gum cleaner | dental robotics

# ACTUATOR FOR ORAL CARE IN EDENTULOUS ELDERLY PATIENTS

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## executive summary

There are currently no technological options in the market for the oral care of edentulous population. Dental Robotics, a company already involved in the production of dental care devices for elderlies, is interested in new technological solutions to attend this sector.

The design is challenging as it has to meet several requirements: 1) be built upon an existing platform (the Air 1 handle), 2) to demonstrate potential for efficiently clean different mouth morphologies, 3) to use an actuator that requires minimal maneuver and is easily accepted by patients and be practical for nurses, and all these while showing manufacturing feasibility and production scalability.

The methodology followed a combination of design thinking and lean startup, meaning a human centered, technology-based iterative and integrative process of prototyping and test.

Through this progressive development, diverse strategies were applied, including literature research, field work observations and empathizing with the problem, comparison of market-available alternatives, exploration of materials and prototyping processes, evaluation of effectiveness and acceptance of different design versions, image analyses to evaluate cleaning capacity, manufacturing process, etc.

The result is a validated prototype that meets the technical requirements and represents the optimal solution within the explored options; however, future progress could result from optimizing the motion of the Actuator, improve design features to make the assembly easier, explore different arrangements of tufts textures to increase comfort, increase the sample of mouth morphologies to better represent the edentulous elderly population in The Netherlands, to test the effect of the gum cleaner with Laser Doppler Flowmetry to find out if it could stimulate blood flow (Irrigation) on the gingiva, and for how long, and evaluate the long-term impact of this device in the reduction of Residual Ridge Resorption clinical tests. If proven, this could be an added value offered by the company.

The actuation for oral care in edentulous elder patients developed in this work proved promising as market product after further performance and manufacturing process refinements.



(Cover page) figure 1 . Photo by Diana Spatariu on Unsplash

# aknowledgements

This thesis is the final step of the MSc Integrated Project Design at the Delft University of Technology, in collaboration with Dental Robotics. These two years of master studies at TU Delft challenged me and made me a better designer; I have no doubt that coming to this school was the best choice. I am grateful because this project gave me the chance to apply the knowledge I gained during this time. Dental Robotics is a company that entrusted me with the development of a gum cleaner, an idea they wanted to explore, and I am grateful for that opportunity.

All the staff at Dental Robotics, I am going to miss you. You made everyday fun and this the best job I had ever had.

I want to thank my supervisory team, for their enthusiasm towards this project and your support through it. Richard, even though I hadn't had the chance to work with you before I knew you would be a great contributor to this project. Thank you for believing in me and for your sharp feedback. Maurits, thank you for joining me on another project. You always understand what I want to say and where I want to go with my thoughts. And Daan, who has been a guide from the start, complementing the project with a completely different mindset (Entrepreneurship). Thank you for always motivating me.

Wikash Lala, for welcoming me into his workshop, for giving me his opinion about my device during its different phases, and for giving me mouth models that, for me, were gold and allowed me to have a product that was more real and competitive.

I would like to thank specially to all the users, Janie, Bep and Wim, who welcomed me into their homes, dared to use my prototypes and gave me their insights and feedback. Meeting them pushed me to keep going. And thank you to Joppe and Lot for introducing me to their families.

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Actuator. Refers to the element that is inserted in the mouth of the patient. It is composed of a frame and the SPA.

Air 1. The first device of Dental Robotics. Automated toothbrush for the elderly.

CAD. Computer-aided design is the use of computers to aid in the creation, modification, analysis, or optimization of a design.

Edentulism. Also known as toothlessness, is the condition of being toothless to at least some degree; in organisms (such as humans) that naturally have teeth (dentition), it is the result of tooth loss.

FDM. Fused Deposition Modeling is a 3D printing process that uses a continuous filament of thermoplastic material to create 3D models.

LSR. Liquid silicone rubber molding is a thermoset process that mixes a two-component compound together, which is then heat cured in the mold with a platinum catalyst to produce a final LSR part.

Masticatory mucosa. Covers those areas of the oral cavity such as hard palate and gingiva (gums) that are exposed to masticatory forces.

MVP. A minimum viable product is a product with just enough features to satisfy early customers and provide feedback for future product development.

Overmould. Overmolding is a process where a single part is created using two or more different materials in combination. Typically the first material, sometimes referred to as the substrate, is partially or fully covered by subsequent materials (overmold materials) during the manufacturing process.

Retromolar pads. A pear-shaped mass of soft tissue located at the posterior end of the mandibular alveolar ridge.

RRR. Residual ridge resorption occurs after the extraction of teeth.

SLA. Stereolithography is a form of 3D printing technology used for creating models in a layer by layer fashion using photochemical processes by which light causes chemical monomers to link together to form polymers. Those polymers then make up the body of a three-dimensional solid.

TPE. Thermoplastic elastomers are a diverse family of rubber-like materials that, unlike conventional vulcanized rubbers, can be processed and recycled like thermoplastic materials.

# introduction

This graduation assignment is a collaboration with the company Dental Robotics, who have the mission to enable care facilities to deliver better oral care in less time. Currently, they are about to release their pilot automated toothbrush in order to test it within partner elderly care homes.

During a feedback session with a geriatric dentist, this specialist was intrigued to know if the device could also provide oral care to people without teeth. For these people the oral hygiene goes beyond cleaning the dentures, and for the care of the endentulous mouth, there are currently no high-tech solutions. Similar as the toothbrush, those solutions require dexterity, discipline or even training, and therefore are often skipped.

Major differences in the anatomy of those patients create the opportunity for the introduction of a new product to the market. Now the company wants to extend its catalog and develop the "gum cleaner". This refers to an automated solution for edentulous patients, who represent 65.4% of the elderly population in the Netherlands (Felton, D. A., 2009). Defined as the loss of all permanent teeth, edentulism can be aided with two main different types of reconstructions: fixed dentures and implant-supported overdentures, which are the two target groups of this research project.

Evidently, an innovative product could be introduced for edentulous patients in order to provide them with proper oral care. Before that research has to be carried out to deeply understand the technical challenges, and therefore execute design solutions that could fit the company expertise and values.

Working with the handle system that has been developed for the Air 1 (the first product from  the same device developed by Dental Robotics) is the main limitation that the company has presented, meaning that the proposed solutions have to connect and function with their platform. A soft actuator should be proposed in any shape and behavior, as long as it requires minimal maneuver from the patient/nurse, as ease of use is the core value of Dental Robotics devices. Also, the actuation should last no more than 30 seconds in order to result convenient for the elderly care homes, who are their main clients at the moment.

## Research question

Dental Robotics focuses on developing solutions in preventive oral care for elderly people in care homes, where nurses are looking after them, but still, oral hygiene is not executed frequently enough. The scenario for edentulous patients is even worst since they seldom receive oral hygiene. Sometimes the nurses clean their dentures, but rarely they would also clean their mouths. It is believed that a new design of a soft actuator, connected to DR's system, could perform oral care for edentulous patients. This project aims to answer, through design exploration, the following question:

**How can soft robotics provide oral care for edentulous patients?**

Understanding oral hygiene for edentulous patients does not only include finding the most efficient way to clean their mouths, but also which areas/tissues have to be cleaned, compared with dentate patients. Also analyzing different kinds of denture attachments and learning the ways to clean them. Finally, another important function desired is stimulating blood circulation in the gingiva (gums), therefore is also important to find out how to provoke this.



figure 2 . Edentulous elder woman
Photo by Joseph Chan on Unsplash

## inspiration

The first activity within this research was elaborating an inspiration board figure 3) to reflect on the elements that motivated me to choose for this graduation topic. Following, these elements are briefly explained.

My work is often inspired by nature, and in this topic was inevitable desiring to create a biomimicry concept. Soft actuators for the elderly are difficult to design since they have to look friendly at the same time as they must accomplish their function. The same happens with the texture on the actuator, the equivalent to a toothbrush bristle tuft, which is the part that must clean the dirt in the mouths.

A strong connection with soft robotics was established. It was easy to choose this project thanks to the confidence I gained after my previous internship with Dental Robotics. That period gave me enough knowledge of soft robotics technology and on how to prototype soft actuators. Moreover, I could understand better the challenges and possibilities with the idea of the gum cleaner, and I was intrigued to see what could come out of this explorative project. And I was curious to bring back one of those concepts I worked on during my internship.

But of course, the most important factor was working for a meaningful project where my work could have a positive impact. I came to the Netherlands to focus on Healthcare innovation and improve as a designer, and this project offer gave me those possibilities.

Right away after completing the collection of the inspiration board, the ideation phase started. This happened because the inspirational board was unconsciously also a selection of directions from the very beginning. To see the sources of each image, please see Appendix A.

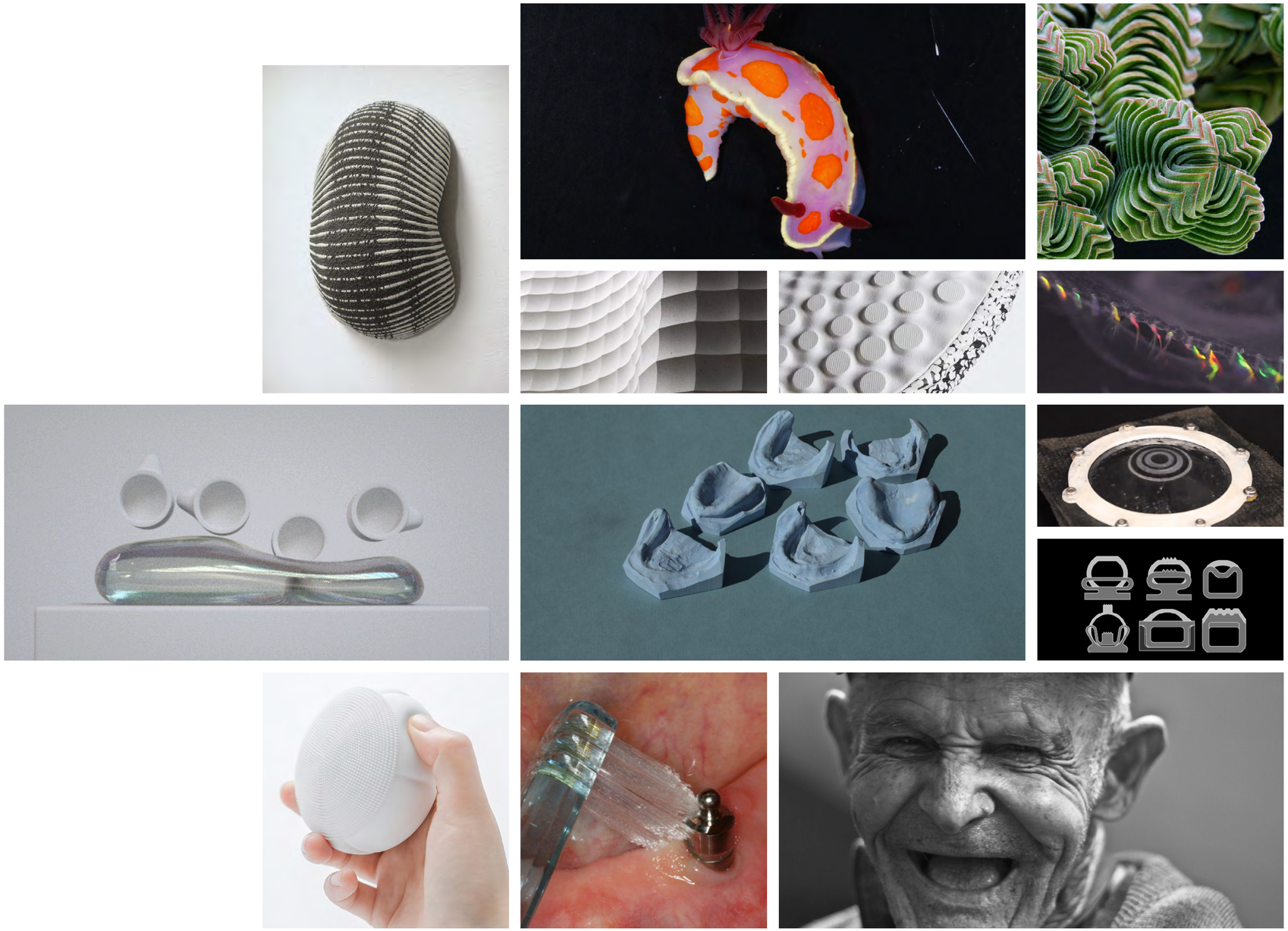


figure 3 . Inspiration board

This project methodology followed a combination of design thinking and lean startup.

Design thinking is characterized as an iterative process understanding the user's pain, challenge assumptions, redefine problems in order to create new strategies and solutions (Mantini, 2018). This methodology is a very logical selection when a design case is focused on the research and development of one of its kind products. With this methodology is intended to merge both, the human-centered mindset, with technology possibilities, as well as the requirements for business success.
At the same time, this research wanted to incorporate the way that Dental Robotics (DR) works, based on the Lean Startup methodology. With it, DR has been able to steer the development of their first product (the Air 1). Lean startup favors experimentation over elaborate planning, customer feedback over intuition, and iterative design over traditional "big design up front" development (Blank, 2013). This way of working helps this med-tech startup optimizing their resources and focus on creating value with the simplest experiments, with a fast-paced environment.

As a result, this project proposed the inclusion of the lean startup methodology into the "Iterate" phase, which was the longest and most fruitful. The phases are proposed as seen on figure 4, and they are also found on this report as the chapters, which chronologically tell the story of this product research and development.

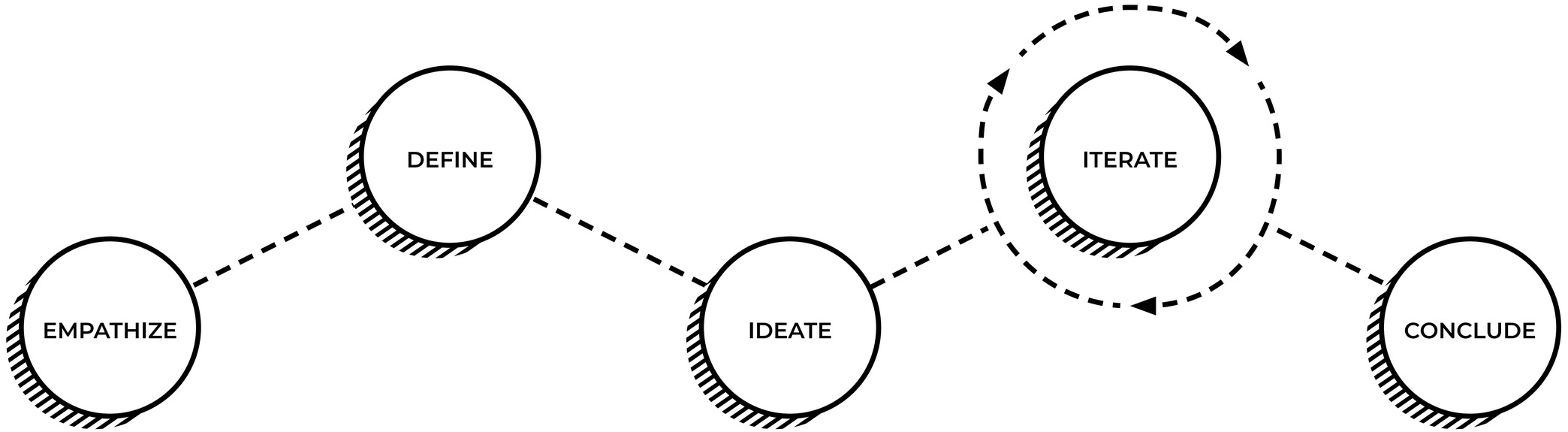



figure 4 . Combination of design thinking and lean startup

CHAPTER 1

# EMPATHIZE

This chapter focused on conducting literature research about edentulism and its complications, as well as understanding the oral care procedures given to patients without teeth through field research. The general aim of this phase is providing evidence of the need for a better solution for edentulous patients in elderly homes. Similar products were analyzed their approach on gum care. Finally, a brief explanation about the company (Dental Robotics) is shared, as well as their expectations for this project.

figure 5 . Elders in care home, by Elien Dumon on Unsplash

## Denture users

The aim of this research is to provide care for denture users.

Within nursing homes, elders' mouths can be found in varying conditions. While some elders may still have most of their teeth, most are edentulous patients: this means they do not have teeth anymore. Edentulism can be treated in different ways. Often this is done through dentures. Two examples of dentures within the scope of this project are removable dentures and implant-supported dentures. The target group of this research will be able to take off their dentures in order to receive oral care.

Dental Robotics believes that their technology could be integrated into a design that can provide oral care for both groups of denture users.

## Oral care for edentulous

For people with edentulism is sometimes unclear on how they are supposed to take care of their mouths, as recently reported from the campaign "Mouth not forgotten" aimed at the oral health of Lelystad residents ("Tandarts en mondzorgcoördinatoren bij Woonzorg Flevoland krijgen veel vragen," 2019).

Even though edentulism is fairly common, the target group rarely receive proper oral care and current protocols are time-consuming.

Consequences of insufficient oral care for the target group can range beyond poor hygiene and can lead to medical complications. Not only edentulous patients are more prone to get oral infections, but this condition has been linked with the increase risk of electrocardiographic abnormalities, hyperthension and heart failures. More frequent complications are dry mouth and the most important one: Residual ridge resorption (RRR). The use of dentures are limiting blood flow in gingiva because of the tight fit. Combined with the lack of pressure on the bones, this leads to the resorption of the jaw bone.

One extreme case of a edentulism complication was from a visually impaired, 93-year-old woman with advanced dementia whose dentures had become stuck in her mouth after they had been left in for weeks. Over the weeks that she did not receive proper oral care, her gums had grown around her dentures. She was taken to a hospital's emergency department and the dentures had to be surgically removed (Triggle, 2019).

## Pitch

A presentation was prepared for a couple of experts at Centrum voor Tandzorg, in Hertogenbosch. These experts serve as consultants and provide services such as yearly check-ups. They check the state of the gums and update dentures as needed.

Here, the project brief was pitched to the geriatric dentist that first suggested Dental Robotics to create the Gum Cleaner. There was mostly positive feedback, confirming the basic understanding of the potential challenges.

At the same time, the experts expressed that remains too complicated to prevent RRR with such a product. From this feedback, we concluded that treating bone loss should remain outside the scope of this project. However, a new direction emerged out of this meeting: blood flow can be beneficial for the health of the gums. Therefore provoking blood circulation on the gums became a new desired function.

Preliminary sketches have been prepared in order to show some possible directions, getting an optimistic response from the experts (figure 6). It was gratifying to see experts working with nursing homes as clients also showing interest in the device.



figure 6 . Preliminary sketches shown to the geriatric dentist

## Visiting a nursing home

In order to actually observe the oral care that is been provided at the nursing homes, field research was conducted in the Bieslandhof Center, a nursing home in Delft, Netherlands.

The annual oral check-up was taking place, so patients with dentures were brought to the denture technician, who was checking the fit and state of the dentures. On this day nurses were also cleaning the mouths of the patients. Six patients were observed, and three of them had a huge amount of food residues that needed to be removed. The nurse and the denture technician explained that this was normal to see since they do not have the time to clean them all every day. This field research helped illuminate how time-consuming the current protocol for oral care is (detailed in the next section), and emphasized the need for a specialized tool.

The field research was helpful in getting a sense of side factors that make this field quite complicated. For example: how busy the nurses are, and how detailed and careful they can be when performing care to the elders.

A third and very important perspective gained in this visit was that of the patients. We saw how confusing or otherwise intense this interaction can be for the patients (the ultimate target group for our design), and why it is important to consider aesthetical, user experience and user interaction factors in the design.

## Current procedure

Oral care for edentulous requires attention and can be time-consuming. The current protocol is be detailed in the following manual, “De Mond niet Vergeten” (2016).

Here is an overview of the oral cleaning procedure with a cloth:

- The caretaker removes the dentures and cleans the dentures.
- They then wrap their finger with cloth.
- Open the patient’s mouth. Often this needs to be forced and maintained, which presents a big challenge.
- Caretaker passes the cloth through the entire mouth of the patient in order to collect the food residues / dirt.
- The caretaker then removes their finger and disposes of the cloth.
- Repeat as many times as needed. When a patient has not been cleaned for days they can accumulate so much that even three of fourth cloths needs to be used. This also means repeating opening the mouths of the patients more times.

## Challenges

Through talking with experts and conducting field observations, several challenges to anticipate in design emerged.  These are general challenges in oral care for those with edentulism, and are necessary to consider in order to create a product that will improve the level of care for the focus group.

- Gag reflexes. Reaching deep into a patient's mouth can trigger a gag reflex.  An apparatus should be properly sized as not to avoid this unpleasant experience for the patient.
- Communication is important so that the cleaning procedure does not feel overly invasive.  The patient should be able to know or figure out what is going on at any point.
- Confusion in the case of unsuccessful communication can lead to unpleasant fear for the patients, and in worse case, accidents.
- Unanticipated behaviours. Patients can bite the fingers of the caretakers. Also they cannot always control saliva and others coming out of their mouths.
- Lastly, successful oral care can be time consuming. This challenge causes other problems current procedure, because it causes barriers to creating regular, habitual oral care regimens.

## Denture technician

During the visit at Bieslandhof, the project was pitched to a denture technician, Wikash Lala. Lala has made uncountable amounts of dentures and explained the challenges of doing dentures for elders with ridge resorption and other complications.

He believes that better oral care is needed on the field and kindly offered his feedback, as well as donating edentulous models from real patients that he normally discards after doing the dentures (figure 7).

figure 7 . Edentulous models obtained from Wikash Lala

Edentulism is the result condition after losing teeth. Complete edentulism refers to the loss of all teeth; meanwhile, partial edentulism refers to the loss of some teeth. The prevalence of this disease was approximately 158 million people globally in 2010 (Vos, 2012). It can be caused by many factors, mainly by poor oral hygiene habits. Amongst the elderly, old fillings, dry mouth, gum recession, and plaque may all play a role in edentulism.

This condition modified the way people need to masticate food, as well as challenge them to pronunciate various sounds appropriately. The progressive bone volume loss that occurs after the extraction even has a negative effect in the social security and decrease the face aesthetics of an individual.

More worrisome, bad hygiene on denture wearers can lead to more serious diseases, including denture stomatitis, angular cheilitis, and oral candidosis (Emami, E., 2013). These are only a few examples of infections consequence of a bad oral hygiene on edentulous patients, allowing the growth of oral biofilms.

## Oral biofilms

The network of microbial interactions within oral biofilms plays a significant role in oral health and dental disease. A sudden change in oral environment can have profound effects on the ecology of the micro bacterial community. Such effects impact microorganism interactions and can increase the risk of disease. Improper care can lead to the buildup of detrimental bacterial communities can lead to inflammation and infection (Marsh and Zaura, 2017). Oral microorganisms often adhere to other, existing microbes, resulting in a feedback process. Maintain good oral hygiene practices can help combat the development of microbatcterial communities which have are potentially damaging. Since drastic changes in oral environment can disrupt the oral ecosystem, a design that facilitates regular cleaning is key.

## Residual Ridge Resorption

In addition to hygiene-related infections, edentulous patients have to face residual ridge resorption (RRR), which is the major oral complication after the extraction of teeth (Abirami, G., 2016). It is characterized by an oral bone loss in both maxilla and mandible, where it is often more accentuated. Cawood and Howell (1988) analyzed patterns of residual ridges resorption and proposed a classification for this phenomena (see figure 8).

The diversity at edentulous mouths (summed to the diversity of dental arches) brings extra challenges to the project. For instance, holding the actuator in a correct position inside of a patient's mouth, when their ridges are completely resorbed.

If the product gives appropriate oral care and performs a pleasant experience to its users, consequently their dentures will settle in the ridges better, and therefore RRR could be slow down.

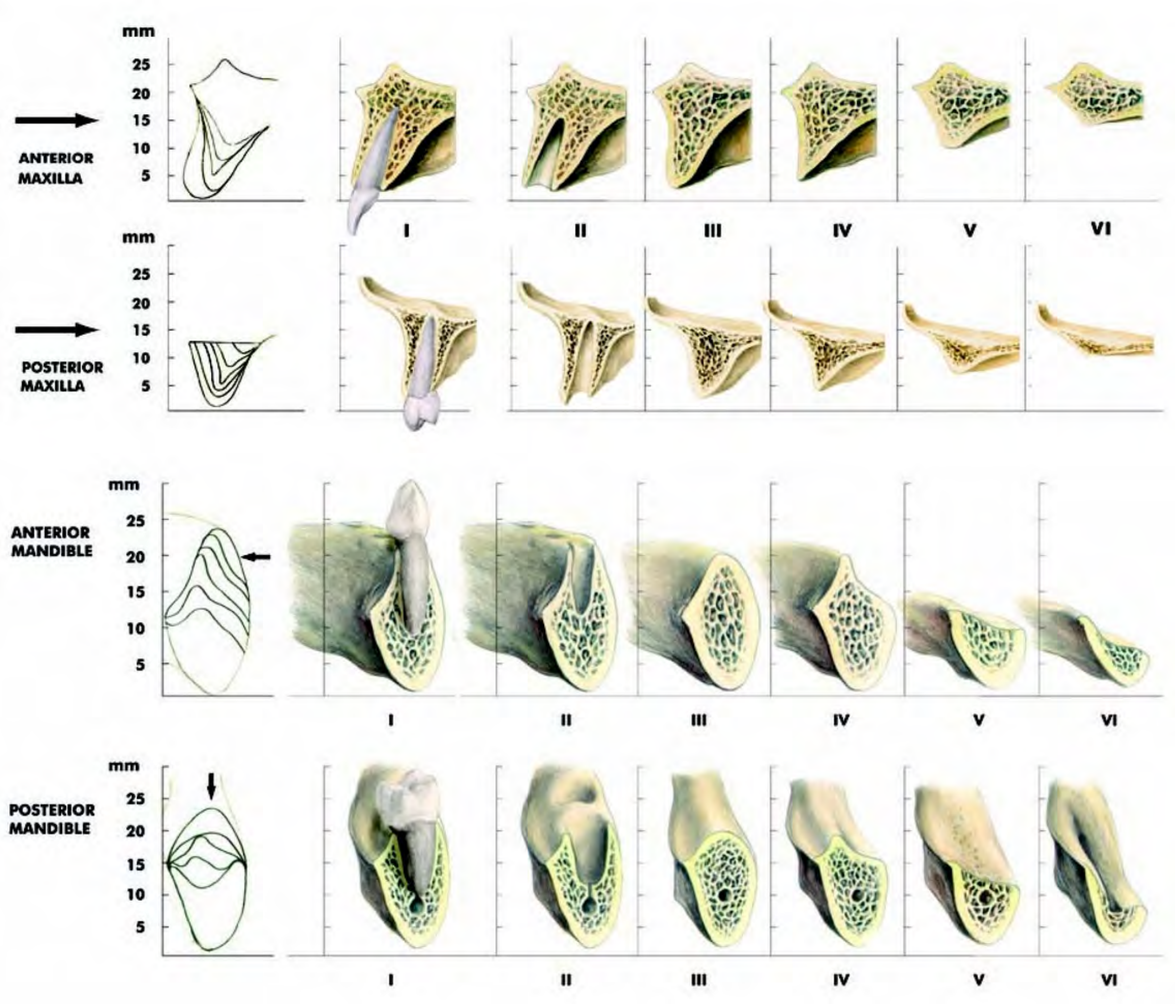



figure 8 . RRR classification by Cawood and Howell (1988)

## Edentulous Anatomy

In order to understand the diversity of mouth shapes that edentulous patients present, an understanding of the Anatomical landmarks of this condition was needed to be done. For this, the transcript from the course "Anatomy of the Denture Foundation Areas" (Roumanas) was reviewed.

Normally this information is sourced by those in charge of constructing the dentures. In this case, the development of the gum cleaner needed this understanding to propose not only the fitment but also to decide on the areas to be addressed.

With this review, it was found that cleaning and massaging the alveolar ridges should be the main focus of the device. Despite the level of resorption, it is crucial to remove the dirt from the ridge. Those are the areas that could be more likely to grow biofilms, while covered by the dentures. Also, it is important to secure direct contact between dentures and ridges, since these last could be better stimulated, resulting in healthier masticatory mucosa.

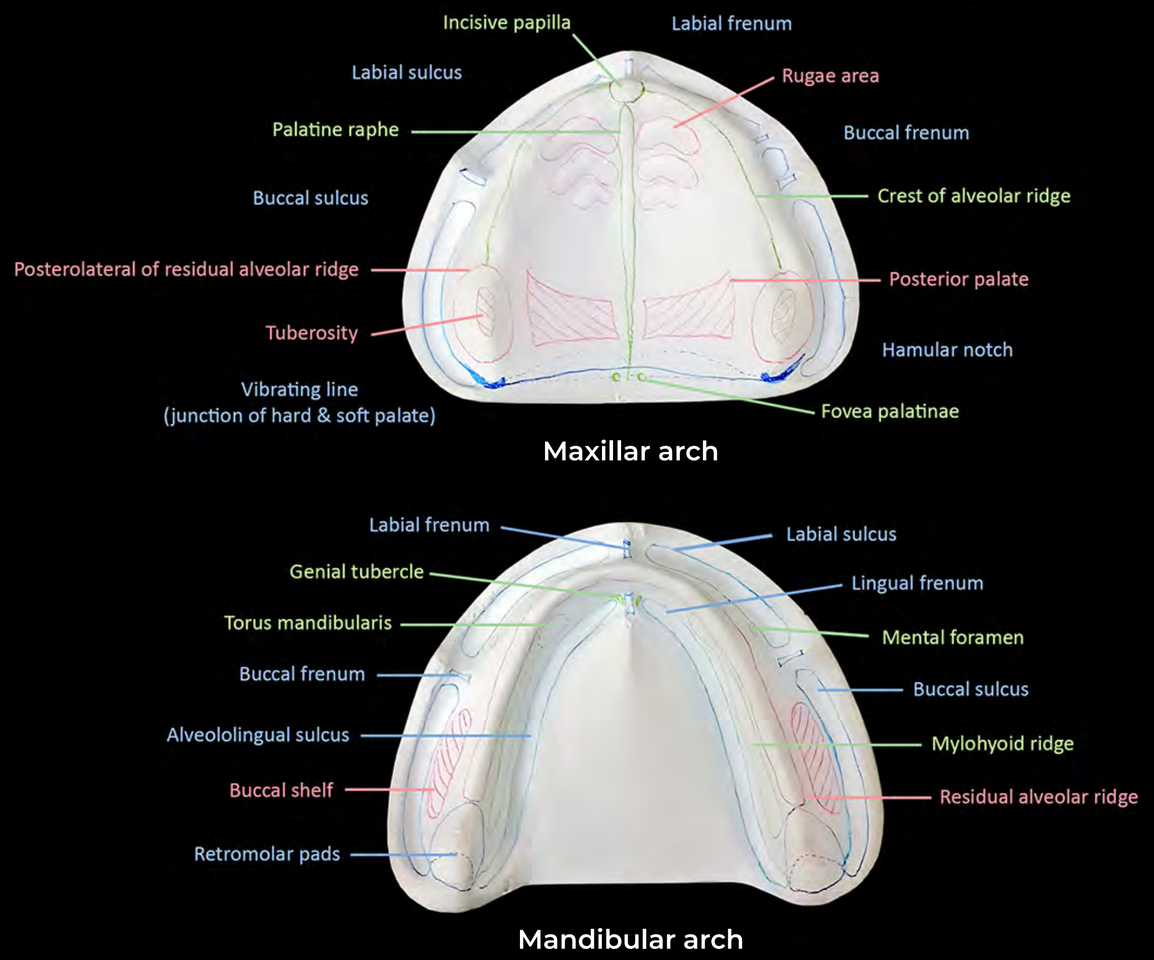



figure 9 . Anatomical landmarks of edentulous jaws

Implant-supported overdentures are the evolution from the conventional removable dentures that feature additional support by the implantation of different attachments on the jaws of the patient. Prior to performing this surgery, dentists have to evaluate which are the most suitable attachments per patient, at each of their jaws. Factors as severely resorbed jaws, large antra, unfavorable jaw relations, and financial restrictions can drive the selection and number of attachments (Bergendal, T., & Engquist, B., 1998).

There are different attachments, including balls, locators, bars, and they all have to be cleaned slightly different (see figure 10).

Oral hygiene is crucial for the success of the implants, especially at the peri-implant soft tissues. Even if edentulous patients lack teeth, they still form plaque, as well as they can present gingivitis, candida, or other infections. Vulnerable elders with bad hygiene cannot only ruin their denture attachment system (leading to more reconstructive surgeries) but it can affect their general health in several ways, increasing their mortality rate (Emami, E., 2013).

## Peri-implantitis

As advances in dental implantology create new solutions for edentulism, it is important to understand and mitigate the risks of such implants.

An example of a challenge that comes with implants is increased susceptibility to infectious peri-implant diseases (Marrone et al, 2012). Peri-implantitis is an inflammatory disease associated which affects the tissue surrounding a dental implant. One study looked at the occurrence of peri-implantitis in 103 patients. The study included a consideration of the oral hygiene habits of the patients and concluded that proper oral hygiene reduced the risk of peri-implantitis occurrence. The study highlights the importance of plaque controlling practices for edentulous patients, as 71.4% of edentulous subjects in the study had one or more implants affected by peri-implantitis. With such a significant percentage of patients experiencing peri-implantitis, the importance of timely information and good oral care options is of the utmost importance.

figure 10 . Edentulous models with attachments implants. From left to right, #7, #8 and #9

Similar products were sought to see how they solve different aspects of oral care. Their forms, materials with which they are made and how they work were observed. So although some interesting insights can be used later during the ideation phase, none of these can be applied in elderly homes promptly.

The previous confirms that a niche exists to introduce a new product for gum care, especially for an automated solution.

## Gum stimulator

This is a widely known product that has been on the market for a long time. Features a pointy rubber pick, attached to a metal handle, that has to be moved around the periodontal areas, helping irrigating the gums. This is quite a complicated maneuver even for healthy people, and really time-consuming. Also, the gum stimulator is not meant to be used as a dirt removal tool.

## Fluxion Gumcare

Fluxion GumCare is a product from a Dutch startup in that focuses on the cleaning of gums for people with teeth and implants, using a mechanism of water and vacuum. This product has proven to improve pocket depth and gingival bleeding on pockets (Van Dijk, 2018).

The downside to this product is that it is meant to be used by oral care professionals only, so nurses would not be able to use this device in the elderly homes.

## Baby finger brush

This product is used to clean and stimulate the gums of babies. The brush is very user-friendly and has no sharp edges. It also served as an inspiration to generate concepts for this project.

This could be a solution for edentulous patients, but it would not protect the nurses' fingers. Moreover, it remains too intrusive for the patients.

figure 11 . Similar products. From left to right, Gum stimulator, Fluxion Gumcare and Baby finger brush

Dental Robotics is a Delft-based startup focused on the oral care for the elderly. After almost three years of research and development, they are about to release their first product, the Air 1. Founded by an Industrial Designer, and co-lead by a Entrepreneurship expert, this company has an intelligent approach on fast-paced product development, while staying close to their potential clients and understanding their needs. They have mastered the rapid prototyping of soft robotics and even nowadays are capable of producing injection molding trials on a minimum amount of time.

As previously mentioned, they follow the lean startup method, especially by trying to get the MVP (Minimum viable product) which have given them the possibility of getting immediate feedback from the eventual stakeholders. Getting into the mindset of the MVP was crucial to meet the expectations of this company.

## Air 1

The first product of DR, an automated toothbrush for the elderly market (see figure 12). This is already introduced in partnered elderly homes as pilot studies, getting feedback for its continuous improvement.

## Brand identity

As seen on the Air 1, DR's desire is to convey friendly aesthetics in their portfolio. This could help the acceptance of their devices in a complex context where elders are not always eager to try new devices. For the gum cleaner, it is also important to maintain a simple, casual, and inoffensive look, rather than a complex appearance that could lead to confusion in the elders.

The same values apply for the user experience of the product. From having a very straight forward shape that is easily understood to belong inside the mouth, to providing a behaviour with the actuator that gives a pleasant sensation.


figure 12 . Air 1, automated toothbrush from Dental Robotics

CHAPTER 2

# DEFINE

In this phase, the problem statement is presented. The aspects surrounding edentulism are now familiar, and a better understanding of this condition allows for reframing the project challenge. Assumptions were created, prioritizing the exploration of the cleaning functionality of the soft actuator (over stimulating blood flow). The collected insights are translated into design requirements, reviewed and accepted by DR.

figure 13 . Elder woman, Christian Langballe on Unsplash

Dental Robotics (DR) focuses on developing solutions in preventive oral care at care homes, where nurses are looking after the elderly people, but still, oral hygiene is not executed frequently enough.

The scenario for edentulous patients is even worst since they seldom receive oral hygiene. Sometimes the nurses clean their dentures, but rarely they would also clean their mouths. It is believed that a new design of a soft actuator, connected to DR's system, could perform oral care for edentulous patients.

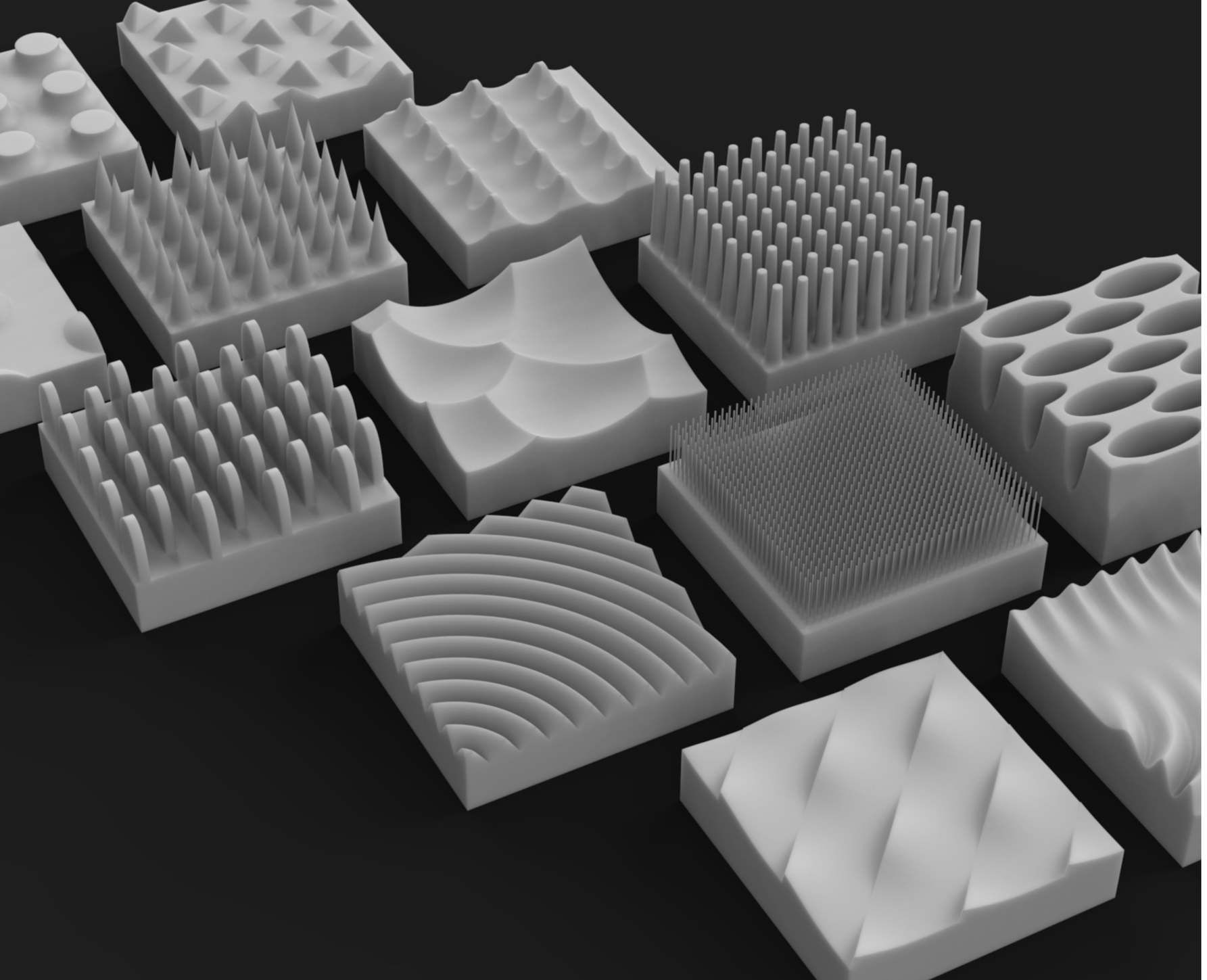
problem statement:

**[ Oral care for edentulous patients in nursing homes is insufficient. The lack of a specific instrument to attend the needs of denture users results in a complicated procedure that nurses often avoid. This neglection of oral care causes serious health problems to frail elders.]**

## Assumptions

- The most important assumption that needed to be taken was on expecting that the cleaning of the gums by friction would eventually stimulate blood flow on these areas.
- Three selected edentulous models with implants represent the more challenging scenarios at denture users, featuring three different attachments.
- It was assumed that the performance on edentulous without attachments will be even easier, and would not require major design changes for this group.
- On trying to prioritize on the practical research, it was assumed that the gum cleaner could feature symmetrical surfaces on mandible and maxilla.
- Later on this report is shown how to asses on the cleaning performance. Top views of the models were established as the standard images to appreciate such performance.


figure 14 . Elder man, by Federico Alegría on Unsplash



CHAPTER 3

# IDEATE

Even though ideation inevitably occurred from the first day of the project, it was until the third phase of the project when the complete brainstorm of solutions ignited. In this chapter, this phase shows how the actuator was decomposed to ideate into subfunctions, and the results are briefly explained. Then a morphological chart helped to create an overview of the possibilities and the more interesting directions that the gum cleaner could take. Finally, the chosen direction is presented, which happened to be the very first sketch for this project.

figure 15 . Textures ideation results

CHAPTER 4

# ITERATE

During this phase, different actuators designs were built and tested. While being mostly a practical stage, the digital files have been rendered, as well as images of the product are presented to illustrate the evolution of the gum cleaner. A couple of critical activities took part within this phase, such as the ergonomics refinement and the image processing, that secured the progression of the iterations. Each iteration design is briefly explained and their results are shared. At the end of this chapter, you can find the user tests results, that were performed, once the design was freeze.

figure 16 . Surface coverage test

## ergonomics refinement

Before the new iteration of the suction concept, an ergonomic refinement needed to be done. Actuator 1 did not fit appropriately on the models, so it was required to apply reversed engineering to provide a better fitment.

By the use of the Artec Spider 3D scanner, digital files were created from the oreviously collected edentulous models. Application of dry shampoo on the transparent models was needed, so the scanner could still recognize them. With their 3D files, it was now possible to generate CAD around them and take the edentulous morphologies into account while designing the Actuator #2.

First, the 3D files were oriented, and then a curve was sketched describing the ridge arches of each jaw. At the same time, the outlines of the implants were drawn. Also, a surface was positioned on the beginning of the retromolar pads to mark the maximum length possible for the Actuator. Finally, a channel was drawn around the resulted lines, so the Actuator design had a starting point.

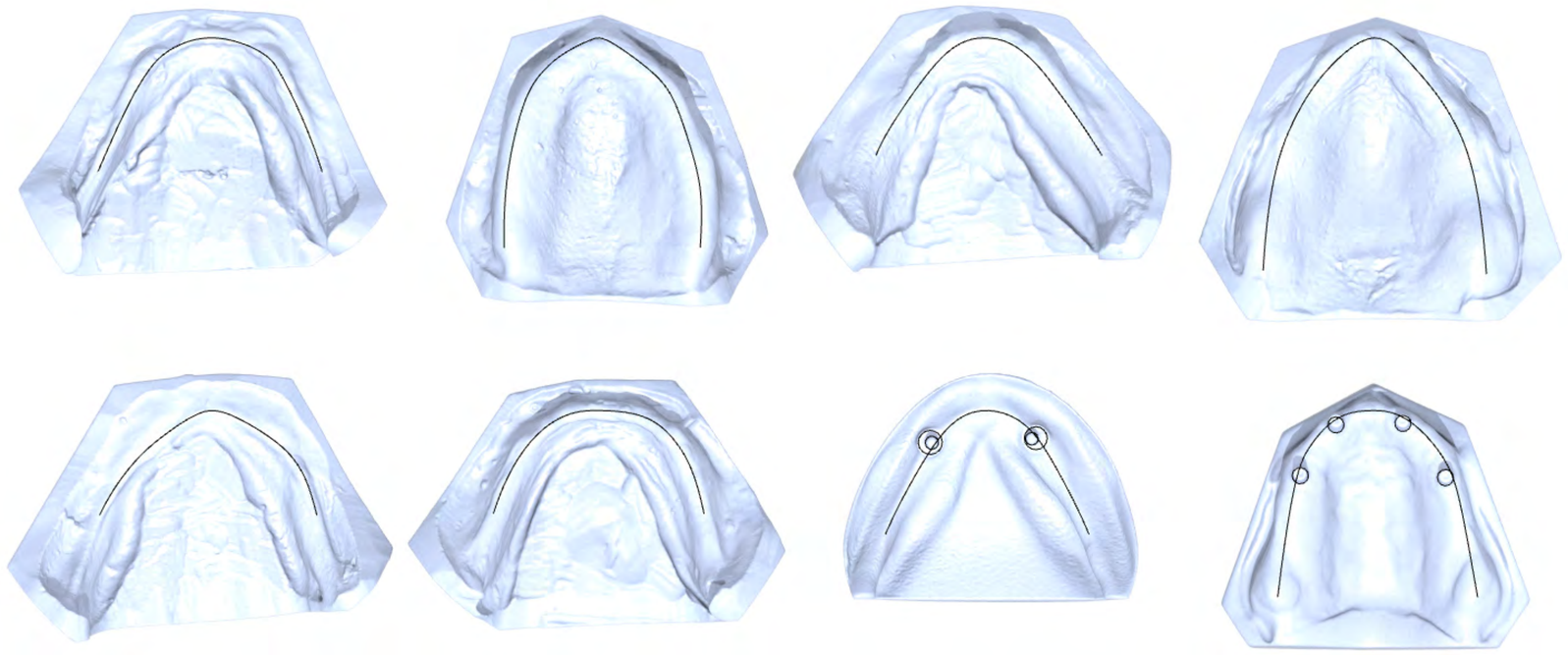


figure 17 . Reverse engineering applied to the gum cleaner

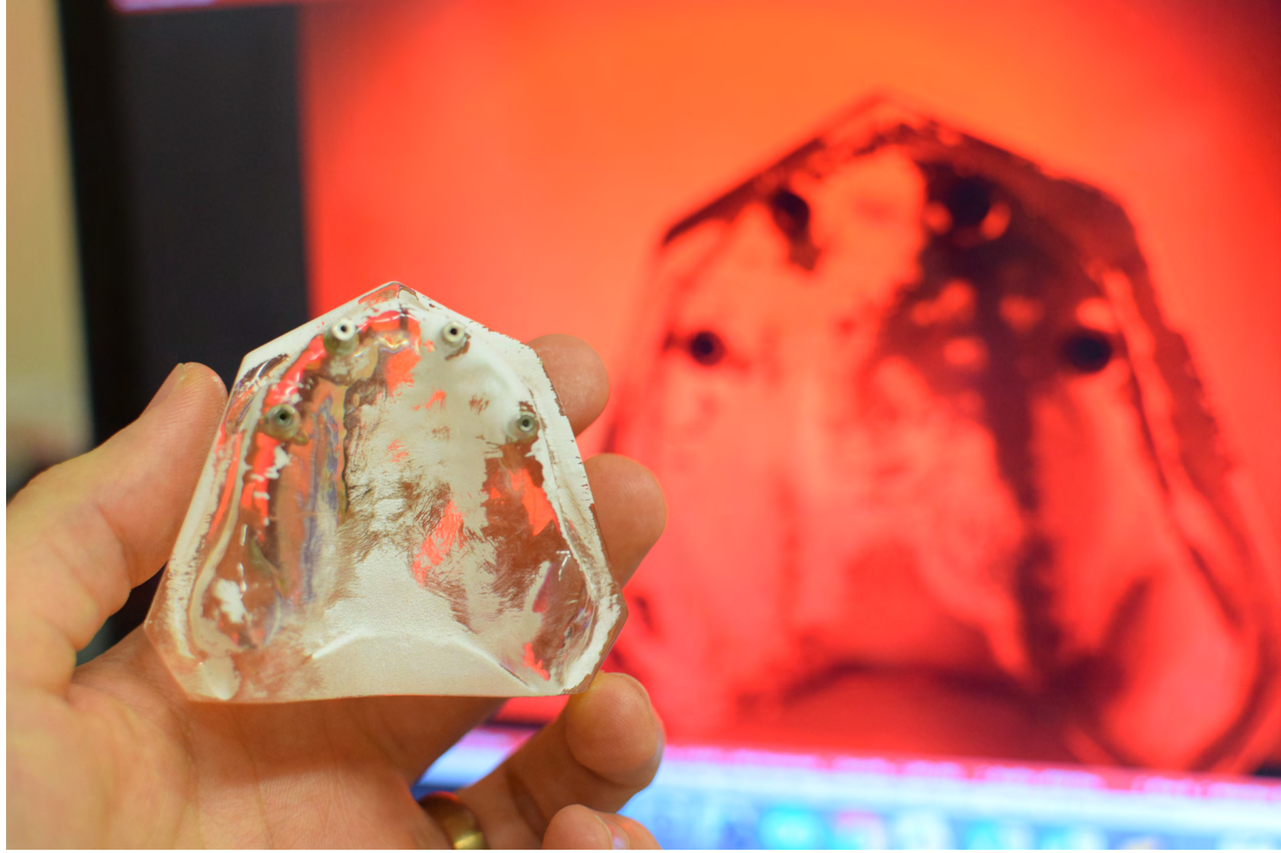
## surface coverage test

The standard product to apply a simulating layer of biofilm on the gingiva (occlusion spray) remains quite hard to remove from the models, since it attaches strongly into some areas, the implants for instance. Therefore trials with dry shampoo are taking place, a material that could provide a similar effect but with easy removal. Another challenge is to get an image with enough contrast so processing the result can be easily done by software. And it was found out that maybe using a LED to light up from behind these models could work.

Last week I had to focus on solving the imaging for the tests. It is crucial to measure the performance of the proposed actuators, and for this descriptive photographs have to be taken. The five days I had to invest in finding a perfect combination between the camera parameters, the best oclussion agent to be sprayed on the models and most importantly finding a good light source to illuminate these transparent models from behind.

Composed by an RGB Led matrix and a Arduino, a lighting tool has been built. This one emits a strong red light from behind the edentulous models, previously diffused by an acrylic sheet on this same color. As if it was a red screen, this lights up in front of the camera sensor, and those areas that have been touched by the actuator will let the light pass through. Both have been achieved on the image, a bright homogenous red color, but also the shadow of the spray.

Now the three transparent models can be photograph obtaining not only a contrasted image but also focused. The next step will be to digitally separate the areas of interest: peri-implant areas, palate, as well as gum wall and gum flat surfaces. This way late could be analyzed which areas should be reached by further designs. All parameters have been saved and documented so the test procedure can be now written.



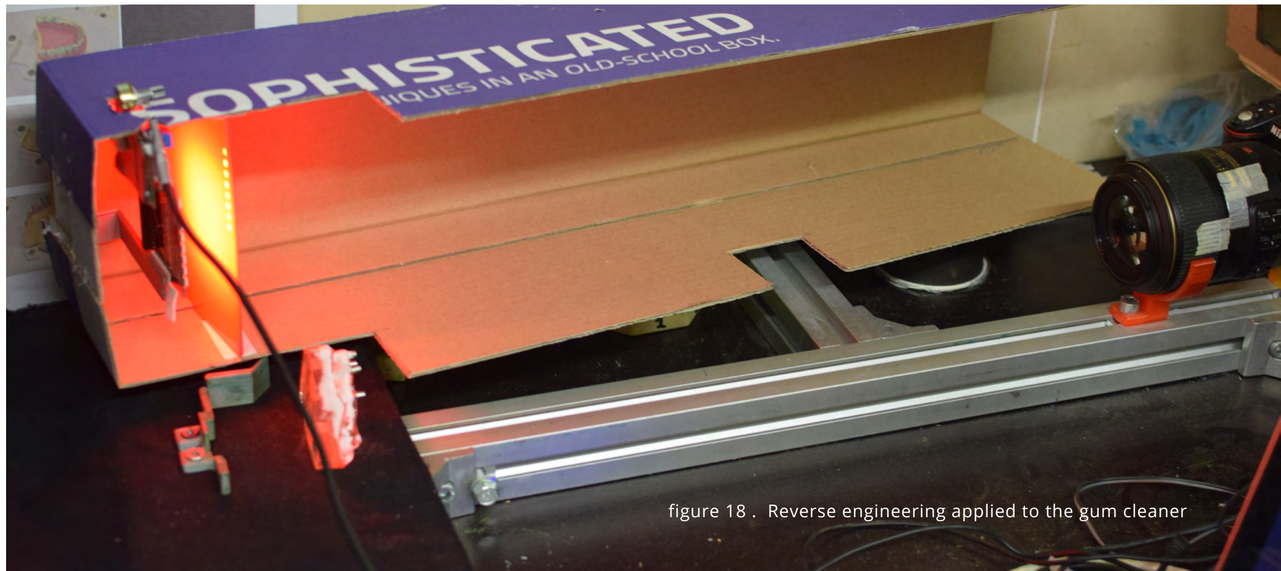



figure 18 . Reverse engineering applied to the gum cleaner

## Performance tests

Now the mouthpiece was rebuilt and tested. Its results were not as good as expected in some areas (Slopes) as it can be seen on the two first following pictures. On the other hand, the third picture (Model with high state of ridge resorption) shows a very good performance already.

## Visual inspection

In order to understand this problem, a visual inspection took place, revealing that the bristles were too short to reach those areas. Since those bristles that are supposed to touch the slopes are the ones that rotate closer to the frame, then this limitation has to be compensated with a redesign to make this bristles long enough. This also required the redesign of the mould (In green).

With the design freeze, the moment to test the acceptance of the device arrived. It was decided to first test the prototypes with elders able to communicate the feeling of the actuations. That is why three persons that have been using dentures for a long time were visited and introduced to the gum cleaner.

A questionnaire was written in order to extract as much information from the tests, at the same time as making it as easy going as possible for them. Not only that but the format created (attached in this email) gave me a solid structure to proceed with the test and not biased my results. One interesting part of the questionnaire is where the patient is asked to relate the feeling to some words provided. The aim of this is to really discover how does the actuator is perceived by the user. You can find the questionnaires filled by each patient on Appendix E, and following a brief story of each user test.

## Wim

Wim was highly excited with the product. The first thing he noticed once the actuation finished was the presence of wine stains on the actuator. So that convinced him to believe that the actuator cleaned his mouth. He was playful with the product in his mouth. He moved it around to reach different areas, and he thought it was faster than rinsing with mouthwash, as he usually does. He liked the motion and even would like it to be faster. Three minutes after the actuation, he interrupted the interview to share that he was still feeling some stimulation in his gums.

## Janie

Janie, a sweet woman living with her husband, was eager to help taking the first user test of the gum cleaner, and she took it very seriously. She has been using dentures for 50 years now, and she is currently using her third pair. She only rinses her mouth but does this every morning and night, after cleaning her dentures. She thought the device gives a nice experience and was surprised by the softness of the mouthpiece. She had a small mouth so she struggled a bit inserting the prototype into her mouth. She thought she had to move the actuator up and down, touching mandible and maxilla separately.

## Bep

This charming woman repeated quite a few times how pleasant was the sensation of the actuator in her mouth. She was surprised on how soft it feels when she touhed the actuator with her hands. She was so positive about the device that even if she struggled a bit to insert it, she denied it. When questioned about a hypothetical scenario, where her dentist suggested her to use the gum cleaner from next day,  she said she would not mind starting using this new device.

figure 19 .  Wim looking at the gum cleaner

figure 20 .  Janie trying the gum cleaner

figure 21 .  Bep filling the questionnaire

CHAPTER 5

# CONCLUDE

In the final phase of the project, the gum cleaner was validated, and prepared for manufacturing. Positive feedback from nurses as well as a positive acceptance of the device invites to think that the gum cleaner is close to be introduced as a pilot study at care homes. The dirt removal test shows that the actuator does not only displaces away dirt from the ridges but also is keeping a considerable amount of dirt after the actuation. The manufacturing proof of concept showed that the most difficult part of the production of this actuator needs only some minimal improvements to be ready for the first batch of gum cleaners. Then an evaluation of the development is presented, as well as conclusions, recommendations and final reflections.

figure 22 . Dirt removal result

## Dirt removal

Another validation requested by DR was dirt removal. Such validation was quite similar to the surface coverage test, but now using an agent that could simulate the dirt found on the mouths of dentures users. This dirt, as mentioned in the denture cleaner development (Folkers, 2019), is a result of a combination of three main substances: food residues, plaque, and tartar. For the cleaning tests performed during that master project, peanut butter was used as fake dirt. Adding some food colorant to the peanut butter made it even easier to inspect the results of the tests.

The rest of the procedure was very straight forward: Covering the edentulous models in the fake dirt, actuating for 30 seconds, take pictures, and finally analyze them. See the photos of the results in Appendix G.

Even though the dirt removal validation did not wholly represent the use of the gum cleaner on an edentulous mouth, a couple of interesting insights were still obtained.

The most crucial objective when cleaning the mouths of the elders would be to be able to detach the dirt from the masticatory mucosa, so later can easily be removed by a rinse. And according to the results of these tests, this has been succeeded.

figure 23 . Dirt removal test

I feel satisfaction because an exploration of soft robotics applied to healthcare was done. The main research question was answered in my opinion: The actuator proposed can provide oral care to edentulous patients. This while is connected on the Air 1 platform.

At the same time, I wish I had more time to apply more of my ideation results, explore the area of the palate, and perfection the motion of the actuator.

Since this projected was offered to me, I was already excited to know that It would end on a first of its kind product. But it was throughout the development that I realize the impact this innovation could make. After been on the elderly homes, seeing the conditions of the mouths of the elders, and also considering the prevalence of edentulism around elders, I still do not understand how a practical device for gum care has never been introduced.

I consider that respecting the MVP mindset that Dental Robotics pursues was an excellent way of working on getting fast results. Gaining this mindset is highly valuable for my career. I actually would have liked to stay a bit longer within the iteration phase, to redesign the actuator a couple times more. But this thought only makes me realize that my passion is on designing and building, and naturally, I needed to show other skills through this graduation project. I deeply hope that this startup keep pushing the development of this device, as I am extremely curious to see how it could end.

On the other hand, even I (The number one believer of the gum cleaner) feel a bit skeptical about convincing care homes to invest their money on a problematic that it is either unknown or neglected. At least it has a very low priority for the staff, judging by my visit to the Bieslandhof.

Doing the design vision as a recommendation is something I learned to do at TU Delft. It did not happen as an instruction necessarily but just a more creative and detailed way to share with the client how I visualize the product in the future. The freedom within the design vision let me include extra possibilities that do not necessarily fit in the actual state of the development, but I feel they could very promising.

If I reflect on my planning, the big change I would have made was on actually respecting this path, since I took a detour on trying to design a precise testing method (The surface coverage test). Especially the image processing procedure took me so much time from my calendar, and I think I could have ideate a faster way to assess the performance of my prototypes.

About the weekly updates, this activity that kept me thinking on the gum cleaner even on the weekends, I have contrasted thoughts. On one side I am aware of how focused they kept me, and that it obliged me to write even a bit each week, but on the other side, I felt that the more advanced and deep the project was,  the more they become repetitive, and made my work look less appealing.

Finally, having chosen a project about healthcare innovation was critical to keep my motivation high, as this field gives me a sense of accomplishment. I have only selected projects within the healthcare field during my master studies, and after completing this last one, I can say that I enjoy solving these issues.

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# APPENDICES


figure 24 . Patient filling user test questionnaire

## appendix a: inspiration references

1 . Clown nudibranch, Ceratosoma amoenum

2 . Crassula 'Buddha's Temple'

3 . Ceramics By Enno Jäkel

4 . Lithos Design, Claudio and Alberto Bevilacqua

5 . Adidas Men's AlphaBounce 1 Running Shoes

6 . Cilia in Mnemiopsis (Jellyfish)

7 . J.H. Pikul et al., Science (2017)

8 . "Process" Amazon ID motion graphics

9 . Edentulous models

10 . Soft actuators principles

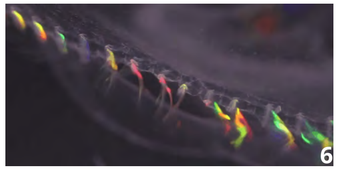
11 . Amiro cotton, by Messizon

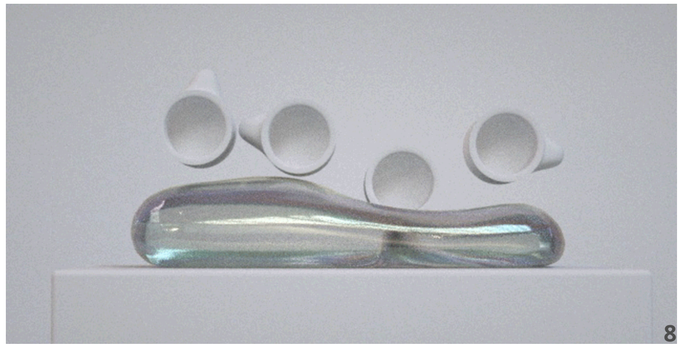
12 . Cleaning of dental implants for overdentures

13 . An old man having a big smile and no visible teeth

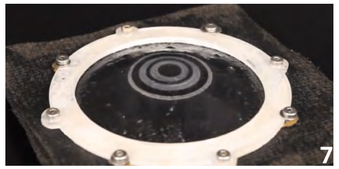


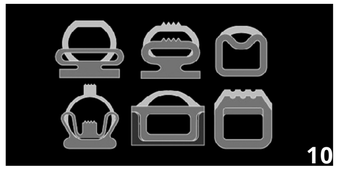


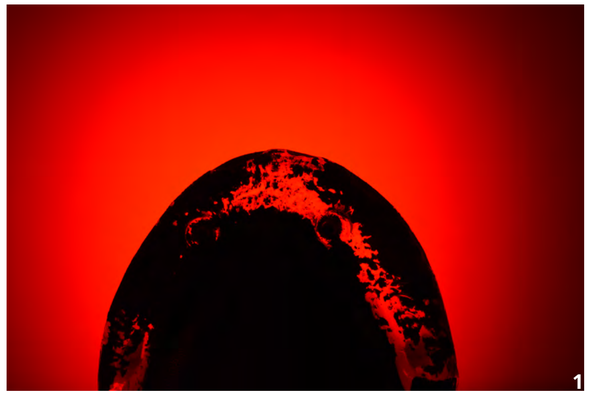


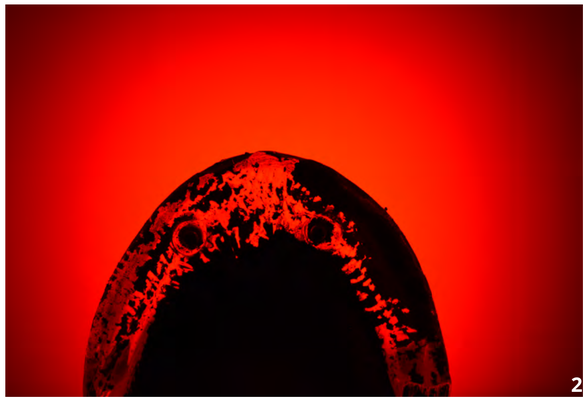


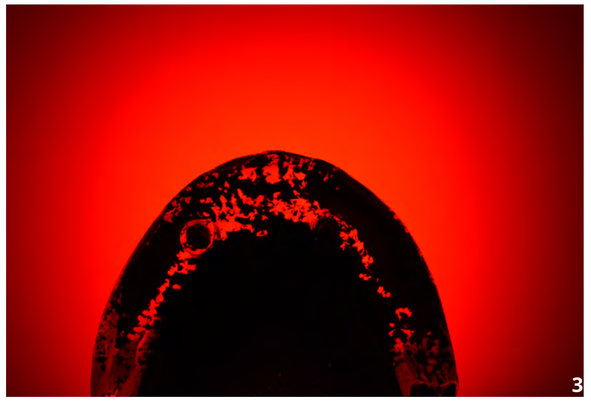






# appendix b: surface coverage results







## Actuator 1

1 . Edentulous model # 7 after actuation (Test 1)

2 . Edentulous model # 7 after actuation (Test 2)

3 . Edentulous model # 7 after actuation (Test 3)

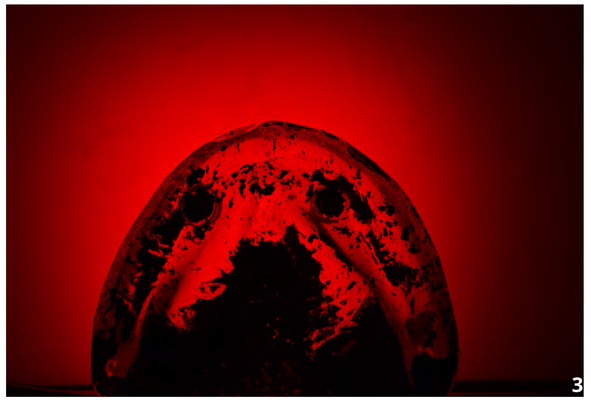
4 . Edentulous model # 8 after actuation (Test 1)

5 . Edentulous model # 8 after actuation (Test 2)

6 . Edentulous model # 8 after actuation (Test 3)

# appendix b: surface coverage results









## Actuator 2

1 . Edentulous model # 7 after actuation (Test 1)

2 . Edentulous model # 7 after actuation (Test 2)

3 . Edentulous model # 7 after actuation (Test 3)

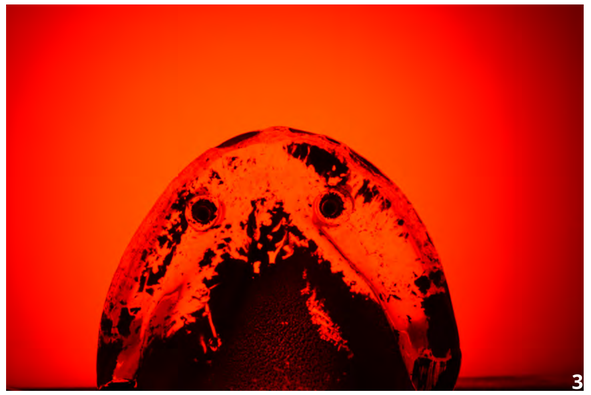
4 . Edentulous model # 8 after actuation (Test 1)

5 . Edentulous model # 8 after actuation (Test 2)

6 . Edentulous model # 8 after actuation (Test 3)

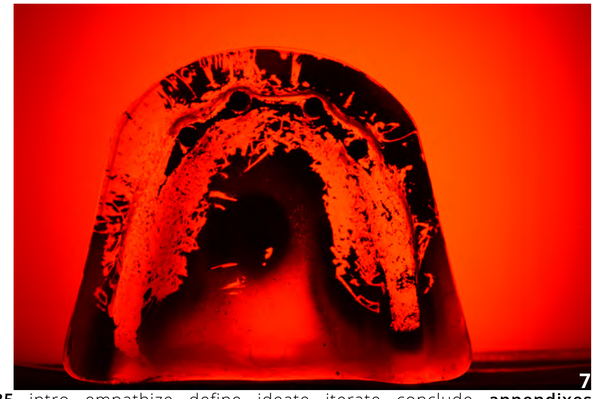
# appendix b: surface coverage results














## Actuator 3

1 . Edentulous model # 7 after actuation (Test 1)

2 . Edentulous model # 7 after actuation (Test 2)

3 . Edentulous model # 7 after actuation (Test 3)

4 . Edentulous model # 8 after actuation (Test 1)

5 . Edentulous model # 8 after actuation (Test 2)

6 . Edentulous model # 8 after actuation (Test 3)

7 . Edentulous model # 9 after actuation (Test 1)

8 . Edentulous model # 9 after actuation (Test 2)

9 . Edentulous model # 9 after actuation (Test 3)