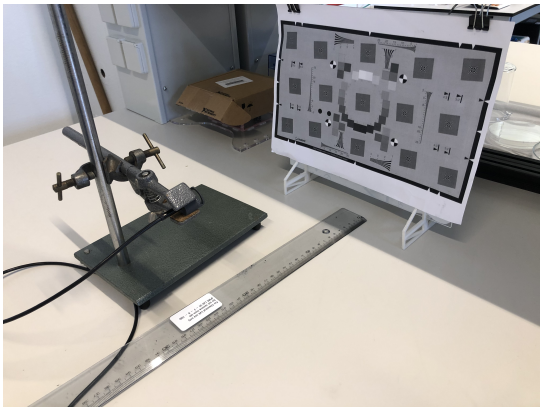
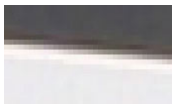


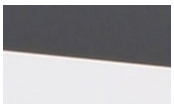
Figure 2.6: Photo of the described setup seen in figure 2.4.

One of the outputs of the SFR is the Modulation Transfer function (MTF) which shows how many lines are needed to transition from one colour to the other. Simplifying this, the spatial frequency is measured in cycles per pixel, taking one darker and one lighter line as a cycle. Figures 2.7a and 2.7b give a good representation of a low and a high SFR.

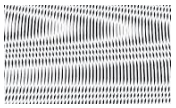
The changeover from one dark to one bright pixel, determines that the Nyquist frequency is 0.5 cycles per pixel as minimally two pixels are needed to form one colour transition [33]. Once this frequency is passed, spatial aliasing will occur which is also known as a moiré pattern seen in figure 2.7c. This is also displayed in the spatial frequency plot below, in figure 2.8D.



(a) Image quality close to 0.15 cycles per pixel [33].



(b) Image quality close to 0.5 cycles per pixel [33].



(c) Moiré pattern, image quality above 0.5 cycles per pixel[34].

Figure 2.7: Different spatial frequencies of images.

Calculation

The following steps were done to calculate the MTF and a visualisation of this calculation is shown in figure 2.8, These steps were automated in a MATLAB® script, shown in Appendix B.1.

1. Capture image; (figure 2.8A)
2. Find four registration circles to determine general angle of image and estimate coordinates of the 16 squares; (figure 2.8B)
3. Calculate slope and offset of the slanted edges of each square in the linearised image; (figure 2.8C)
4. Compute a one-dimensional derivative of the edge-spread function;
5. Apply a Hamming window filter to compute the Discreet Fourier Transform (DFT);
6. Derive the DFT to acquire the modulus;
7. Normalise the modulus by the zero-frequency vector to obtain spatial frequency response;(figure 2.8D)
8. Amongst other data, the MTF could now be calculated.(Figure 2.8E)
9. For a good comparison, the calculated MTFs were averaged per sample set, by generating a box-plot.(figure 2.8F)

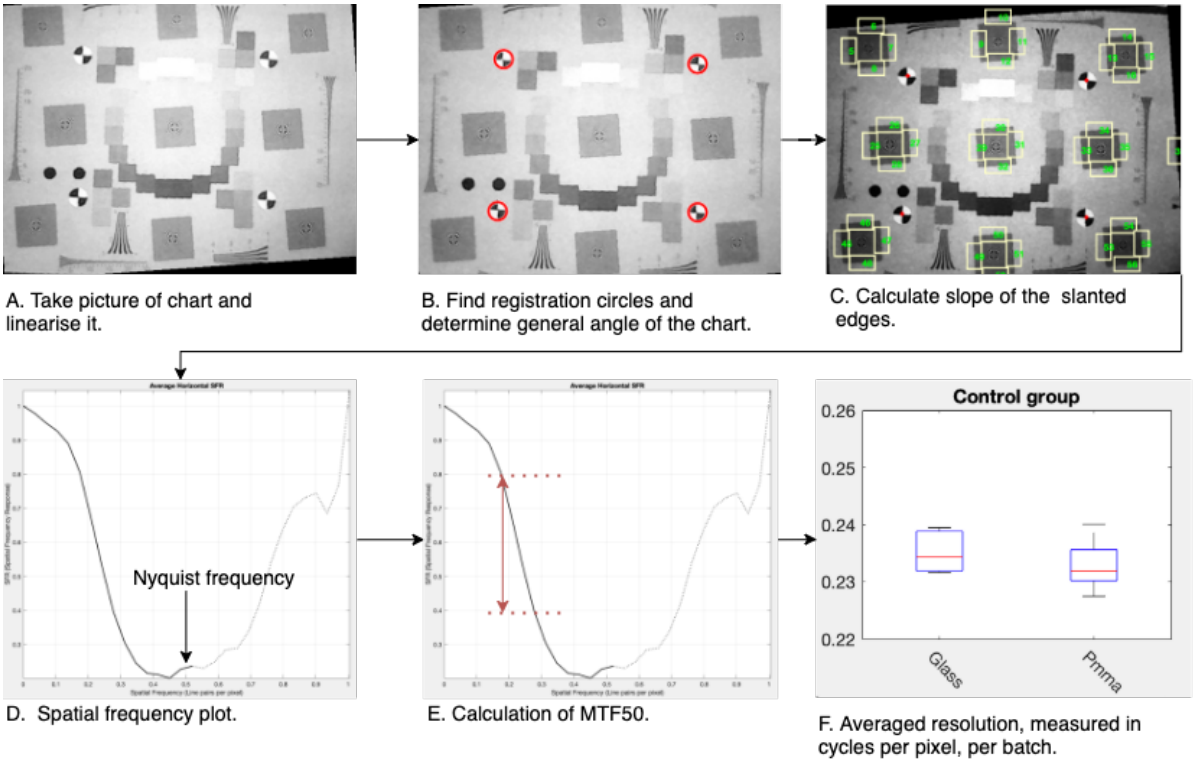


Figure 2.8: Process of calculating the sharpness of images acquired through the lenses.

2.2.3. Experiments

The experiments consisted of three general phases:

1. Placement of each set of samples in the different chemicals;
2. Removal of the batches from the chemicals, and rinsing them with tap water;
3. Placing the samples in the experimental setup for evaluation.

The difference between the experiments was the duration and repetition of each phase. The first experiment involved approximately 50 cycles of 20 minutes by placing the sample set in the chemicals for a duration of 17 hours, after which they were rinsed and evaluated according to the ISO 12233:2017 standard [18].

The second experiment was done to see what effect the rinsing with water in between each cycle had on the transparency of the samples. Therefore, the sample sets were placed in the chemicals for 20 minutes after which they were rinsed with tap-water, this was repeated 50 times to compare the samples to the results obtained from the first experiment.

The third experiment was a replication of the first experiment, however, this time, the samples were placed in the containers for a week, which resembled approximately 500 cycles of 20 minutes. As with the first experiment these were then rinsed with water and placed in the endoscope mount for evaluation. This experiment was done to see the more long-term effects of the chemicals on the samples. This was done four weeks in a row as this would resemble 2000 cycles, which is the desired lifespan of the VL, according to R. Straathof, who indicated this in an internal report [17]. Every 500 cycles, the samples were removed from the liquids to test the transparency. An overview of the experiments is given in table II, below. For consistency across all three experiments, a constant temperature of 20 °C was maintained throughout all phases of the experiments.

Images taken after the first week of experiment 3, showed that ceiling windows influenced the lighting, which in turn interrupted the auto focus of the camera, generating images with varying quality. For this reason, the first and second experiment and following weeks of the third experiment, took place in a room were the lighting was not affected by external light sources.

Table II: An overview of the experiments and their purpose.

Experiment	Information	Duration [Cycles]	Duration [Time]	Repeat	Total cycles	Total time
1	Short term effect of chemicals.	50	17 hours	No	50	17 hours
2	Effect of rinsing with water.	1	20 minutes	Yes, 50 times	50	19 hours
3	Long term effect of chemicals	500	1 week	Yes, 4 times	2000	4 weeks

2.2.4. Price-durability ratio

To find the price-durability ratio for the used materials, wholesale factories were searched for and if necessary, contact to get quotes for both glass and pmma lenses. As for this research, with a low quantity of lenses, custom made lenses were not readily available, the results were based on made pricing requests.

2.3. Qualitative research

To obtain a qualitative design optimisation for the VL, the following methods were used. A state-of-the-art research was conducted to find already existing solutions to the sealing problem. After which a morphological overview was created by inquiring possible solutions and options to the problem and finally a Harris profile was created to select the best design optimisation.

2.3.1. State-of-the-art research

To find state-of-the-art solutions, a literature search was conducted, in which not only articles, but also patents were included. The inclusion of patents was necessary as these would include designs that were purposefully built to create a hermetic seal. To find both articles and patents, Google Scholar was used. The following terms were used to conduct an effective search in August 2020:

1. Cap, Closure, Cover, Enclosure, Hermetic, Isolate, Lid, Seal*, Waterproof. Separated by an ‘OR’ operator;

2. Chemical resistance, Corrosion resistance. Separated by an ‘OR’ operator;

3. CIDEX®, Chlorine, Glutaraldehyde, Isopropanol, Ortho-phthalaldehyde, Water. Separated by an ‘OR’ operator.

The first element was used to find all literature on the designs of seals that could create a hermetic environment. The second and third option were used to find different materials that were chemically resistant to the chemicals used for disinfection. As these materials are necessary to create a sealed environment without deteriorating over time due to the aggressiveness of the chemicals.

In short, the search was conducted by combining the elements as such: 1 OR (2 AND 3). This combination would gather all necessary results in terms of both sealing capacity, as well as chemical resistance to the liquids used in the Kenyan hospitals.

Patents

The first search term promptly showed that patents were sorted by different classifications, therefore the focus was shifted towards the European website for patents, `espacenet.com`. This lead to a classification for caps, being "B65D41/00 - Caps, e.g. crown caps or crown seals, i.e. members having parts arranged for engagement with the external periphery of a neck or wall defining a pouring opening or discharge aperture; Protective cap-like covers for closure members, e.g. decorative covers of metal foil or paper"[35]. As this patent classification clearly defines the requirement of creating a hermetic environment by means of sealing a compartment, it was used to find patented state-of-the-art designs. Within this main class of caps, several sub-classifications were defined. As seen in figure 2.9.

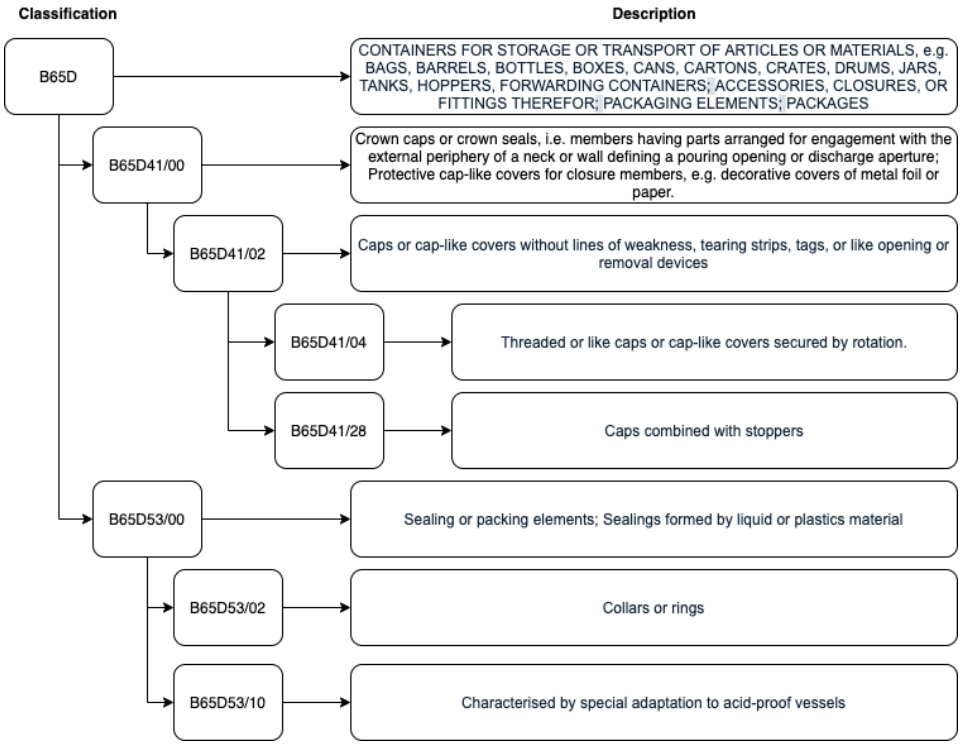


Figure 2.9: Classification of useful state-of-the-art patents for sealing compartments. According to the Cooperative Patent Classification described by Espacenet [35].

Literature

Finding literature on chemical resistance to the used chemicals, terms (2) and (3), generated 171 papers of which seven papers were based on chemical resistance to- and decontamination with the used chemicals. Three of the included papers contained chemical resistance charts which could be referenced in a later stage of this thesis. Among the disregarded papers, 150 papers were on biosynthesis of polymeric membranes with Glutaraldehyde and its chemical compatibility.

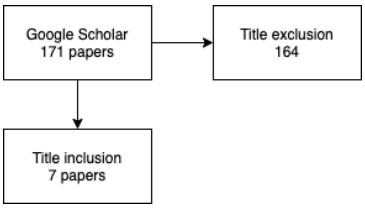


Figure 2.10: Conducted literature search on chemical resistance.

2.3.2. Morphological overview

To generate possible design optimisations several criteria were used. These criteria were established based on functionalities of the VL as well as the desired usage and the disinfection procedure.

Table III: Morphological overview of design requirements.

Parameter	**Options**		
Body	Unibody	2-Component	3-Component
Screen	Attached to VL	External screen	Mobile phone
Connection	Wired	Wireless	
Power	External power	External battery	Internal battery
Charging	Induction	Charging port	[−]
Modularity	No	Simple replacements	Fully customisable
Removable lid	No	Screw cap	Double screw cap
Seal	O-ring	Wad	Thread form

As seen in table III, above, 8 functional requirements needed to be taken into account for the design optimisation. Below, every function will be justified.

Body
To keep the body as simple as possible in terms of manufacturing and handling, the design could be optimised to exist of one, two or three components. More components would mean higher costs in production however a greater amount of modularity. This option would be defined by the removable lid function.

Screen
The use of a screen is inevitable for a VL, however, the way it is used is still adaptable. The screen could either be directly attached to the VL, by means of connecting to an external screen or a third option would be to use a phone as explained in the background section of chapter 1.

Connection
The type of connection the VL could have with an external device, being a phone or screen. This could be wired or by placement of a transmitter in the VL, either Bluetooth or WiFi. However, with a wireless connection multiple regulatory requirements will come into force as latency and compatibility requirements will need to be adhered to.

Power
The endoscope in the VL could either be battery powered enabling the above-mentioned wireless connection, or it could be powered by an external power source. This could either be the main power or through the battery of a phone or external device.

Charging
In the case that the VL would have an on-board power source the charging option would need to be included. This could be by means of a power plug or USB-inlet. Another option would be to include wireless charging through induction, as seen in electric toothbrushes.

Modularity
When the VL breaks down in any of its components, this functionality will either make it easier or more difficult to replace the parts. Another option would be to make a standard laryngoscope more modular so that it could be used as a standalone laryngoscope or by placing an endoscope to give it video capabilities. In regard to the disinfection process, this functionality would be to remove the whole or part of the electronics before disinfecting.

Removable lid
In combination with the above-mentioned modularity, the lid could make the VL more or less modular. By using two lids, a function could be added where the electronics are held in place with the first lid and a second lid could be screwed on to prepare the VL for disinfection in the case of a wired connection.

Seal
To seal the removable lid, there are two options, either by using an O-ring that is placed conveniently or by the usage of a wad or liner which is a softer material to make a seal. Lastly, the form of the threads of the screw cap could create an airtight closure.

These criteria lead to the composition of three different designs which were consequently evaluated by creating a Harris profile.

2.3.3. Harris profile

To correctly assess the designs that came forth from the above mentioned morphological overview, multiple criteria, seen in table IV, were used to create a Harris profile. The criteria were subdivided according to the MoSCoW method, Must do, Should do, Could do and Won't do, the latter applies when the first three criteria are not met [36]. These criteria were based on the context the VL will be placed in. The scoring of the designs was based on a 4-point grading system seen in table IV on the right side.

Table IV: Grading system.

0	Won't do
1	Must do
2	Should do
3	Could do

Table V: Grading criteria of the Harris profile.

Criterion	MoSCoW	Explanation
Connectivity	Must do	The VL must be able to operate without video.
	Should do	The VL should provide video through a cable connection.
	Could do	The VL could provide video wirelessly.
Disinfection	Must do	It must be able to withstand disinfection cycles.
	Should do	It should be able to withstand disinfection cycles with little modification.
	Could do	It could be able to withstand disinfection cycles without modifying the setup.
Ease of handling	Must do	Laryngoscopy must be possible with 2 process steps
	Should do	Laryngoscopy should be possible with 1 process step.
	Could do	The VL could be able to operate as is.
Maintenance	Must do	The electronics must be savable, when the VL breaks down
	Should do	The electronics should be replaceable, when they are broken
	Could do	The VL could be completely modular for future upgrades
Power	Must do	The VL must be able to intubate without an endoscope.
	Should do	It should be able to intubate with an endoscope by mains electricity.
	Could do	It could be able to operate on battery power.

The Harris profile criteria of table V are designed to grade the designs based on the context and the phases the VL goes through.

Connectivity

The connectivity criterion is based on the different types of connection that are possible, the VL must in all cases be able to operate without an active video connection, it is desirable that a screen could be connected for actual video laryngoscopy, however, a wired connection could disconnect causing video loss, therefore a wireless connection could be preferred.

Disinfection

In terms of disinfection, the VL must be able to withstand multiple disinfection cycles by any means as it is a multi-use laryngoscope. It should be able to withstand disinfection after singular preparation steps, such as twisting on a cap or removing a part. Desirable would be to need no steps before disinfection, to keep human error at a minimum.

Ease of handling

Regarding the ease of handling, the VL must have a connection to a video screen after a couple of process steps have been followed, such as booting an external screen, connecting the screen to the endoscope and to a battery source. It should, however, be able to operate by plugging in just one connector. If possible, the VL could be able to operate as is, by turning on the power.

Maintenance

In the case that the VL breaks down, or the electronics start malfunctioning, the VL will need to undergo maintenance. In terms of the requirements, the electronics must be savable when the VL breaks, as these could be valuable for placement in a new VL. The electronics should be replaceable when they malfunction, without needing to disassemble the whole VL. If conceivable, the VL should be completely modular, so that future updates for the electronics can easily be Incorporated.

Power

Lastly, in LMICs power outages are common, therefore the VL must be able to operate without an endoscope [37]. Regardless of the endoscope, in all cases must the VL be able to power a light source, to aid in direct laryngoscopy. When there is power, the VL should be able to operate by the mains electricity. Desirable could be to have a battery or Uninterruptible Power Supply (UPS) so that, at any moment the VL would be able to operate.

2.3.4. Wireless design

To research the possibility of a wireless design, the above method for designing was used in combination with the regulations on medical devices. In the morphological overview the option of wireless was combined with a review in the Harris profile generating a feasible design. Together with regulations on medical devices, the feasibility was researched.

2.4. Placement of the lens

The best moment to place the lens was investigated by combining both the quantitative and qualitative research. As the quantitative research would generate results determining which type of lens could be used, and the qualitative research would bring forth the design into which the lens would be incorporated. Together these two types of research delivered the optimal moment to include the lens into the design, in either the production phase or during post-processing.

3

Material properties

This chapter will discuss the results that were obtained during the quantitative research on transparency properties of different materials. The questions that needed answering were:

- Which material will retain its transmittance property the longest during disinfection?
- How many disinfection cycles will the materials endure?
- Will rinsing with water between the disinfection cycles effect the transparency of the materials?
- Which material has the best price-durability ratio?

Answering these questions will be done by displaying the results from the data that was collected during each of the three experiments.

The experiments involved the placement of these materials in different types of chemicals for different amounts of time. The data collected from these experiments have been split up per experiment. These experiments were focused on a decline in resolution, therefore the resolution obtained by the samples from the control groups of glass and pmma were used as the standard as, these show less than 1 cycle per pixel decay, on average, in regard to the use of no lens, as seen in figure 3.1 and table VI correspondingly. These results were obtained by calculations made with Matlab®, seen in appendix B.1 and described in section 2.2.2. The figure also shows that the used endoscope in combination with a printed image of the ISO 12233 test chart generates a sharpness of approximately 0.285 cycles per pixel, which will be the reference frame for further results.

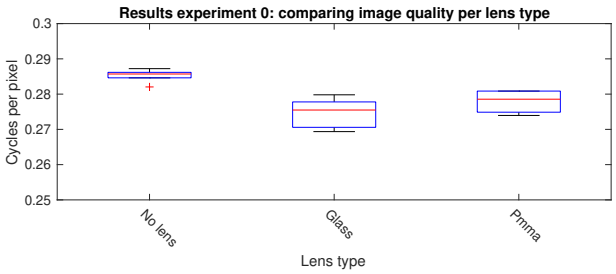


Figure 3.1: Difference in sharpness between images without a lens and with the glass- and the pmma lenses.

Table VI: The mean value of the sharpness in cycles per pixel per lens type.

Sample Set	**Average sharpness [cycles per pixel]**
No lens	0.285
Glass	0.275
Pmma	0.278

3.1. First experiment

The first experiment generated results that were mostly in line with the expectations. After 17 hours, representing 50 cycles, the transmittance property of the glass lenses showed no decline, as seen in figure 3.2. The control group showed an average of 0.275 cycles per pixel, and the samples from all four containers displayed similar averaged values, seen in table VII.

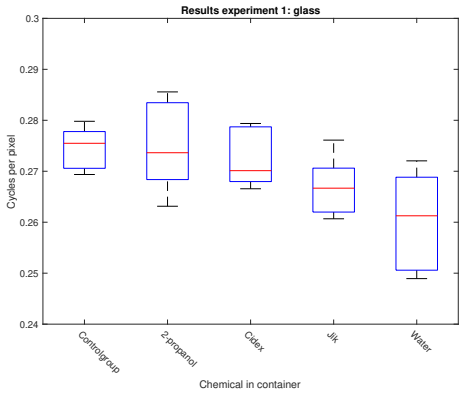


Figure 3.2: Results of the glass samples of experiment 1.

Table VII: The average cycles per pixel from the glass samples of experiment 1.

Sample Group	**Average cycles per pixel**
Control Group	0.275
2-propanol	0.275
Cidex	0.273
JIK	0.285
Water	0.260

The figure below, with the average results shown in the table beside the figure, show that pmma lenses placed in CIDEX®, JIK and water, are not affected by the liquids in terms of decay in transparency, measured in cycles per pixel. Pmma placed in isopropanol, however, shows a considerable deterioration.

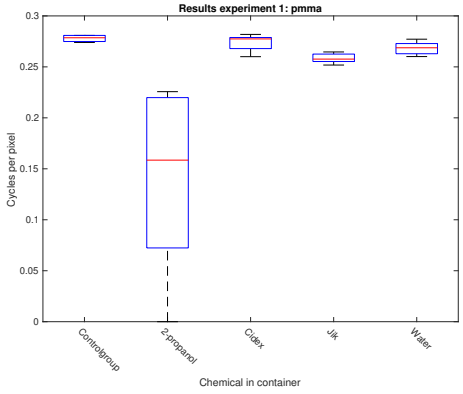
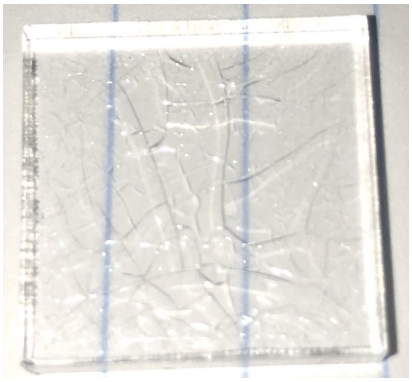


Figure 3.3: Results of the pmma samples of experiment 1.

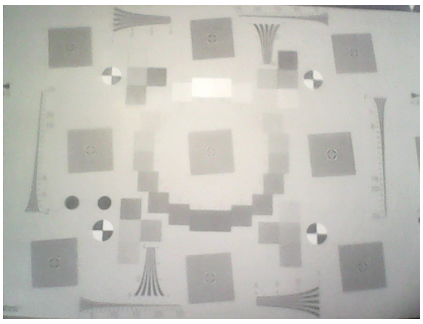
Table VIII: The average cycles per pixel from the pmma samples of experiment 1.

Sample Group	**Average cycles per pixel**
Control Group	0.278
2-propanol	0.140
CIDEX®	0.274
JIK	0.269
Water	0.268

The assumption made in chapter 2 that pmma would not be affected by alcohols, as no stresses were applied, was incorrect. The isopropanol samples showed a considerable amount of solvent crazing. A photo was taken of this occurrence, seen in figure 3.4a. Images taken through these lenses where in multiple cases too hazy to calculate the sharpness. Figure 3.4b shows how the ISO 12233 image was too blurry to appropriately calculate the sharpness in Matlab® generating a very low value in terms of sharpness [18, 38].



(a) Photo of a pmma lens on which solvent crazing occurred.



(b) Image of the ISO 12233 taken through the cracked lens.

Figure 3.4: The effect of solvent crazing on the lens and its sharpness.

Experiment 1.2

The results of the pmma, placed in isopropanol, were not expected, as the lenses in experiment 3 did not show any anomalies after three weeks, a second trial was done to validate this discovery. By placing a new set of samples in a new container with a fresh amount of isopropanol. This batch showed noticeable solvent crazing in less than two hours, however, to compare the results with the first experiment, the batch was submerged for 17 hours, generating the results seen in figure 3.5. The boxplot, of this second trial, clearly shows that pmma is not able to withstand an alcoholic environment and deterioration is imminent.

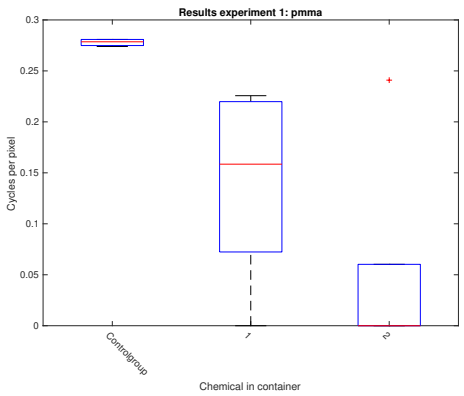


Figure 3.5: Second trial done to validate solvent crazing in the first experiment.

3.2. Second experiment

The second experiment involved the rinsing with water in between the disinfection cycles. This was repeated 50 times to compare the results against the first experiment. Figure 3.6 shows boxplots of the results, primarily grouped per chemical and within the boxplot, per material and per experiment. This gives a good comparison of how the rinsing with water would affect the process of hazing.

As with experiment 1, for CIDEX® and for JIK, no unexpected behaviour occurs. Although pmma in JIK shows a slight decline this is not different in regard to the first experiment where no water was used in between the disinfection cycles. As the mean value lies slightly higher herehan the value seen in experiment 1.

In terms of the pmma samples that were placed in the isopropanol, a same trend appears where during the disinfection cycles, solvent crazing occurs. The figure shows a decay, which is not as steep as in the first experiment, however, 75% of the values, of the second experiment, overlap with 50% of the values of the first experiment. This could indicate that although the boxplot of the second experiment displays a higher mean value, it is only because all images were still computable, that this value is higher.

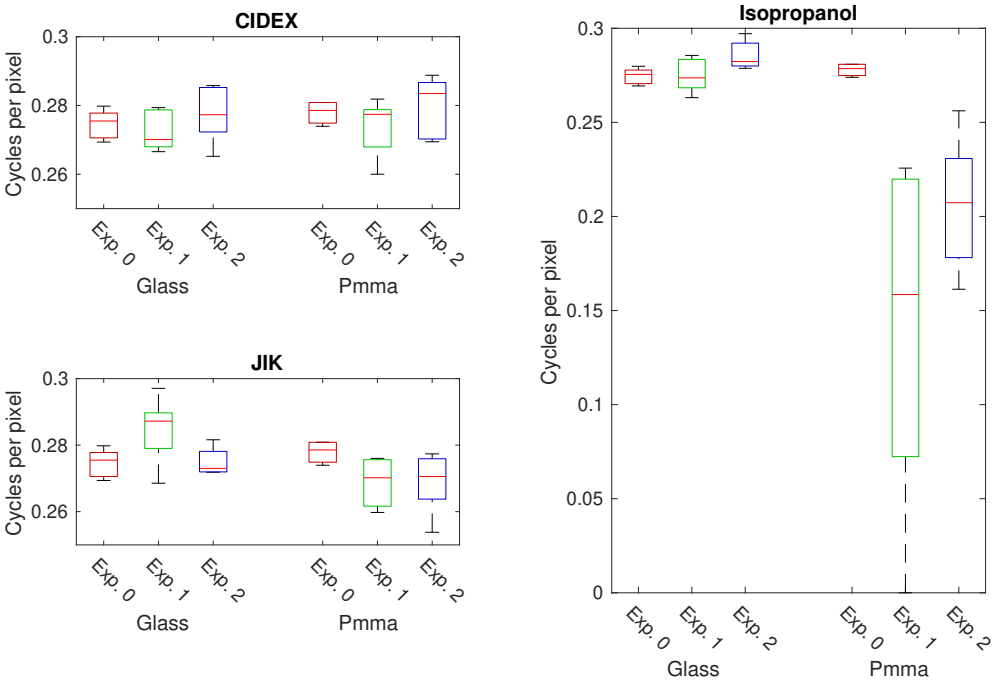


Figure 3.6: Comparison of the results of experiment 2, with the control group, presented as exp. 0, and experiment 1.

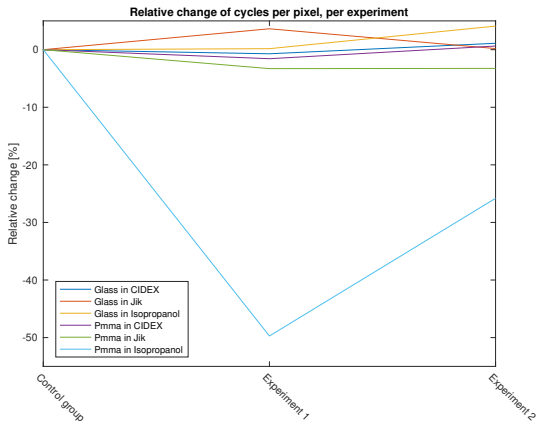


Figure 3.7: Relative change in percentage of the obtained results in transparency of the experiments, in regard to the control group.

Table IX: Relative change in percentage per experiment in regard to the control group.

Chemical	Lens type	Experiment 1	Experiment 2
2-propanol	Glass	0.18 %	4.09 %
	Pmma	-49.72 %	-25.8 %
CIDEX	Glass	-0.71 %	1.11 %
	Pmma	-1.57 %	0.63 %
JIK	Glass	3.63 %	0.2 %
	Pmma	-3.3 %	-3.25 %

The relative changes between the control group and both experiment 1 and 2 have been calculated using MATLAB® and are shown in figure 3.7 with corresponding values in table IX. It clearly shows how there is almost no change in the transparency of the samples, as they fluctuate above and below the control groups referenced value. The fluctuation could indicate that the difference is due to the focus of the camera, or a slight difference in lighting.

3.3. Third experiment

The third experiment showed that the transmittance properties stayed approximately the same during the 2000 disinfection cycles for all samples. In the method section, a statement was made, that the lighting in the room varied during the imaging after the first week. This influenced the focusing of the endoscope and therefore some images, in the results of the first week, showed a lower resolution. This was prevented in the following weeks by placing the setup in a different room with controlled lighting. Thereafter, the results stabilised. After seeing the results of experiment 1 and 2 regarding the pmma samples placed in isopropanol, one would expect

that, this sample set would also show solvent crazing. As this did not occur, the sample set was placed in a new container after week 3, with a new quantity of isopropanol. This, however, did not lead to changes in the results, of week 4, as seen in the figure below.

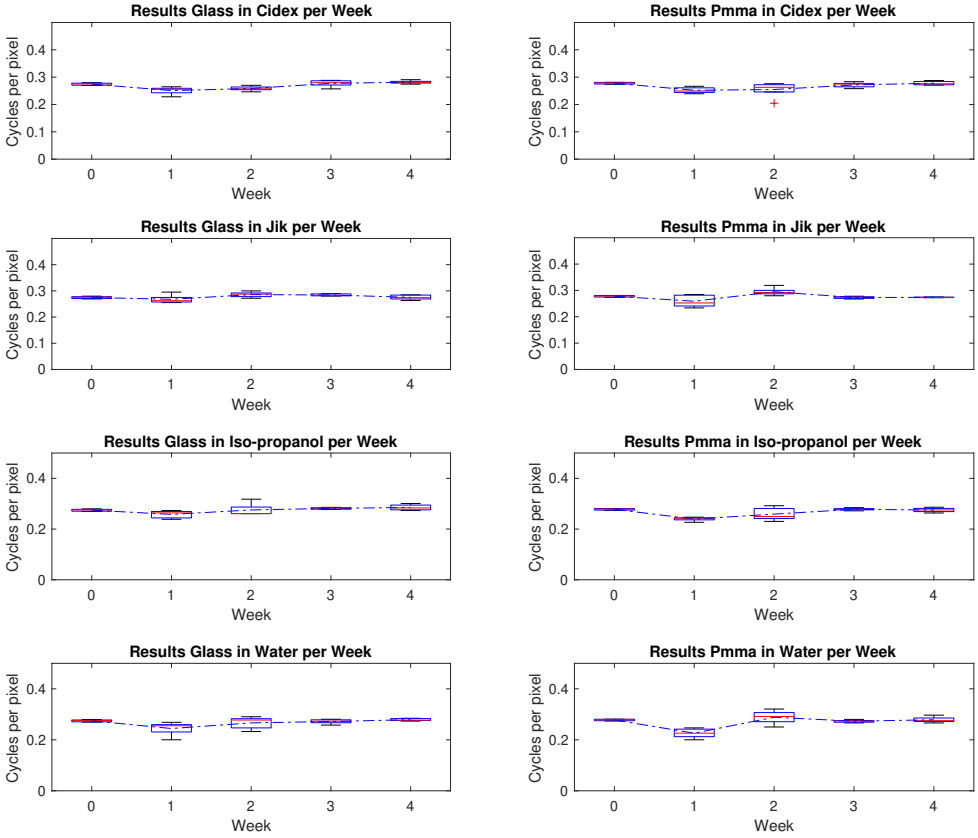


Figure 3.8: Boxplots of the results of experiment 3, sorted per chemical and per material.

3.4. Price-durability ratio

As discussed in the method section, custom-made lenses would not be obtainable for less than 1000 pieces, therefore these results are based on price requests made at wholesale factories.

For glass lenses, of the 5-by-5 mm size, no local manufacturers could be found, therefore a factory in China was contacted through the Aliexpress. This factory could produce the lenses at a minimum quantity of 1000 pieces, for $0.54 per piece [39]. At a conversion rate of $1,00 = €0,84 this would mean that one lens would cost €0,46, or in total, €460 per 1000 lenses. This request was made for round lenses, with a 5 mm diameter and 1 mm thickness. This price is without taxes, as it is shipped from China, and import fees might be applicable, depending on how the items are shipped.

For pmma lenses, a search was conducted online, checking websites for their prices per sheet material. As these sheets could be laser cut, it was not necessary to make custom requests. The found results are displayed in the table below, table X. The table states how much it would cost per lens, as a lens would be 5-by-5 mm, this would mean 40.000 lenses could be cut from 1 m^2. As the total amount is a combination of the price per m^2 and the delivery costs, the total price will decline more, if larger or multiple sheets are bought. Furthermore, due to Covid-19, sheets of 1 mm thickness were not available and therefore the prices of these sheets were not obtainable, thus the thicker, 2 mm, sheets were used for this case study.

Table X: Results of online search for transparent pmma sheets.

Company	**Price [€]**	**Delivery costs [€]**	**Total [€]**	**Size[m^2]**	**Thickness[mm]**	**Per lens [€]**
Kunststofplatenshop.nl [40]	24	7,05	31,05	1	2	0,00078
Perlaplast-kunststofshop.nl [41]	29,04	8,69	37,73	1	2	0,00094
Plexiglas.nl [42]	20	15	35	1	2	0,00088
Voordeligkunststof.nl [43]	28,18	15	43,18	1	2	0,0011

The results seen in the table above show that, from the cheapest Dutch supplier of pmma, 590 lenses could be manufactured for the cost of one glass lens.

3.5. Summary

Summarising the findings in this qualitative research, the sub-questions, required to answer the main research question, could be answered. To see which material would retain its transmittance property the longest during disinfection, 2 experiments were conducted. The first experiment involved the short-term effects and the second, the long term effects. Both experiments showed odd results in regard to the batches placed in isopropanol, as solvent crazing was not expected to occur due to the exclusion of applied stresses during research. Therefore, the results of the first experiment, which was repeated to confirm the findings were unanticipated. After seeing the same phenomenon during the repetition and experiment two, acceptance arose, however, no solvent crazing occurred during the third experiment. Therefore, the answer to this question will not give a confirmation to either glass or pmma being the material which would retain its transmittance property the longest during disinfection.

The same answer is to be given to the question, how many disinfection cycles will the materials endure? As both materials show no decay in transparency with experiment three, however with the first experiment pmma loses its transparency within 50 cycles if placed in isopropanol. Regarding the other chemicals, both glass and pmma show an indefinite resistance towards losing their transmittance properties.

The results obtained during experiment two show that, rinsing with water does not affect the transparency of both glass and pmma samples. This is substantiated by the batches that were placed in water in experiments one and three. As these showed no difference during the experiments.

Regarding the best price-durability ratio, a distinct difference is found between both materials. Glass would cost €0,46 per lens, if ordered from a Chinese factory, whereas, 590 pmma lenses could be made for this price. Thus, a conclusion could be made that pmma lenses are the most durable choice, price wise.

4

Design results

In this chapter, results regarding optimisation of the design of the VL will be discussed. These results were required to answer the following three questions:

- Is a design optimisation possible to create a sealed environment for the electronics during disinfection?
- Is a wireless design possible?
- In which production stage should the lens be added to the design?

The first question was answered by using different design methodologies, which included, a state-of-the-art research, followed by the creation of a morphological overview, which was then evaluated by applying a Harris profile. The Harris profile was combined with the MoSCoW method, explained in chapter 2.3.3, to generate measurable criteria for the evaluation of the concept designs.

To identify the feasibility of a wireless design, a combination was made with the design optimisation as well as regulations and literature found on the subject.

Lastly, a design concept to firmly secure the lens in the VL is shown, to rule out any possible airway difficulties due to a loose lens dropping down the laryngeal tube.

4.1. Design optimisation

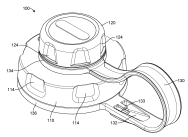
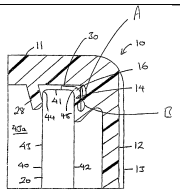
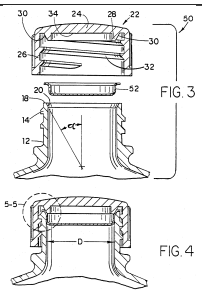
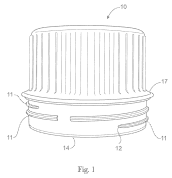
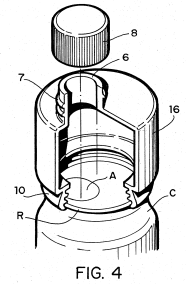
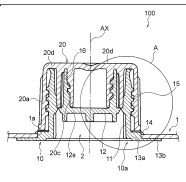
4.1.1. State-of-the-art

During the state-of-the-art research on different closures and materials that were chemically resistant to the used chemicals in Kenyan hospitals, multiple papers and patents were found that could be of use to create a hermetic seal for the VL.

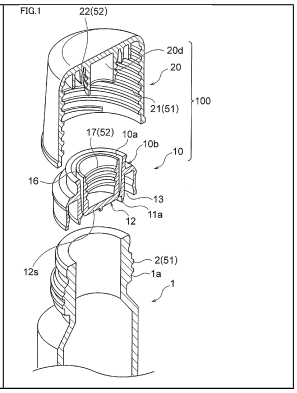
Patents

The patents that could aid in the generation of design ideas are displayed in the table below, with a description of how the innovation could be of value to the design of the VL.

Table XI: Table with figures of the patents that showed innovative ideas for the design.

	**Patent US9771189B2: Water bottle cap** This patent shows how, in the case that a cap is used, the cap could stay attached to the VL [44].
Patent US7975864B2: Linerless bore seal closure This patent shows a linerless seal through usage of a bore seal. In the case that liners deteriorate due to the disinfection chemicals, this could be a design option VL [45].	 FIG. 2
 FIG. 3 FIG. 4	**Patent US4858776A: Bottle closure assembly** This patent uses an extra sealing plug which is designed to engage with both the cap and body. Creating a hermetic seal [46].
Patent US20110290756A1: Threaded cap This patent describes the use of a cap that has an inner male thread, which could be useful for the designs with extra compartment space, as seen in two of the above patents [47].	
 FIG. 4	**Patent US20030178433A1: Beverage can cap with an ice compartment** As with the above patent, this patent uses a double cap, but uses the first cap to create more room in the compartment [48].
Patent US20150353247A1: Container sealing device This patent shows how both compartments could be sealed, thus, creating a double sealed electronics compartment [49].	

Patent EP2949596B1: Container sealing device
This patent describes the use of an inner plug in combination with outer plug. This combination could make it possible to, for instance encapsulate the electronics and keep an opening for an outlet, which consequently could be sealed before disinfection [50].



4.1.2. Literature

As described in the method section, the performed literature search produced seven papers which could be of value. Three of these papers described a method to select protective clothing and gloves when working with specific chemicals [51–53]. Two displayed a chemical compatibility chart, one described 'the effect of sterilization on plastics and elastomers' and the last was a paper on 'infection control in endoscopy' [54–57].

The chemical compatibility charts described the different materials that could be used in, due the extensiveness of these charts, materials could be selected that could aid in the design towards a hermetic environment. Table XII shows the different polymers that could be used, and how these react to the chemicals that are used in LMICs. Scoring an E means that the material has not reacted to the chemicals after 30 days of continuous exposure and it is therefore suitable to be used in the designs. One polymer group that stands out, is the group with Teflon polymers. Teflon is a widely used material for isolation and therefore its chemical resistance in this context would be convenient, as O-rings and liners of this material are commonly available.

Table XII: Chemical resistance of polymers to the used chemicals in LMICs [57].

Material	Full name	Chlorine	Isopropanol	CIDEX® OPA	CIDEX® ADS - Glutaraldehyde
LDPE	Low-density Polyethylene	G	E	E	E
HDPE	High-density Polyethylene	G	E	E	E
PP	Polypropylene	F	E	E	E
PPCO	Polypropylene copolymer	F	E	E	E
PMP	Polymethylpentene	N	E	E	F
PETG	Polyethylene terephthalate copolymer	-	E	E	-
FEP	Teflon FEP (fluorinated ethylene propylene)	E	E	E	E
TFE	Teflon FE (tetrafluoroethylene)	E	E	E	E
PFA	Teflon PFA (polyfluoroalkoxy)	E	E	E	E
ECTFE	Halar ECTFE (ethylene-chlorotrifluoroethylene copolymer)	E	E	E	E
ETFE	Tefzel ETFE (ethylene-tetrafluoroethylene)	E	E	E	E
PC	Polycarbonate	G	E	E	E
RPVC	Rigid polyvinyl chloride	E	E	E	E
FPVC	Flexible polyvinyl chloride	E	G	G	F
PSF	Polysulfone	N	G	E	G
PSF	Polystyrene	F	E	G	E
FLPE	Fluorinated polyethylene	G	E	E	E
PMMA	Polymethyl methacrylate (acrylic)	F	N	E	G
SAN	Styrene acrylonitrile	F	E	E	-
PEI	Polyetherimide	F	E	E	E
XLPE	Cross-linked high-density polyethylene	E	E	G	-
PVDF	Polyvinylidene fluoride	E	E	E	E

E = No damage after 30 days;
G = Little to no damage after 30 days of constant exposure;
F = Some effect after 7 days of constant exposure;
N = Immediate damage, not recommended for continuous use.
- = No confirmed compatibility.

4.1.3. Morphological overview

From the morphological overview in chapter 2.3.2, three designs have been created to be evaluated by the use of a Harris profile. Each concept shall be described according to a table showing the choices made per functionality. Alongside the table, a figure will be shown to conceptualise the design options.

4.1.4. First concept

The first concept design is designed according to the options marked in yellow in table XIII. The electronics shall be encapsulated in the design, with one port for a USB connection. This port can be used to both charge the internal battery when the VL is not in use, or, connect to the phone to create a video connection with the mobile phone. To make the design waterproof, a screw cap can be screwed on and off. A wad is placed in the top of the cap to create the seal. Figures 4.2 and 4.3 give a visualisation of the conceptual design.

Table XIII: The chosen options that are fitted into the first concept design.

Function	Options		
Body	Unibody	2-Component	3-Component
Screen	Attached to VL	External screen	Mobile phone
Connection	Wired	Wireless	
Power	External power	External battery	Internal battery
Charging	Induction	Charging port	[–]
Modularity	No	Simple replacements	Fully customisable
Removable lid	No	Screw cap	Double screw cap
Seal	O-ring	Wad	Thread form

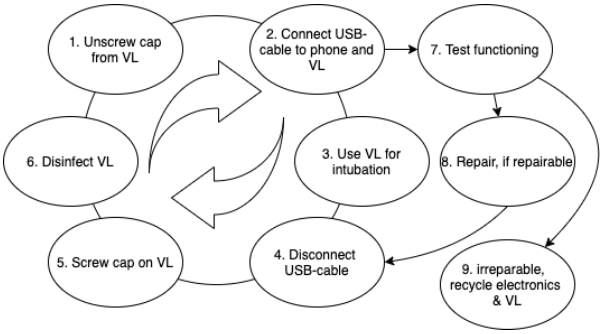


Figure 4.1: The process of the VL with this concept design.

As seen in figure 4.1, the use and disinfection of this concept design requires 6 steps for usage with an additional three steps for maintenance. Before an intubation is required, the VL should be prepared and tested, steps 1 and 2. If the VL functions accordingly, the intubation should be proceeded, step 3, if the VL malfunctions, it should be replaced, and biomedical engineers should test its functioning. If they could repair the VL, step 8, it should be brought back into the cycle in step 4. If irreparable, the VL should be recycled, by sending it back to the manufacturer. Steps 4 and 5 are the steps where human error could occur. In step 4 as the disconnection could happen without care, damaging either the USB-plug or the cable. Step 5 could be forgotten, meaning that the USB-port was not sealed before disinfection. Although the design itself and the USB-port might be resistant to the chemicals, a connection using power in the succeeding process, might cause a power shortage, due to fluids in the USB-port, which in turn could damage all electronics. After disinfection, the VL re-enters the life cycle in step 1.

Figure 4.2 shows multiple design options that came forth from the morphological overview. Figure 4.2.1 displays the VL as is. 4.2.2 shows a cross section of the VL with the space that is included for the battery and some space left to place electronics. Zooming in on the cap in figure 4.2.3, it shows how the cap is placed over the USB-port. Figure 4.2.4 shows how the cap would create a seal by means of a wad placed in between the body and the cap. Figure 4.3 presents the slot that is used to connect the VL with a micro-USB cable to the mobile phone.

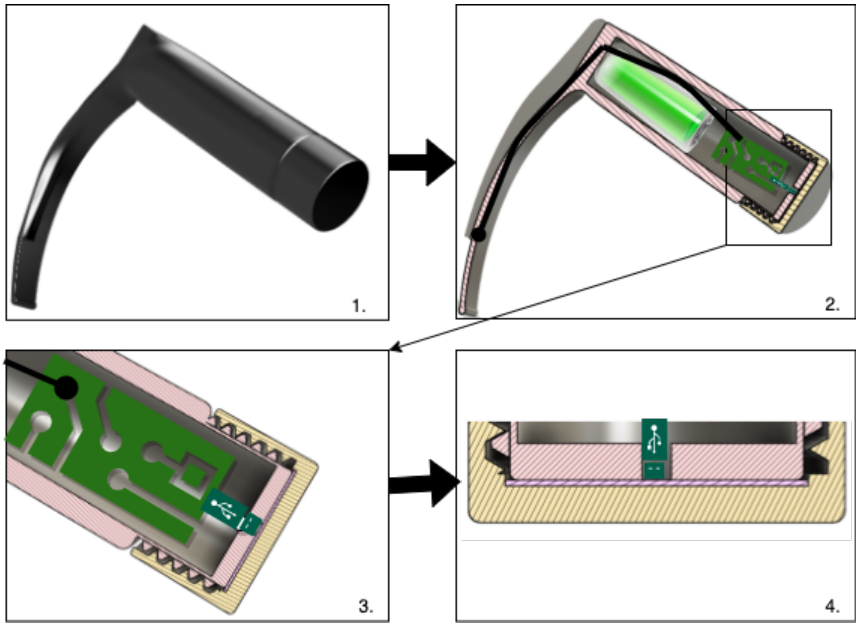


Figure 4.2: A concept design of the first concept. 2. Shows a cross-section of the VL, with space for a battery. 3. Shows a cross section of the cap. 4. Shows how a wad is placed between the body and the cap to insulate the design. Designed with Autodesk Fusion 360 [32].

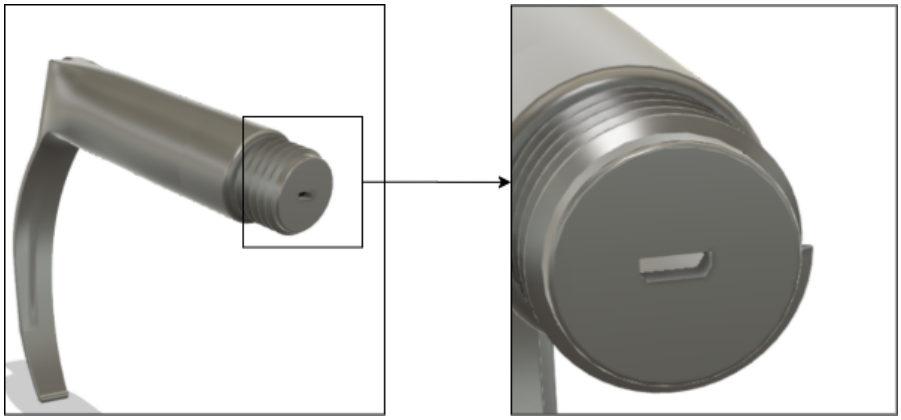


Figure 4.3: Another conceptual design of the first concept. This figure shows the slot for the micro USB-port that is used for both the mobile connection as well as charging the battery. Designed with Autodesk Fusion 360 [32].

4.1.5. Second concept

The second concept design has been inspired by the-state-of-the-art patents, by using a double screw cap, the VL is completely modular. The inner screw cap will function to keep the electronics inside the VL with a USB-port to connect the endoscope to an external screen. As the power will come from the external screen, an external battery will be used which could be charged whilst separated from the VL. The outer cap could be used to seal the USB-port before disinfection, which would create a double sealed device, as seen in figures 4.5 and 4.6.

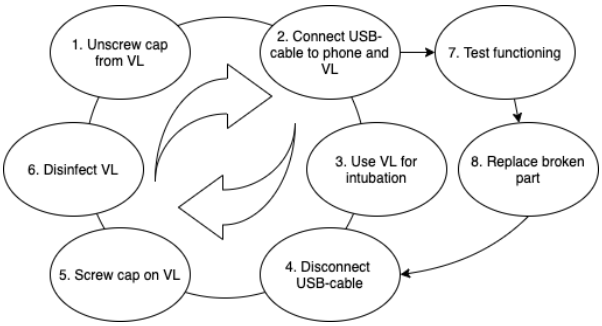


Figure 4.4: The process of the VL with this concept design

Table XIV: The chosen options that are fitted into the second concept design.

Function	Options		
Body	Unibody	2-Component	3-Component
Screen	Attached to VL	External screen	Mobile phone
Connection	Wired	Wireless	
Power	External power	External battery	Internal battery
Charging	Induction	Charging port	[–]
Modularity	No	Simple replacements	Fully customisable
Removable lid	No	Screw cap	Double screw cap
Seal	O-ring	Wad	Thread form

The difference in process steps between the first and second design, as seen in figure 4.4, is the complete modularity. In the case that the VL breaks down, any part could be replaced or repaired, making it a more sustainable design than the first concept. Despite the great modularity, this leaves more room for human error, as two threads could be screwed on incorrectly, breaking the hermetic seal, causing an internal leakage. A solution could be to make the design in such a way that the handle, seen in red in figure 4.5 would not suddenly come loose when the cap, in green, is unscrewed. For instance, by making a left-handed thread on the handle, causing it to tighten when the outer cap is unscrewed.

Another benefit of this design is that the complete VL could be disinfected, without requiring additional steps to clean for instance the thread seen in the first concept. Additionally, due to the handle being detachable from the blade, this design would facilitate the use of single-use blades, if deemed a necessary requirement for infection control.

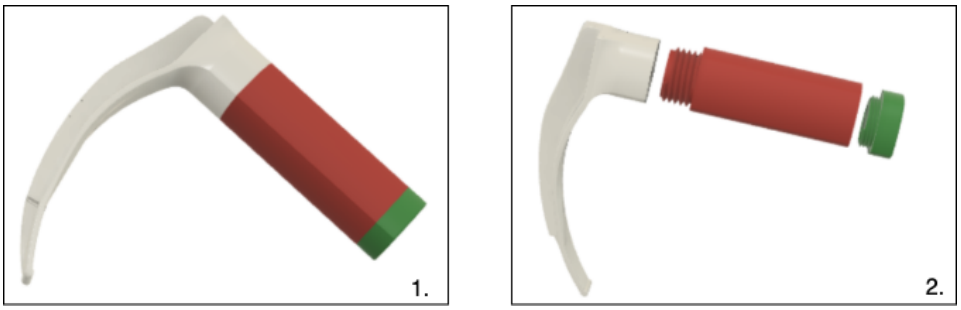


Figure 4.5: 1. Design of the second concept. 2. The three components of this concept, the white segment is the blade, the red segment is the handle and the green segment is the screw cap. Designed with Autodesk Fusion 360 [32].

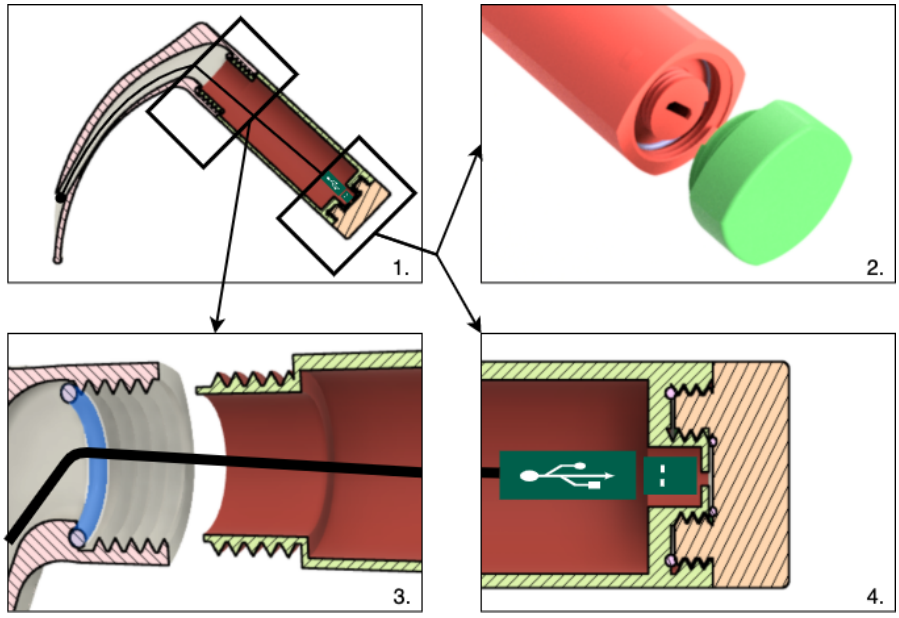


Figure 4.6: 1.The innovation seen in the second design. 2. A view of the micro-USB port, and the threading of the cap. 3. A close up of the intersection of the blade and the handle, a thread with an O-ring to seal the compartment. 4. A section analysis of the parts seen in 2., with a double threaded screw cap that creates a double seal for the electronics compartment. Designed with Autodesk Fusion 360 [32].

The figure above shows the innovative design of this concept. As seen in figure 4.6.3 the electronics are sealed by the handle in red, with a slot for the micro-USB port seen in figure 4.6.2. To make sure this slot is also sealed and protected against the used chemicals, the cap, in green, is used. Due to the double seal, precautions are taken to ensure the hermetic environment as well as the preservation of the modular capabilities. By inverting the screw thread of the handle, and holding the handle when screwing on the cap, the compartment will stay hermetically sealed. There aren't any batteries included in this design as the endoscope will be powered externally. To make direct laryngoscopy possible, a small battery could be included to power the light source.

4.1.6. Third concept

This third concept is based on a more future-proof design. It uses a wireless connection and the internal battery charges through induction, as seen in electric toothbrushes and smartphones. As all electronics can be placed inside and the connection is wireless, the design could be a unibody. This has great benefits in terms of disinfection and ease of handling, as there are no openings through which chemicals could seep through and no mistakes, due to human errors, could be made during the process of disinfecting.

Table XV: The chosen options that are fitted into the third concept design.

Function	Options		
Body	Unibody	2-Component	3-Component
Screen	Attached to VL	External screen	Mobile phone
Connection	Wired	Wireless	
Power	External power	External battery	Internal battery
Charging	Induction	Charging port	[–]
Modularity	No	Simple replacements	Fully customisable
Removable lid	No	Screw cap	Double screw cap
Seal	O-ring	Wad	Thread form

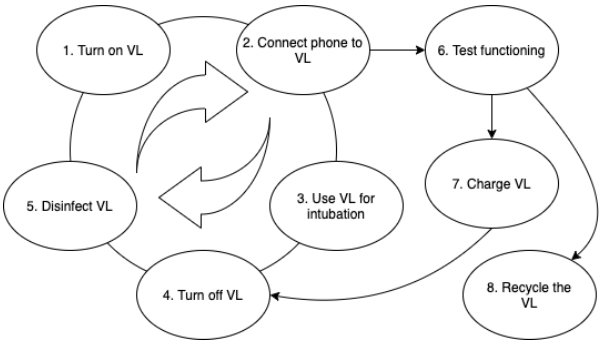


Figure 4.7: The process of the VL with this concept.

This third design, is different in regard to the process, seen in figure 4.7, than the past two designs. Due to the wireless connections and the unibody, the VL will require fewer steps in during regular usage. Due to the general steps, steps 1, 2 and 4, only involving the switching on and off and wirelessly connecting to the VL,

human error during disinfection can be omitted. An additional step, not seen in previous concepts is that the VL will need to be charged regularly, depending on the battery capacity. Another negative element is that due to the unibody, if the device breaks down, it cannot be repaired, as the electronics are not accessible.

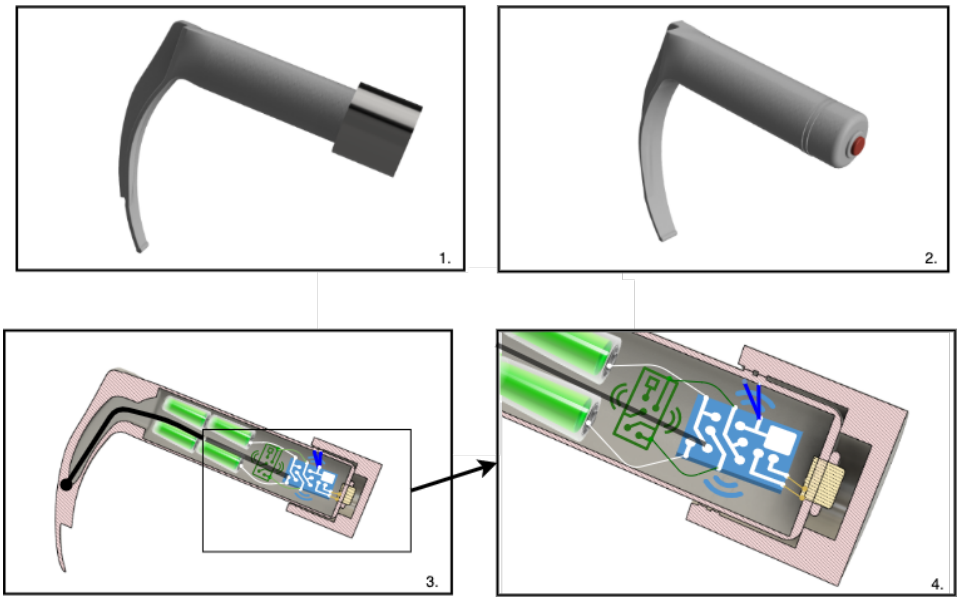


Figure 4.8: Concept design 3, with a focus on the placement of both the wireless charging and -connectivity as well as the power button. Designed with Autodesk Fusion 360[32].

As seen in figure 4.8, above, this design includes a wireless design. The charging is done through induction, the charger is seen in figure 4.8.1 and in figure 4.8.4 the connection with blue lines is made between the processor and the outer induction rings. As will be stated in chapter 4.2, on wireless design, such a design will demand a higher voltage, thus a bigger battery is required, seen in figure 4.8.4. The wireless connection is represented by the green processor board in figures 4.8.3 and 4.8.4. Lastly, figure 4.8.2 shows how a button is to be placed on the top of the handle. To ensure that the button is not pressed during charging, a cavity has been designed in the charger, as seen in figure 4.8.4.

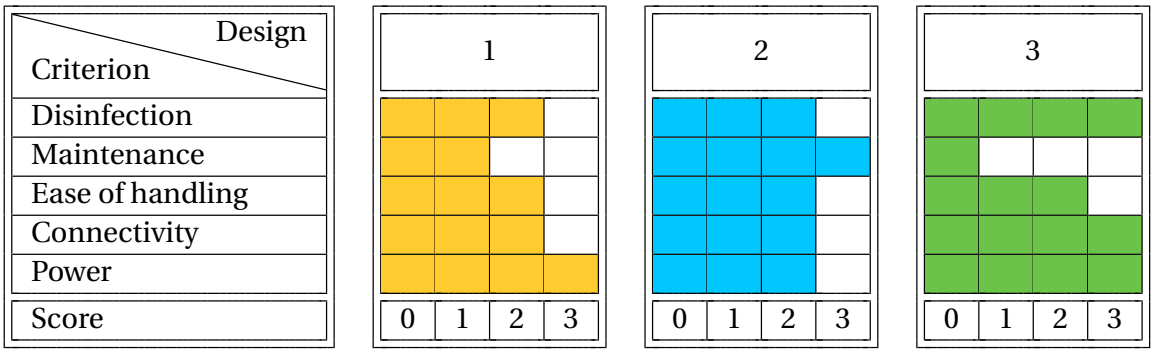
4.1.7. Harris profile

The criteria of the Harris profile have been sorted by importance of the criterion. Due to this sorting, the Harris profile will be efficient for the selection of the best design. As the design with the most desired outcome will have a fuller colour profile, and the lesser design will show more gaps. Although there are frequent power outages, all designs employ a battery of some sort, therefore this criterion is the least important criterion of all.

The same applies for the connectivity, were the only difference is being wireless instead of connected. The wireless option might be desirable but would not be the best option in terms of regulations. In the case of wireless connections, multiple certifications, proving that the wireless connection is safe, will need to be acquired. Furthermore, a wireless connection brings along more latency than a wired connection, which as well might not be preferable in life threatening situations.

As this thesis is focused on disinfection, this criterion is the most important. The concept should in all cases guarantee a sealed compartment for the electronics, and therefore, the process of sealing is inspected. More steps to be taken before the VL could be disinfected, means there is more room for human error, causing an unsafe environment. Accompanied by this criterion is, thus, the ease of handling and maintenance. These are equally important, as a more difficult process in terms of preparing the VL for surgeries and after, for the disinfection, will lead to more stages in which the VL could break down. Therefore, the maintenance should be uncomplicated to save costs of repair or returns. Most desirable would be to have a completely modular design which could be upgraded at any time to benefit of a one design fits all, as well as reducing waste due to recycling.

Table XVI: Harris profiles of the three designs.



As seen in the above Harris profile, all three designs show good scoring in regard to the requirements. Discussing the results from the top down, the third design shows to be most compliant to the disinfection criterion. However, this benefit of having a unibody is also the downside in regard to maintenance as the electronics will not be reachable for repair or modulation.

The double cap design of the second design shows that for giving in on the unibody design as well as the process of disinfection. By creating a three-component device, it gains in the maintenance criterion, becoming completely modular. Although this design requires an extra process step to become waterproof, every part of the design that could be a potential infection hazard, can be disinfected.

The first design seems to be the least favourable design regarding the upper two criteria. It uses a screw cap to seal the USB-port during disinfection, thus requiring an extra step in the disinfection process. Furthermore, as the electronics are enclosed in the design, it also loses the greater part of its modularity.

In terms of ease of handling, all three designs score the same. Where the first two designs require a cable to be connected to both the VL and the screen, the third design will need to make a wireless connection to phone, before a video connection is established. Therefore, this criterion scores the same for all three.

The third design scores the best in regard to its connectivity as the wireless connection ensures the omission of cables. Cables that could entangle or disconnect during intubation, causing a loss of video function. A wireless connection additionally makes the design untethered, causing an increase in freedom during operations. The downside of a wireless connection in regard to the wired connection is the latency that comes along with it. To decrease the latency, a higher voltage output is required, thus a bigger battery, which will be a trade-off in current design dimensions.

The last criterion, power, is met by two of the three designs. They all make use of a battery either internally or externally, therefore being independent of the mains power, which is of great benefit for the context the VL will be placed in. However, as the second design requires power from an external device, this design would not be applicable for direct laryngoscopy, where a light source is required to give a clear view of the larynx.

4.2. Wireless design

As seen in the Harris profile above, the possibility of creating a wireless design is feasible. However, trade-offs will need to be made. First of all, the dimensions of the handle in which all electronics will need to fit, have to be altered. Either the handle will need to become thicker, creating a slightly less comfortable grip for the user, or, the handle will need to become longer. Making the handle longer is not necessarily unfavourable, but the ease of manoeuvring the VL will decrease. Another downside of putting all the required electronics in a small compartment, is that it will generate heat. Therefore the component selection and thermal management are all part of the design considerations [20].

4.2.1. Electronics

To make the design wireless, certain electronics need to be included. These are:

- Rechargeable batteries, for reuse of the VL and to power all enclosed electronics;
- Charging port, to recharge the batteries;
- Power button, to switch the VL on;
- Endoscope, for video imaging;

- Wireless chip, to communicate with an external device;
- Wireless antenna, to give a range to the wireless chip's communication;
- Microprocessors, for on board intelligence;

The two accessories that generate the most heat are the microprocessor and the endoscope, therefore, these should be selected carefully. As the endoscope is inserted into the larynx, it is important that the heat is dissipated accordingly to prevented burn marks in the laryngeal tract.

4.2.2. Design considerations

As stated earlier, to incorporate all electronics the dimensions of the VL need to be alternated. Another element which should be considered, is the power button. The power button should be placed in such a way that, when operating the VL, it cannot accidentally be switched off. As seen in figure 4.9, placement of the thumb could accidentally be on top of the VL which could cause the VL to switch off in the case that the power button is placed there. A possible solution to this issue, could be to use a power switch that can only turn on the power, after which a timer triggers the turning off of the VL. Making the VL 'smart' in this way, will also have its benefits, as due to the wireless connectivity certain functions could be turned off or on by the external device. For instance, the endoscope camera will not need to be used the moment the VL is turned on therefore an option could be included in the external device to trigger this. The same applies for the method to turn off the VL, this could also be a command from the external device.

Figure 4.9: The manner in which a VL is held [58].

4.2.3. Feasibility

Creating a wireless VL has potential as it creates an untethered environment, and due to the unibody a hermetic environment is guaranteed. However, when going wireless, multiple aspects regarding the regulations are to be accounted for, such as latency and electromagnetic compatibility. The latency of wireless devices that transmit video should be no more than 300 ms, as a study has found that beyond this time, lag is felt which acts counter-intuitive [59]. Bringing down the latency is done by acquiring high performance processors, which come with a price, and more battery usage.

Electromagnetic compatibility is a requirement found in ISO 21730 which falls under ISO 13485. The definition of this requirement is that a wireless mobile device should be compatible with other devices, without causing electromagnetic interference, which could interrupt the process of other devices, causing them to malfunction [60]. As this falls under ISO 13485, this certification will need to be acquired before the VL could be placed onto the market. Both the design considerations as well as the additional regulatory requirements, will require more processing time and therefore, a bigger investment before the VL can be placed onto the market.

4.3. Affixing the Lens

Fitting the lens into the VL could be done in two ways, the first being, during production, where the lens is part of the body and the second method would be to place the lens in post-production. Both methods with their pros and cons are presented in the flowchart of figure 4.10.

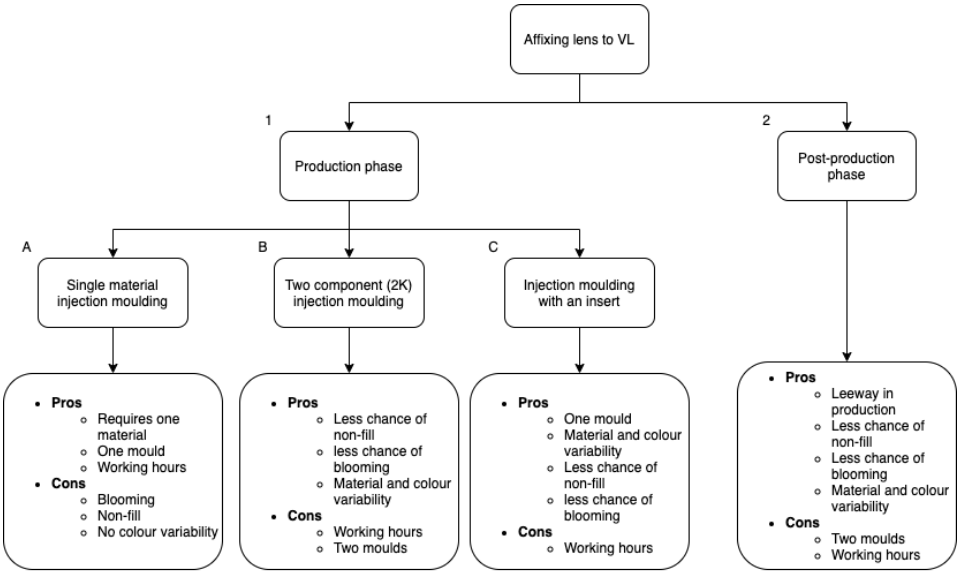


Figure 4.10: Flowchart of the possible methods to include a lens in the final product.

4.3.1. Production phase

Single material injection moulding

The first method, during the production phase, requires for the VL to either be made of one material, option 1A in the flowchart or by means of two component (2K) injection moulding, in which case the lens would first be moulded after which the body of the VL could be moulded around it, option 1B in the flowchart. A single material, option 1A, has its advantages and drawbacks:

1. One material would be cheaper to buy and produce with, however, this limits the design of the VL to certain transparent materials which would not necessarily be the right materials in terms of rigidity and colour.

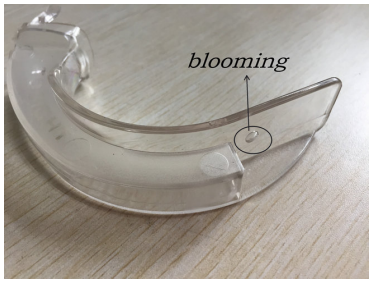
2. One mould, would mean less set up fees, which would lead to cheaper overall production costs.

3. Less working hours, due to only needing one mould, less working hours will be necessary to produce the VL.

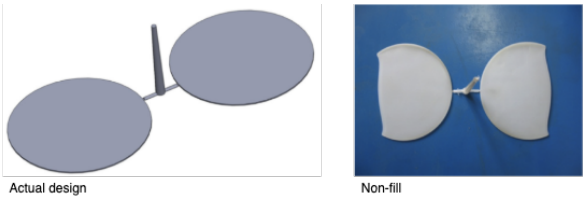
4. Blooming, due to material flow speed and pressure and design dimensions some areas could develop air bubbles as seen in figure 4.11a [61].

5. Non-fill, as with blooming to multiple factors, corners or edges could encapsulate air bubbles which lead to incomplete designs, as seen in figure 4.11b. This generally occurs in parts of the design that are too restricted for the injected material to pass through, the lens could be one of these areas.

6. Colour variability, due to only having the transparent colour option, the colours could not be adapted to, for instance conceal the electronics inside, or have a more environmentally friendly look.



(a) Blooming, when an air bubble becomes stuck in the design[61]. Also known as voids.



(b) Non-fill, when restrictions in the design reduce the material flow to certain areas. Also known as short shot [62].

Figure 4.11: Possible manufacturing errors of injection moulding.

2K injection moulding

The second method, option 1B in the flowchart, of figure 4.10, utilises a two-component injection moulding process. This method increases the variability in both colours and material options as only the lens will need to be transparent. Furthermore, there is less chance of non-fill and blooming as a separate mould will be used to produce the lens. However, requiring a second mould would mean that set up fees will rise as well as the working hours used to produce the VL.

Injection moulding with an insert

A third alternative in the production phase, option 1C, would be to place an insert before the material is cast into the mould. Figure 4.12 shows an example of the way in which an insert would be used to produce a screwdriver. Specifically point 5 in the figure shows how this is done [63]. This method could bring down the costs of not needing a second mould, as well as increasing the material and colour variability. Moreover, working hours will be higher than single material injection moulding, but about the same as 2k injection moulding, as the insert will need to be placed each time. Lastly, the lens could now be made of any material, which could mean that every VL could be manufactured more specifically for the context it is placed in, according to the used methods of disinfection.

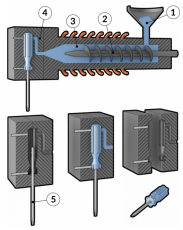


Figure 4.12: Example of how an insert is placed in the mould before the material is injected [63].

4.3.2. Post-production phase

Assembly

The fourth option, option 2 in the flowchart, would be to place the lens during the post-production phase. Due to restrictions in the design of the VL, an option would be to produce the VL in two halves and assemble these afterwards, by means of ultrasonic welding. Because of this option, it would be possible to insert the lens into placeholders in the design after which the design could be welded together.

Ultrasonic welding is a type of manufacturing that “uses ultrasonic energy at high frequencies to produce mechanical vibrations. These vibrations generate heat at the joint interface which results in melting of the materials ” [65]. As seen in figure 4.13, the left image shows how the parts are designed before the ultrasonic welding takes place. The right image shows how a seamless connection, a weld, is formed after the ultrasonic welding has taken place.

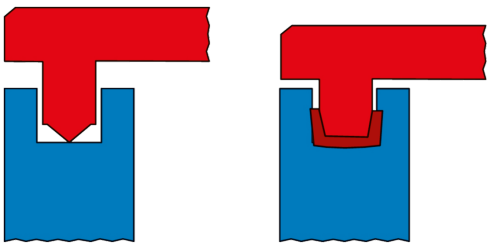


Figure 4.13: Process of ultrasonic welding [64].

Not only does this method allow for greater variation in the design of the VL, it is also possible to create a sealed environment around the lens, making this side of the compartment waterproof. This design change has been modelled with Autodesk Fusion 360®, and a clear view of this change is shown in figure 4.14 [32]. The dimensions of the joint between the VL and the lens, are based on the dimensions used for a ‘step joint’ as seen in the ‘Handbook of Plastics joining’ [65]. Another benefit of this method is that it creates a seamless joint, where bacteria and fungi will not be able to accumulate in undesirable places as these will be hermetically sealed to the outside world.

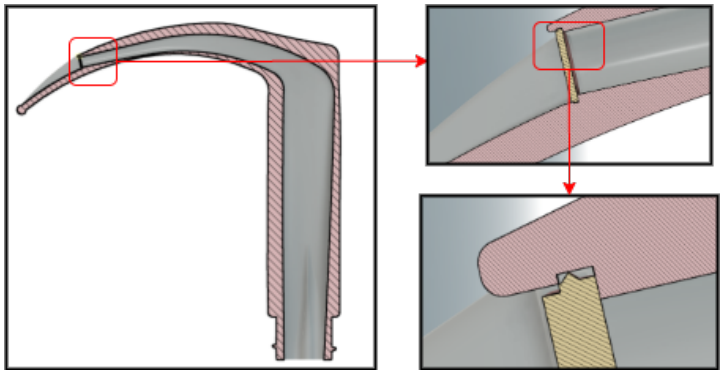


Figure 4.14: A design change of the VL to optimise the lens opening for sonic welding. Created with Autodesk Fusion 360 [32].

4.4. Summary

Summarising the qualitative research that was conducted to find answers to the design phase of this research is done by answering the corresponding questions, introduced at the beginning of this chapter.

The first requirement was to design an optimisation that would create a sealed environment for the electronics during disinfection. To generate concepts for this design, three methodological methods were used, being, a literature- and state-of-the-art research, creating a morphological overview and assessing the concepts generated through the morphological overview by means of a Harris profile.

The state-of-the-art research gave key insights to possible designs for a sealed environment, followed by a literature search that specified, by means of a chemical resistance chart, the materials that could be used, in this context, to create the sealed environment. Teflon was a commonly available material, used for sealing, that stood out as it was resistant to all used chemicals.

From the morphological overview, three feasible concepts were generated, which were subsequently evaluated by the use of a Harris profile. From these results it became clear that a three-component design would be the most desirable as 2 components would create a hermetic environment inside the VL and the third component would make a secondary seal, closing off all entries from possible liquid penetration.

The first conceptual design had a similar approach, however, if the electronics malfunctioned, repairing or recovering the electronics would bring along multiple complications.The third design, a wireless design, showed to be very potential as well. However, for the VL to become wireless, far more costs need to be taken into consideration. As regulations require wireless devices to have a low latency and multiple ISO-certifications are required to comply with regulations. Not only will the regulatory costs be higher, the maintenance of the device will also require more structure. As the device will regularly need to be charged and repairing problems to the electronics will not be possible without compromising the unibody of the VL.

The last requirement in the design phase was to find the best approach to incorporating the lens into the body. The requirement for this optimisation was, that there should be no possibility of the lens coming undone. If this were to occur during surgery, it would mean that the lens could drop down the throat causing even greater complications. With this requirement in mind an optimal solution was found. Due to the form of the VL, production will need to be done in two halves which would be solidified by means of ultrasonic welding. Due to this fact, the lens could be placed during that stadium. Encapsulation could then be done due to the form of the lens and its surroundings as seen in figure 4.13. Another benefit of this manufacturing technique is that the lens is fused with the VL, generating a sealed environment as well as avoiding the cause of greater complications.

5

Discussion and Conclusion

The main research question for this thesis was to find the design modifications that are required to create and sustain a hermetic enclosure to incorporate the electronics into the video laryngoscope. This was done by splitting the research into two sections, the first being the investigation of the material properties of different transparent materials, and the second being the design optimisation. Different types of lenses were researched to find the material best suitable to the context it is placed in, low-resource regions. The design phase was used to find an optimisation which could create a sealed environment for the electronics, involving different design methods and drawing conclusions through these methods.

5.1. Material properties

5.1.1. Retaining transmittance properties

In terms of retaining transmittance properties during disinfection of the VL, glass shows to be the most reliable material for all types of disinfection. As it shows that it is not affected by the disinfection chemicals used in Kenya.

On the other hand, pmma endures disinfection with CIDEX®, JIK and placement in water. The anomaly in this research was that the pmma samples used for experiment 3, showed no form of solvent crazing, after four weeks, whereas the short-term, first and second, experiments showed no resistance to the used alcohol. The samples where all laser cut from the same sheet of pmma, after which they were divided randomly per batch. All batches regarding the used chemicals where placed in the same containers. A reason for this sudden solvent crazing to occur, could be that, during the third experiment, a contamination of the batches of the first and second experiment had occurred. As the samples were all stored in an airtight container until they were used, this was deemed unlikely.

As this occurred during the third week of the third experiment, this specific batch was placed in another container with a new quantity of isopropanol, which consecutively has led to no form of solvent crazing, as seen in figure 3.8 of the results.

5.1.2. Number of cycles

To make concluding remarks on the number of disinfection cycles, for glass it could be stated that it will outlive the desired lifespan of the VL as it has shown no loss in transmittance after 2000 cycles. For pmma however, more research will need to be done to uncover the odd observations, seen with the disinfection by isopropanol. As solvent crazing was assumed to only occur when stresses were applied, during submersion of the samples.

In general, however, the advice would be to not use pmma lenses for VLs that are used in hospitals that disinfect equipment with alcohols. As solvent crazing occurred in fewer than 50 cycles, causing for multiple samples to become too hazy, to generate a clear enough image, for the MATLAB® script to calculate its sharpness. To solve this problem, the solution could be to apply a coating, which would drive up the costs, however, comparing the costs between glass and pmma lenses, it would still be a cheaper solution.

For the other disinfection chemicals, pmma shows no decline in transmittance and will therefore outlive the desired lifespan of the VL.

The adhesive, used to adhere the protective layer to the pmma, might have caused the samples from the third experiment to not show any form of solvent crazing. To rule this out, a fourth experiment was conducted,

where the layer was removed from all samples simultaneously, and the samples where placed in the containers with isopropanol in consecutive days. Thus the fourth day, the remaining adhesive on the fourth sample would have been exposed long enough to possibly show solvent crazing on the pmma. However, this did not occur and therefore, more research should be conducted, as the samples from the first and second experiment might have been contaminated.

5.1.3. Rinsing with water

The results of the second experiment showed that water would neither increase or decrease the decay of transmittance properties of the glass- and pmma lenses. In regard to the pmma lenses from the isopropanol batch, it appeared to have an effect, as the median of the second experiment was higher than the median of the first experiment. But a more extensive look at the boxplots shows that three-quarters of the results lay within half of the results of the first experiment.

The batch used in the first and third experiment, which was placed in water substantiates the findings of the second experiment. As these samples showed no decrease in transmittance properties, meaning that water does not obscure the lenses. Therefore, it can be assumed that rinsing with water in between the disinfection cycles will not affect the transmittance properties of both the glass and pmma lenses.

5.1.4. Price-durability ratio

From the results seen in chapter 3.4, a conclusion can be drawn that the lenses made of pmma are much more cost effective than the lenses made of glass. As 590 plastic lenses could be manufactured for the price of one glass lens. This difference in cost per lens will also make up for any coatings that need to be applied to cover for the fact that the pmma lenses could not withstand submersion in isopropanol containers.

5.2. Design requirements

5.2.1. Design optimisation

Following the methods for idea generation, brings about multiple benefits. As endless designs could be created, simply by mapping the options and desires, consequently combining them to generate an endless amount of ideas.

The literature and state-of-the-art research gave insights to the possibilities regarding multiple ways of sealing as well as different chemical resistant materials that could be used to create the seal. Teflon was the trademarked material that stood out as it shows to be fully compatible with the disinfection chemicals used in this context. Therefore, Teflon would be very suitable to be used as a liner or for o-rings in the concept designs.

From the morphological overview three viable concepts were created by combining the different alternatives of the various parameters. After generating the designs, a Harris profile was made to compare them. In the Harris profile key elements came forward which would determine how well the designs would meet the requirements of the specified context, being low-resource countries.

Concluding this qualitative research, the second concept design was most favourable. Due to its high possibility of modularity and the ability to create a double seal ensuring the hermetic environment.

5.2.2. Wireless design

Of the concept designs, one was designed to be wireless, which was feasible. However, after looking into all the requirements that needed to be met, it did not seem desirable to place a wireless VL onto the market as the first version. Before a final version with a unibody is placed onto the market, all the teething problems should be filtered out, as it will be hard to tackle these, once the VL is in use. Apart from the requirements, multiple trade offs have to be made, as there won't be enough space to place both a large enough battery accompanied with a good microprocessor. For the latter, another trade off has to be made as a processor with better calculating power will generate more heat which will need to be dissipated accordingly. Thus, both component selection and thermal management should be taken into consideration when designing the VL

5.2.3. Assembly

The third question in the design section was to find the best moment for placement of the lens. As it is crucial that, once the lens is placed, it cannot come undone during intubation. This fixation could be done in two stages of the production, during the production phase, or, during the post-production phase. During production gave three options, all requiring injection moulding.

The first option was to injection mould the whole VL in one transparent material. This option had multiple downsides as the lens will be less than 1 mm thick, both blooming and short shot, seen in figure 4.11 could occur.

The second option included two component injection moulding, which would increase the variability in both colours as well as materials. This method was, however, less preferred as it would need an extra mould solely for the injection of the lens.

The third option was to injection mould the VL, including the use of an insert. An example of this is the production of the screwdriver, seen in figure 4.12. This method however requires more working hours as each insert will need to be placed before the production, which would be more expansive than the former two methods.

The other phase in which fixation of the lens could be done, is the post-production phase. As, due to the form of the VL, it will need to be produced in two halves. The two halves can then be assembled by a method called ultrasonic welding, this method uses ultrasonic energy at a high frequency. The high frequent vibrations generate heat causing the two parts to fuse together, forming a seamless joint. This method is ideal for the fixation of the lens as it could then be permanently fixated to the VL as well as create a hermetic seal, being an excellent solution for the design requirement to create a hermetic environment for the electronics.

5.3. Main research question

Combining the made conclusions above, an answer to the main research question could be given. Regarding the material that should be used for the lens, pmma would be the most economical solution as it is resistant to the used materials, and the problem that arose with solvent crazing will require further research as the batch that was placed in isopropanol for four weeks showed no degradation. The price difference between the two materials, being that 590 pmma lenses could be bought for 1 glass lens, also means that there is more room for a medical coating which could solve the eventual solvent crazing problem.

Regarding the design, to create a hermetic environment for the electronics, the answer would be to use a three-component design. The electronics could then be sealed with two components and a third component would then seal the USB-port. The literature study showed that Teflon® is resistant to the used chemicals in this context, and it could therefore be used as O-rings to seal the different compartments.

As the design is made in two halves, and welded together through ultrasonic welding, the lens could also be placed in this stage. Due to this method, a seamless seal is created. These design optimisations would therefore be the best solution to create a hermetic environment for the electronics.

5.4. Recommendations for Smart Medics Company

In terms of the recommendations for usage of the lenses, the recommendation would be to use lenses made of pmma as these are not only the most cost effective, but they also have more options regarding their remodelling. These lenses could be injection moulded into the design as well as custom designed to fit in the VL seamlessly, ensuring a waterproof design. Furthermore, the lenses show the same transparent values as glass does. The negative side of the pmma lenses would be the discovered solvent crazing in alcohols, however, this fragility could be minimised by coating the design, with a medical grade coating.

As seen in chapter 4, there are endless possibilities to create a design specifically intended for use in low-resource countries. As the company has no products on the market, a recommendation would be to start with a wired design. The wired design could then be used to create a proof of concept which could then be updated to become wireless in a later stadium. As certification for wireless devices will ave additional costs, which could be made after the return on the first investment is achieved. If the second design were to be used, the great modularity would accompany future designs which might include wireless connectivity. Furthermore, the modular design is ideal to create more variability in the products offered. As one hospital could want an external screen accompanied by it, whereas another medical institution would be happy to use a mobile phone.

5.5. Final conclusion

To conclude this research, regarding the main research question, the material best suitable for the lens of the VL would be pmma. As it has shown to be equally durable as glass, however 590 times as cheap as glass in terms of production costs. Furthermore, after fabrication it is still mouldable, making it ideal for production techniques such as ultrasonic welding.

Regarding the design, the best concept would be to use a three-component design, as this shows great modularity for future opportunities and possibly single-use blades. Secondly, the way the screw cap is designed, makes it accessible to thorough disinfection without potential contaminated area's.

The above mentioned design optimisations will create and sustain a hermetic enclosure to incorporate the electronics into the video laryngoscope.

Appendices

A

Scientific paper

Chemical resistance of transparent materials to disinfection chemicals used in low-resource regions

M.A. Willemsen[1] and J. Klein[1]

***Abstract*— A medical device designed specifically for the context of low-resource regions will incorporate a lens to seal a compartment containing a boroscope. In the context of low-resource regions, hospitals use different types of chemicals to disinfect the medical devices. To test the resistance of glass and polymethylmethacrylate (pmma) to these chemicals, multiple experiments were conducted that, resembled the conventional disinfection methods. The chemical resistance was measured by placing the samples in front of a camera and measuring the resolution in cycles per pixel. A decay in resolution would mean that the material would become less transparent, thus, being unresistant to a particular chemical. Results showed that the materials were resistant to the used chemicals and a price-durability comparison revealed that pmma would be the preferred option for the medical device.**

I. INTRODUCTION

Disinfection of medical devices in hospitals in low-resource regions is done by placing the devices in containers filled with chemicals. These include the following chemicals: CIDEX® ADS, CIDEX® OPA, Isopropanol, JIK (3.5% active chlorine), soap and/or water [1]. These chemicals are known to decrease the durability of medical devices, therefore, medical devices placed in this context should be designed to be chemically resistant to these chemicals[2].

A. INTUBATION

Intubation is the placement of an endotracheal tube, a breathing tube, needed when patients undergo general anaesthesia with muscle relaxation, when they have to be ventilated, or because their airway is obstructed.

An important consideration during some types of surgery is the use of mechanical ventilation. Mechanical ventilation via an endotracheal tube can be indicated when muscle relaxants are used during the operation, to prevent stomach contents from entering the lungs, as well as, to control oxygenation during surgery. Intubation is also a requirement when a patient has serious breathing problems for instance due to a Covid-19 infection [3].

A laryngoscope is an assistive device used to aid with the intubation of a patient. After the patient is asleep, the laryngoscope is inserted into the patient's mouth and by lifting the jaw, the vocal cords are exposed. Once the vocal cords are exposed, the endotracheal tube can be advanced into the upper part of the trachea, creating a pathway for air to flow to- and from the lungs.

Laryngoscopy is thus used for the following:

- Expose the upper part of the larynx and give a clear visual for diagnosing of infections;
- Aid in the insertion of the endotracheal tube;
- Find congestion's in the throat;

In general, laryngoscopes can be categorised in direct- and video laryngoscopes. Both methods have their benefits, however the video laryngoscope is becoming more widespread. Recent studies have also shown the importance of the use of video laryngoscopy, in regard to patients with Covid-19. As research has shown that the highest viral load of the virus, SARS-CoV-2, is found in the upper tracheal tract, generating aerosol particles, contamination the personal protective equipment, possibly even, body parts that are exposed, of the medical personnel handling the airway[4]. Due to this, video laryngoscopy is recommended, to minimise the infection risk as the distance between the patient and the anaesthetist is increased [5].

B. DISINFECTION PROCEDURE

The disinfection procedure is to submerge the instruments in a plastic container filled with one of the above stated liquids for 15 to 30 minutes, however in the desired context, this is often more than a week as the equipment is kept in the containers until it is used again [1, 6].

This method of disinfection is based on the fact that the used chemicals create an acidic environment in which the bacteria and viruses will not survive. However, these acids could also react with the used transparent materials, making them dull.

C. PROBLEM STATEMENT

Glass and pmma are known to withstand current western disinfection techniques, by means of autoclave [7–9]. However, no research has been conducted on the effect of these chemicals on glass and pmma. Assumed is that the chemicals will not cause a reaction, however, a known effect of isopropanol on pmma, when stresses are applied, is solvent crazing [10, 11].

D. GOAL

The goal of this research is, to investigate the effects of CIDEX® OPA, JIK, Isopropanol and water on the transparency of glass and pmma. This investigation will consequently show which material would best be suitable for the desired context it will be used in.

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II. MATERIALS & METHOD

A. MATERIALS

As the experiment is focused on the transmittance property of materials, the materials involved in this experiment, were all required to be transparent and readily available. The selection came down to four materials, listed below.

1) Glass;
2) Pmma;
3) Polyvinylchloride (pvc) (Excluded due to production restrictions);
4) Polycarbonate (pc) (Excluded due to production restrictions).

Glass was chosen as it is a material that is resistant to all chemicals apart from hydrofluoric acid [12, 13]. It should therefore be the most sustainable solution, in regard to the used disinfection chemicals, compared to the chosen plastics.

The above-mentioned plastics were chosen as they are mass-produced and for this reason, relatively cheap and readily available in Low- and Middle-Income Countrys (LMICs) [14]. Furthermore, chemical resistance charts show that these plastics should negligibly be affected by the chemicals used in this research [15]. This implies that although it is insignificant, the clarity of the transparent plastics might be affected by corrosion causing haze and therefore, decreasing the resolution of images obtained through the boroscope.

Due to restrictions in productions, both pc and pvc could not be used in this research.

B. CHEMICALS

The chemical liquids in which the materials were submerged were chosen based on the context the Video laryngoscope (VL) would be used in. However, some liquids were not acquirable in the Netherlands, for this reason a liquid was either replaced by equivalent chemicals, or, it was disregarded for this research.

1) JIK; 3,5% chlorine, not obtainable, a solution was made by mixing 3.5 parts bleach with one part water.
2) CIDEX® OPA; Fabricated by Johnson & Johnson [16].
3) Isopropanol; Fabricated by Sigma Aldrich [17].
4) Water; Ordinary tap water.
5) CIDEX® ADS; Was not obtainable and no products similar to the active chemical agent glutaraldehyde were found to substitute this disinfection liquid.

As seen above, JIK could be mimicked by using household bleach of 4.5% active chlorine and diluting it to 3.5%. This chemical solution was based on a document provided by the Pacific Public Health Surveillance Network on disinfection and sterilisation in 2001, and the World Health Organisation (WHO) described the protocols for disinfection and sterilisation in 2016 [18, 19].

C. SAMPLESIZE

Per chemical a batch of five samples per transparent material was used. For four liquids and a control group this amounts to 20 samples per material per experiment. The second experiment did not contain a batch to submerge in water, thus only required 15 samples per material. The three experiments and a control group of five samples add up to a total of 60 samples per material.

D. EXPERIMENTAL SETUP

Consistency across the different images, acquired through the boroscope, was maintained by creating a setup as seen in figures 1, 3 and 4. In this setup, the boroscope was placed 25 cm away from the image, to allow for a 4:3 ratio image to be acquired. This ratio was necessary as the resolution of the boroscope was 640-by-480 pixels. To test the samples consistently after each experimental phase, a mount seen in figure 2 was 3d-printed to keep the boroscope in the correct position, with a slot in which the lenses could be placed. To acquire calculable data, an image, seen in figure 3, is used. This image is used in photography to calculate the maximum obtainable resolution of a camera, standardised by ISO 12233:2014 [20]. The image has 60 slanted edges, at a 5° angle divided over 15 squares. This angle offset has been done to sample the edges in countless different phases, allowing estimation of the Spatial Frequency Response (SFR) [20].

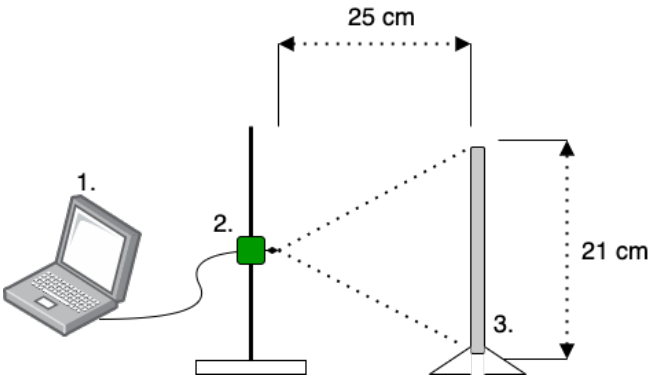

Fig. 1. Schematic drawing of experimental setup. 1. The computer running the imaging software. 2. The mount that holds the lens in place in front of the boroscope, as seen in figure 2. 3. The screen that holds the test chart seen in figure 3.

One of the outputs of the SFR is the Modulation Transfer function (MTF) which shows how many lines are needed to transition from one colour to the other. Simplifying this, the spatial frequency is measured in cycles per pixel, taking one darker and one lighter line as a cycle.

The changeover from one dark to one bright pixel, determines that the Nyquist frequency is 0.5 cycles per pixel as minimally two pixels are needed to form one colour transition [21]. Once this frequency is passed, spatial aliasing will occur, also known as a moiré pattern.

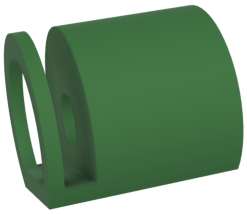

Fig. 2. A small mount to hold the lenses in place in front of the boroscope during the image capturing. Designed with Autodesk Fusion 360 [22].

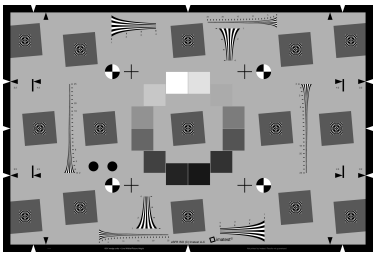

Fig. 3. ISO 12233:2014 test image used to calculate the resolution of cameras by evaluating the slanted edges of the 15 squares[20].

Fig. 4. Photo of the, in figure 1 described, setup.

E. Experiments

The experiments consisted of three general phases:

1) Placement of each set of samples in the different chemicals;
2) Removal of the batches from the chemicals, and rinsing them with tap water;
3) Placing the samples in the experimental setup for evaluation.

The difference between the experiments was the duration and repetition of each phase. The first experiment involved approximately 50 cycles of 20 minutes by placing the sample set in the chemicals for a duration of 17 hours, after which they were rinsed and evaluated according to the ISO 12233:2017 standard [20].

The second experiment was done to see what effect the rinsing with water in between each cycle had on the transparency of the samples. Therefore, the sample sets were placed in the chemicals for 20 minutes after which they were rinsed with tap-water, this was repeated 50 times to compare the samples to the results obtained from the first experiment.

The third experiment was a replication of the first experiment, however, this time, the samples were placed in the containers for a week, which resembled approximately 500 cycles of 20 minutes. As with the first experiment these were then rinsed with water and placed in the boroscope mount for evaluation. This experiment was done to see the more long-term effects of the chemicals on the samples. This was done four weeks in a row as this would resemble 2000 cycles, which is the desired lifespan of the VL, according to R. Straathof, who indicated this in an internal report [23]. Every 500 cycles, the samples were removed from the liquids to test the transparency. For consistency across all three experiments, a constant temperature of 20 °C was maintained throughout all phases of the experiments.

TABLE I

AN OVERVIEW OF THE CONDUCTED EXPERIMENTS.

Exp.	Duration [Cycles]	Duration [Time]	Repeat	Total cycles	Total time
1	50	17 hours	0	50	17 hours
2	1	20 minutes	50	50	19 hours
3	500	1 week	4	2000	4 weeks

To compare the difference in lens quality, an initial experiment, named experiment 0, was done. The resolution obtainable by the boroscope without a lens was compared to the glass and pmma lenses that were untreated. These results were consequently, used as the control group results.

F. Price-durability ratio

To find the price-durability ratio for the used materials, wholesale factories were searched for and if necessary, contact to get quotes for both glass and pmma lenses. As for this research, with a low quantity of lenses, custom made lenses were not readily available, the results were based on made pricing requests.

III. RESULTS

The experiments involved the placement of these materials in different types of chemicals for different amounts of time. The data collected from these experiments have been split up per experiment. These experiments were focused on a decline in resolution, therefore the resolution obtained by the samples from the control groups of glass and pmma were used as the standard as, these show less than 1 cycle per pixel decay, on average, in regard to the use of no lens, as seen in figure 5 and table II correspondingly. These results were obtained by calculations made with Matlab®. The table also shows that the used boroscope in combination with a printed image of the ISO 12233 test chart generates a sharpness of approximately 0.285 cycles per pixel, which will be the reference frame for further results.

TABLE II

AVERAGE VALUES IN CYCLES PER PIXEL OBTAINED IN EXPERIMENT 0.

Sample Set	Average sharpness [cycles per pixel]
No lens	0.285
Glass	0.275
Pmma	0.278

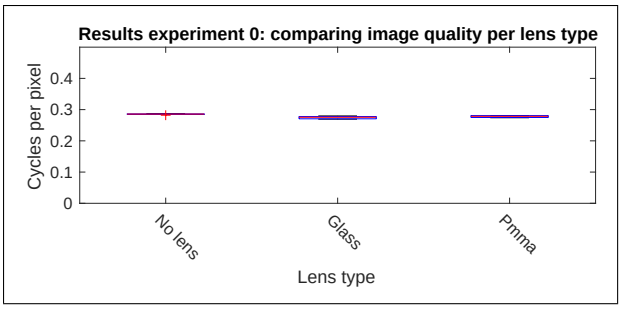

Fig. 5. Experiment 0, Difference in sharpness between images without a lens and with the glass- and the pmma lenses.

A. Experiment 1

The first experiment generated results that were mostly in line with the expectations. After 17 hours, all but one sample group showed no decline. As seen in table III, apart from the pmma, in isopropanol, sample group, the other batches show similar values to those of the control group of that material.

The odd one out in this experiment is the pmma batch placed in isopropanol.

TABLE III
AN OVERVIEW OF THE EXPERIMENTS AND THEIR PURPOSE.

Sample Group	Pmma Average cycles/pixel	Glass Average cycles/pixel
Control Group	0.278	0.275
2-propanol	0.140	0.275
CIDEX	0.274	0.273
JIK	0.269	0.285
Water	0.268	0.260

Figures 6 and 7 give a representation of the distribution of the obtained values in cycles per pixel. As seen in the table, no irregular values were obtained apart from the batch with pmma samples placed in isopropanol. All the samples show a decrease in resolution.

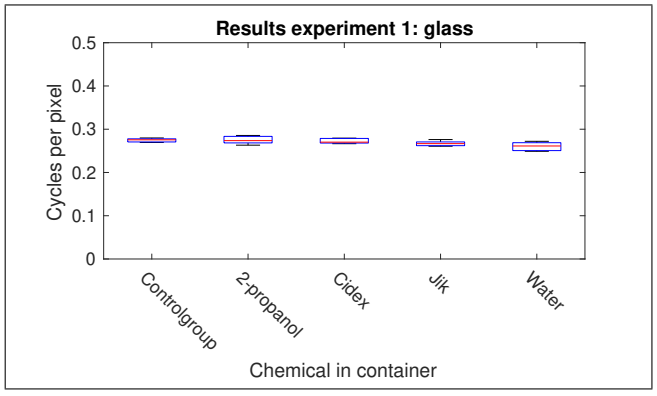

Fig. 6. Results of the glass samples of experiment 1.

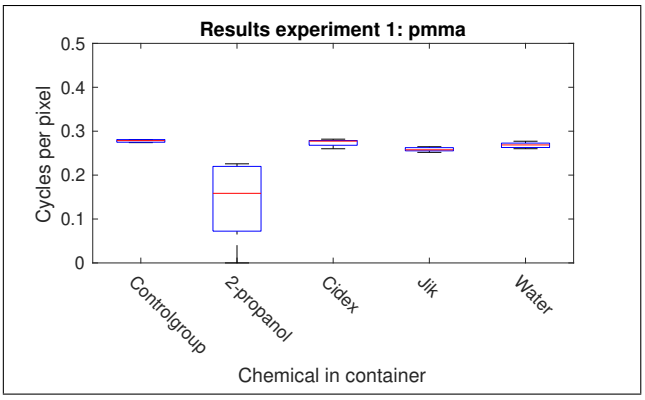

Fig. 7. Results of the pmma samples of experiment 1.

The phenomena of solvent crazing, was unexpected as, no stresses were applied to the samples during submersion. Therefore, a secondary experiment was conducted, experiment 1.2 with a new batch group in a separate container filled with isopropanol. This batch showed noticeable solvent crazing in less than two hours, however, to compare the results with the first experiment, the batch was submerged for 17 hours, generating the results seen in figure 8. The boxplot, of this second trial, clearly shows that pmma is not able to withstand an alcoholic environment and deterioration is imminent.

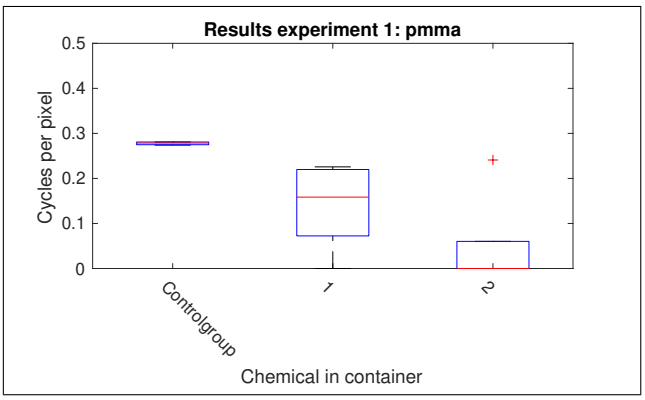

Fig. 8. Second trial done to validate solvent crazing in the first experiment.

An example of solvent crazing is shown in figure 10. The figure shows how the phenomenon generates random lines of scratches, making the lens dull.

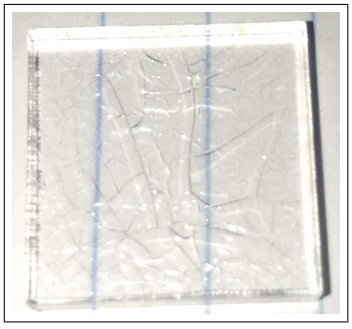

Fig. 10. Photo of a pmma lens on which solvent crazing occurred.

B. Experiment 2

The second experiment was conducted to see if rinsing with water would affect the decrease in resolution in between cycles. This experiment involved a normal disinfection cycle of 20 minutes followed by rinsing with water, and repeating this 50 times, to compare the result against the values of experiment 1, as seen in the table below (table IV).

TABLE IV

RESOLUTION IN CYCLES PER PIXEL OF EXPERIMENT 1 AND 2, WITH A RELATIVE CHANGE IN PERCENTAGE IN REGARD TO THE CONTROL GROUP.

Chemical	**Lens type**	**Experiment**	
		1 [Cycles/pixel]	**2** [Cycles/pixel]
2-propanol	Glass	0.275 (0 %)	0.286 (+4 %)
	Pmma	0.140 {-50 %}	0.206 (-25%)
CIDEX	Glass	0.273 {-1 %}	0.278 (+1 %)
	Pmma	0.274 {-2 %}	0.280 (+1%)
JIK	Glass	0.285 {+4 %}	0.275 (0 %)
	Pmma	0.269 (-3 %)	0.269 (-3 %)

Figure 11 shows the relative change, noted in table IV, of the samples in regard to the control group. The small values of relative change between the two experiments shows that rinsing with water does not negatively affect the resolution of the samples. Regarding the smaller percentage change of the pmma samples placed in isopropanol, it shows that rinsing with water does slow down the solvent crazing, however, this is only a delay of the effects.

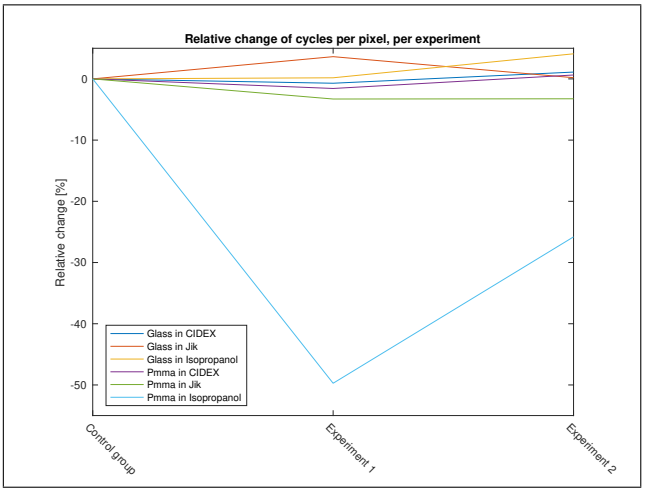

Fig. 11. Comparison of the results of experiment 2, with the control group, presented as exp. 0, and experiment 1.

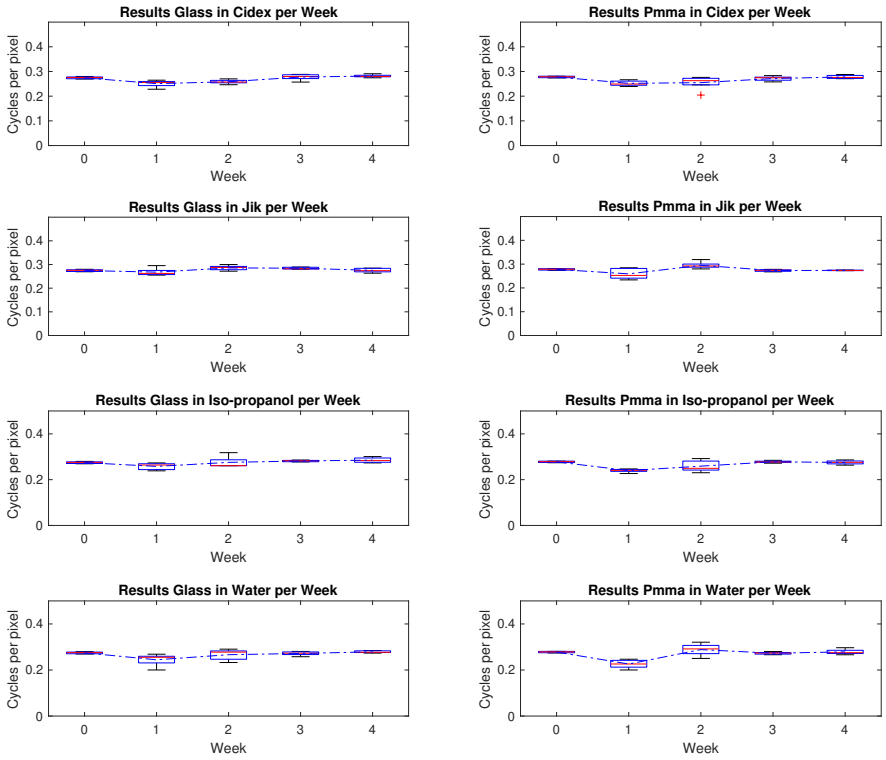

Fig. 9. Boxplots of the results of experiment 3, The resolution, in cycles per pixel, is sorted per chemical and per material.

C. Experiment 3

The third experiment revealed the long-term effects of the chemicals. Expected was that the results would not differ from the first experiment, however, this was the case. The results are in line with the expectations set in the introduction, in which both glass and pmma would not be affected by the chemicals. All boxplots in figure 9 show a slight decline in the resolutions of the first week. This was due to ceiling windows that affected the lighting in the room, causing the camera to lose focus, capturing a slightly less quality image. The setup was thereafter moved to a room where lighting was controlled, this generated stable results in the following weeks. The table below, table V, shows the relative change between the results of the control group and after 4 weeks, resembling 2000 disinfection cycles.

TABLE V

CHANGE IN RESOLUTION BETWEEN THE CONTROL GROUP AND THE SAMPLES AFTER 2000 DISINFECTION CYCLES.

Material	**Chemical**	**Experiment**	
		0 [Cycles/pixel]	**3**(After 4 weeks) [Cycles/pixel]
Glass	2-propanol	0.275	0.285 (+3%)
	CIDEX		0.282 (+2%)
	JIK		0.275 (0%)
	Water		0.279 (0%)
Pmma	2-propanol	0.278	0.275 (-1%)
	CIDEX		0.278 (0%)
	JIK		0.274 (-1%)
	Water		0.279 (0%)

D. Price-durability ratio

As discussed in the method section, custom-made lenses would not be obtainable for less than 1000 pieces, therefore these results are based on price requests made at wholesale factories.

For glass lenses, of the 5-by-5 mm size, no local manufacturers could be found, therefore a factory in China was contacted through the Aliexpress. This factory could produce the lenses at a minimum quantity of 1000 pieces, for $0.54 per piece [24]. At a conversion rate of $1,00 = €0,84 this would mean that one lens would cost €0,46, or in total, €460 per 1000 lenses. This request was made for round lenses, with a 5 mm diameter and 1 mm thickness. This price is without taxes, as it is shipped from China, and import fees might be applicable, depending on how the items are shipped.

For pmma lenses, a search was conducted online, checking websites for their prices per sheet material. As these sheets could be laser cut, it was not necessary to make custom requests. The found results are displayed in the table below, table VI. The table states how much it would cost per lens, as a lens would be 5-by-5 mm, this would mean 40.000 lenses could be cut from 1 m^2. As the total amount is a combination of the price per m^2 and the delivery costs, the total price will decline more, if larger or multiple sheets are bought. Furthermore, due to Covid-19, sheets of 1 mm thickness were not available and therefore the prices of these sheets were not obtainable, thus the thicker, 2 mm, sheets were used for this case study.

TABLE VI

RESULTS OF ONLINE SEARCH FOR TRANSPARENT PMMA SHEETS.

Company	**Price [€]**	**Delivery costs [€]**	**Total [€]**	**Size[m^2]**	**Thi**
Kunststofplatenshop.nl [25]	24,00	7,05	31,05	1	
Perlaplast-kunststofshop.nl [26]	29,04	8,69	37,73	1	
Plexiglas.nl [27]	20,00	15,00	35	1	
Voordeligkunststof.nl [28]	28,18	15,00	43,18	1	

The results seen in the table above show that, from the cheapest Dutch supplier of pmma, 590 lenses could be manufactured for the cost of one glass lens.

IV. DISCUSSION

Observations done in the experiments show that both glass and pmma are durable materials. The solvent crazing phenomenon, that occurred with the pmma samples which were placed in isopropanol, requires further research. Different variables were changed to analyse the findings. This included a secondary research, seen in figure 8 to validate the observations.

As solvent crazing also occurred during the second experiment, the findings were confirmed. Odd was however that during the third experiment, there was no sign of solvent crazing.

The third experiment was started three weeks before the former experiments, thus, it was thought that the isopropanol in the container was less potent and this was therefore exchanged for a new quantity in the last week. Yet, this showed no form of solvent crazing.

Another variable, that could influence the obtained results, was the glue layer of the thin protective film, which was applied to the pmma sheet, which might have evaporated between the start of the third experiment and the start of the first and second experiment. To investigate this, another experiment was conducted, with a new sheet of pmma.

This experiment was focused on the duration between removal of the protective layer and placement in the container. This was done in four time intervals, the first, was a direct placement, the second, was 24 hours later, the third was a week later and the last was two weeks later.

All four samples showed no form of solvent crazing, therefore, further research should be conducted to find the root cause to this phenomenon.

The price-durability ratio comparison shows that the lenses made of pmma are much more cost effective than the lenses made of glass. As 590 plastic lenses could be manufactured for the price of one glass lens. This difference in cost per lens will also make up for any coatings that need to be applied to cover for the fact that the pmma lenses could not withstand submersion in isopropanol containers.

V. CONCLUSION

To conclude this research, both glass and pmma show to be resistant to the chemicals used in this context. Although pmma showed solvent crazing in two experiments, multiple inquiries have shown that a contamination of some sort has caused the occurrence. The final experiment also showed no

form of solvent crazing, therefore, it is assumed that pmma is chemically resistant to isopropanol under normal conditions.

As both materials are chemically resistant, the difference was sought in the price-durability ratio. This produced a steady difference, with 1 glass lens costing as much as 590 pmma lenses.

In conclusion, both lenses show to be durable, however, lenses made of pmma would be the most economical.

List of Abbreviations

LMIC	Low- and Middle-Income Country
MTF	Modulation Transfer function
pc	polycarbonate
pmma	polymethylmethacrylate
pvc	polyvinylchloride
SFR	Spatial Frequency Response
VL	Video laryngoscope
WHO	World Health Organisation

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B

Deliverables

B.1. Matlab code

```
%% Results from experiment 1
%   Mark Willemsen
%   Biomedical Engineering department
%   3mE
%   Tu Delft

clear all
close all
clc
%% Control group
fds = fileDatastore('~/images/*.jpg', 'ReadFcn', @importdata);
fullFileNames = fds.Files;
numFiles = length(fullFileNames);

% process images and coordinates
for k = 1 : numFiles
    imageArray{k} = imread(fullFileNames{k});
    rgb=imageArray{k}(:,:,[1 1 1]);
    I_lin = rgb2lin(rgb);
    % This code was used to find the X and Y points for image
       allignment
%     figure
%     imshow(rgb);  % Display image.
%     % find registration points
%     [X{k}, Y{k}] = ginput(4);  %top left-right bottom right-left
end

% Coordinates for the measurements of sharpness resulting from
% the image alligment data above
X={[172;480;488;158],[172;482;486;158],[170;482;484;156],...
    [172;482;488;160],[172;482;486;158]};
Y={[110;114;352;346],[110;116;352;348],[110;116;352;346],...
    [110;116;350;346],[112;116;354;348]};

% Loop over all files to calculate sharpness.
for k = 1 : numFiles

    chart = esfrChart(imageArray{k},'RegistrationPoints',[X{k}, Y{k}]);
```

```
    %measure sharpness
    [sharpnessTable{k},aggregateSharpnessTable{k}] = measureSharpness(
        chart);
    sharpnessTable{k} = measureSharpness(chart,'ROIIndex',1:60,'
        PercentResponse',[70 30]);
    %split sharpness variable into RGBy values
    aggregateSharpnessTable{1, k} = splitvars(aggregateSharpnessTable
        {1, k}, 'MTF50');
    %calculate average of RGBy value
    aggregateSharpnessTable{1,k}.Avg = mean(aggregateSharpnessTable{1,k
        }{:,3:6},2);
    avg = mean(aggregateSharpnessTable{1,k}{1,3:6},2);
    avg_sharpness_exp0{k} = avg;
    %fprintf('%g cycles per pixel \n',avg)
end

% Split results in glass and pmma
avg_Sharpness_exp0   = cell2mat(avg_sharpness_exp0') ;
mean_sharpness_exp0 = mean(avg_Sharpness_exp0);

disp('Finished calculating no lens samples')
%% run experiment 1 to compare results
disp('Running control group')
week0
disp('Finished running control group')
%%  Display results experiment 2
exp0 = [avg_Sharpness_exp0 avg_sharpness_glass_0 avg_sharpness_pmma_0];

figure
% subplot(2,1,1)
    boxplot(exp0,'Labels',{'No lens','Glass','Pmma'})
    ylim([0.25 0.3])
    xtickangle(-45)
    title('Results experiment 0: comparing image quality per lens type'
        )
    ylabel('Cycles per pixel')
    xlabel('Lens type')
```

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