

Enabling Effortless Imaging of Dental Structures Utilizing Ultrasound

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Acknowledgments

This master thesis is the result of an initial challenge from Tannhelsetjenestens Kompetansesenter Midt-Norge to revolutionize the diagnostic procedure for periodontal pockets. I want to thank Astrid Jullumstrø Feuerherm and Hege Ertzaas Fossland for their enthusiasm of my pre-master thesis findings and wanting to pursue this further. Thanks to supervisor Martin Steinert for the interesting topic which has challenged my knowledge and opened my eyes to a field I never had worked with before. To Achim Gerstenberg and the rest of TrollLABS , a big thanks for bouncing ideas and generally being good support along the way.

To Olav Inge Larsen and Mats Säll for being my insight into the dental profession. And last but definitely not least, Alfonso Rodriguez-Molares, for being engaged and using many work hours helping with imaging and doing post-processing for my thesis.

Abstract

Periodontal disease is the leading cause of tooth loss in adults. Diagnosis of periodontal disease varies from visual inspection to invasive probing of the gums. In this master thesis the goal is to enable the use of ultrasound imaging to assist in diagnosis and classification of periodontal disease. Utilizing ultrasound could allow for a non-invasive, simple and painless imaging technique. Through dialog with dental and ultrasound experts the latest equipment and knowledge was sourced. As there has not been any widespread use of ultrasound in dental imaging, a novel sleeve system for in vivo imaging has been developed to further investigate the potential of ultrasound. Utilizing the sleeve resulted in improved image quality that could not be matched by modern post-processing algorithms. The dental structure can be clearly seen, but to further investigate the possibilities a clinical trial is required to acquire images of unhealthy periodontium. The main objective of this thesis is to advance the knowledge about ultrasound in dental imaging, and be as a stepping stone between the initial idea and the start of a research project at NTNU.

Sammendrag

Periodontal sykdom er den viktigste årsaken til tanntap hos voksne. Diagnosen av periodontal sykdom varierer fra visuell inspeksjon til invasiv undersøkelse av tannkjøttet. I denne masteroppgaven er målet å muliggjøre bruk av ultralyds for å hjelpe til med diagnostisering og klassifisering av periodontal sykdom. Ved hjelp av ultralyd kan det oppnås en ikke-invasiv, enkel og smertefri avbildningsteknikk. Gjennom dialog med tannelege og ultralydekspert ble det siste utstyret og kunnskapen hentet. Siden det ikke har vært en utbredt bruk av ultralyd i avbilding av tannkjøtt har det blitt utviklet et nytt posesystem for "in vivo" avbilding for å undersøke potensialet for ultralyd. Å bruke hylsen resulterte i forbedret bildekvalitet som ikke kunne oppnås kun ved hjelp av moderne etterbehandlingsalgoritmer. Tannstrukturen kan tydelig sees, men for å undersøke mulighetene en klinisk prøve er nødvendig for å skaffe bilder av usunt parodontium. Hovedformålet med denne oppgaven er å fremme kunnskapen om ultralyd i tannbehandling, og være som en bindeledd mellom den opprinnelige ideen og starten av et forskningsprosjekt ved NTNU.

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Abbreviations

a :
Canine
Central Incisor
First molar
First premolar
Stiffness
Lateral Incisor
Lower Right
Density
Second molar
Signal-to-noise ratio
Second premolar
Third molar (wisdom tooth)
Upper Right
Acoustic Impedance

Chapter _

Introduction

1.1 Introduction

Periodontal disease is the main reason for tooth loss in adults, leading to the degradation of the gingiva and bone supporting the teeth (Lynch et al., 2006). In Norway, around 8 percent of 35-year old's have periodontal disease, which could lead to tooth loss if not treated properly (Lyshol and Hånes, 2016).

Periodontal pockets are traditionally measured with a periodontal probe, which is a thin piece of metal, where results are not easily replicatable between practitioners (Renatus et al., 2016). More advanced probes have been introduced, however, because of their exponential cost increase without significant measurement improvements, they have not seen widespread use (Ss et al., 2011). Almost all newer probes are based on the same principle of intrusive measurement, causing discomfort to the patient and possibly more damage to the gums. In a clinical environment, advanced 3D scanning equipment based on CT technology have been developed. Along with the high cost, the size of the system makes this a static system for clinical use (Mohan et al., 2011).

There is a need for a non-invasive method for measuring periodontal pockets and surrounding dental structure in the clinic and in the field that gives replicable results. In addition, it is important that the instrument is portable, fast, simple and without harmful radiation. Based on a feasibility study performed in the authors pre-master thesis the use of ultrasound to image a longitudinal cross-section of the dental structure was selected as a technology with potential of performing the intended task and complying with the criteria mentioned. The authors pre-master thesis will be referred to as (Bakken, 2017) and can be found in its entirety in Appendix F

This master thesis is aimed at enabling the best ultrasound images possible to further analyze, interpret and investigate the use of ultrasound in the classification of periodontits. This is done by using modern product development methods, together with the known properties of ultrasound to engineer a solution that allows for simple, non-invasive imaging of the periodontal structure to further advance the technology needed.

This master thesis is divided in sections. The theory section provides the necessary knowledge on dental, ultrasound and product development theory to understand the process and choices made on the product development journey. Chapter 3 which involves the development of the necessary equipment to acquire ultrasound images good enough for processing. Following the product development mindset, testing the setup with a periodontist expert is done to validate the setup and show the potential of the system.

1.2 TrollLABS and the Partners

TrollLABS is a multi-disciplinary research group located at the Norwegian University of Science and Technology in Trondheim, Norway. TrollLABS aims to understand the development of radical new ideas in the early phases of product development. The entire project started with TrollLABS receiving a challenge from Tannhelsetjenestens Kompetansesenter Midt-Norge (TkMN) that involved investigating technologies that can aid in the identification and classification of periodontal disease in a non-invasive, replicable manner.

After ultrasound was selected as the best option and to take this master thesis further, contact with Department of Circulation and Medical Imaging was established. The department, which is part of the Faculty of Medicine and Health Sciences at NTNU has its own ultrasound research group with the right technical knowledge to assist in the development. Alfonso Rodriguez-Molares, a senior engineer at the department assisted in the imaging and post-processing of data, as he is an expert in in advanced medical ultrasound imaging. A declaration of invention was delivered to NTNU Technology Transfer to further investigate the need and patentability of the imaging technique, which will be covered in Section 6.1, Future work.

1.3 Previous and Similar work

Using ultrasound for imaging is nothing new, and even for periodontal pockets it has been tested and patented. US patent US4501555A (Ditchburn, 1985) is a method for measuring the periodontal pocket using a single element ultrasound transducer entering the top of the pocket as a manual probe, and is nothing like the solution suggested in this thesis.

US6050821A (Klaassen and Asch, 2000) envisions an ultrasound array to image the whole teeth morphology in a single measurement for creating dental impressions. This system can only be created with low frequency ultrasound, which will not reveal the periodontal structure which is the main interest for this thesis. Nguyen et al. (2016) have tested the use of ultrasound imaging of periodontal tissue in an ex vivo pig mandible and compared this to a CBCT scan. The paper described differences between the ultrasound and CBCT measurements of about 10%, which shows the promising future of ultrasound in dental

imaging.

As of first quarter 2018, there is no known commercial product that utilizes the concepts that are covered in this master thesis. No papers are published on in vivo ultrasound imaging of a longitudinal cross-section of human periodontium.

Chapter 2

Literature Review

2.1 Dental Theory

When working with oral health a basic understanding of the anatomy of periodontium is needed. A tooth is suspended in the alveolar socket and connected with collagen fibers. Its these fibers, known as the periodontal ligaments, that are connected to the alveolar bone and cementum, the outer layer of the tooth root. These elements are collectively called the periodontium (Williams, 1990). Covering these structures are the gums, gingiva (along with some oral mucosa). In Figure 2.1 a drawing of the periodontium can be seen.

In its healthy state, the gingiva is nice and flush with the teeth, covering the alveolar bone and tooth root, just above the cemento-enamel junction, which is the junction between the tooth crown and root. When discussing periodontal diseases, it is usually divided into the ones that involve only the gingiva, and the ones that involve destruction of the underlying periodontium.

Each tooth has its own specific name, shown in Figure 2.2. Along with the names, they are denoted with Lower Right (LR), Lower Left (LL), Upper Right (UR) and Upper Left (UL). This means that the Lower Right First Premolar will be denoted as LRFP. Along with names, teeth have to main sides, one facing the cheek named *facial* and one facing the tongue, *lingual* (Nelson, 2014).

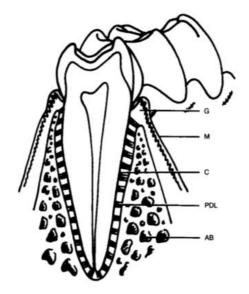


Figure 2.1: The periodontium consists of the gingiva (G) and alveolar mucosa (M) that covers the alveolar bone (AB), periodontal ligament (PDL), and cementum (C) (Williams, 1990)

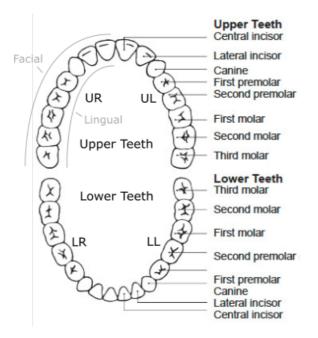


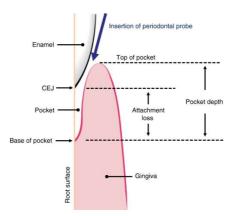
Figure 2.2: Name of teeth

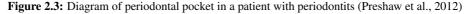
2.1.1 Periodontal disease

Most adults have a mild form of periodontal disease known as gingival diseases which is an inflammation of the gums, or gingiva, caused by a variety of reasons including pregnancy, prescription drugs, diabetes or general hygiene issues. Gingivitis, the most common form is not considered as troubling as the periodontal diseases because no permanent damage is caused. It is generally found in places where it is difficult to clean (Hansen, 2004) and if the inflammation is left unattended over time, it extends into the periodontal ligaments and alveolar bone. This leads to the destruction of the bone, and the periodontal disease is classified as periodontist. Periodontial pocket. As the periodontal disease progresses, the alveolar bone and periodontal ligaments retracts more and more, and the teeth become looser and looser, and eventually fall out if treatment is not initiated.

2.1.2 Examination

Identification of gingivitis is mainly done visually, identifying the gums for a color change and if the gums are more prone to bleeding than a healthy area of the gums. To identify gingivitis different indexes has been developed, as an example the Gingival Index have a zero to four classification that is used for simple classification of different states of periodontits (Hansen, 2004). The main parameters are color, consistency, form and bleeding. The examination and diagnosis of periodontitis must be done by a dentist where he employs special probes to examine the patient. The probe measures the periodontal pocket, which becomes deeper as the disease progresses and can enter the periodontal ligament, between the alveolar bone and tooth root. The diagnosis of periodontal diseases requires 3 main parameters be recorded: Probing depth (PD), Attachment Loss (AL), and Bleeding on Probing (BOP) (Renatus et al., 2016). These values are recorded from 2 to 6 times around one tooth for all teeth. This means that the periodontal pocket is penetrated with a probe 2-6 times per tooth. This process can be rather unpleasant and cause additional damage to the gingiva.





2.1.3 Current measuring technology

When it comes to measuring of periodontal pockets there is one main standard that is in used, the Williams probe. There are also different, newer measurement devices that take the semi-automated approach, but most rely on the physical penetration of the pocket (Bakken, 2017)

The Manual/Williams probe

The most common used probe is the manual Williams probe. The probe is a metal rod with a diameter of 0.5 mm, and marked along its entirety with distance measurements from the probe tip (Vartoukian et al., 2004).

The probe is inserted into the periodontal pocket between the tooth and gingiva to measure the depth. The dentist should apply a constant load of 0.25 N to get a correct reading. Applying the correct amount of force requires training and experience but will never be exactly the same each time. Dentists will also calibrate themselves on a scale before performing the measurements to get a feel for the force required. Issues with this type of probe occur when buildup along the teeth makes inserting the probe difficult. This can in some cases result in the probe not settling in the correct position which can result in measurement errors. This could in worst case scenarios lead to the misclassification of the disease (Renatus et al., 2016). As this measuring technique is invasive, it can cause discomfort for the patient and additional damage to the gingiva.

Gold standard

Besides rather manual probes giving a limited feel and view of pockets and the conditions, more advanced equipment can be used to judge periodontal disease and how far it has progressed. Utilizing 3D ConeBeam imaging a 3D image can be constructed of the jawbone and teeth (De Vos et al., 2009). Planmeca ProMax 3D is such a scanner, giving a standard voxel size of 200 qm. The radiation dose of these machines limits the use of such machines to specific use cases where the dentist can specify the need based on symptoms and cannot be used as a tool for regular follow up. This limits the systems use in preventive care, because a justification must be present before use. While this image gives a clear image of the bone structure, it does not convey information about the gingva and pocket depth.

A 3D ConeBeam image can be combined with a 3D intra-oral surface scan, such provided by 3shape Trios. Combining these images the distance from the top of the gingiva and down to the bone can be measured, giving an indication of the health of the gingiva (White, 2008). While the pockets cannot be measured with this technique, this gives the dentist a clear indication of the condition of the bone structure and gingiva, especially underneath the gingiva surface.

2.2 Ultrasound imaging

Ultrasound imaging is a widespread diagnostic technique that can be used in everything from fetal inspection to heart surgery. For diagnosis and imaging two main techniques in ultrasound is used; The pulse-echo method for imaging of tissue distribution, and the Doppler method for tissue movement and blood flow (Robinson, 2007). In the case of imaging of teeth, gingiva and alveolar bone, a pulse-echo approach is appropriate. This takes advantage of the difference in acoustic properties between different mediums and makes an image based on the partial reflection of sound waves.

The two commonly found types of transducers used to transmit the sound waves are convex and linear. A convex transducer is mainly used in abdominal imaging that require deep penetration and wide field of view. To achieve deep penetration a lower frequency must be used, but since lateral resolution is determined by wavelength, the resolution suffers (Robinson, 2007). When deep penetration is not needed, linear higher frequency probes can be used which will increase the resolution possible.

2.2.1 Reflection, Refraction, Scattering and Attenuation

Understanding the physical principles that governs ultrasonic sound waves is crucial when designing equipment that interacts with the sound. As a beam of ultrasound travels through a material it reacts to the material. A reflection of the wave is called a echo. Reflection happens in the boundary between two materials. Materials have different acoustic impedance Z, which is the ratio of acoustic pressure to flow and can be described y its density (p) and stiffness (k) such that $Z = \sqrt{p * k}$ (Robinson, 2007).

	Speed of sound [m/s]	Density [kgm ⁻³]	Acoustic Impedance[kgm $^{-2}s/1$]
Gingiva	1540	1060	1.63
Enamel	5700	2900	16.5
Dentine	3800	2100	8
Cementum	3200	2030	6.5
Bone	4080	1600	6.47

Table 2.1: Properties of the periodontium (Nguyen et al., 2016), (Hoskins et al., 2010).

A change in acoustic impedance at a boundary results in reflection at a boundary layer. If the difference in acoustic impedance is very large, the ultrasound wave will be reflected in its entirety. On the other hand, if the difference is small, almost nothing will be reflected and the sound waves continues (Abu-Zidan et al., 2011). Bone and air are example of thing that create large echoes, where a tissue- air interface reflect more than 99.9% of the beam (Aldrich, 2007).

An aspect of ultrasound is that the sound wave only travels straight in the material. When a ultrasound beam enters a boundary at an angle it is called *refraction*, and the angle the ultrasound wave hits a boundary layer is called the *Angle of Incidence*. the echo will return

from the boundary at the *AoI*, as shown in Figure 2.4. The amplitude of an echo detected from a interface depends on the orientation of the of the probe in respect to the reflected sound.

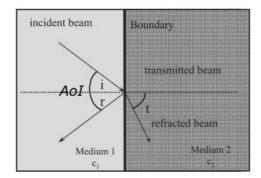


Figure 2.4: Angle of Incidence. (Aldrich, 2007)

The energy of an ultrasound wave is reduces with distance. Energy can be lost by both scattering and absorption (conversion to heat). *Scattering* happens with objects that are small compared to the wavelength. This energy loss is called *attenuation*, and for soft tissue it is around 0.3-0.6 dB/cm/MHz Robinson (2007).

2.2.2 Artifacts

When producing an ultrasound image there are some basic assumptions that are considered known (Aldrich, 2007):

- Sound waves travel in straight lines.
- Reflections occur from structures along the central axis of the beam.
- Intensity of reflection corresponds to the reflector scattering strength
- Sound travels at exactly 1540 m/sec
- Sound travels directly to the reflector and back

These assumptions may not always be true, and this is when artifacts can appear in the image. While some artifacts can give valuable insight, most of the time it can clutter the image and confuse the examiner (Tay et al., 2011).

Ring Down artifacts occur when air bubbles resonate at the ultrasound frequency and emit sound. This will lead the system to believe that the sound is coming from deeper within the body and return a false structure.

Mirror Image artifacts occur when sound bounces of a strong, smooth reflector such as enamel. The enamel will work as a mirror and reflect the sound to a different layer, and the system will think that the second layer is behind the enamel, while actually being in

front.

Reflections are similar to *Mirror Images*, but are caused by multiple reflections that return from a strong reflector back to the transducer. This shows up as a structure deeper in the image that is not real.

Enhancements are areas with abnormal high brightness, and occurs when sound travels through a medium with an attenuation rate lower than surrounding tissue.

2.2.3 Ultrasound algorithms

While this master thesis will not focus on the actual image processing the latest stateof-the-art processing techniques has been utilized during development. The algorithms include delay and sum (DAS), mixed transmit and receive incoherent compounding (ITXRX), backscattering tensor imaging (Paris) and plane reflector beamforming (PRB) (Papadacci et al., 2014).

Most medical ultrasound equipment uses DAS, but it is limited by the frequency and aperture size and may provide lower image quality (Matrone et al., 2015), but is good for live viewing while imaging. This is why different algorithms has been tested, with PRB being a unpublished, proprietary algorithm by Alfonso Rodriguez-Molares.

2.2.4 Current intraoral ultrasound transducer

The leader in intra-oral transducers are Alpinion with their IO3-12 model with a 2 - 12 MHz linear transducer. The main applications is imaging of salivary glands, parotid gland and sub maxillary gland for abnormalities and tumors. While this probe is designed to operate intra-orally, the transducer head is oriented parallel with the tool, which is the wrong orientation to image the tooth cross section. While this probe could be used to image some teeth, when reaching inside to the further back molars, this would not be able to image the cross section needed.

Along with probes especially designed intraoral probes, there are probes like the Medistim 15MHz Epicardiac Probe, design for imaging directly on cardiac tissue, which is smaller in size and could possibly be used for intraoral imaging or prototyping on the issue. The probe was sent for testing by Medistim, but this was to late to actually include imaging with this probe in this master thesis.

2.2.5 Coaxial ultrasound cable

The ultrasound transducer consists of usually between 64 and 256 elements each requiring its own, single coax element. These elements have an outer diameter of upwards of 0.3 mm, giving a standard ultrasound cable with 128 elements a diameter of about 8 mm. The cable can not be kinked, but has a lifespan of about 250,000 flex cycles (Medical, 2014).



(a) Alpinion I03-12 intraoral transducer (BPLMedical, 2017)



(b) Medistim Epicardiac Probe

Figure 2.5: Current ultrasound Probes

2.3 Product development

In product development, innovation is one of the most important aspects. Innovation is the match between unmet needs or problems, its solution and the human knowledge needed (Welo, 2011). To facilitate the innovative product development process a framework is needed. Combining ideas from agile product development, design thinking and prototyping might lead to the best possible solution to a given problem. When developing new, innovative products it is important to have a framework to support the development process.

2.3.1 Agile

Agile software development is a development method established to develop computer software in an ever-changing market. While the agile methods is mostly used in software development, it has had great effect on productivity and has led to the introduction of agile practices in product development (Dybå and Dingsøyr, 2008).

Some key values presented in the agile method are (Abrahamsson et al., 2002):

- Iterative, rapid cycles
- Adaptive and rapid changing requirements
- Collaborative working style
- Convergent approach to minimize risk

Being able to adapt to ever changing requirements is crucial, because of the chaotic nature of product development. In early stage product development the future is unknown and new requirements can surface during the development process. These adaptive requirement leads to a convergent approach, where every step of the cycle has been tested, and all the best aspects converge to the best solutions. This minimizes the risk for big setbacks in later stages of the product development (Highsmith and Cockburn, 2001).

A collaborative working style is important to be able to share experiences with each other, to receive and give feedback and build on the collective knowledge base. Iterative, rapid cycles aid in the progress of the project, and aids in the ability to adapt to changes and the converging of solutions. An agile method to achieve iterative, rapid cycles is Scrum, which will be covered in more detail.

2.3.2 Scrum

The Scrum approach has been developed to oversee the development process. It enhances the iterative and incremental approach in product development, while assuming that the development process is unpredictable and complicated (Schwaber, 1997).

The Scrum is in short divided into a planning- and a sprint phase. Where the planning phase is represented with the Product Backlog. This quantifies the functional requirements and what needs to be investigated further. The sprint phase is a cyclic phase where

each cycle can last from 1 week to a couple of months, depending on the project. The sprint backlog represents what the current sprint is focusing on solving or implementing of functionality into the prototype. When one sprint is finished, the current sprint backlog should have a working solution, and this knowledge is used further in the development cycle. If new questions or interesting ideas are realized during a sprint, it can be added to the backlog for further investigation.

2.3.3 Prototyping

To facilitate Agile product development the concept of prototyping is introduced. Ulrich and Eppinger (2012) define a prototype as "An approximation of the product along one or more dimensions of interest." This includes both physical and non-physical prototypes, but definitions also go further in defining a prototype as a tangible artifact, and not abstract descriptions (Buchenau and Suri, 2000). Prototyping has a diverse role and is used and evaluated in a wide variety of use cases and disciplines (Elverum et al., 2016).

In engineering design, it is most commonly used to check and confirm calculations or assumptions made during the development process. It is also used as "milestone" prototypes, also known as proof of concept (Ullman, 2003). In design thinking, the prototypes are there to transfer novel ideas into exploratory models that can be evaluated further (P. Seidel and Fixson, 2013). Focusing on lessons learned to be implemented in the next prototyping stage. A prototype addresses specific questions developers have during development.

Ulrich and Eppinger (2012) classifies prototypes along two dimensions: analytical vs. physical and focused vs. comprehensive. A focused prototype focuses on a certain attribute of the prototype, while a comprehensive prototype combines various aspects or functions. A physical prototype focuses on the form and function, giving a proof of concept. An analytical prototype is not physically built but give insight with simulations and other computer models.

Elverum and Welo (2015) proposed a model explain how prototypes are used in the development of innovations. They define prototyping as either directional or incremental prototyping. Directional prototyping is when a team is working on a new, unproven design. These type of prototypes gives guidance and help in the evaluating of the direction they are heading. Incremental prototypes are used to optimize design and further increase the understanding, without making considerable changes.

2.3.4 Design Thinking

Design Thinking is a design methodology that focuses on solutions when solving problems that are ill-defined or unknown Melles et al. (2012). This by understanding the human needs involved, using a human-centric approach to the problems, utilizing brainstorming sessions to generate many ideas, and using hands on prototyping and testing.

Hasso-Plattner Institute of Design at Stanford proposes a five-sage model when it comes to Design Thinking D.School (2010)

Empathize, to observe, engage and immerse in the problems you are trying to solve, by gaining first hand experience that might give valuable insight. *Define* is where you synthesize your learnings into a problem that you want to solve. After the problem is defined, it is time to *Ideate*. Here you focus on exploring the solution space, looking for possible solutions for the problem at hand. *Prototyping* involves taking the ideas into the physical world by prototyping them, to deepen our understanding for the ideas. By *Testing* the prototypes, we are then able to refine our solutions and gain new insight.

2.4 Application of theoretical knowledge

The theoretical background chapter is split into three sections, and these sections represent the backbone of knowledge needed for this master thesis.

The dental theory is used to be able to know what we are looking for in images found with the ultrasound, as well as in dialog with dentists and experts on the medical side of this thesis. On the other hand, the ultrasound theory is used to understand the physical principles that govern ultrasound, and how the prototypes built in this thesis affects the image quality or other aspects of the ultrasound method.

Product development theory enables the efficient work progress needed in the relative short time frame of a master thesis. Without a good understanding of product development principles and how they can be used, an effective progress can not be achieved.

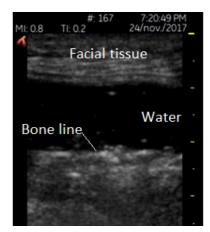
Chapter 3

Development

From the author's pre-master thesis, the possibility of using ultrasound was investigated both with a literature study, and by the use of a GE Healthcare Vscan portable ultrasound system. This system is made for imaging of the heart, lungs, arteries and joints, but not detailed images of small features. These initial images showed the ability to image the bone line from outside of the mouth, using only water between the facial tissue and bone. This can be seen from Figure 3.1, were the different layers are highlighted. More detailed images had to be acquired to further investigate the ultrasound as a viable method.



(a) Front teeth



(b) Lower Right cheek and bone line



3.1 Interview

While a theoretical knowledge of dentistry can be gained by literature, to really understand the problem a visit to a dental office and interview with a dental professional was arranged. Empathizing with the end users fits with the Design Thinking methodology mentioned in Section 2.3.4. Furthermore it gives the current status of technology and experience in the field of dentistry.

Olav Inge Larsen, a periodontist and dental surgeon, with ties to TkMN was contacted and asked about sharing his views and experience with periodontists and dental equipment. The following is a summary of the main insight gained from the conversation with Olav Inge Larsen. The session was unscripted, but talking points regarding the current technology, the patients experience and his experience were made in advanced to ensure a good dialog.

When utilizing any equipment inside the mouth, there are two main issues that can cause discomfort for the patient. The first being the gag reflex, a protective response that prevent foreign objects from entering the pharynx, the area behind the mouth (Leder, 1996). The gag reflex varies from person to person, but from Olav Inge Larsens experience, a general rule is that the object should not be bigger than a thumb, at around 20mm in diameter. The majority of patients he treated did not have any issues with equipment which is smaller than this. Secondly, the mouth also has a vast amount of nerve endings that assist sensing, eating, drinking and the prevention of foreign objects (Haggard and de Boer, 2014). When introducing a foreign object and putting pressure on the tissue inside the mouth, the patient will receive a pain response to alert about the foreign object and especially were there is bone underneath the nerve endings. This is also an issue when dealing with dental procedures were contact with the tissue is necessary, or with accidental poking of the gingiva or surrounding tissue. This was tested in practice by pushing a metal tool into the gum, which was not a pleasant experience, emphasizing that considerations have to be made in regards to the design.

The lips and cheeks can be moved and pulled on without much discomfort for the patient, which allows for easier access to the facial side of the teeth. Sufficient lighting is never a issue, even with bigger equipment like the 3shape Trios mentioned in Section 2.1.3. Equipment like the 3shape Trios is usually handled with a pen grip, in the same way as you would manipulate a pen or a pencil, this allows for a relative large handle. Sterilization of equipment is not a big issue as long as it does not penetrate the skin and is considered noninvasive.

Related to the use of ultrasound, Olav Inge Larsen was very interested in something that did not give of radiation and therefore could be used more frequently, and not requiring a thorough justification. When using x-ray imaging, a preexisting condition is needed, you can use ultrasound to check the status of the teeth as a precautionary or routine step of a dental visit. He also mentioned that if the ultrasound was able to image and relay information about the surface of the alveolar bone underneath the gingiva as well as gingiva thickness, this could give valuable insight about possible lesions, or areas of bone that is

damaged or changed (Dib et al., 1996).

The information gathered helped the author to better understand possible issues that can occur in dental practice. This accumulated knowledge is used as part of the background information to be able to develop solutions that do not create new problems, but solve existing ones.

3.2 Ultrasound test setup

To achieve more detailed images than the Vscan is able to provide, all imaging from this point forward is done on a Verasonics Vantage 256 Research Ultrasound System (Verasonics, 2016), enabling real time imaging as well as capturing raw data for signal processing to enhance specific features. As this is a cutting-edge research ultrasound imaging system, one can expect the best possible results that today's technology can provide.

The probe used for all tests is the Verasonics L22-14V High Frequency Imaging Probe (Verasonics, 2015), and will from this point on be referred to as "the probe". The probe is designed for high-resolution imaging for structures within 1 cm of the transducer face, this makes it ideal for our use case. Imaging at 15 MHz enables high detailed imaging that is not available on commercial ultrasound systems. The ultrasound gel used is the AQUA-SONIC 100 ultrasound transmission gel, which does not contain any harmful substances and is able to be used inside the mouth for testing (Parker, 2015)

The main parameters used on the Verasonics Vantage 256 during imaging can be seen in Table 3.1

Voltage	20V
Focal Depth	3.94 mm
Frequency	15.625 Mhz

Table 3.1: Ultrasound settings

3.3 Initial imaging

When investigating the validity of using ultrasound as a method of measuring the dental structure, initial tests were conducted with the probe outside of the mouth. This allowed the cheek to be used as the contact patch. The probe is aligned vertically along the tooth and over the gingiva to get a longitudinal cross-section of the dental structure. Figure 3.2 shows how the probe is situated relative to the tooth and gingiva. Figure 3.2 is rotated 90 degrees, as this is how the ultrasound images of the lower teeth are shown. The images of the upper teeth on the other hand are flipped horizontally compared to the lower teeth so they can be easily distinguished from each other by the reader.

As mentioned, to image the outside of the teeth, the probe does not need to be inside the mouth but could rather be used against the cheek. As the skin and fat of the cheek is flexible, a good probe contact can be made by applying ultrasonic gel. The initial image of the dental structure is shown in Figure 3.3a. There are four main parts that can be viewed from this image, starting from the top there is the facial tissue or cheek. The area of interest consists of three parts. The gingiva can be seen following the bone and connecting down to the tooth in point A (Figure 3.3b), the bone can be seen underneath the gingiva on the left side of the image and the interface with the tooth is found in point B. The tooth is the whiter line shown from point B and exiting the right side of the image

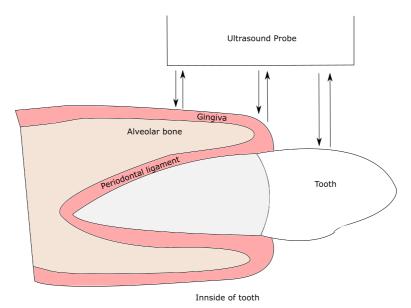
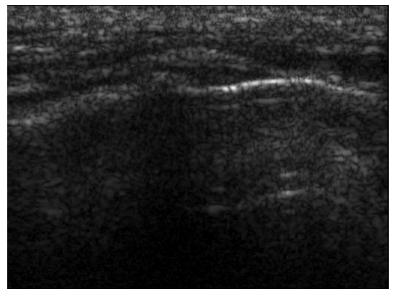


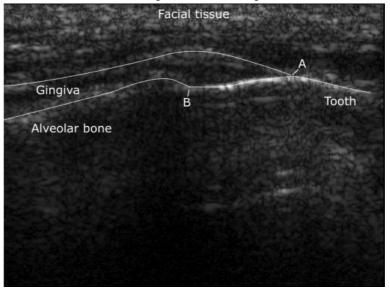
Figure 3.2: Orientation of images and location of probe

Even without post processing the features that are desired can be viewed quite easily. A problem that became immediately apparent is that if the person being imaged has a beard covering the area, the image could be affected. This is something that needs to be considered if imaging outside the mouth is the way forward.

While the beard could be an issue, in general the images shows the validity of the concept. The following development will be to improve these images, and better understand issues that can arise under imaging.



(a) Original ultrasound image



(**b**) Ultrasound image with outlines

Figure 3.3: Outside the mouth ultrasound image of Lower Right Canine (LRC)

3.3.1 Imaging of lingual side of teeth

While the image in Figure 3.3 shows the desired features, the cheek creates damping and noise, and not the best image possible. Furthermore from the outside of the mouth, only the facial side of the tooth can be imaged because of the large difference in acoustic impedance. To image the lingual of the tooth, the ultrasound probe must be inside the mouth. Because the research probe used is rather big and not intended for intraoral use imaging of the lingual side is not possible. Instead the facial side was imaged, but with direct contact between the probe and tooth/gingiva by pulling away the cheek. This will not only provide a test for imaging directly on the facial side, but also the next best thing in regards to the lingual side.

When you remove the cheek the probe has to be in direct contact with the tooth and gingiva. These parts are not as flexible as the cheek, and a solid contact might not be able to form by the ultrasound probe alone. In Figure 3.4 the Lower Right Canine (LRC) without the cheek is imaged, but with ultrasound gel applied directly on the tooth and gingiva. The gel is more viscous than water, but when you apply the probe, the gel flows away. This is especially apparent when the gel is against a hard surface. The tooth surface can be seen as the horizontal line on the right side of the image. The gingiva is partially visible in the top left corner. Replicating the results found in Figure 3.3 was not possible, even with different amount of gel.

There were two main lessons learned from this test. The dental structure of interest came very close to the probe resulting in challenging imaging conditions due to restriction in movement. It also made it difficult to visually see the area being imaged on the live view, as there was no layer between as with the cheek. A major drawback of this approach is that it is nearly impossible to get a stable picture since the ultrasound gel flows away. In addition when the ultrasound probe comes in contact with the tooth and gingiva, as the hard, uneven surface does not lend itself well to imaging.

To combat this problem a solution has to be designed that can uphold the same contact between the probe and the teeth as when imaging is done from outside the mouth, while being small enough to fit inside the mouth.

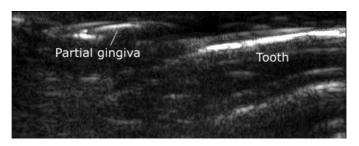


Figure 3.4: LRC without cheek

3.3.2 Prototyping aids

When engaging in rapid prototyping, it is vital to have the necessary tools available to continually test the prototypes that are being developed. However, the testing of prototypes on the real research ultrasound system was not realistic, as it is used for many projects and is not available for testing at any given moment. Meaning that to achieve a high turnover and deliver new prototypes and ideas to every Scrum cycle an alternate approach was needed. To overcome this challenge phantoms where created to replicate certain key objects that where needed during development

For faster and easier testing of prototypes, a model of the teeth and gingiva was made. A 3D scan of a set of teeth were found on Thingiverse (milad64, 2015), a 3D printing community. The scan was 3D printed in booth 1:1 and 2:1 scale, one for realistic scale and one for better visualization of prototypes. While not having the same elastic properties of the real gingiva, it can provide a fast way to both visualize and test different designs without using a real mouth.

Because the Verasonic probe used for testing is quite expensive, and located at a research lab with multiple users, a replica was made to be used during prototyping at TrollLABS. While the official CAD model or machine drawings of the probe would have been ideal, it would take too much time and effort to obtain. With a caliper the required measurements were taken to be able to make a CAD drawing from scratch. The first version of the probe phantom did not have the correct curvature of the transducer head. When testing prototypes on the first phantom, it was clear that a second iteration was needed, and the correct curvature was added to better match reality. The shape of the phantom probe is not as organic as the original, but the main dimensions are preserved.

3.3.3 ultrasound phantoms

When developing ultrasound equipment and training personnel on the use of such equipment, ultrasound phantoms have been created to mimic the acoustic properties of human tissue. These phantoms can be made of polyacrylamide gel (Lafon et al., 2005), gelatin (Bude and Adler, 1995), agar (Earle et al., 2016), polyurethane (Kondo et al., 2005) and other materials. Using such materials as a cheek substitute to be able image the dental structure will be considered.

As these materials are made to mimic the behavior of tissue, the sound velocity, attenuation (one-way passage), and specific acoustic impedance have to be roughly the same as human tissue. While ultrasound phantoms are good at mimicking tissue, they dampen the ultrasound as tissue would and is therefore not ideal as an intermediate layer that is supposed to dampen as little as possible. Another issue is that most medical ultrasound equipment operates up to about 7MHz, and not at 15 MHz, so the behavior of high frequency ultrasound in these materials is not as known.

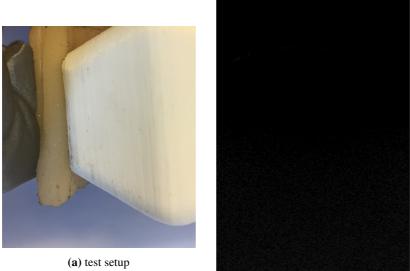
Each material has different issues regarding its use as an intra-oral pad. Polyacrylamide

gel is toxic to manufacture, while being classified as nontoxic after manufacture (Lafon et al., 2005). Gelatin has to be refrigerated before use and will alter its properties when heated up as contact with the mouth would allow for (Kondo et al., 2005). Agar is a cheap and simple gel to produce but it is a hydrophilic organic material that allows bacteria to propagate quite easily which alter the acoustic characteristics over time (Kondo et al., 2005). Agar has low toughness and is prone to fracture under load (Oates et al., 1993) Polyurethane gel has high toughness, but is more complex to manufacture than its gelatin equivalents (Kondo et al., 2005).

From the research polyurethane gel was chosen for further testing because of its stable state and high toughness, but with enough flexibility to be deformed.

Polyurethane Pad

A polyurethane pad was tested. The pad, about 5 mm thick, is reasonably flexible and can be deformed appropriately around the tooth phantom. It is observed that the pad is quite sticky, but this is more an observation and is not significant. When testing the pad with a 6 MHz probe, the material worked well as an intermediate layer, but with the 15 MHz probe, the damping effect of the material was too much, not allowing for imaging using this material. The test setup with pad and the image generated can be seen in Figure 3.5. The initial test with the polyurethane pad did not yield any promising results, and further testing of this type of material was not conducted, adhering to the agile development methodology.



·····r

(**b**) Ultrasound image

Figure 3.5: Polyurethane pad test

3.3.4 Pouch

Instead of using a rigid pad of polyurethane or similar materials, a pouch design was considered.

Three main concepts were considered:

- 1. Loose pouch: A loose pouch which could be placed in the region that is going to be imaged.
- 2. Tooth sleeve: A pouch sleeve that can be placed around the tooth and then allow for the probe to be pressed against this sleeve (Figure 3.6a).
- 3. Probe sleeve: A pouch sleeve that is wrapped around the probe and moves with the probe around the mouth for imaging (Figure 3.6b).

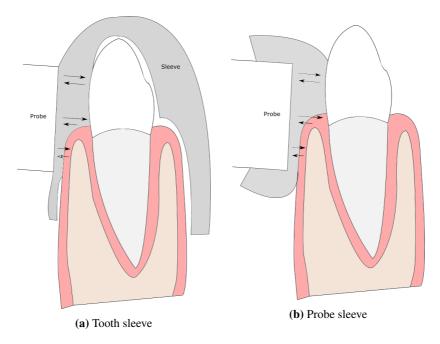


Figure 3.6: Pouch concepts

Loose pouch

The first step in developing the pouches was to find out how they could be created, and what they should contain.

Plastic welding is the method of welding together plastics by applying heat and pressure (Grewell and Benatar, 2007). By utilizing the properties of thermoplastics, which allows

materials to be bonded together, the process of heat sealing is a good option for producing the pouches. To produce prototype pouches an Audion Elektro Sealboy 235 (Elektro, 2016) was acquired, which is a manual impulse machine that produces a 3mm seal. To experiment with vacuum, a OBH Nordica food sealer was also acquired for its ability to seal while creating a vacuum with a built-in compressor. When testing the OBH Nordica vacuum sealer, it only created vacuum with special design plastic sheets which have special ridges that allows the air to leave the bag before it is heat sealed. These ridges makes the plastic rather thick and rigid. IKEA ISTAD Zip-lock bags and Soft Style 6-liter bread bags were acquired for their thinner construction. They are both made of low density polyethylene allowing for easy heat sealing.

The first test was conducted to check what effect the plastic thickness has on the ultrasound. Each of the three plastic types were cut into two squares of roughly 50 mm x 90 mm which were put on top of each other and sealed on three sides. Then they were filled with water and sealed on the fourth side. To see the effects of the plastic thickness, the tooth phantom was used as the part being imaged. Observing the interface between the plastic layer of the pouch and the plastic of the phantom, Appendix A, the difference between the different thicknesses can be seen, which show that the thinner plastic layer is better, which seems logical since the thicker plastic would reflect more of the ultrasound and be stiffer.

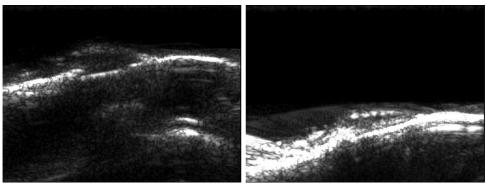
3.3.5 First in vivo images with loose pouch

The first in vivo images were done with the IKEA zip-Lock pouch measuring about 50 x 30 mm filled with water that was placed over the lower right canine and the surrounding gingiva. The probe was coated in ultrasound gel and placed on top of the pouch.

The same features as highlighted in Figure 3.3 can be seen in Figure 3.7. The tooth to the right, with the gingiva on top of the bone and down to the tooth. One of the main differences is the lack of any facial tissue above the parts being imaged. This completely black area does not reflect any sound and does not interfere with the imaging. An added benefit of this way of imaging it helps declutter the image, which makes interpreting the image easier

There are several issues when using a loose pouch. Firstly, the pouch is not stable, and does not stay in the same spot as it was originally placed. As seen in Figure 3.7, were both images are captured with the same pouch, but at different instances. The loose pouch can cause large difference in the distance from the probe and down to the area that is being imaged based on the amount of pressure and placement of probe on the pouch.

Secondly the pouch has three degrees of freedom when placed inside the mouth, as well as being able to flex when pressure is applied to it. The probe has 6 degrees of freedom, therefore getting the correct orientation to take a good image is not easy, especially when some of the tactile feedback is lost when the pouch is inserted between the teeth and probe. Minute changes to the probe can generate large differences to the image viewed on screen



(a) LRC

(b) LRC

Figure 3.7: Images of LRC with loose pouch

because the probe has a tendency to slide more easily on the pouch. The sliding is mainly caused by adding the ultrasound gel to the probe, which makes the surface extra slippery.

Based on the insight gained from this test, it was clear that the pouch makes the image clearer than when utilizing the cheek. Challenges that need to be addressed is the replicability and general stability issues regarding the use of a loose pouch.

3.3.6 Tooth sleeve

A sleeve that can cover the tooth could be a viable option to achieve a good interface (Figure 3.6a). The use of such a design would allow for the use of any probe design as long as it would fit in the mouth, as it would generate an artificial layer that would work similar to the cheek. While the loose pouch moved around a lot, the sleeve would probably be more stable, but it would still move around.

A long, rectangular pouch was created to be able to fit over the the tooth as shown in Figure 3.6a and wrapped over the tooth. An apparent issue with such a design is that the pouch has to be rather large to allow the pouch to form around. To wrap it around the tooth it cannot be filled adequately with liquid and when imaging begins all the liquid flows away from the imaging area to the other side of the tooth were no force is exerted on the pouch.

While the stability increases slightly, the solution lacked to give any positive insight and it was decided to stop the prototyping process at this stage and not continue into another Scrum session.

3.3.7 Probe sleeve

The third concept is to have the pouch connected to the probe, and the pouch moves with the probe around in the mouth. By wrapping the pouch around the probe, a good contact can be made between the pouch and probe.

The first iteration of the design is a rectangular pouch measuring 20×30 mm. This pouch is made the same way as the loose pouch, but with fringes that allows the sleeve to be held tight without touching the liquid filled pouch. This early design can be seen in Figure 3.8.



Figure 3.8: Water filled pouch with long fringe

The pouch is wrapped around the probe and makes contact with the probe head as shown in Figure 3.9a. The surface of the sleeve is tight and makes a nice, rounded surface with good contact down to the transducer. The pouch has to be kept tight against the probe while the imaging is taking place, and to make this happen a clamp mechanism was created as seen in Figure 3.9a. The clamp connects the sleeve to the probe by the fringes, keeping it stable.

When transferring this concept and design from the probe phantom and over to the real probe, some apparent flaws came to light. When rapid prototyping the probe phantom, the general shape was in focus, but not the texture and finish. The problem with this was that the real probe has a surface with lower friction and slight curvature. This meant that the clamp did not work as intended and became too loose to perform as expected as can be seen in Figure 3.10. To try to make the prototype more stable, rubber friction pad were added to increase the friction, but the clamp was still unstable. Figure 3.10 shows the probe in use with sleeve and clamp. As a rapid prototype backup, a rubber band was used to hold the sleeve in place (Figure 3.9b), which worked much better than expected and is the solution that will be used for the remaining images.



(a) Clamp mechanism

(b) Rubber band fastening

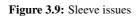




Figure 3.10: Imaging with pouch clamp

3.3.8 In vivo imaging with probe sleeve

Imaging of the interfaces with the new probe sleeve design as seen in Figure 3.11 was conducted to gain experience and insight in how the pouch behaved during imaging.

The pouches on the sleeves can be filled with different amounts of liquid, which in turn gives the pouches different rigidity and flexibility. To test how this would influence imaging, three different sleeves were created. The dimensions of the pouches are still 20mm by 30mm but filling them with different amount of liquid gives the pouches different properties. A pouch filled with less liquid will become thinner, but because the outer dimensions are the same, the liquid has more space to move around, even though there is no air in the pouch. The thickness (T) varies based on the amount of liquid. Three different thicknesses were tested, at 2 mm, 4 mm and 6mm.

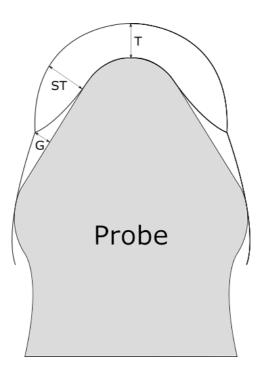
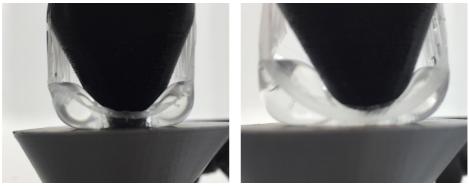


Figure 3.11: Initial probe sleeve design

The 2mm thickness combined with the pouch size meant that the thickness (T) under imaging was reduced to zero, and the side thickness (ST) increased (Figure 3.12a). Because T was reduced to zero, the tooth and gingiva surface were located right at the top of the image, and it was difficult to obtain a clear image because there was no play(wiggle room) present to find the right angle for the probe.

The 4mm thick pouch reduced its size anywhere from 2-3 mm thickness when imaging, making it easier to find the correct angle with the probe. When the thickness was increased

to 6 mm, it did not seem to yield easier imaging, and there appears to be a sweet spot for the thickness that is around the 4mm mark. An issue with the 4 and 6 mm pouches is the sideways movement caused by shear forces while imaging. As the probe is pressed against the gingiva and tooth, the inner and outer wall of the pouch does not necessarily stay in alignment. The probe has some freedom to move on the inside of the pouch, which minimizes the tactile feedback and spatial awareness of the operator, making the imaging more difficult than preferable. In Figure 3.12b the two side thicknesses are different, and the probe is pushed over to the right, even though the pouch has stayed in the same location compared to the imaging surface. This could be caused by the gap (G) between the probe side wall and the sleeve, seen in Figure 3.11, which gives the probe a bit of wiggle room even when the sleeve is wrapped tight around the probe.



(a) 2mm pouch with probe touching

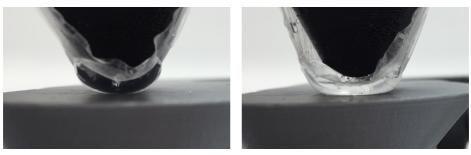
(b) 6mm pouch with movement

Figure 3.12: Sleeve issues large pouch

To mediate the issue with shear forces causing unwanted movement, the pouch was shrunk about 15 mm in length to only cover the probe tip. Because part of the issue is the gap between sleeve and probe, reducing the size of the pouch will also reduce the size of the gap, as seen in Figure 3.13b. Testing the smaller pouches yielded similar results with the same thickness pouches. Figure 3.13a shows that the probe still touches the imaging surface with the small 2mm pouch. The horizontal movement of the probe seen in Figure 3.13b is not as pronounced, but still present making the imaging challenging for the same reasons as mentioned above.

To completely remove the gap between the probe and sleeve, the pouch must be redesigned. The concept is to ensure that bottom layer of the sleeve has continuous contact with the probe, to alleviate the issue with movement. And by allowing the top layer of the pouch to be oval, the volume in the pouch that does not contribute transferring the ultrasound to imaging surfaceis minimized.

This design enables the pouch to be a natural extension of the probe, and not a foreign object that makes the imaging more challenging. In figure 3.14a shows the contact patch

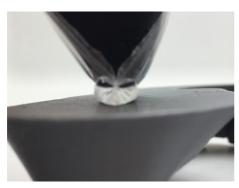


(a) small 2mm pouch with probe touching

(b) small 6mm pouch with movement

Figure 3.13: Sleeve issues small pouch

between the pouch and imaging surface is significantly smaller than on the previous designs. This small contact patch made the probe easier to place during imaging, along with more horizontal stability by reducing the size of the pouch. When force is applied, there is not an issue with liquid escaping to the side and increasing the side thickness. No gap between the probe and sleeve is observed in the latest iteration of the pouch, and this design will be used to collect the required ultrasound data.



(a) Oval pouch while imaging



(b) Oval pouch design with fastening

Figure 3.14: Final sleeve prototype

3.4 Issues during development

There were issues during development of such an importance that they were explored in greater detail to learn what the cause was, and to find possible solutions.

3.4.1 Air bubbles

When producing the final version of the sleeve prototype for imaging there were issues with using water due to the low viscosity which makes it flow out while sealing. Also, it was a challenge to not damage the water filled pouches while sealing, which in turn made the pouch leak during testing. Using the Aquasonic 100 ultrasound gel the same production issues were not present, and the pouches sealed as they should. Due to the high viscosity gel air bubbles that were trapped in the gel do not float to the surface as it would in water. During production of the pouches with gel, it is nearly impossible to remove all the air trapped in the small cavities in the outer corners of the pouches, and these bubbles will propagate and make the pouch unusable after a certain time. To combat this problem methods for reducing the amount of air in the pouches and gel solution were investigated.

In an attempt to remove the air bubbles from the gel, the method of degassing was tested. Degassing in a vacuum chamber works by lowering the pressure to near vacuum, thereby making the bubbles inside the liquid expand, and flow more easily to the surface (O'Hanlon, 2005). While this works for water, the effect it has on the ultrasound gel is not known.

Three pouches were created and filled with gel. The pouches were intentionally injected with a couple of air bubbles. While the samples made for testing would not have these obvious air bubbles, it helps in the visualization and understanding of what is happening. The pouches were placed in the vacuum chamber with one unsealed facing upwards to allow air to escape the pouch.

The first test ran for 15 minutes but did not yield any good results. The pouches were then subjected to 30, 45 and 60 minutes and checked between each run. When this did not yield any great effect, it was left in the vacuum chamber for four hours, but still without yielding any positive results. After the degassing procedure was completed the air bubbles in the pouch had grown as predicted, but not escaped as they would in water. This is probably due to the fact that the gel is too viscous, not allowing for effective degassing. Further testing could be done, by adding a vibrator to agitate the bubbles. This might lead to the bubbles having an easier time escaping. An interesting observation is that during the testing, it seemed as the top layer of gel became stiff and formed a boundary layer. The cause of this could be the combination of viscous gel and vacuum which allows the water of the top layer of gel to evaporate.

To check if there was an issue with degassing in the pouches directly, a simple dish of ultrasound gel filled with air bubbles was put in the vacuum chamber. This did not yield any different result than the degassing of the pouches in removing of the air bubbles. An interesting note is that no film was formed on the dish of ultrasound gel, which might have

something to do with the increase surface area compared to the pouch.

While removing the air bubbles did not have a simple solution, the method of administrating the gel in the pouch was changed. A syringe filled with gel without air bubbles was administered into the bottom of the pouch with a 0.8mm diameter needle. This fills the pouch from the bottom up, not allowing for air to be trapped under the gel. Another benefit of using a syringe is that it can work as a vacuum cleaner, sucking out any excess air that is trapped in the gel.

3.4.2 Artifacts

As mentioned is Section 2.2.2, there are different types of artifacts that can occur during ultrasound imaging, and this is something that was dealt with during prototyping.

One of the issues was related to air bubbles being trapped between the sleeve and the tooth-gingiva intersection. These small air bubbles caused a clear *Ring Down* effect, as seen in Figure 3.15. A fix for this problem could be to add ultrasound gel, but since this is inside the mouth this is not desirable. Instead of using ultrasound gel, the subject took a sip of water and swirled it around the mouth. This was done to test if this would make the area contain more water, which could provide a better interface. After the water swirling, no more *Ring Down* effect was observed, and has not been an issue in the later imaging.

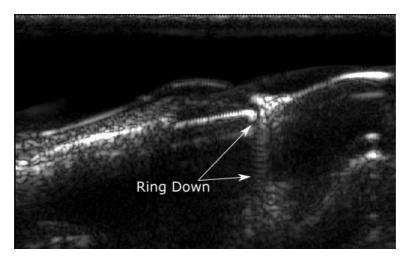


Figure 3.15: Ring Down artifact

Reflections are visible in many of the images and vary in intensity. An example of a reflection is shown in Figure 3.16. Here it can be seen that the sleeve is not making the desired contact along the tooth surface. The tooth underneath the sleeve is not visible when insufficient contact is present, and a significant reflection is seen further down in the image. While the reflection itself might not disturb the area of interest, it could be used as an indication that the pouch may not have sufficient contact. The insufficient contact can also be discovered by investigating the difference in intensity from the tooth on the left compared

to the sleeve on the right. since the tooth and alveolar bone is relative smooth reflectors, reflections will be present in the image, but because there is no interference with the area of interest it can for the most part be ignored.

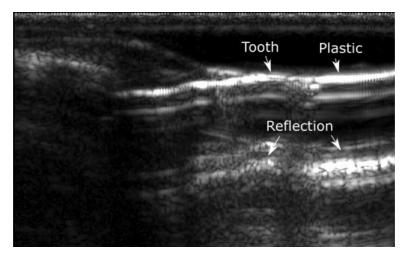


Figure 3.16: Reflection due to bad contact between sleeve and tooth

In Figure D.4 a reflection can be seen as in Figure 3.16, but here the underlying bone is still visible. While the contact between sleeve and gingiva in not sufficient to remove the reflection, the difference in *Acoustic Impedance* is low enough to allow for the imaging of the underlying bone structure.

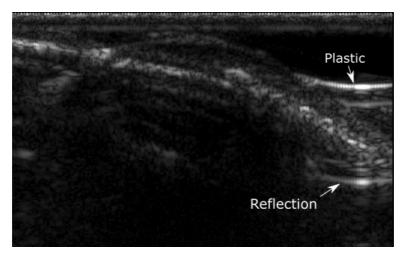


Figure 3.17: Reflection of sleeve with visible alveolar bone underneath

3.5 Probe Design

When it was apparent that the research probe was too big to fit on the lingual side of the teeth, ideas on how an intraoral probe could function started to form. While not being the main focus area of this master thesis, some of the experience gained could give valuable insight in the future design of the equipment that needs to be used. Compared to the intraoral transducer mentioned in Section 2.2.4, the transducer head needs to be oriented vertically along the tooth height to be able to image the intersections. This is shown in the early prototype in Figure 3.18.Here the horizontal part of the straw representing the handle can be seen, and the vertical straw and MDF represent the transducer head.

An apparent flaw in this type of design is that the probe needs to be able to image both the upper and lower teeth, and only the lower left and upper right side can be imaged with the probe in Figure 3.18. That is, if the straws flexible joint to rotate or flip the transducer head 180 degrees is not used. Another option would be to have a transducer array on both sides of the probe head, but this would complicate the design and make the probe more expensive. Another drawback with such a design is that a double set of ultrasound cable is needed, making the whole construction larger in size.

An idea that came up during testing is to attach the transducer head (MDF part) to a glove, so that the dentists finger and hand would be the tool that is inserted into the mouth. As the dentists already use their fingers in the mouth, this could be a natural technique. It is difficult to test the feasibility of the idea without a transducer that fits in the mouth, but theoretically it should be possible. An issue might arise when imaging the back teeth, getting the finger far enough back. Making small changes in orientation could also be a challenge when imaging the back teeth.



Figure 3.18: Early prototype of transducer design

A question that arose is how one can rotate or flip the probe head. From the imaging, it is clear that the probe angle has a large impact on the image quality. To have good control of the angle, it is desirable that the adjustment can happen in small increments for the complete 180 degrees. During an ideation session involving members of TrollLABS, different concepts were generated, utilizing different mechanisms.

The transducer head could be manually moved to the desired position before imaging starts. This could be done by friction fitting the head to the handle, with enough freedom to rotate, or a locking bar could be operated by the user to ensure a complete lockup after adjustment. This manual adjustment was tested with the simple prototype in Figure 3.18. While simple, issues arise if it necessary to change the angle while imaging. Because of the size limit of the mouth opening, maneuvering the prototype probe to the right angle is a challenge. Being able to adjust the probe while imaging, a continual optimal angle can be achieved between the probe head and surface being imaged.

Being able to adjust the probe while imaging is ongoing could make the process faster. Furthermore allowing for small adjustment could make the imaging more comfortable for both patient and practitioner. Utilizing a mechanism such as worm drive or bevel gear will allow for rotation of the transducer to solve the problem. Keeping in mind the size requirements of about 20 mm from Section 3.1, it all must be in a relative small package.

A rotating transducer prototype was created to understand potential issues that could arise from such a mechanism, as can be seen in Figure 3.19. This prototype has a servo motor located in the handle, with a 3mm shaft running to the gearbox located in the head of the probe. The gearbox consists of two bevel gears, which transfers the rotation 90 degrees to the transducer head. As seen in Figure 3.20 a channel runs along the shaft, allowing the ultrasound cable to be connected to the probe head.

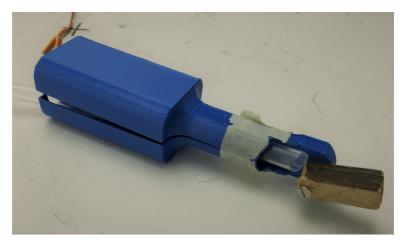


Figure 3.19: Rotating probe prototype



Figure 3.20: Rotating probe prototype internals

3.5.1 Testing tilt function

While this was mainly a focused prototype to test the tilt movement and how this could be used, it also highlighted aspects of size and cable management issues that would classify it as a comprehensive prototype as mentioned in Section 2.3.3. To get feedback and insight on how it felt in the mouth, the prototype was tested on people at TrollLABS. The feedback is both from the test subjects and the author, who used the probe during the test.

While the transducer head can rotate, the entire probe needs to rotate when transitioning from imaging the right to the left lower side for example. This means that if any tilt controls were to be added to the handle, it has to be ambidextrous to allow for a similar experience throughout the imaging process. When testing the prototype in the mouth, the size was a bit big to comfortably be used. But as a proof of concept, the tilt mechanism worked, and minimized how much the whole probe had to be moved while navigating from the front to the back teeth. Utilizing a gearbox and motor in handle works and could be sized down sufficiently to fit in the mouth. An option would be to find a small motor that could fit in the head itself, making the system less complicated and requiring less parts. The issue with this solution would be finding a motor small enough with low speed and high torque to be able to rotate the transducer head.

The main issue that became apparent when you start rotating the transducer head, is the coaxial cable that is needed to transport the signal. A conventional coaxial cable and joint can not be bent enough to allow for a small form factor during a 180 degree rotation. Commercial transducers have a similar cable connection to that of the Medistian probe, and a new connector between the probe and cable would be required to fit the requirement for 180 degree rotation.



Results

The results are split into three section. The sleeve developed, the images and the feedback from radiologist. This section covers only the results whereas the discussion is in chapter 5

4.1 Sleeve

The final pouch and sleeve design can be seen in Figure 4.1. It is constructed of clear low density polyethylene, a thermoplastic, which allows heat welding to be used as production method.

The pouch base is designed to cover the transducer head and is 7mm x 30mm. The top layer of plastic is heat sealed to be shaped as a half circle and is designed to act like an extension of the probe head. From the pouch, the sleeve runs 60 mm to either side allowing for the fastening of the pouch to the probe. The pouch is filled with gel and sealed to be air free. During manufacturing it is manually filled to be full enough to not allow the probe to touch the imaging surface during imaging. For reference, the procedure required to make the pouch is explained in Appendix E.



(a) Pouch side view



(**b**) Pouch curvature view

(c) Pouch top view



4.2 Images

The final images show both the gingiva, alveolar bone and tooth (Figure 4.2). The dark area above the gingiva and tooth is the pouch that follows the contour of the dental structure. Reflections can be seen below the area of interest.

In total, 13 teeth were imaged with the last pouch design from Section 4.1. Seven images of the lower right facial side were imaged starting with the central incisor going all the way back to the second molar. On the upper right side 6 teeth where imaged starting with central incisor and back to the first molar. The second molar was not imaged on the upper teeth because of space restrictions. All the final images can be seen in Appendix C

All images are taken of the same person, utilizing the ultrasound equipment and settings detailed in Section 3.2.

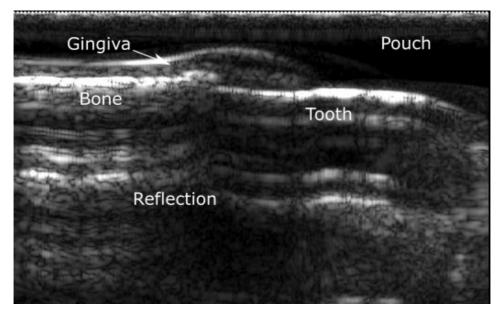
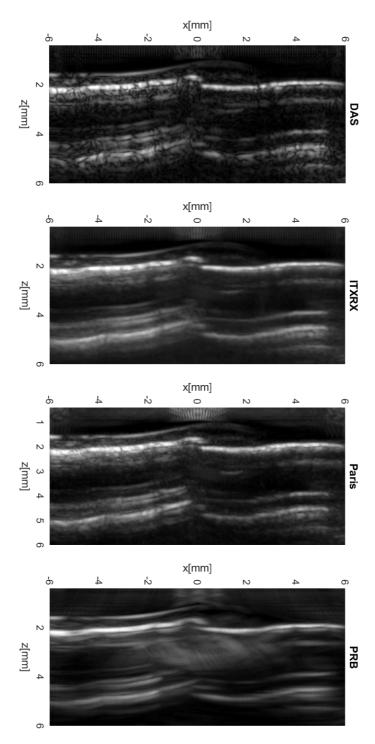
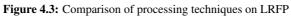


Figure 4.2: LRFP taken with sleeve

Raw ultrasound data was recorded for the LRC, LRFP, LRSP and LRFM utilizing the same setup as mentioned above. Utilizing the algorithms outlined in Section 2.2.3 the data was post processed for analysis. Figure 4.3 show the result of the LRFP. The rest of the post-processing results can be found in Appendix D.





4.3 Specialist feedback

To complete the product development cycle, the final prototype and images presented in section 4.1 & 4.2 were shown to Mats Säll, a jaw and facial radiologist with ties to TkMN. He was given a basic introduction to the ultrasound equipment used during the testing, as well as a live demonstration of imaging with the sleeve to show how to properly align the probe, how to adjust the angles and what effects this has on the image. The following are Mats Säll's views and thoughts during the session.

Mats Säll observed the rather fine motor function required to maneuver the probe into the correct angle, and compared the training and experience required to effectively acquire these images to the training and experience required to perform the probing of periodontal pockets. Even though they are different skills, his view is that it still requires practice to be able to do the imaging, and he questioned how much easier the imaging would become.

Concerning what can actually be viewed on the image Mats Säll talked about how the periodontal pocket can protrude down into the periodontal ligaments between the tooth and alveolar bone and expressed concern about this not being able to be viewed on the images. His view is one that this technique at its current stage could not replace the manual probing. He did think of some use cases that these images could be used for in its current stage, which were measuring of marginal bone loss, location of cemento-enamel junction and gingiva thickness were good parameters that could be measured with this technique.

Mats Säll's general impression is that of a technology and procedure that can provide new insight and a possible use case in dentistry is worth investigating further. He liked the idea of a noninvasive solution that can acquire detailed images without radiation.

Chapter 5

Discussion

5.1 Image quality

When imaging from outside the teeth, significant damping effects from the cheek made the boundary interfaces less intense and difficult to interpret. By developing the sleeve, the images obtained were of a much better quality, making it possible to easily distinguish the different intersections and boundaries.

Artifacts were highlighted, such as the Ring Down effect caused by trapped air bubbles. This issue was solved by applying water to make the mouth moist. The effectiveness of this step led to it being part of the standard procedure during imaging. The low viscosity of water does not make it ideal for such an application and a ultrasound gel would be better. Current gel is not meant for intra-oral use, and while the gel is not harmful, it does not taste good and improvements to the gel should be made if it is going to be used intra-orally.

Because of the hard surfaces of enamel and bone with large acoustic impedance, there will be reflections from these boundary layers. This is not a big issue, because we know the sound waves will not pass through these boundaries. All reflections that are underneath this layer is not of interest, as it is know that they are artifacts and not actually structures beneath the enamel and alveolar bone. To an informed user, these elements can be ignored with no impact to the selected imaging area.

When a boundary layer is at 45 degrees, the Angle of Incidence will be 90 degrees and reflects the sound perpendicular to the transducer thereby no sound returns to the transducer. This will cause the boundary layer to not show up on the image. This means that the image can change based on the angle of the probe if there are multiple sections of boundaries at 45 degrees the practitioner has to choose what section to focus on. This is all about adjusting the angle to to get the right image for the area that is being imaged. Therefore, in some cases, the practitioner has to sacrifice the image quality of one section to better the image quality of another. Four of the final ultrasound images were post-processed using ITXRX, Paris and PRB algorithms (Section 2.2.3). A slight improvement in the images can be observed compared to the standard DAS image (Appendix C). For example, the PRB gives a slightly better signal, with better signal-to-noise ratio(SNR). Even tough a slight improvement in the image is observed, with more defined boundaries, it is not a leap in quality. All information can be viewed from the original DAS image. This means that the major factor in producing quality images is not the image processing, but the real-time imaging. The probe sleeve, combined with the correct technique and a skilled operator provides significant increase in image quality.

From the images gathered there are different parameters that should be possible to measure. The CEJ, or cemento-enamel junction can be seen in Figure 5.1. From Section 2.2.1 it can be seen that the enamel and cementum have different acoustic impedance, and should reflect the ultrasound differently enough to have a visible CEJ. The gingival thickness is measurable with the ultrasound image. Allowing for simple thickness measurements without using probing or CT scanning can assist in post-surgery observation of guided tissue regeneration, which is now measured by invasive probing (Anderegg et al., 1995). The bone level can be measured from the CEJ and down to the alveolar bone. This can convey the marginal bone loss without having to resort to x-ray imaging.

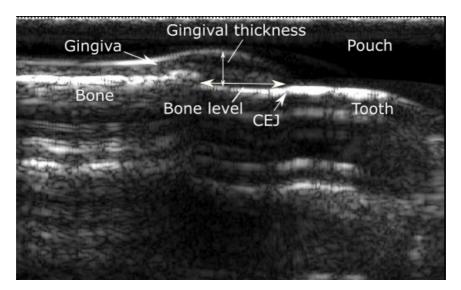


Figure 5.1: LRFP measurable parameters

5.2 User experience and feedback

When imaging the intersection with a probe, the main aspects is to generate good contact with the probe. It was discovered during the development that the actual probe location is crucial to get images with satisfactory quality.

Ultrasound images is not used in the dental industry and because of this dental practitioners do not have any in depth knowledge about the technology or experience interpreting ultrasound images. There is a learning curve in being able to acquire reliable images fast. An usual error made by new users is to either not applying enough pressure to actually get the desired image. When not acquiring the required image, it might be logical to think that the probe is not pressed hard enough against the imaging surface and to just apply pressure until the correct picture appears. This is not necessarily always the issue. The placement of the probe before imaging plays a big role in acquiring the correct image, along with finding the correct angle. All these factors has to be taken into account during imaging. The final pouch design has a small contact area that actually connects the probe to the gums, thereby making it easier to visually confirm that the probe is in the correct location compared to early prototypes were the pouch covered a bigger area.

When the correct location is found for imaging, rather fine motor skill is needed to adjust the probe to get the exact image. While this can take some time to master, it becomes quite natural. In the same way that the probing is hard to replicate, the ultrasound imaging is also difficult to replicate do to the placement variations between imaging. The difference is that this technique is not as dependent on exact force application to acquire the correct measurement, giving a larger margin of error. From the experience gained through this thesis, it is a probable assumption to assume that images done by different people to the same area will give smaller variation in for example gingiva thickness than with invasive probing, given the invasive nature of this method.

Currently the distance from the top of the gingiva down to the alveolar bone can be manually stipulated based on the ultrasound image. This could be done by having a touch interface where the practitioner could touch the intersections, and the distance is automatically calculated. This step is also a good candidate for machine learning, where it could be automated to the point that it automatically detects the features that are of interest, and measures the distance. Such a system would be desirable to relive the workload of the dentist, and minimize possible errors that could occur when the dentist is manually selecting the data points.

5.2.1 Probe Design

Ideas related to possible probe designs using rotatable transducer head were considered and prototyped. Even though the prototype had the form of a probe, it lacked the imaging function, making it difficult to draw a conclusion on whether a rotatable head is actually necessary or a over complicated and over engineered solution to a problem that might not exist. From the initial testing it showed benefits of allowing small adjustments to be made, which could be nice but is something that is not known.

A benefit of having a 180 degree rotatable head is that it could serve as a multipurpose probe that could image other areas of the mouth than just the gingiva making the probe

more flexible. But utilizing a rotatable probe will cause issues as experienced with the ultrasound cable. Being a rather stiff cable this could be a potential issue, or at least a engineering challenge. To further understand the issues regarding the probe design experimenting with the Medistian probe mentioned in Section 2.2.4 could have been done, but the probe arrived to late in the thesis to begin experimenting with intra-oral imaging. Having a real ultrasound probe that could be tested inside the mouth and on the lingual side of the teeth could give valuable insight in the need of a rotating probe or if a static, perpendicular probe head is the best solution.

5.3 Limitations

When working with a new application of an existing technology limitations are to be expected. The main limitation concerning technology was the probe size. Working with a standard research probe that is not design for intra-oral use makes the imaging more challenging, especially further back in the mouth. This also meant that the lingual side of the teeth could not be imaged, leaving this as an unknown. The structure of the facial and lingual side of the teeth are not that different, and imaging the facial side gave the information needed for this stage in the development. Final images where obtained of 13 teeth, giving a good representation of what results can be expected.

When periodontitis develops the periodontal pocket propagates down into the periodontal ligament. The main issue with this is that from the imaging location used the alveolar bone is in front of the periodontal ligaments and reflects all sound. This means that when the pocket is propagating into the periodontal ligaments it cannot be imaged with the proposed setup. For this a single element ultrasound setup as mentioned in Section 1.3 could be used. This solution has a vast amount of potential pitfalls regarding reflections, scattering and air bubbles that can lead to false positives which is one of the reasons why this type of probe is not commercially successfully.

A major limitation in regard to the potential usefulness of this technology is that it has not been tested on actual patients that have periodontitis. Without these tests there is no way of knowing what these images can potentially provide of useful information compared to a healthy subject. Because of lengthy application process for clinical trials that has to go through REK (Regional Committees For Medical and Health Research Ethics), the trials could not be conducted in the time period of this master thesis. A clinical trial is planed and will be covered in future work (Section 6.1).

Chapter 6

Conclusion

This master thesis started out with the goal of enabling imaging of the periodontium utilizing ultrasound. As a starting point the required technical knowledge was acquired from both literature and experts in both dentistry and ultrasound. Following a agile development process employing the latest equipment in ultrasound imaging a system was developed and tested to image the dental structure. It has been shown that the key to ultrasound imaging of the dental structure is not about image processing, but the quality of the initial image. Utilizing the proprietary probe sleeve developed in this master thesis clear images of the dental structure were obtained. The imaging is non-invasive, painless and fast, but does require training and experience. While the periodontal pocket cannot be imaged using this setup, there are many parameters in the dental structure that become easier to visualize. Utilizing ultrasound has shown promising results and the technology should be developed further.

6.1 Future work

The DOFI (Declaration of Invention) was submitted to TTO (NTNU Technology Transfer) in February of 2018. TTO consider the need for such a imaging solution is present and that several clinics would be interested in a ultrasound imaging solution. They also high-lighted the scientific value of exploring ultrasound in dental imaging. While TTO found that patenting the solution might not be possible, they encouraged to go forward with the work and apply for national research grants.

While the author will not continue with the project after the master thesis, it has been decided to start a small-scale research project to conduct a initial clinical trial to better investigate the potential of this imaging technique. This work will be conducted by TkMN and Department of Circulation and Medical Imaging with further assistance from Troll-LABS when the need arises.

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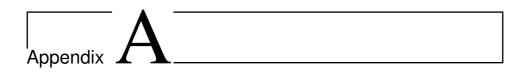
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Pouch thickness

In Figure A.1 the pouch can be clearly seen as the top white layer that covers the entirety of the tooth phantom. The plastic is not flexible enough to fill the hole in the middle of the image, but runs right over it.

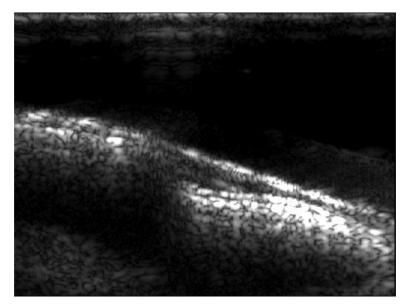


Figure A.1: OBH Nordica vacuum bag

In Figure A.2 the IKEA ISTAD Zip-Lock bag can be seen, but not as clearly as the vacuum bag in Figure A.1, the pouch does not go into the hole in the middle of the image, but ultrasound gel used on the outside of the pouch to create a good connection, filling this gap and allowing for the surface underneath to be imaged. The Soft Style 6-liter bread bag in Figure A.3 shows the least reflection of the plastic material of the three tested.

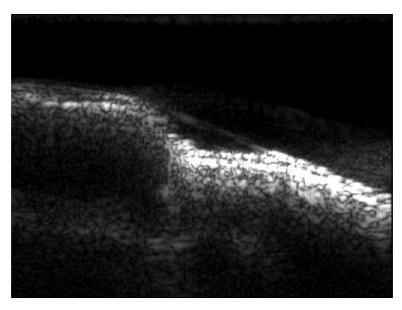


Figure A.2: IKEA ISTAD Zip-lock bag

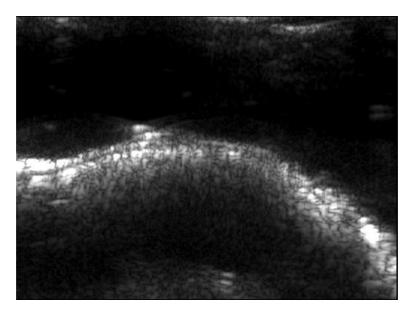


Figure A.3: Soft Style 6L bread bag

Appendix B

Outside mouth ultrasound images

As can be seen from Figures B.1 - B.4 The distance from the top of the image, where the prob is located and down to the gingiva, bone and tooth is gradually increasing as further back in the mouth the tooth is located. This leads to more damping, and makes the placement of the probe even more difficult to get an clear image.

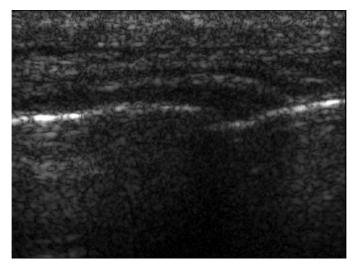


Figure B.1: Outside mouth Lower Right First Premolar (LRFP)

Both the LRFP and LRSP has all parts viewable to the naked eye and where not to difficult to locate with the probe.

When you move to the back teeth, the alveolar bone and tooth is still visible, but distinguishing the the gingiva is becoming more difficult. The increased distance down to the desired imaging area means that the probe placement is more sensitive, and as a result more difficult to image.

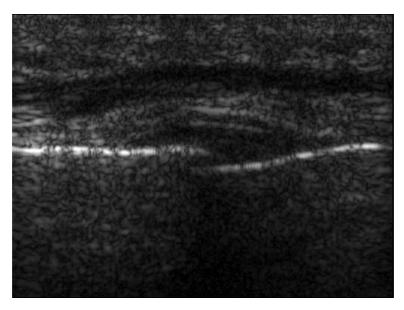


Figure B.2: Outside mouth Lower Right Second Premolar (LRSP)

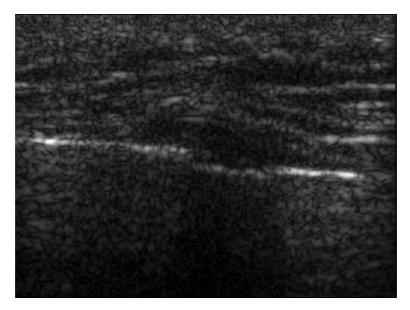


Figure B.3: Outside mouth Lower Right First Molar (LRFM)

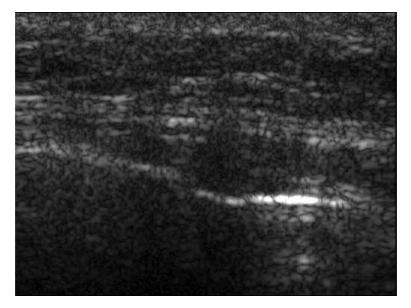
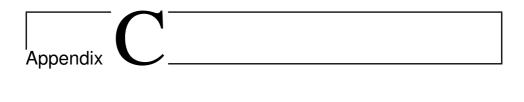


Figure B.4: Outside mouth Lower Right Second Molar (LRSM)



Final images

C.1 Lower Right

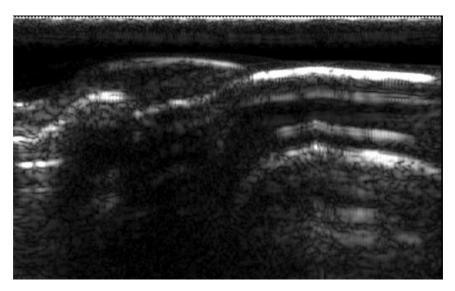


Figure C.1: Lower Right Central Incisor (LRCI)

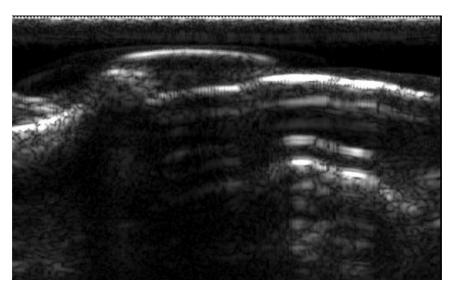


Figure C.2: Lower Right Lateral Incisor (LRLI)

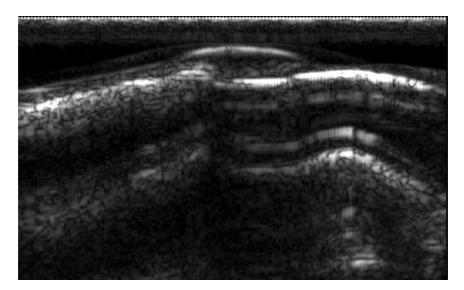


Figure C.3: Lower Right Canine (LRC)

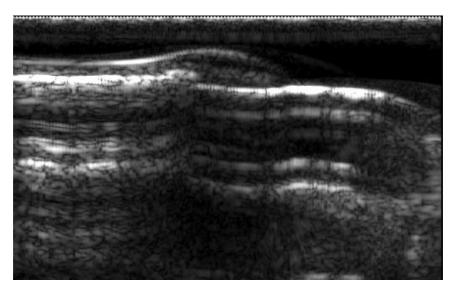


Figure C.4: Lower Right First Premolar (LRFP)

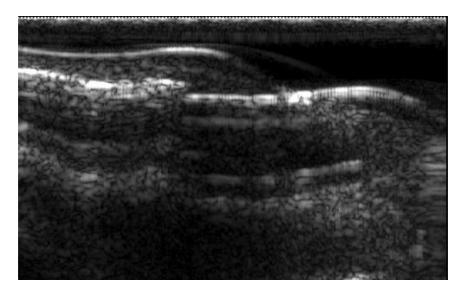


Figure C.5: Lower Right Second Premolar (LRSP)

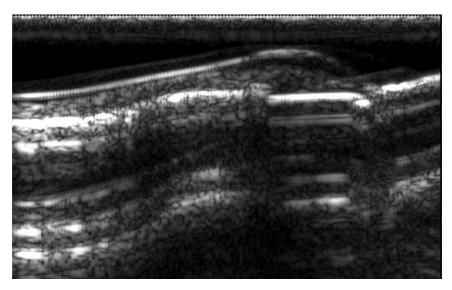


Figure C.6: Lower Right First Molar (LRFM)

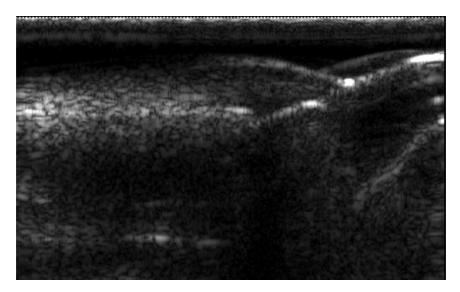


Figure C.7: Lower Right Second Molar (LRSM)

C.2 Upper Right

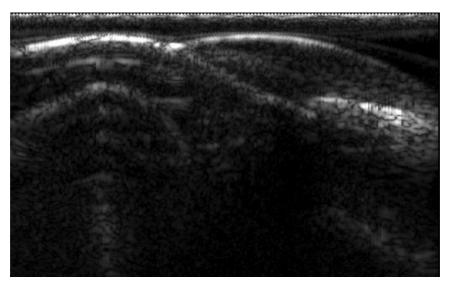


Figure C.8: Upper Right Central Incisor (URCI)

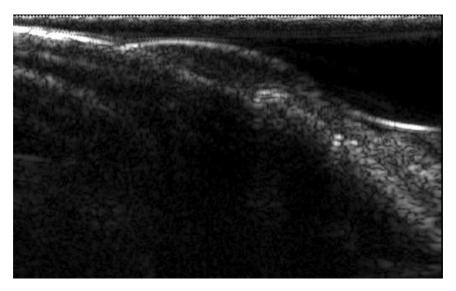


Figure C.9: Upper Right Lateral Incisor (URLI)

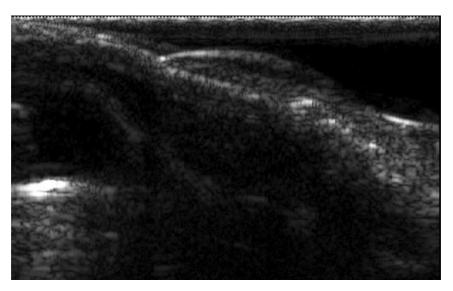


Figure C.10: Upper Right Canine (URC)

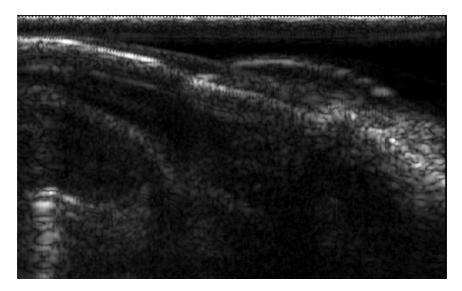


Figure C.11: Upper Right First Premolar (URFP)

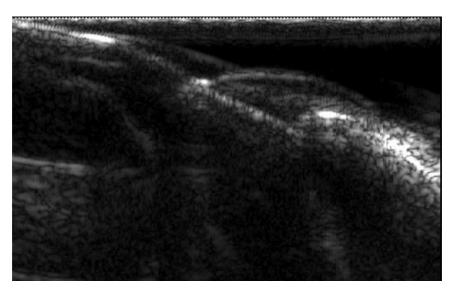


Figure C.12: Upper Right Second Premolar (URSP)

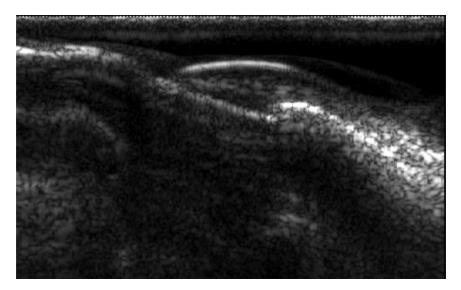
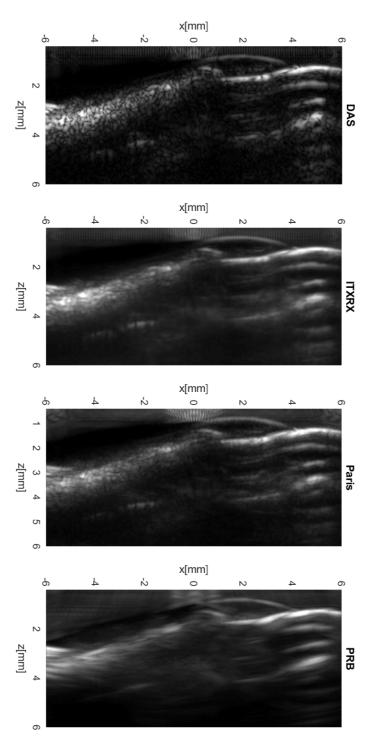
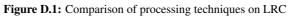


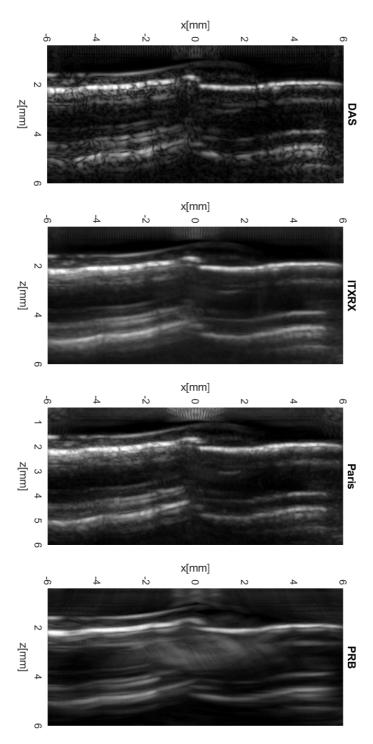
Figure C.13: Upper Right First Molar (URFM)

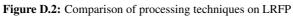


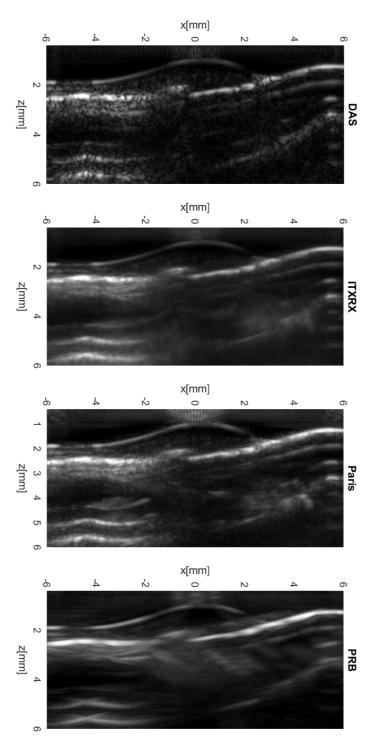
Comparison of processed images

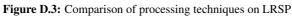


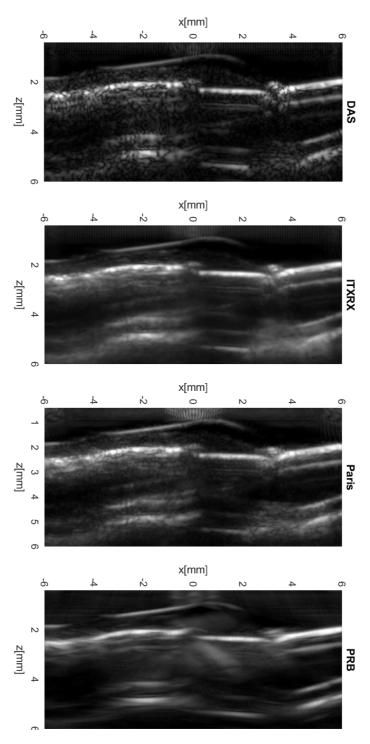


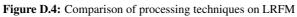












Appendix E

Creating the sleeve

This is a step by step view of creating the final sleeve for reference

Start by cutting out two 70mm x 180mm pieces of thermoplastic. Used in this master thesis is a Soft Style 6-liter bread bag where you can cut out both sheets at the same time. Seal one side of what will be the pouch (Figure E.1a). The second seal is to be done parallel with the first, but with the top sheet 2-3mm loose, as can be seen in Figure E.1b. The third seam is added by folding the pouch in half with baking paper in between the halfs to ensure that the curvature is preserved and the sleeve is not melted together (Figure E.1c. Liquid is added to the pouch and if ultrasound gel is used, from the bottom with a syringe to minimize air bubbles. The fourth end is then sealed. Make sure the last seal is made by pressing out some of the liquid or air will be sealed in the pouch.



(a) First vertical seal



(b) Second vertical seal with oval upper layer



(c) Third horizontal seal



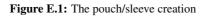
(d) Filling pouch with gel



(e) Pouch filled



(f) Pouch sealed





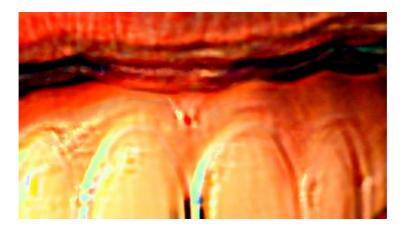
Pre-Master Thesis



Norwegian University of Science and Technology

PRE-MASTER THESIS

Technologies and concepts that can aid in the identification and classification of periodontal disease



Student:

Håkon Sørum Bakken

Supervisor:

Martin Steinert



<u>Abstract</u>

The aim of this pre-master thesis is to establish knowledge on how the identification and classification of periodontal disease can be performed in preparation for a master thesis. The current methods of probing the periodontal pockets is not replicable in a way suitable for medical studies.

Principles from agile product development and design thinking is used to achieve a broad specter of concepts that might lead to new discoveries. By choosing the most promising concepts through this process we ensure best possible prerequisites to later work. While utilizing physical and analytical prototypes these concepts are validated to ensure the plausibility of the concepts.

Technologies covered in detail are light/camera imaging, tactile imaging, blood flow imaging, radarand ultrasound imaging. Based on information gathered from the prototyping the light/camera imaging, tactile imaging and ultrasound seem to be promising concepts. While ultrasound imaging can provide high resolution 3D images, the light/camera imaging can provide useful information regarding the level of periodontal disease with relatively cheap and simple technology. This is the technology that will be explored further in a master thesis.

<u>Preface</u>

This project thesis is written by one master student at the Department of Mechanical and Industrial Engineering at the Norwegian University of Science and Technology

The author is writing his thesis in collaboration with Tannhelsetjenestens kompetansesenter Midt-Norge (TkMN), and this project thesis will serve as a foundation for the master thesis. The author wants to thank Martin Steinert for supervising the project along with Achim Gerstenberg and Carlo Kriesi.

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1 Introduction

The leading cause of tooth loss in adults is due to periodontal disease, leading to the degradation of the gingiva and bone supporting the teeth (Lynch et al., 2006). In Norway, around 8 percent (Lyshol and Hånes, 2016), of 35-year old's have periodontal disease, which could lead to tooth loss if not treated properly. Identifying periodontal disease starts with a visual control, followed by intrusive measurement of periodontal pockets.

Periodontal pockets are traditionally measured with a periodontal probe, which is a thin piece of metal, where results are not easily replicable between practitioners (Renatus et al., 2016). More advanced probes have been introduced, but because of their exponential cost increase, they have not seen widespread use (Ss et al., 2011). Almost all newer probes are based on the same principle of intrusive measurement with probing of the sulcus, causing discomfort to the patient and possibly more damage to the gums.

In a clinical environment, advanced 3D scanning equipment based on CT technology have been developed. Along with the high cost, the space required makes this a very static system for in house examination (Mohan et al., 2011).

Tannhelsetjenestens kompetansesenter Midt- Norge (TkMN) is interested in a new, portable measuring technique that delivers replicable results in a compact package that can be used in the field, in for example medical studies. The system should also be fast to use, as the current methods only takes 2-3 minutes. Visualizing these measurements is also of importance, where the end goal is 3D representation of what surrounds the teeth.

To achieve this goal a study of current technology and possible technologies will be presented. The purpose of this study being:

To investigate technologies that can aid in the identification and classification of periodontal disease in a non-invasive, replicable manner.

To gather information on the topic, the author has interviewed a periodontics expert and done a literature study on periodontal disease. This paper is divided into three main sections, following the work the author did in a "specify-ideate-validate" format. First section is a literature study to further understand the field of periodontics and what technology is available, as well as product development theory to assist in the development process. Section two is an ideation section based on design thinking principles where the author diverges to find as many possible solutions as possible, which again converges in section three in specific concepts and prototypes to test the validity of the concepts. The last main section is the prototyping section, consisting of information on the technology, and prototyping utilizing both analytical and physical prototypes.

Based on these three sections the author will come with a recommendation to feasible technology that will be become the basis for the authors upcoming master thesis.

2 Background

2.1 Anatomy of the periodontium:

To know what to measure an understanding of the anatomy of periodontium is needed. A tooth is suspended in the alveolar socket and connected with collagen fibers. Its these fibers, known as the periodontal ligaments, that are connected to the alveolar bone and cementum, the outer layer of the tooth root. These elements are collectively called the periodontium (Williams 1990). Covering these structures are the gums, gingiva (along with some oral mucosa).

In its healthy state, the gingiva is nice and flush with the teeth, covering the alveolar bone and tooth root, just above the cemento-enamel junction, which is the junction between the tooth crown and root.

When discussing periodontal diseases, it is usually divided into the ones that involve only the gingiva, and the ones that involve destruction of the underlying periodontium.

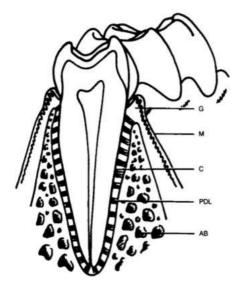


Figure 1 The periodontium consists of the gingiva (G) and alveolar mucosa (M) that covers the alveolar bone (AB), periodontal ligament (PDL), and cementum (C). (Williams 1990)

2.2 Periodontal disease:

Most adults have a mild form of periodontal disease, and is one of the major causes of tooth loss (Lynch et al., 2006).

Gingival diseases is an inflammation of the gums, or gingiva, caused by a variety of reasons including pregnancy, prescription drugs and diabetes or general hygiene issues. Gingivitis, the most common form is not considered as troubling as the periodontal diseases, because no permanent damage is caused. It is generally found in places where it is difficult to clean(Hansen, 2004) and if the inflammation is left unattended over time, it extends into the periodontal ligaments and alveolar bone. This leads to the destruction of the bone, and the periodontal disease is classified as periodontist. Periodontist lead to the loss of connective tissue and the retraction of alveolar bone, this causes pockets to be formed, known as the periodontal pockets. As the periodontal disease progresses, the bone line retracts more and more, and the teeth become looser and looser, and eventually fall out if treatment is not initiated.



Figure 2 X-ray of healthy teeth and x-ray of teeth with severe periodontal disease (Williams 1990)

2.3 Examination:

Identification of gingivitis is mainly done visually, identifying the gums for a color change and if the gums are more prone to bleeding than a healthy area of the gums. To identify gingivitis different indexes has been developed, as an example the Gingival Index is shown in Table 1. The main parameters are color, consistency, form and bleeding. The examination and diagnosis of periodontitis must be done by a dentist where he employs special tools to examine the patient. The diagnosis of periodontal diseases requires 3 main parameters be recorded: Probing depth (PD), Attachment Loss (AL), and Bleeding on Probing (BOP). (Renatus et al., 2016) These values are recorded from 2 to 6 times around one tooth for all teeth.

Criteria for the Gingival Index System (GI)

- 0 = Normal gingiva.
- 1 = Mild inflammation slight change in color, slight oedema. No bleeding on probing.
- 2 = Moderate inflammation redness, oedema and glazing. Bleeding on probing.
- 3 = Severe inflammation marked redness and oedema. Ulceration. Tendency to spontaneous bleeding.

Each of the four gingival areas of the tooth is given a score from 0-3; this is the GI for the area. The scores from the four areas of the tooth may be added and divided by four to give the *GI for the tooth*. The scores for individual teeth (incisors, premolars and molars) may be grouped to designate the *GI for the group of teeth*. Finally, by adding the indices for the teeth and dividing by the number of teeth examined, the *GI for the individual* is obtained.

Figure 3 Gingival Index (Hansen, 2004)

2.3.1 Probing Depth:

Probing Depth is the depth of the periodontal pockets. In a healthy periodontium, the pocket is referred to as the sulcus, and is up to 3 mm deep.(Lynch et al., 2006). Patients with gingivitis, have pockets up to 4 mm deep and for periodontitis the pockets can be even deeper.

2.3.2 Attachment Loss:

Attachment Loss, also known as clinical attachment level is the measured position from the cemento-enamel junction to the base of the pocket. As the disease progresses and the gums retract around the tooth the attachment loss will become greater.

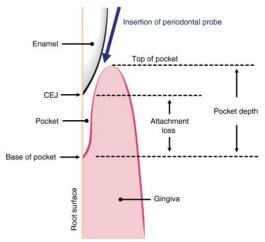


Figure 4 Diagram of periodontal pocket in a patient with periodontits (Preshaw et al., 2012)

2.3.3 Bleeding on Probing (BOP):

When probing, bleeding can occur where the probe touches or penetrate the tissue in the base of the pocket. A general rule is that if it does not bleed, there is no periodontal disease, but bleeding does not mean that there is periodontal disease, but further examination should be performed.

2.4 Current Measuring Devices

2.4.1 The manual/Williams probe:

The most common used probe is the manual Williams probe, shown in Figure 5. The probe is a rod with a diameter of 0.5 mm, and marked along its entirety with distance measurements from the probe tip (Vartoukian et al., 2004).

When the probe is inserted into the periodontal pocket the dentist should apply a constant load of 0.25 N to get a correct reading. Applying the correct amount of force requires training and experience. Dentists will also calibrate themselves on a scale before performing the measurements to get a feel for the force required.



Figure 5 Williams probe (Renatus et al., 2016)

In a broad study, like the Hunt study, the probe is divided into sections identifying the level of periodontits the patient has instead of exact measurements, because of the more statistical nature of the measurements.

2.4.2 Florida Probe

The Florida Probe from 1988 measures the depth of periodontal pockets by a displacement transducer (Gupta et al., 2015). Coil springs in the handle allow the inner probe to ride up and down inside the sleeve (see Figure 6), giving constant pressure of 15 grams on the periodontal pocket. When the edge of the sleeve touches the gingiva, the dentists depress a foot pedal to automatically send the measurement data from the wired probe to a computer.

Studies have shown that the controlled force of the Florida Probe reduces the pain of the patience, but the tactile feedback, angle of attack and insertion point is more difficult to determine with this probe. Compared with a manual probe it delivers more consistent results (Gupta et al., 2015). There are many similar probes that are comparable to the Florida Probe, one being the PA-ON probe which is wireless, but has many of the same drawbacks as the Florida Probe (Renatus et al., 2016).



Figure 6 Florida Probe (Gupta et al., 2015)

2.4.3 UltraSonographic probe

Uses ultrasonic waves to detect and map the upper boundary of the periodontal ligament. The probe head is an ultrasonic transducer tapered down to 0.5 mm, the approximate thickness of the periodontal ligaments depicted in Figure 1. A narrow beam of ultrasonic energy is transmitted between the tooth and bone, from the probe which is held on top of the gingiva close to the tooth, known as the gingival margin (Ss et al., 2011). Water needs to be applied near the probe to ensure proper transmission of the ultrasonic beam. The results from this type of probe can be compared with what you get from a invasive probe, but it is likely able to provide additional information because of secondary echoes from the ultrasound. This technology is still being developed and is currently more focused on research and highly specialized practitioners (Ss et al., 2011).

2.4.4 Cone Beam Computed Tomography

CBCT is the most advanced technology design for head and neck imaging also used in periodontics applications. It is a form of Computed Tomography (CT) based on X-ray radiation imaging, but require lower dosages of radiation compared to a conventional full body CT scanner (Mohan et al., 2011). 3D images are generated by taking 360 degree images of the patient's head. Combining these images generates an 3D image, where the resolution depends on the amount of pictures taken (Mallya, 2016). This leads to the higher resolution images to give the patients higher dosages of radiation, so the use should be limited.

2.5 Discussion of current technology

Based on the information above and the review done by (Ss et al., 2011) a comparison of the different technologies can be performed. There are other probes on the market, most of them in the same category Florida probe, and have about the same characteristics. Most probes rely on physical penetration of the pocket, which can cause discomfort and measurement errors because of possible buildup and inconsistencies. It is clear that a solution should not require the penetration of the pocket, and in that way be an noninvasive measurement technique. This shows that the need for such a measuring device is present, and would be of great interest to the field of periodontics.

3 <u>Theory</u>

3.1 Agile Product development

Agile software development is a development method established to develop computer software in an ever-changing market. While the agile methods is mostly used in software development, the great effect it has had on productivity has led to the introduction of agile practices in product development (Dybå and Dingsøyr, 2008).

Some key values presented in the agile method are (Abrahamsson et al., 2002):

- Iterative, rapid cycles
- Adaptive and rapid changing requirements
- Collaborative working style
- Convergent approach to minimize risk

Being able to adapt to everchanging requirements are crucial, because of the chaotic nature of product development. In early stage product development the future is unknown and new requirements can make themselves present during the development process. These adaptive requirement leads to a convergent approach, where every step of the cycle has been tested, and all the best aspects converge down to the best solutions. This minimizes the risk for big setbacks in later stages of the product development (Highsmith and Cockburn, 2001).

A collaborative working style is important to share experiences with others, to receive feedback and build on the collective knowledge base.

Iterative, rapid cycles aid in the progress of the project, and aids in the ability to adapt to changes and the converging of solutions. An agile method to achieve Iterative, rapid cycles is Scrum, which will be covered in more detail.

3.1.1 Scrum

The Scrum approach has been developed to oversee the development process. It enhances the iterative and incremental approach in product development, while assuming that the development process is unpredictable and complicated (Schwaber, 1997).

Product Backlog Sprint Backlog Sprint Working increment of the software

The Scrum is in short divided into a planning- and a sprint phase. Where the planning phase is represented with the



Product Backlog. This quantifies the functional requirements and what needs to be investigated further. The sprint phase is a cyclic phase where each cycle can last from 1 week to a couple of months, depending on the project. The sprint backlog represents what the current sprint is focusing on solving or implementing of functionality into the prototype. When one sprint is finished, the current sprint backlog should have a working solution, and this knowledge is used further in the

development cycle. If new questions or interesting ideas are realized during a sprint, it can be added to the backlog for further investigation.

3.2 Prototyping

To facilitate Agile product development the concept of prototyping is introduced. (Ulrich and Eppinger, 2012) define a prototype as *"An approximation of the product along one or more dimensions of interest."* This includes both physical and non-physical prototypes, but definitions also goes further in defining a prototype as a tangible artifact, and not abstract descriptions (Buchenau and Suri, 2000). A prototype addresses specific questions developers have during development.

(Ulrich and Eppinger, 2012) classifies prototypes along two dimensions: analytical vs. physical and focused vs. comprehensive. A focused prototype focuses on a certain attribute of the prototype, while a comprehensive prototype combines various aspects or functions. A physical prototype focuses on the form and function, giving a proof of concept. An analytical prototype is not physically built, but give insight with simulations and other computer models.

(Elverum and Welo, 2015) proposed a model explain how prototypes are used in the development of innovations. They define prototyping as either directional or incremental prototyping. Directional prototyping is when a team is working on a new, unproven design. These type of prototypes gives guidance and help in the evaluating of the direction they are heading. Incremental prototypes are used to optimize design and further increase the understanding, without making considerable changes.

3.3 Innovative Design thinking

Innovative Design Thinking (IDT) is a framework that guides the designer to formulate their informal verbal statements as formal logic propositions to perform analysis and synthesis activities in new product development . (Lu and Liu, 2016)

The first phase of design thinking is the inspiration phase (Reimann and Schilke, 2011). This phase is all about creating motivation for the later phase, that require ideation and idea generation. Without the proper motivation and inspiration, the ideation might not generate the best ideas, which it could with top motivated people involved.

In phase two, ideation, the developer is urged to organize his ideas, or verbal statements, so that ideas proposed can be combined, compared, and selected to achieve a better design outcome. IDT gives a framework of cyclic operations consisting of three basic steps:

- The concept Formation Step: Ideas and concepts on how the problem can be solved
- The concept Organization Step: Categorize the ideas based on their functional complexity
- The concept Selection Step: Selecting a particular concept to evaluate further based on the categorization made in previous step.

Another way of looking at these steps is as exploration of the solution space (Meinel, 2011). By diverging the solution space, a great number of alternative concepts are generated. Exploring for possible solutions may lead to novel ideas that can prove valuable in a later stage. These ideas can then be converged into a few core concepts by prototyping and testing.

4 Concepts

4.1 Ideation

To achieve a wide base of possible technologies to be explored further, a method for collecting data had to be established. Principles in design thinking methodology for breakthrough product development (Lu and Liu, 2016) where used to explore the solution space. The concept formation step from IDT was used to achieve the as many concepts as possible, making sure not to leave any stone unturned.

Not everybody had a preconceived knowledge about the purpose of the study, and to not limit the ideation and lead it in any certain direction as little information as possible was given. A question was formulated to give the participants the required information and to motivate the participants to come up with both feasible and outlandish solutions. The first broad phase of design thinking is Inspiration before ideation, and trying to utilize this might light to more creative ideas that can impact the whole project.

4.1.1 Setup

The ideation was done in small teams of 2 - 4 participants of fellow master students, PhD candidates and professors at MTP. As all the participants are knowledgeable in product development principles and technology no guidance was needed in how the ideation session was performed, and it was kept very casual as a discussion. Drawing utensils was provided to invite participants to visualize their concepts, an important step in understanding and building on each other ideas (Jonson, 2005).

The main question being asked to the participants was:

You would like to image the intersection between tooth and bone to visualize and examine the possibility for periodontal disease. What technology would you use, and how could it be used?

From this question, a discussion of different technologies ensued with ideas and concepts. The discussions lasted from 5 -15 minutes, this to keep all participants engaged and the ideas flowing. All ideas were recorded after what core technology was utilized, and a basic description of the working principle that could be explored further.

4.2 Concept matrix

All data from the ideation session were recorded, categorized and evaluated. The evaluation of the technologies and their feasibility in the scope of this paper was done together with PhD candidates to have broad technical background. Advantages and disadvantages where compiled on all the different technologies. Based on this information a feasibility value was given based on the collective understanding of the concepts. While many of these ideas would be interesting to test out, a realistic approach must be taken to ensure that it can be done in the practical time frame and budget of this study. The feasibility value is a subjective value from 1 - 3 based on the current knowledge the author had of the concepts, and what he though was most promising and rewarding to pursue.

	Description	Advantages	Disadvantages	Feasible
Visual Light	Illuminating the gums bright enough to get a visual camera to identify the	Cheap	Not outside mouth	3
IR Light	Illuminating the gums bright enough to get a visual camera to identify the	Cheap	Not outside mouth	3
UV Light	Used in dental practices to cure	None	Not used in imaging applications Prolonged exposure to skin is harmful	1
Laser light	Illuminating the gums with a directional laser beam	Cheap Directional light	Harmful for eyes Not outside mouth	3
Bone vibrations	With bone loss, the tooth will become looser, making different vibration frequencies	None	Have to vibrate/move teeth	1
Blood flow	Measuring blood flow of the gums to see a difference using image processing	Algorithms available Blood flow varies	Not outside mouth	2
Force	Using force to detect where the bone stops and tooth starts	Simple principle of touch	Needs to touch the gingiva Could be affected by inflammation	3
Ultrasound	Using a ultrasound to detect the bone height	Outside the mouth	Discomfort from the soundwaves	3
Magnetic field	Measure the difference in the magnetic field around the tooth	Can give	Similar to MRI Difficult to measure	1
Electricity	Using the electric resistance of bone to measure	None	Needs to apply current	1
Heat camera	Using a heat camera to view difference in heat of the gums	Non-invasive	No reference heat source	2
Temperature	Using a temperature probe to measure temperature differences outside	None	Surface needs to be probed	1
Nuclear imaging	Using a radioactive source and gamma camera	Interesting	Radiation Complex	2

Radar	Using a radar to measure the difference	Outside the mouth	Complex	3
СТ	CT scan of the jaw	Currently in use	Radiation Expensive Not portable	1
MRI	MRI scan of the jaw	Currently in use	Radioation Expensive Not portable	1
X-ray	X-ray photos	Currently in use	Radiation	1

4.3 Converging the concept matrix

From the concept matrix, the following concepts where selected:

- Visual camera: Based on the relative simple principle of being able to visually identify the transition of tooth and bone. The simple principle makes this concept intriguing.
- Radar: The possibility to achieve complete non-invasive by having a sensor placed outside the mouth without touching is the dream scenario and should be investigated.
- Ultrasound: Based on its extensive medical use of ultrasound imaging, the possibility of this technology giving interesting results is present.
- Blood flow: Algorithms that can identify blood flow has been developed and testing if this works on the gums should be conducted.

Each concept chosen to be further investigated will be explored in more detail regarding the technology itself, what the concept based on that technology is, and initial prototyping and literature study to assess the feasibility of the concepts themselves.

5 Prototyping

5.1 Light imaging

A camera can pick up light mainly from visible specter from about 400nm to 700nm, where the whole color spectrum is represented. A color sensor has usually different types of photosites that are sensitive to different wavelengths. The main technology being used is what we call a Bayer color filter array. In this filter array you have 4 contiguous photosites, each photosite sensitive to a specific wavelength (Dxomark, 2017). One for low wavelengths, blue, and one for high wavelengths, red. There is in addition two photosites for medium wavelengths (orange). These photosites are highly sensitive to near-infrared, so most cameras sold have a IR-filter to filter out the near-infrared spectrum so it does not interfere with the sensor.

For the tests, a Raspberry Pi NoIR Camera V2 (Senthilkumar et al., 2014) was used. As the name implies, this camera does not have an IR filter and we can take advantage of higher wavelengths going into the infrared spectrum. With 8 megapixels and capable of 3280x2464 still photos and 1080p30 videos it is a high enough resolution to be able to efficiently do post processing. A benefit of using this sensor in close proximity to the mouth is the size factor. With it relatively small size it can easily be handled and manipulated into the right position. The Pi NoIR Camera V2 comes with its focus point set to infinity. The lens cell is threaded and screwing this counterclockwise moves the lens further away from the imaging sensor making the camera able to focus on closer objects. This essentially makes it a macro lens capable of close up shots of the gums and teeth

5.1.1 Concept

Because the thickness of the gum wall from the bone and tooth to the surface of the gingiva is only a couple of mm thick, shining a bright light at it should give the necessary light required to be able to see through and pick up the difference between tooth and bone. From shining a light at your own finger, you can see that some of the light passes through the finger, and it seems like it is glowing. What if we take this same concept and apply it to the gums. Shining a light from one side of the gums, and seeing the difference in where the light passes through.

5.1.2 Light penetration of teeth

To test the light penetration of teeth, teeth where sampled from TKMN. The teeth where pulled out during regular dental procedures and all participants gave permission for the use of the teeth in research. The teeth used where in fairly good condition with only minor cavities. All light sources where places inside a container with a single hole letting light out. The tooth was placed on top of the hole and light source to see the light effect from the different light sources.

For initial testing a regular 5mm LED in blue, red, yellow and Near infra-red where used. A white LED was not used, as the dominant wavelength of white LEDs is similar to that of blue. The tooth was placed on top of the hole, and the light was concentrated right at the tooth to give the light best possibility for penetration. The photos were taken in dim room lighting to bring out the effect of the

light penetration. Comparison of light penetration was done visually based on the photos and are represented in Appendix A

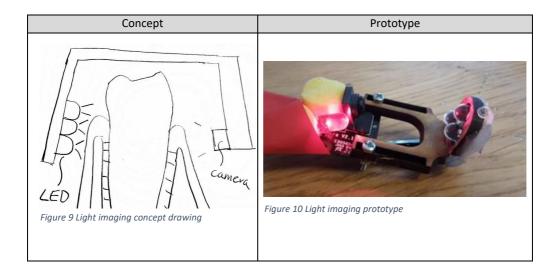
From this initial test with different LEDs we can see a trend that the higher wavelength light gives better penetration of the tooth. Testing of light penetration in tissue was not performed due to the extensive research on the topic, and it is found that higher wavelength light penetrate further in tissue (Stolik et al., 2000). Red and Near infrared LEDs where chosen to be tested further, as it has good light penetration properties in both teeth and tissue.

Initial test where performed with the light shining at the same side as the camera was located. It was found that the light was not giving extra insight into where the divide between tooth and alveolar bone, as can be seen in Figure 8. The only observable transition is that of the tooth and gum, which is always visible. Based on this, it was concluded that it might be best to introduce the light from the other side of the tooth.



Figure 8 Tooth and gum transition

A new test rig was developed to be able to place the light source behind the teeth while photographing from the other side, as this should let the light pass through and difference in light level to be observed. The rig is made up of three LED's on the back of the tooth along with one on the front that could be switched on and off to navigate the camera into place and to assure it was focused properly.



The prototype worked as intended, lighting up the backside of the tooth. The light source, comprised of both three Red and then three Near IR LEDs did not seem to provide the necessary light penetration to pick up anything of significance. To achieve more focused and concentrated light, the LEDs were exchanged with a laser diode with wavelength of 830nm, which gives a much more concentrated beam of light, with higher possibility of providing the light necessary. Switching to the laser diode gave much better results than the LEDs, and provided photos with light penetration of both tooth and gums. From Figure 12 three sections can be observed, where the transition with air bubbles in the lower part of the image is the tooth and gum boundary. Further up there is now a new zone that appears darker than the rest. This could be because of the bone making less light penetrate this part. To better highlight what can be seen from Figure 12, Figure 11 shows a software generated gradient map.

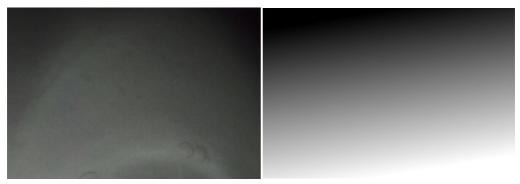


Figure 11 Tooth, gingiva and alveolar bone transition

Figure 12 Software generated gradient map of Figure 12

Figure 13 shows a second image also showing 3 sections of different shades, which could indicate tooth, gum and gum covered bone. To confirm the findings consultation with a dentist was performed, with positive feedback regarding the possibility. But more data must be presented as it is not proved that the shades represent the transition of bone and alveolar bone.

Further development of the prototype needs to be performed, as it is still very difficult to get stable and focused pictures of the area subjected to the test. This can hinder the replicability of the results, as the method is very sensitive to slight different angles, distances and lighting. A camera with adjustable focus would be preferable, as then the focus can be adjusted while registration is taking place, and not be stuck at a predefined focus. The current design also only allows for imaging of the teeth closest to the mouth, because of the size and cables the camera and lighting requires.

One issue encountered during prototyping is that the camera can become fogy because of the breathing of the participant, but this did not happen all the time. Getting the participant to mainly breath through the nose almost eliminated the fogging. The laser diode became very hot during use, and if this accidentally touched the back side of the gum while conducting the imaging, it did cause temporary discomfort for the participant. As of now, no heatsink was attached to the diode which would have helped, along with an enclosing that did not allow the diode itself to make contact.



Figure 13 Tooth, gingiva and alveolar bone transition

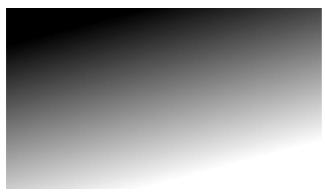


Figure 14 Software generated gradient map of Figure 13

5.2 Blood flow imaging

The blood flow of the gingiva can be a potential indicator of periodontal disease, or rather, the lack of. Studies have shown that the blood flow is lower in a healthy gingiva, and the inflammatory process increases the blood flow of the gingiva (Kerdvongbundit et al., 2002). The lowest blood flow is found in the free gingival areas, which is the top part of the gingiva, as seen in Figure 15. Transitioning to the alveolar mucosa where the highest blood flow is located. This indicates the possibility of identifying certain areas based on the amount of blood flow.

Tissue type	Free gingivae (6 sites/subject)	Interdental gingivae (5 sites/subject)	Attached gingivae (5 sites/subject)	Alveolar mucosae (4 sites/subject)
Healthy gingiva Moderate gingivitis Periodontitis	89.7 ± 9.8 $131.2 \pm 10.4^{\circ}$ $144.3 \pm 11.4^{\circ}$	$\begin{array}{c} 211.2 \pm 17.2 \\ 341.0 \pm 19.8^{\circ} \\ 351.3 \pm 18.1^{\ast} \end{array}$	$\begin{array}{c} 449.3 \pm 21.6 \\ 621.4 \pm 34.9^{\circ} \\ 639.3 \pm 38.1^{\circ} \end{array}$	$\begin{array}{c} 624.9 \pm 36.1 \\ 759.3 \pm 40.4^{\circ} \\ 826.4 \pm 42.9^{\circ} \end{array}$
	m healthy gingiva, at $P < 0.0$ gnificant differences between	01 n every site within the same grou	p, at <i>P</i> < 0.01	



Measuring blood flow of gingiva is traditionally done by Laser Doppler Flowmetry, a method to assess blood flow in microvascular systems such as the gingiva (Asokan et al., 2014). It is an optical measuring method that measures the velocity and number of particles conveyed by a fluid flow. This is done by measuring the amount of light scattered by the particles, both Doppler-shifted and unshifted light. This method has been found to yield good results, but is rather expensive (Høyer et al., 2013).

5.2.1 Concept

Using the method of Eulerian video magnification (Wu et al., 2012) and a video of the gingiva surface there might be a visible difference in the blood flow in the different parts in the gingiva. These differences could then be analyzed to identify gingivitis and possible underlying properties of the gingiva.

5.2.2 Eulerian video magnification

Eulerian video magnification is a method of revealing temporal variations in videos using spatial decomposition and temporal filtering to the frames (Wu et al., 2012). The method has been developed by researchers at MIT and used to amplify blood flow and small motion.

The algorithms are split in two parts, spatial and temporal filtering. The spatial filtering is looking at the color value at any pixel and then amplifying this variation in a temporal frequency band of interest. In example, a temporal frequency of interest could be the approximate frequency of the blood flow.

While the mathematics behind the algorithms are quite complex, the use of the algorithms depends on a set of variables controlled by the user. The main variables are the amplification factor and cutoff frequency. These decide what frequencies should be amplified, and how much they should be amplified. To begin initial testing of the software the variable values where kept the same as in the paper by (Wu et al., 2012), with an amplification of 120 and cutoff frequency of 960. This is optimized for blood flow and should be appropriate for the testing.

5.2.3 Initial prototyping

Before testing the software on the gingiva by itself, a video of the front four teeth was captured, along with part of the gingiva and upper lip. This to benchmark the software and make sure that heart rate can be derived from the video based on variation in blood flow. Variables where kept as they were in the paper and described in section 6.5.2. Appendix B shows a photo of how the stock video looked before applying the Eulerian video magnification, along with links to the original video. While video was taken a pulse watch was worn by the person being filmed to have accurate data of the pulse

The photos have been captured in sequence from the video. Figure 16 is taken at time zero, Figure 17 at 0. 408 seconds and Figure 18 at 0.888 seconds. This cyclic pattern is repeated at the same rate in the duration of the video. This pattern is caused by the blood circulating in the tissue.

The heart rate of the participant being filmed was 65 bpm under the filming. Calculating the stipulated heart rate from the Eulerian video magnification reveals a similar result.

$$bpm = \frac{60 \ seconds}{time \ of \ cyclic \ pattern} = \frac{60}{0.888} = 67.5$$

We can see a good correlation between the measured heartrate and the Eulerian

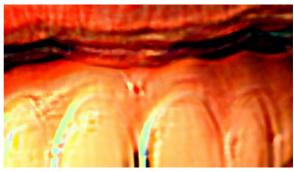


Figure 16 Eulerian video magnification at time 0

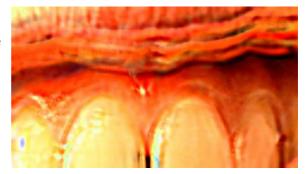


Figure 17 Eulerian video magnification at time 0.408

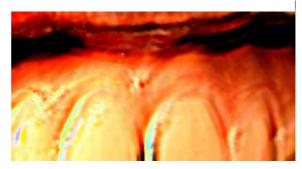


Figure 18 Eulerian video magnification at time 0.888

pulse. This shows that there is a measurable difference in blood flow in the gums that can be measured by a regular camera.

Applying this algorithm to close up videos of the gum, reviled results that were difficult to decipher. No clear differences based on location is recorded. In these videos, there seems to be the same type of behavior from both the gingiva and the tooth itself. This was not observed in Figure 16, where there is a clear difference between gingiva and tooth.

The amplification factor was tested at different levels, but yielding the same results. Figure 19 and 20 are two of the amplifications tested, none gave results that showed any observable difference in blood flow. Appendix B has links to the videos.

What could cause this issue is not clear. Different lighting was tested, but none yielded the desired results. Compared to Figure 16 where the red color is dominant, this does not seem to be the case. While



Figure 19 Eulerian video magnification with amplification =100



Figure 20 Eulerian video magnification with amplification =120

not all combination of settings where tried, the lack of results reflects the concept might not be feasible.

5.3 Ultra-wide band radar

The overall concept of an ultra-wide band (UWB) radar is the basic principle of reflecting signals that are recorded and analyzed (Staderini, 2002). The underlying principle of UWB imaging in the human body is to detect the significant contrast in dielectric properties of different materials (Abbosh, 2008). In UWB imaging a very narrow pulse is transmitted from an TX antenna. When this pulse propagates through the various layers, scattering occurs at the interfaces between layers and is picked up by a RX antenna. A radar can consist of 1 antenna pair, or multiple depending on their purpose. In the medical field radar technology is used for respiration monitoring.

5.3.1 Concept

Because the radar does not require direct contact with what is being imaged, it can be used because the electromagnetic pulses propagate through air as well. The gums and bone have different dielectric properties (Gabriel, 1996) and there should be a visible difference to the radar.

5.3.2 Initial testing

To investigate radar technology and to get a feel for what it can be used for a radar module was acquired. The Novelda XeThru X4M200 radar is a module optimized for pulse monitoring, but works for distance tracking as well. The included software XeThru explorer is preconfigured to measure the distance to an object, and can also send raw data acquired by the antennas.

An issue with radar is the amount of noise generated from the surroundings. From initial testing of the radar it was found that both static and moving objects in the vicinity could interfere with the readings. To reduce the interference aluminum foil was used to block the radar from picking up signals beyond the subject being measured.

The radar was found to be accurate in detecting the distance to the individual itself, but is not optimized for distinguishing finite details. To explore this possibility Professor Lars Magne Lundheim of the Depeartment of Electronic Systems was contacted. Professor Lundheim belongs to the Signal Processing Group and is a valuable resource regarding the use of radar and possibilities of imaging the jaw bone and periodontal pockets. While he had no experience in this use case, he thought that the main issue is the signal processing issue. Jan Roar Pleym, employee at Novelda, was also contacted to shed some light of possible similar use cases that he knew about. Novelda did not have any experience in imaging of static objects, and are more focused on movement, being it locating moving objects or registering breathing. An attempt was made in acquiring a Walabot (Walabot, 2017) radar, as it is built up of a multiantenna array and comes with a software development kit giving easier access and manipulation of the radar and data. As this radar was on backorder, it was not possible to test.

Through this dialog with experienced users and developers of radar technology, it seems that the main issue is data processing, and how you design the antenna array.

5.4 Tactile imaging

Palpation, or the use of one's hands to examine the human body by touch, has been used in medicine since 1852 (Merriam-Webster, 2017). In dentistry, the sense of touch in the form of a periodontal probe and visual inspection lays the foundation for the diagnosis of periodontal disease. One of the main issues with palpation, is that all practitioners have different techniques and sensitivities, so the results of the measurements will vary. (Galea, 2004)

To get more accurate data from the sense of touch, tactile imaging has been developed. It takes the sense of touch and transforms it to data that can be analyzed. It can use an array of passive pressure sensors to map the surface pressures from the sensors being pressed on to the surface subjected to imaging. Common uses for this type of imaging is in the examination of vaginal- and breast tumors (Galea, 2004).

5.4.1 Concept

A tactile imaging probe can probe the outside of the gums to feel the pressure differences from where there is bone and tooth. In other words, an image of the bone and tooth surface should be able to be generated because of the difference in gum thickness and pressure dispersion.

5.4.2 Initial Prototyping

To get a feel for tactile imaging and how this can be used a basic probe was created using two resistive pressure sensors, given the probe two readings. A resistive pressure sensor measure changes in resistance depending on the pressure applied and works as a variable resistor, giving analog readings to an Arduino. Applying the probe to the forearm, a clear difference in the readings is observed from where the bones are located and where there is only soft muscle.

The probe was also tested on a partially swollen forearm due to an unrelated injury. This affected the readings to the point that there was no difference in

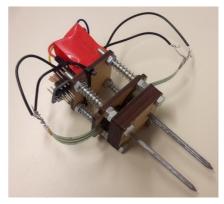


Figure 21 Simple tactile probe

where there was bone and not. There was also increased discomfort because of the pressure applied to the swollen area. Using this type of tactile pressure probe in the mouth where the gingiva is possibly inflamed could lead to excess discomfort to the patient and potentially disturb the readings. According to (Heft et al., 1991) the discomfort felt from probing is dependent on the stage of periodontits.

Because of how little space is available in the mouth, a probe must be very small, and the sensor array must be equally small. An array that small is not commercially available, but there is a big interest in small tactile arrays due to their application in touch sensors for robotics. These include silicon based capacitive sensing arrays (Muhammad et al., 2011) and flexible piezoelectric tactile sensor arrays (Yu et al., 2016).

5.5 Ultrasound imaging

As with the radar technology, ultrasound relies on sending a pulse with frequency between 2-500 MHz and waiting for the echo to return. For diagnosis and imaging two main techniques in ultrasound is used; The pulse-echo method for imaging of tissue distribution, and the Doppler effect for tissue movement and blood flow (Robinson, 2007). In the case of imaging of teeth and jawbone, a pulse-echo approach is appropriate. This takes advantage of the difference in acoustic properties between different mediums and makes an image based on the partial reflection of soundwaves.

The two commonly found types of transducers used to transmit the soundwaves are convex and linear. A convex transducer is mainly used in abdominal imaging that require deep penetration and wide field of view. To achieve deep penetration a lower frequency must be used, but since lateral resolution is determined by wavelength, the resolution suffers (Robinson, 2007). The resolution required in imaging of periodontal pockets and surrounding bone requires a high resolution found in the linear probes at about 30 to 60 Mhz where a resolution of less than 50 µm is possible (Mahmoud et al., 2011). This high resolution ultrasound data can be analyzed to achieve high resolution 3D representation of the jawbone, giving valuable insight in the field of periodontics.

5.5.1 Concept

Using the probe on the outside of the gum, or even outside the mouth a lateral image of the gum, bone and tooth wall can be made. This data can then be used to make a 3D representation of the alveolar bone mapping possible defects and recession of the bone.



Figure 22 Ultrasound concept drawing

5.5.2 Initial prototyping

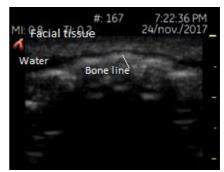
To test the vadility of this concept a comparison of data with Mahmoud et al., 2011 was preformed using a GE Helathcare Vscan portable ultrasound. This is a dual probe ultrasound, but only the linear probe (7MHz) was tested do to the information gather on ultrasounds behaviour and usecases. The size of the probe head limited the testing to ouside of the mouth, as it was difficult to get it posisiond correctly for adequate imaging directly on the gingiva. To get the best possible probe skin contact ultrasound transmission gel was used under all testing of the probe.

While performing the first test it became apperant that the air between cheek and gum made it difficult to get readings on the ultrasound deeper than the cheek. Water is a simple way to remove the airpocket and get a continous path for the ultrsound to tavel. It can be noted that the water made the probing more awkward because of the pressure applied with the probe pushes the water. Images were collected with the linear probe in the horisontal direction to compare with the findings of Mahmoud et al., 2011.

Horizontal image of the lower jaw displaying the lower lip, water filled gap, gum and bone is displayed in Figure 23. The oval shape of the front teeth and bone is clearly visible.

Horizontal image of the cheek pointing at the premolar teeth is shown in Figure 24. A clear water layer is seen between the facial tissue and gingiva and bone line. Compared to Figure 25 the image is comparable with the same elements present, even though the bone line is not as clear, which could be caused by the ultrasound not being tuned to bone detection.

From the comparison, we can see a clear similarity between the results with the commercial probe and that of Mahmoud et al., 2011, even though there is a big difference in operating frequency. The main issue facing this type of technology is generating useful data from a ultrasound image. To get a second opinion Professor Alfonso Rodriguez-Molares, who is a researcher in the field of acoustics and ultrasonics, was contacted. While he had no knowledge about the imaging of jawbone and periodontal pockets ultilizing ultrasound, he was intregued by the idea. The conclusion drawn together with Alfonso is that from this stage it requires deep knowledge in signal processing to retrive usefull data from this type of imaging technique, but it is certainly possible.



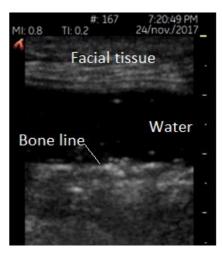


Figure 25 Ultrasound of premolar teeth and alveolar bone

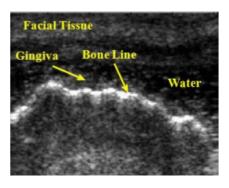


Figure 24 Ultrasound from (Mahmoud et al., 2011)

6 Discussion

From the initial introduction of this task it has been very open and fuzzy regarding both the challenge and how to solve it. By first gaining a deeper understanding for the issue, and the anatomy of periodontium it made the whole project more tangible. When first deciding how to proceed with the project I decided combine different techniques and models to base my product development process on.

With principles from Agile product development which mention the importance of problem solving rather than following an exact process or procedure. This concept with following the ideas, and exploring led to a somewhat chaotic development process with many ideas and concepts being worked on at the same time. To combat this problem, I initiated Scrums lasting one week, to set finite goals to actually complete tasks and moving on. Utilizing weekly scrums made the work more organized and there was actual progression in the work I was doing. Even though the prototyping process became more structured, it was still in some sense chaotic, because you never know what new insight might arise from one Scrum to the next. These insights are one of the big reasons prototyping is such a strong tool when designing a new product and researching new methods to perform a task.

The ideation stage has an important role because it guides the direction of the entire project. There is always a possibility that a concept was overlooked in the ideation stage and was not picked up on during prototyping. That being said, when doing ideation sessions with multidisciplinary groups with different backgrounds, you cover as much ground as could be expected. I am confident that most possible solutions have been covered, if not in great detail.

When selecting concepts to pursue further into prototyping, it was done with a combination of prior knowledge and engineering judgment. With prior knowledge about current technology and their limitations excluded advanced technology like CT and MRI because of their cost and complexity. Due to my experience with material properties, tactile imaging was considered even before knowing that this was a field with potential. Only going for the most logical and safe approach might not yield the best result, and choosing some concepts that challenge what you think is possible, like measuring blood flow visually, could lead to innovative solutions.

From the selected concepts, I personally found the Light/camera penetration imaging to be a very interesting approach. In theory it's a simple principle, and don't require the same specialized equipment that makes other approaches expensive. Working with light waves gives many possibilities and variations that may change the images drastically. While discovering that higher frequency light work best, it might also be a matter of brightness, and that you could compensate with a brighter light source. Using Near-infra red lasers could pose a safety hazard, but with the proper precautions this could be reduced. Taking detailed photos in the tight space of the mouth was one of the biggest challenges. There is constant movement and moisture that can interfere with the photos. That said, when proper photos were taken, there was a clear division into three sections. Initial inquires indicate that there is a correlation between the photos and the tooth and alveolar bone transition. While the level of detail obtained from the images cannot detect the periodontal pockets, it can give valuable information about the bone recession, and how far this has progressed without using x-ray imaging or other methods. If there is a good correlation and replicability is

something that needs to be explored further. To do this a better setup with a smaller camera would be preferable, as the current setup did not fit in between the cheek.

Using blood flow might actually be a viable method of confirming periodontits, and distinguishing different parts of the gingiva. Using a camera and Eulerian magnification did yield good results in measuring pulse on videos taken farther away, but on close-up videos the method did not yield any meaningful results. What causes the close-up images to behave in such a way is not completely apparent. While the initial testing of this concept highlighted the functionality of the software, it does show its limitations. There could possibly be a way to tweak the setup to get the desired results, but during the testing the software did not provide meaningful results.

While the concept of tactile imaging is quite interesting, the inflammation of the gums can affect the readings. Tactile sensors rely on many data points to get readings that can be analyzed. Because of the location and dimensions of the gingiva, finding sensors small enough and with enough data points were not achievable to test on the gingiva. The small pressure arrays are in a research stage, and depend on nanotechnology and advanced algorithms. While I do believe that this technology could be used, based on mechanical properties found in the gingiva, the advanced technology necessary pushes it outside the scope of this study.

UWB Radar and Ultrasound fall into the same category, where one looks more promising than the other. Radar is used in a wide area of applications, but it has not been applied in imaging of static objects in medicine. While identifying movement and heartbeat are common use cases, static imaging is difficult to do at the scale required, but the limiting factor being the amount of data processing required. While initial prototyping and testing was quite limited, the information gathered from Lars Magne Lundheim and Jan Roar Pleym indicates that theoretically its possible, but that the main limitation is antenna design and signal processing. Further testing using a more customizable interface and development platform could have given more insight and been able to further test the concept, but for imaging ultrasound is more common.

Ultrasound is widely used for noninvasive imaging in medicine, and is very promising in regard to image the jaw, including any defects and recessions present. Through the initial prototyping it has been revealed that the linear probe works well, if there is no air pocket between the probe and imaging area. While having water in the mouth works, it is a bit awkward for the patient because of the pressure applied with the probe on the cheek. This might not be a big concern, but makes this concept more invasive than for example a radar. The technology seems very promising in delivering high resolution 3D images of the bone structure and possible defects, but it comes at a high cost. It might not be the best solution if lower resolution is acceptable.

7 Conclusion

Through this project thesis, I have discovered the importance of structuring the innovation process when working on initial concept development and testing. Even with a framework to guide the progress, the work was at time chaotic.

All the possible solutions explored have some potential to yield replicable results that can aid in the identification and classification of periodontal disease. Highlighted in this study is the main difficulties and challenges regarding the concepts.

Tactile imaging, while seeming promising, lacks the technology to be properly evaluated for such small-scale imaging, while blood measurement with Eulerian magnification did not yield any meaningful results, but difference in blood flow is an indication of periodontal disease.

The most promising concept based on price, size and simplicity is the light/camera imaging relying on light penetration of tooth and gingiva. The preliminary findings show the possibilities of identifying the height of alveolar bone, but also its resolution limitations. Further investigation is needed to properly validate the results presented here. For high detail imaging, also in 3D, ultrasound is the best solution because of its high data output, but is rather expensive.

7.1 Further work

The next step in regarding future work would be to take the most promising solution, the light/camera imaging, to the next step. Investigating this further, refining the prototype to be able to make replicable, consistent photos without the current hassle of focus and size issues. Being able to properly test the concept in every area of the mouth, and comparing these images to X-rays to get a clear understanding of this solutions limitations and possible use cases.

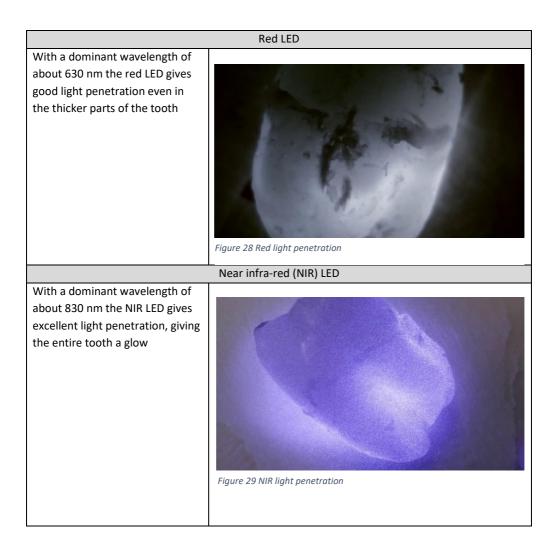
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Appendix A – Light penetration





Appendix B – Eulerian video magnification



Figure 30 Teeth and gingiva before Eulerian video magnification



Before Eulerian magnification https://youtu.be/163E_awajzM



Eulerian magnification close up. Amplification =100 https://youtu.be/sFSgN0Xus8c



After Eulerian magnification https://youtu.be/AETWIq8WItU



Eulerian magnification close up. Amplification =120 https://youtu.be/8pdgDe8u4LU