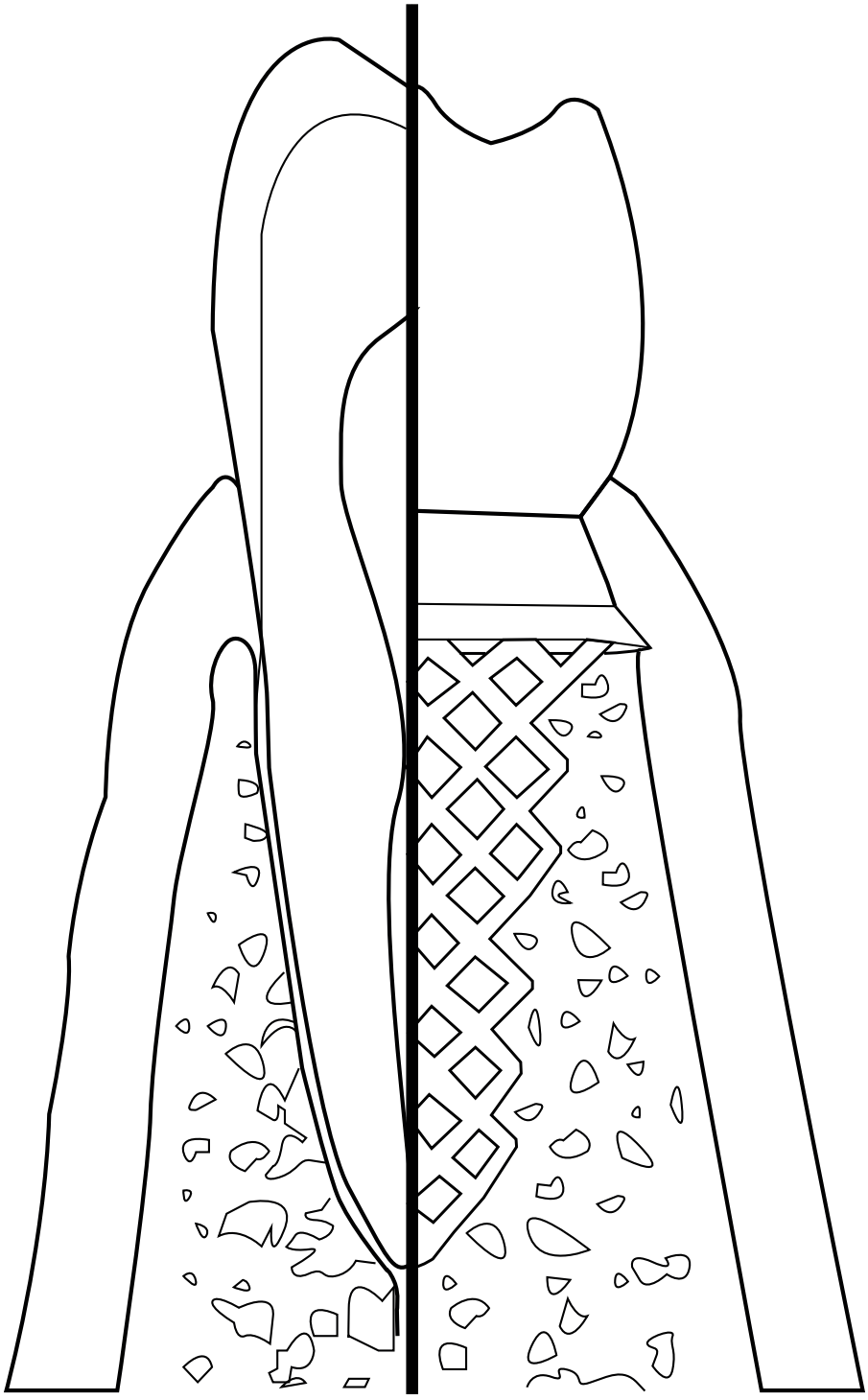
Master thesis

Design of a new personalized dental implant and its surgical procedure

Xandra van Megen



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Design of a new personalized dental implant and its surgical procedure

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Summary

Dental implants are used to replace missing teeth. Replacing teeth is required, since neighboring teeth can move and reposition in undesired positions if there is an empty space. A dental implant consists of three parts, a dental prosthetic (crown), an abutment and the implant which is fixated in the bone.

Dental implants are placed during a surgical procedure performed by an oral surgeon. For this project five surgeries are observed to gain more insights in this procedure. The total treatment takes long, because in between different steps of the procedure bone healing is required. The main concerns of patients are the long treatment time, anxiety and stress. Next to that, there is a failure rate of 3-5% which is mainly caused by loosening of the implant due to a lack of osseointegration and infection, also called peri-implantitis.

Development to promote osseointegration and to prevent infection are taking place. Additive manufacturing techniques are used to promote osseointegration. Research into antimicrobial surfaces are aimed to lower the risk of infection.

Based on the analysis of the problem and the developments that are taking place a new type of dental implant is designed. The new implants are patient-specific and have a porous structure to promote osseointegration. The implants are made to be placed immediately after extraction.

The implant is designed based on the following design features: Shape, structure, abutment, stability and antimicrobial surface.

Shape
The patient-specific shape is retrieved from a CBCT scan of the jaw of a patient. The required data of the tooth that needs to be replaced is collected. Using image segmentation software, the particular root of the to be replaced tooth is isolated.

Structure
A porous structure is created to allow bone-ingrowth. A computational method can be used to create the desired porosity inside the implant. A pore size between 300 and 900µm is required to allow bone ingrowth.

Abutment and antimicrobial surface
The abutment, the connector between the implant and the crown, is in the new design connected to the implant itself. The abutment also functions as the connector to the power supply needed to apply an antimicrobial surface. This antimicrobial surface is needed to prevent infection. The surface of the implants is biofunctionalized by plasma electrolytic oxidation with silver nanoparticles. Silver is an antibacterial compound and show antibacterial activity against a wide variety of bacteria.

Treatment
With this new type of implant the surgical procedure will be shortened to 6 months, instead of 9/12months. The main advantage is that bone healing after extraction is not required, which saves 3-6 months.

The design and manufacturing process are changed as well. Current implants are mass produced, while the new implants will be designed for one specific case and will be produced one-by-one. This affects the planning of the total treatment, a good collaboration between all stakeholders is needed.

The design is validated with four oral surgeons. All of them see added values in the patient-specific design. Different opinions have been formed about the porous structure and the antimicrobial layer.

In conclusion, the design shows large potential to positively impact the dental implant surgical procedure. More research and testing is needed to further develop these new type of implants.

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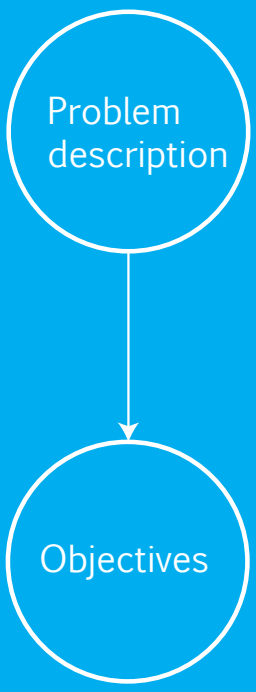
8. Appendix

Introduction



1 Introduction phase

In this chapter the objectives of this graduation project will be given, based on the problem description.

1. Introduction

This master thesis report is created for the graduation project “design of a new personalized dental implant and its surgical procedure“. This project is a combined project for the masters Integrated Product Design (IDE) and Biomedical Engineering (3ME). This report is focused on the Integrated Product Design part of the project.

Problem description

Losing a tooth can happen due to a disease or a trauma. Missing teeth can be replaced by dental implants. Dental implants replace the root part and the crown part of the tooth. The first dental implants were created 4000 years ago from bamboo pegs. Later on other options such as sea shells, animal teeth, copper teeth were used to replace teeth. The first engineered implant was placed in a patient by Dr. Branemark in 1965. After the first implantation in 1965, a considerable amount of developments have taken place. Nowadays, a large variety of dental implants is available. Developments are still going on to make the implants even better and to improve the success rate (Figure 1).

The global dental implant market is large and growing. It is expected that the total revenue will increase from €3.2 billion in 2016 to €3.8 billion in 2022. This is mainly due to the ageing population and tooth loss due to poor oral conditions. Next to that, more focus is put on the awareness of oral health.

A dental implant consists of three parts, the implant

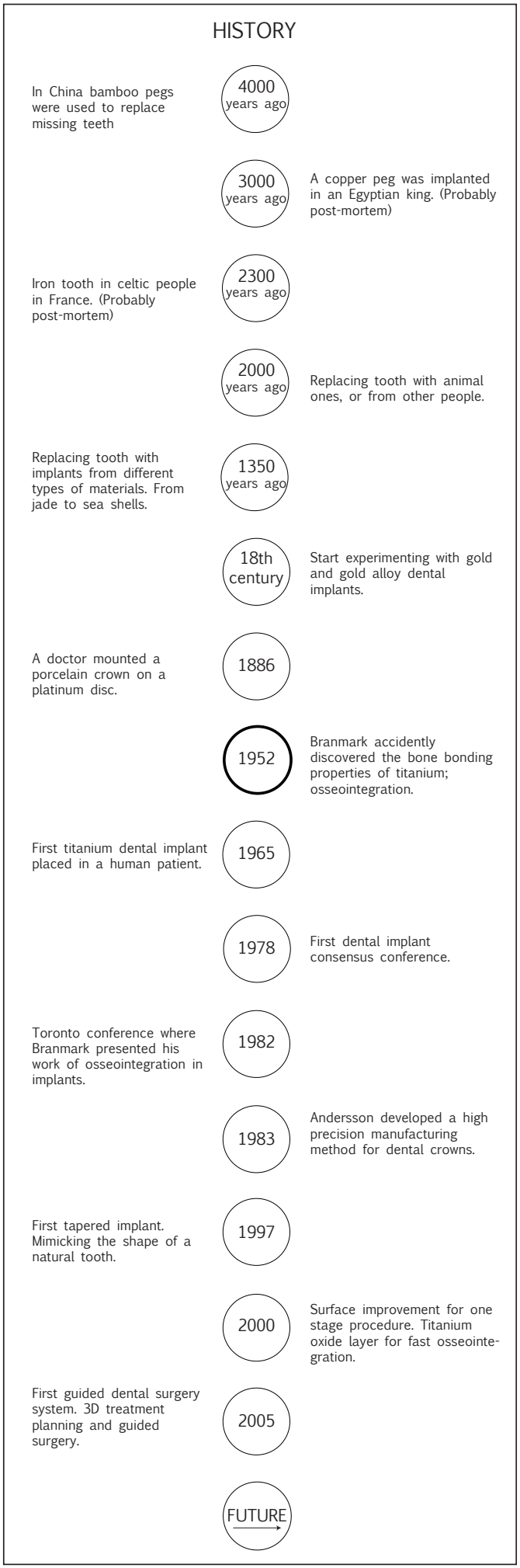


Figure 1: History of dental implant

itself, the abutment and the dental prosthetic (Figure 2) . The implant itself is placed in the jawbone and functions as the root. This is the most crucial part of the implant in order to perform well. The implant needs to integrate with the bone, which is called osseointegration. Dr. Branemark was the first one who accidentally found out that titanium has osseointegration properties, which means that bone integrates with titanium. Since then, titanium implants are made from titanium.

Dental implants are placed in the jawbone during a surgical procedure performed by an oral surgeon or a specialized dentists. After implantation the implant will integrate with bone to ensure good stability of the implant. An abutment is placed on top which penetrates through the gingiva on which a dental prosthetic, such as a crown, can be mounted (Figure 2).

The procedure is not free of risks. Implant failure happens in 3-5% of the cases due to implant loosening, infection or a lack of osseointegration. This is undesirable and should be prevented. In this graduation project the focus is on developing a new implant that will reduce the failure rate.

The objectives of this graduation assignments are:

- *Design a new dental implant that prevents infection and promote osseointegration*
- *Design a new procedure for the newly designed implant.*

This project is done in combination with the master biomedical engineering. The biomaterials research group, linked to this master, is focusing on antimicrobial surfaces to lower the risk of infection on implants. The knowledge of this research group will be used in this project to design the first dental implant with such an antimicrobial surface. Promoting osseointegration will be researched by investigating new ways of manufacturing of implants. A newly designed implant might affect the implant procedure, depending on the new technologies that will be proposed in this report.

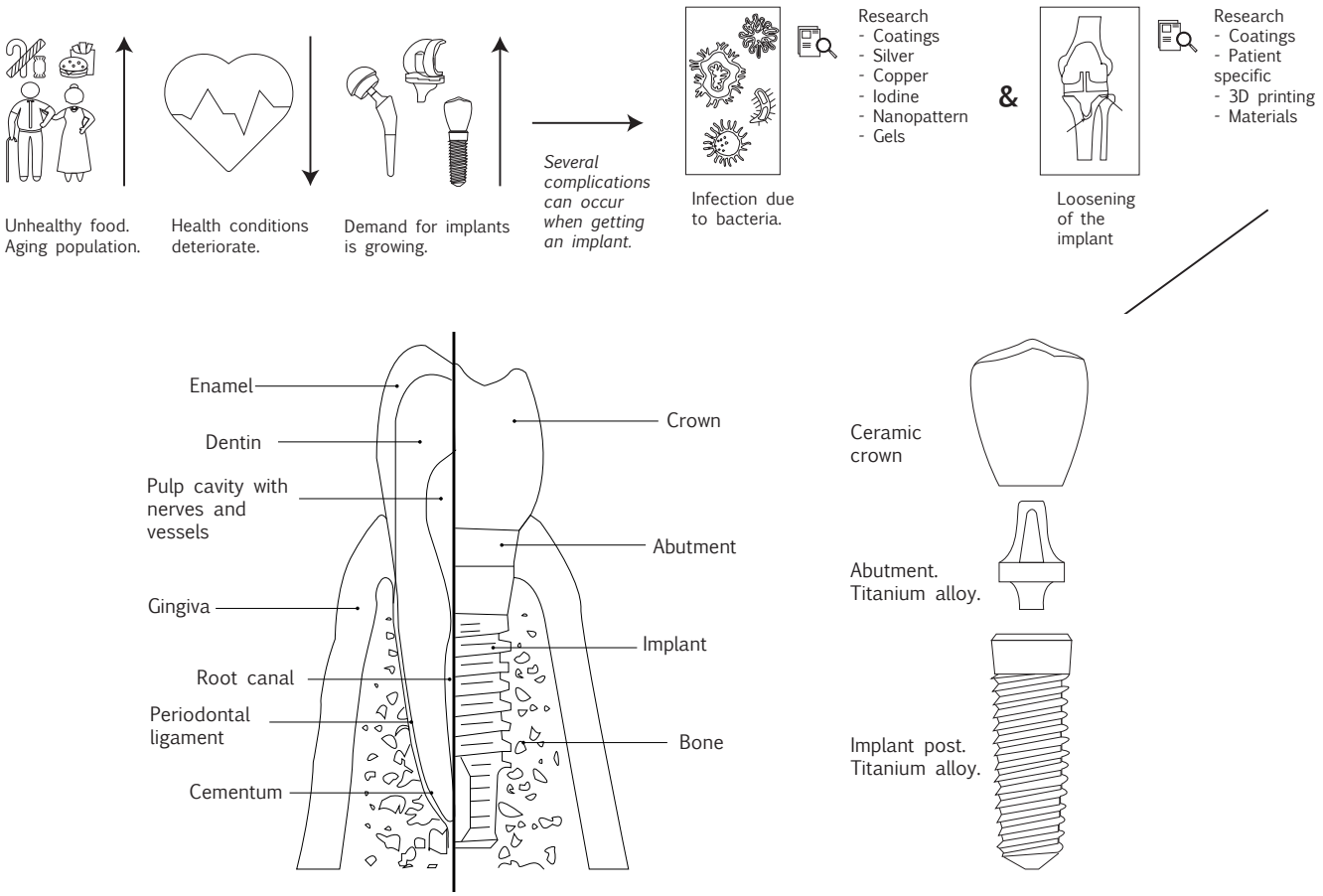


Figure 2: Context of the project

Report structure

The report is divided into five phases: the introduction phase, the analysis phase, the design phase, the implementation phase and the evaluation phase (Figure 3).

In the analysis phase a view of the context is given including a literature study and field observations. This resulted in a design vision including a list of requirements for the design of a new dental implant.

In the design phase a final design is presented which is developed through idea generation, many iterations, prototyping and testing.

In the implementation phase, the design is placed in its context and the steps to implement the design in the current context are described.

In the evaluation phase the new implant design is validated and tested on the requirements. This chapter ends with a final conclusion, recommendations and a reflection on the process.

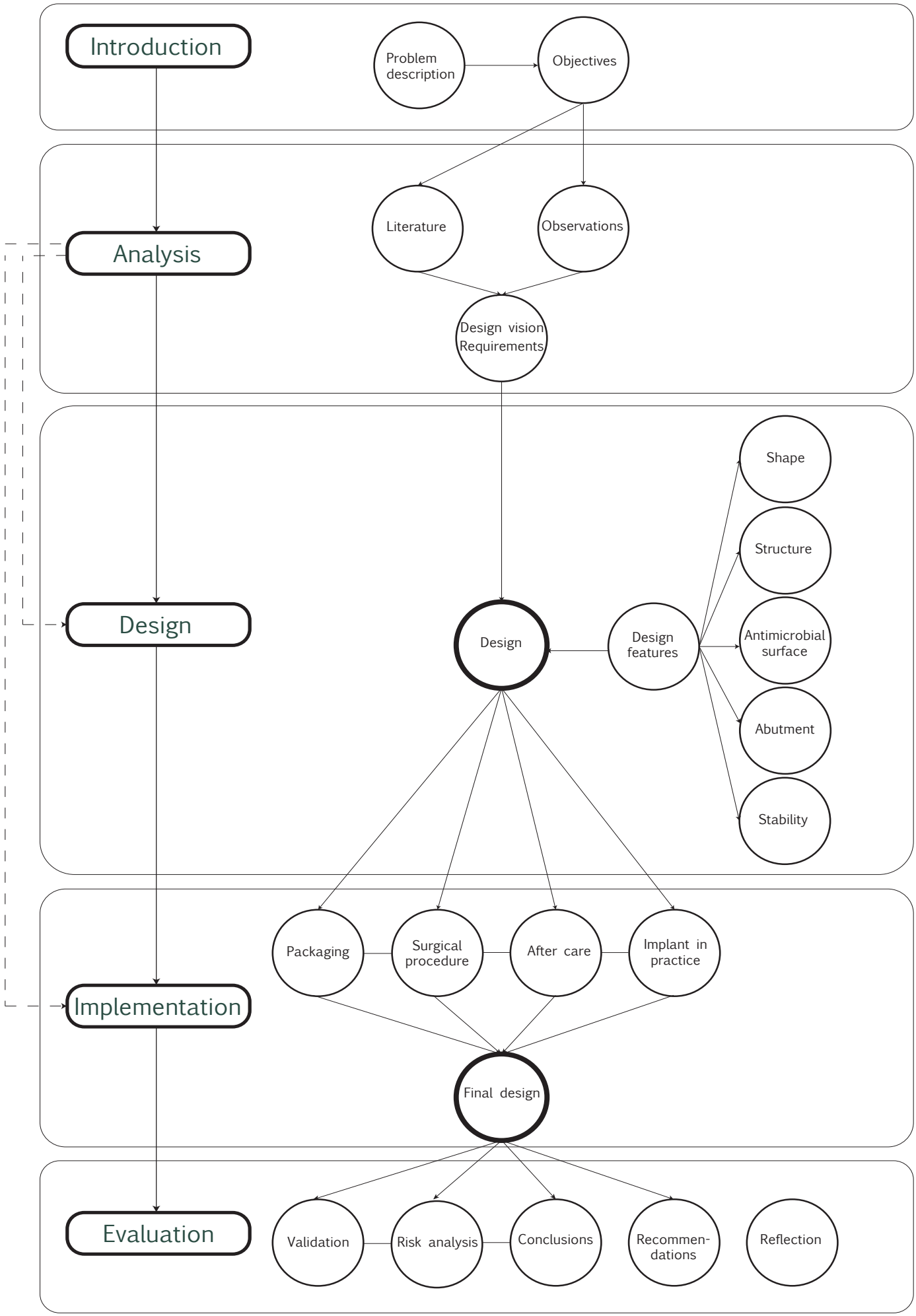
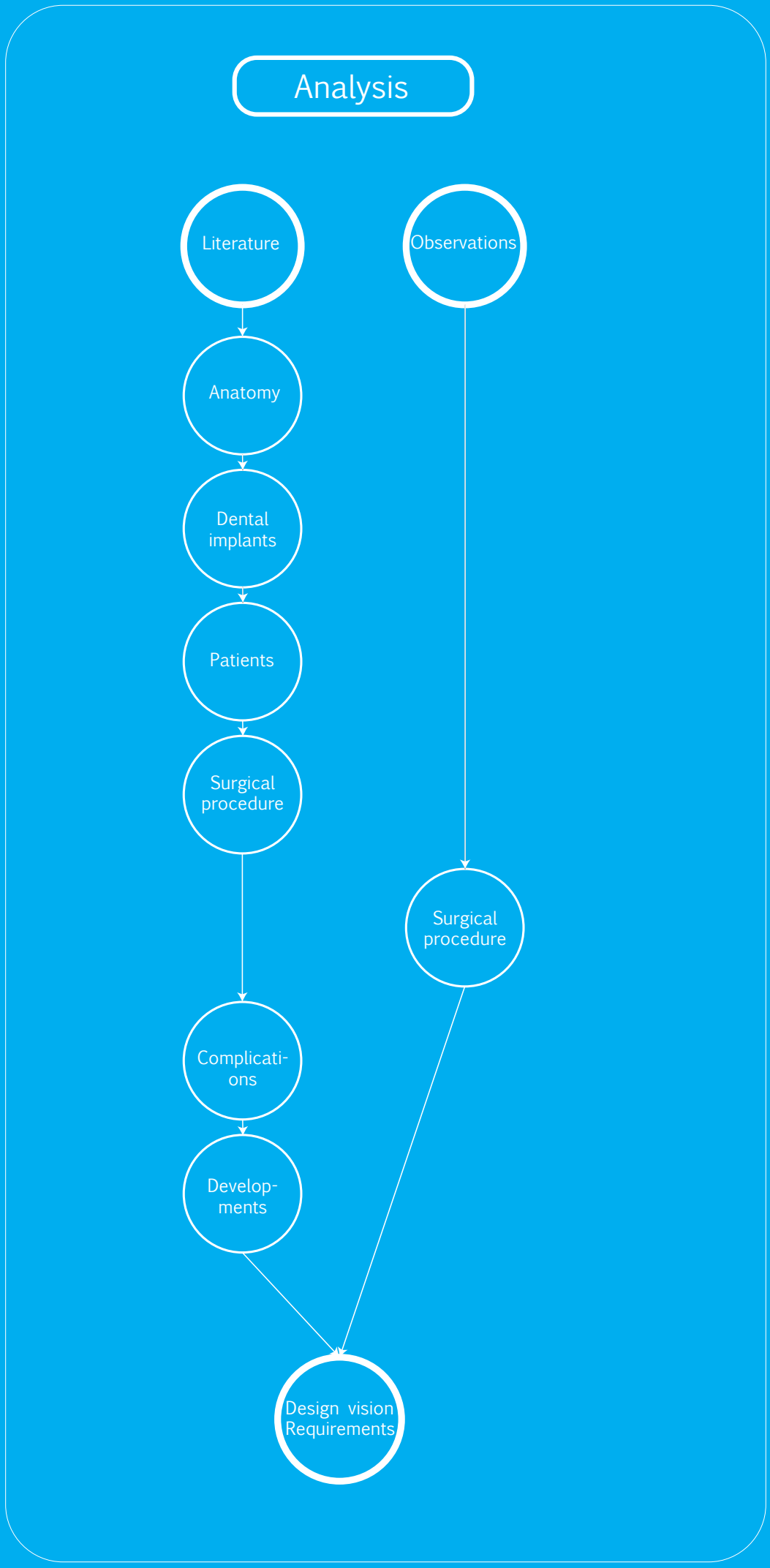


Figure 3: Report structure


Analysis
Literature
Observations
Anatomy
Dental implants
Patients
Surgical procedure
Surgical procedure
Complicati-ons
Develop-ments
Design vision Requirements

2 Analysis phase

This chapter will provide information that is necessary to understand how dental implants function. The chapter is divided into 6 sections: anatomy of the jaw and teeth, a description of dental implants, dental implants seen from a patient perspective, the surgical procedure, complications and the developments that are taking place in the dental implant industry.

2.1 Anatomy

This section focuses on the anatomy of the jaw and a single tooth.

The anatomy of the jaw is important regarding dental implants. Figure 4 and Figure 5 show the anatomy of the jaw. The upper jaw, called the maxilla, consists of 15/16 teeth; central incisors, lateral incisors, canines, premolars and molars. The incisors and canines have one root, the premolars have one or two roots and the molars have two or three roots. The lower jaw, called the mandible, consists of the same kind of teeth as the maxilla. The mandible is harder because its consists of more cortical bone than the maxilla, which has more cancellous bone.

In dentistry, every tooth is indicated with a number. In principle, all teeth can be replaced with an implant.

In Figure 4 the maxillary sinus is shown. The dentist or oral surgeon should not come in contact with the sinus while placing a dental implant, because this can lead to an infection and can affect the healing process in a negative way. (Encyclopedia Brittanica, Jaw, 2017)

The anatomy of a tooth itself is shown in Figure 6. As can be seen the tooth consists of enamel, dentin, pulp, cementum, blood vessels, periodontal ligament, lateral canals and nerves surrounded by gingiva and bone (Hoffman, 2017).

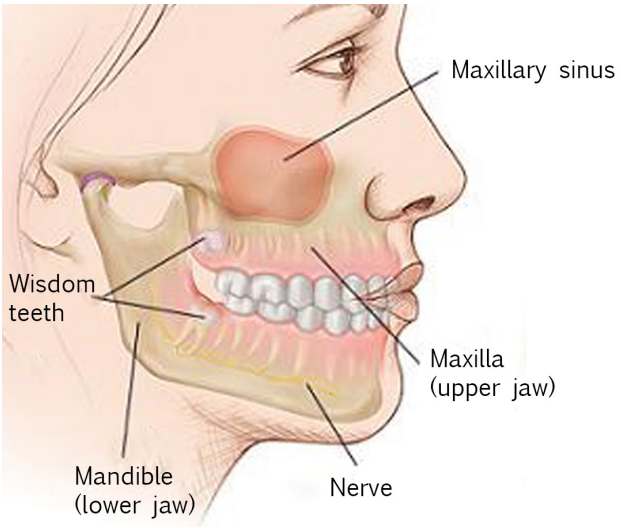


Figure 4: Anatomy of the jaw. Courtesy of mouthdairy.com (2016)

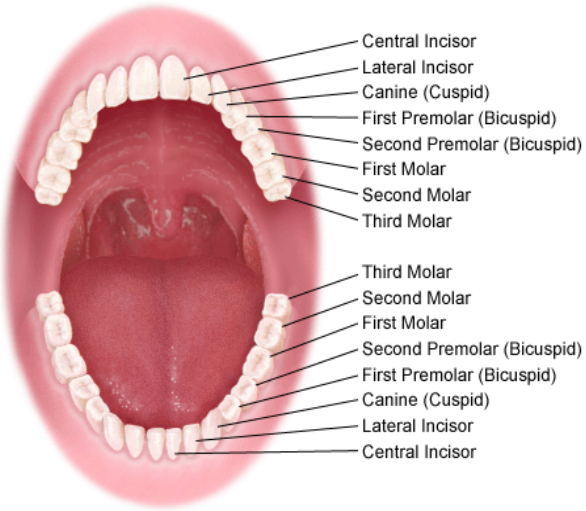


Figure 5: Teeth names. Courtesy of phoenixchildrens (2018)

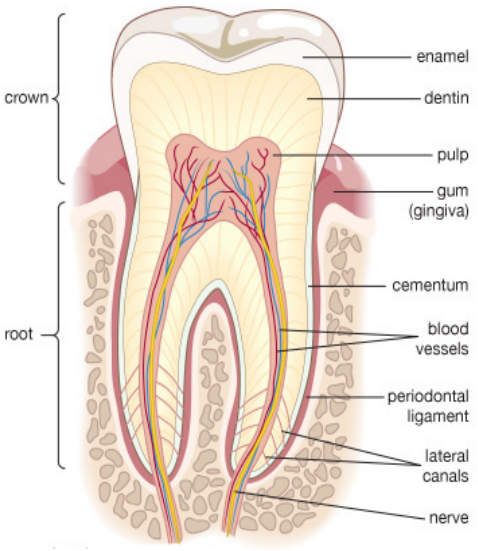


Figure 6: Anatomy of the tooth. Couresy of Encyclopedia Britannica, tooth anatomy (2017)

2.1 Dental implants

This section focuses on the dental implant itself, first a clear description is given of all its components, thereafter an overview is given of all dental implant types, followed by an anlysis of the implants available on the market.

Dental implants are placed inside the jawbone. It is a replacement for a missing tooth. A complete implant consists of three parts; a dental prosthetic (crown, bridge, denture), an abutment, and an implant (Figure 7). The implant itself functions as a root to support the dental prosthetics. The complete dental implant restores the function of a natural tooth.

During this project, the focus will be on the dental implant that will be fixated in the bone.

An implant is highly recommended after losing one or more teeth, because the empty spaces in the mouth can lead to deterioration of jawbone, and to shifting of other teeth in undesirable directions. The dental implant will maintain the natural shape of the jaw, and therefore the face and smile (Wikipedia dental anatomy, 2017).

Dental implants are placed during a surgical procedure. This surgical procedure will be described in section 2.4.

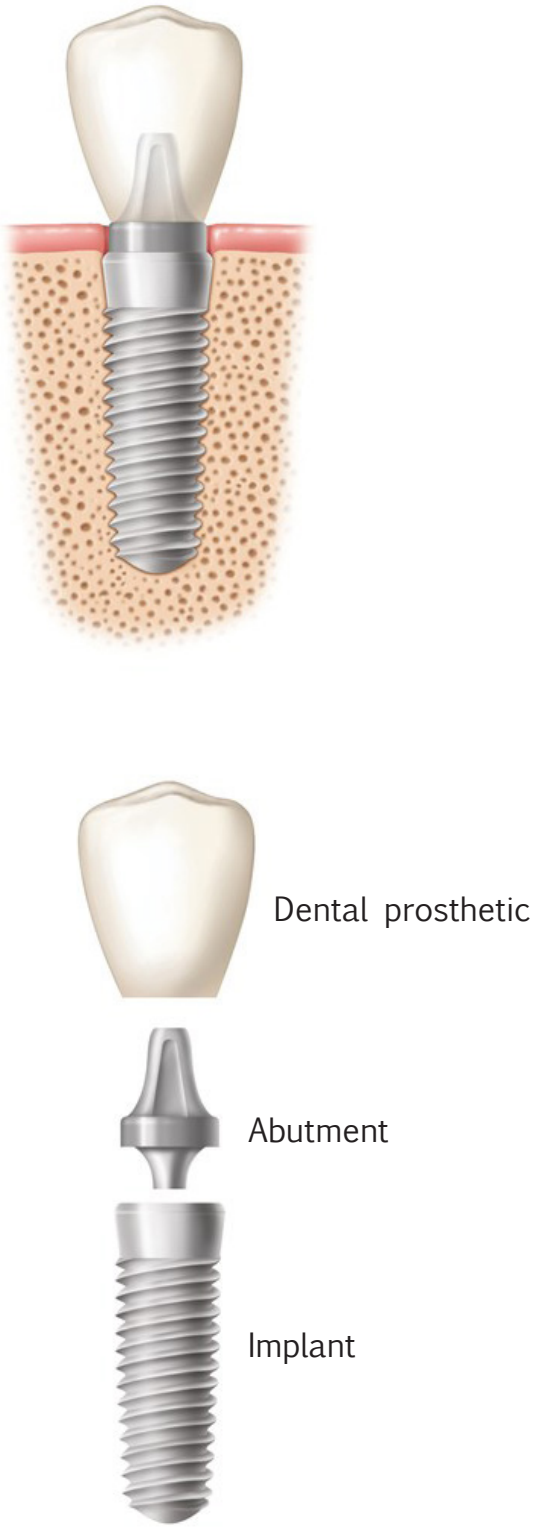


Figure 7: Dental implant and its components. Courtesy of juliadentistdental implants (2017)

Dental implant types

A considerable number of dental implants is available on the market. Typically, a dental implant is a screw-shaped implant made of titanium. However, a lot of other shapes and materials can be used as well.

In Figure 8 dental implants are presented in groups by different characterizations. By placement type, by shape, by type of treatment, by size, by type of material and by type of coating (Dental-implants, types of dental implants, 2017).

Placement type
First of all, dental implants can be ordered by type of placement. An implant can be implanted from the chin through the jawbone. These implants were used for people with very limited bone structure. Nowadays, these types of implants are not used anymore. Another type is the subperiosteal implant, this implant is placed on top of the jawbone below the gingiva. This type of implants is used in patients with insufficient bone width or height. Also, this procedure is not used anymore. The implants that are used nowadays are endosseous implants. These implants are placed in the jawbone to substitute the root. This type of implant is also referred to in this report.

Shape
Endosseous implants can be categorized by shape. Three main different shapes exist; blade shaped, cylindrical shaped and root/screw shaped. The most commonly used implant is the screw shaped implant. To this type of implant is referred to in this report.

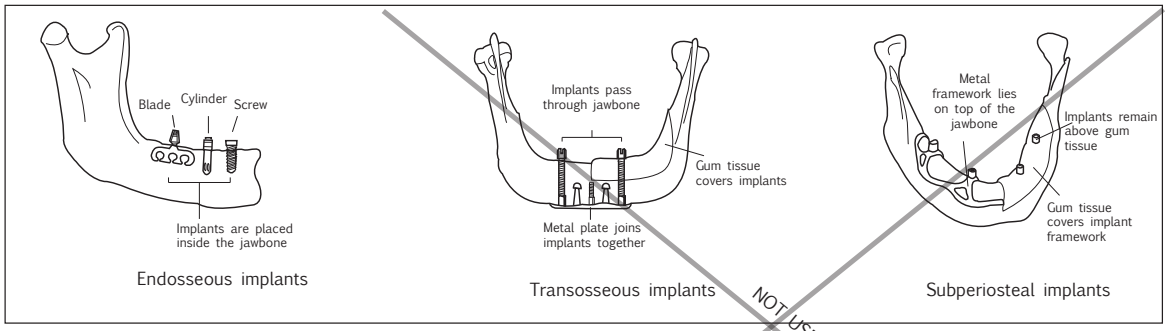
Treatment type
Different surgical procedures are used to place a dental implant. The two main procedures are the two-phase and the one-phase.
For the two-phase procedure bone-level implants are used. The gingiva is covering the implant during healing.
For the one-stage procedure tissue-level implants are used. The implant punctures through the gingival tissue. It is important that the implants are placed in the right way and no bacteria can enter the body via openings that exists.

Size
Dental implants can change in width and length. A standard implant has a width of 3.5-4.5mm and a length of 8-10mm. Narrow implants are used if there is a small space in the bone next to other roots and are mainly used for incisors. Narrow implants have a diameter of 1.8-3.5mm. Wide implants with a diameter of 4.5-6.0mm are used to replace molars. They withstand more load during chewing. Shorter implants can be used, mostly in case of incisor replacement, to prevent the risk of damaging the sinus or nerves.

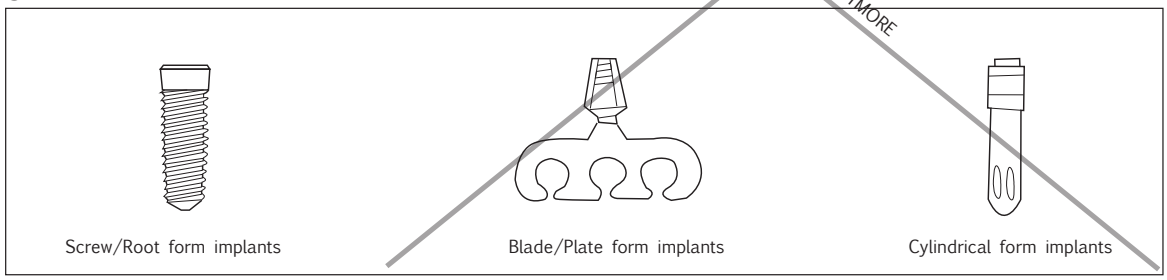
Material
There are several types of material used to manufacture implants. The main material used is commercially pure titanium. At the moment, this is shifting towards titanium alloys, such as Ti6Al4V, titanium with aluminum and zirconium which is slightly harder than pure titanium. Other materials that can be used are ceramic and zirconium. Ceramic and zirconium implants are white and are not visible through the gingival tissue. Grey titanium implants are visible if the patient has thin gingiva, which has an unaesthetic effect (Wataha, 1996).

Coating
Coatings can be applied on the implants to support better osseointegration, to prevent infection, or to increase surface area. Different methods can be used for this, for example sandblasting, anodizing or plasma spraying or applying an hydroxyapatite layer (Dental-implants, types of dental implants, 2017).

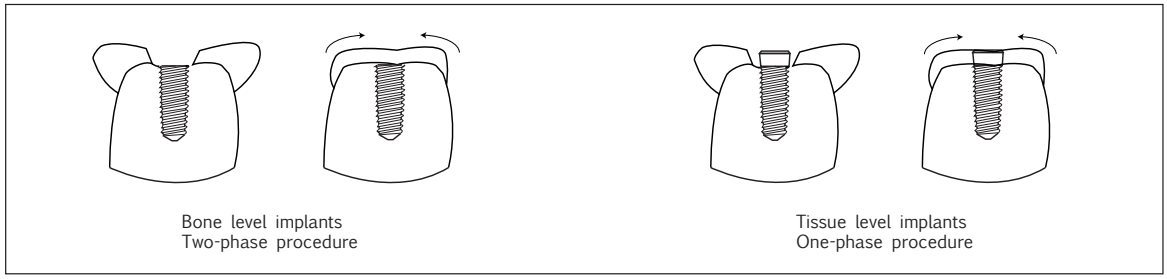
PLACEMENT TYPE



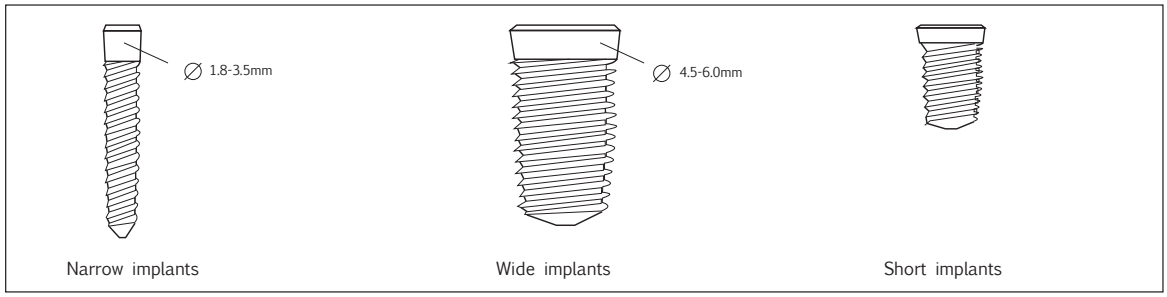
SHAPE



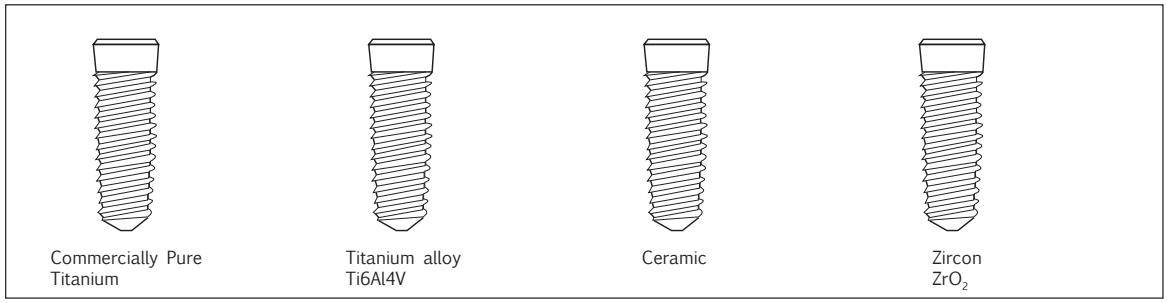
STAGES OF TREATMENT



SIZE



TYPE OF MATERIAL



TYPE OF COATING

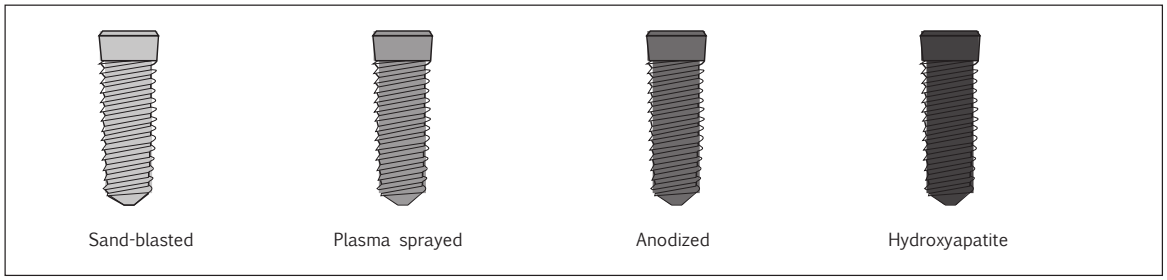


Figure 8: Dental implant types ordered in groups

Dental implants on the market

The two largest companies producing dental implants are Straumann and Nobel Biocare. Other large companies offering dental implants are Dyna and Zimmer Biomet.

Straumann

In Figure 9 the implant product portfolio of Straumann is shown. As can be seen, they have divided their implants into tissue level implants and bone level implants. They also offer ceramic and roxolid implants. Roxolid is a titanium alloy with zirconium and it has a higher strength than that of titanium, so the implants made out of this material can be made shorter. This leads to shorter treatment times and less post-operative discomfort, because it has better vascularization (Straumann, products and solution, 2017). All implants are available in different lengths and diameters. The shape can be straight or tapered.

Nobel Biocare

Nobel Biocare offers dental implants. All implants are available in many widths and lengths (Figure 10). No clear distinction is found between bone level implants and tissue level implants. More focus is on the connection type to the abutment (Nobel Biocare, products and solutions, 2017).

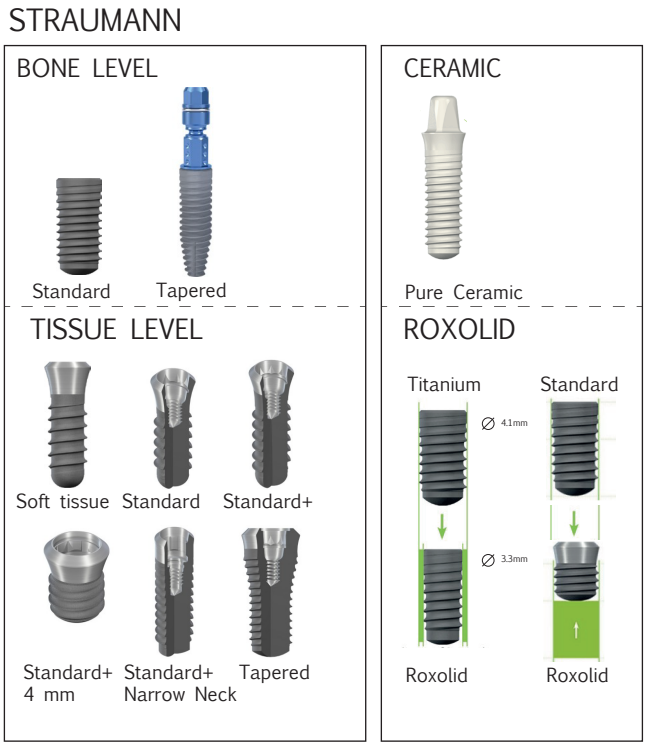


Figure 9: Dental implant types Straumann. Courtesy of straumann.nl (2018)

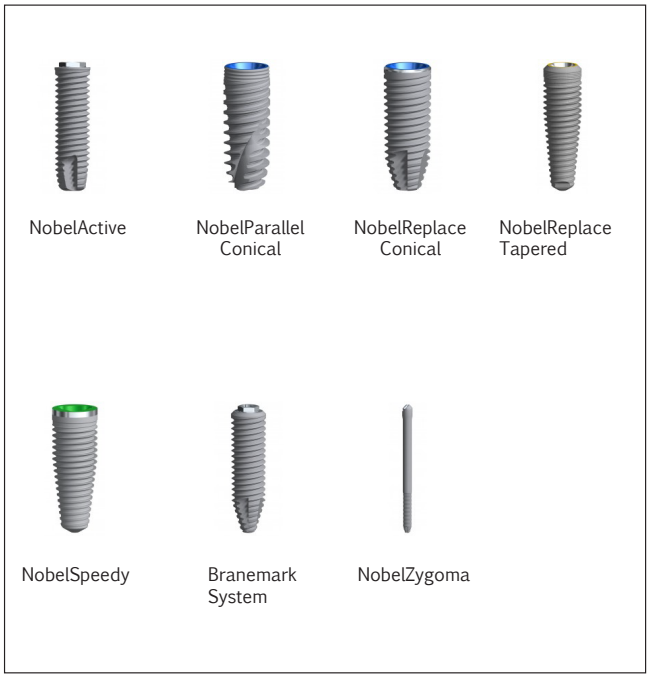


Figure 10: Dental implant types NobelBiocare. Courtesy of nobelbiocare.com (2018)

Conclusions

The demand for dental implants is growing. There is an aging society and people care more about aesthetics. Dental implants are able to restore the function of teeth and thereby it will increase the quality of life of people.

There is a high variety of dental implants on the market. Implants can differ in length, in diameter, internal structure, shape, material and coating.
For the patient, the optimal dental implant can be picked. The choice is dependent on which implants are available in the hospital and the preference of the surgeon.

However from the wide variety of implants the actual differences between the implants is very small. All the implants look like a screw and only the dimensions differ. With a more critical view one could say there is not a lot of difference between the implants on the market.

The reason for this could be that titanium implant screws are the preferred implants, because they are proven to have a long-life time, are biocompatible and are able to be surface treated to change structure and to apply a coating. The screw implants are easily implemented by using the same method every time. Dentists and surgeons are used to this way of working.

2.3 Patients

This section focuses on the the patient. First the diagnosis and treatment steps from a patient perspective are described, including an overview of all stakeholders involved. Thereafter an analysis of the patient expectations and outcomes is given.

Stakeholders

All relevant stakeholders active during the complete dental implant procedure are shown in Figure 11.

Figure 11: Stakeholders involved in the entire treatment

Diagnosis and treatment

Before receiving a dental implant, the patient should be diagnosed by a dentist. The dentist will suggest and indicate that an implant is needed. When the diagnosis is made, appointments to discuss the treatment option are made. Thereafter the procedure can start and will be successfully finished if the right steps are taken. (Straumann brochure, 2017; Suy (2017)

The steps that are relevant for a good diagnosis and treatment are:

Step 1: Patient is aware of missing teeth or limited function of the teeth.

Step 2: Appointment with the dentist and diagnosis.

Step 3: Referral to oral surgeon or specialized dentist. Checks are done, scans are made, patient is informed.

Step 4: Next appointment with the oral surgeon: Removing teeth that needs to be replaced.

Step 5: Next appointment with the oral surgeon: Implant placement by oral surgeon.

Step 6: Next appointment: Removal of the sutures by dentist.

Step 7: Next appointment: Crown placement by dentist. Crown is made by a dental technician.

Step 8: Next appointments: Regular check-ups by oral hygienist to check the oral health.

In Figure 12 a schematic overview is given to show the path of a patient through the diagnosis and treatment phase.

In Figure 13 an overview of the diagnosis and treatment steps are given. In the figure, it is also shown which stakeholder is involved in which step of the procedure.

A more elaborate description of the steps is presented in appendix I.

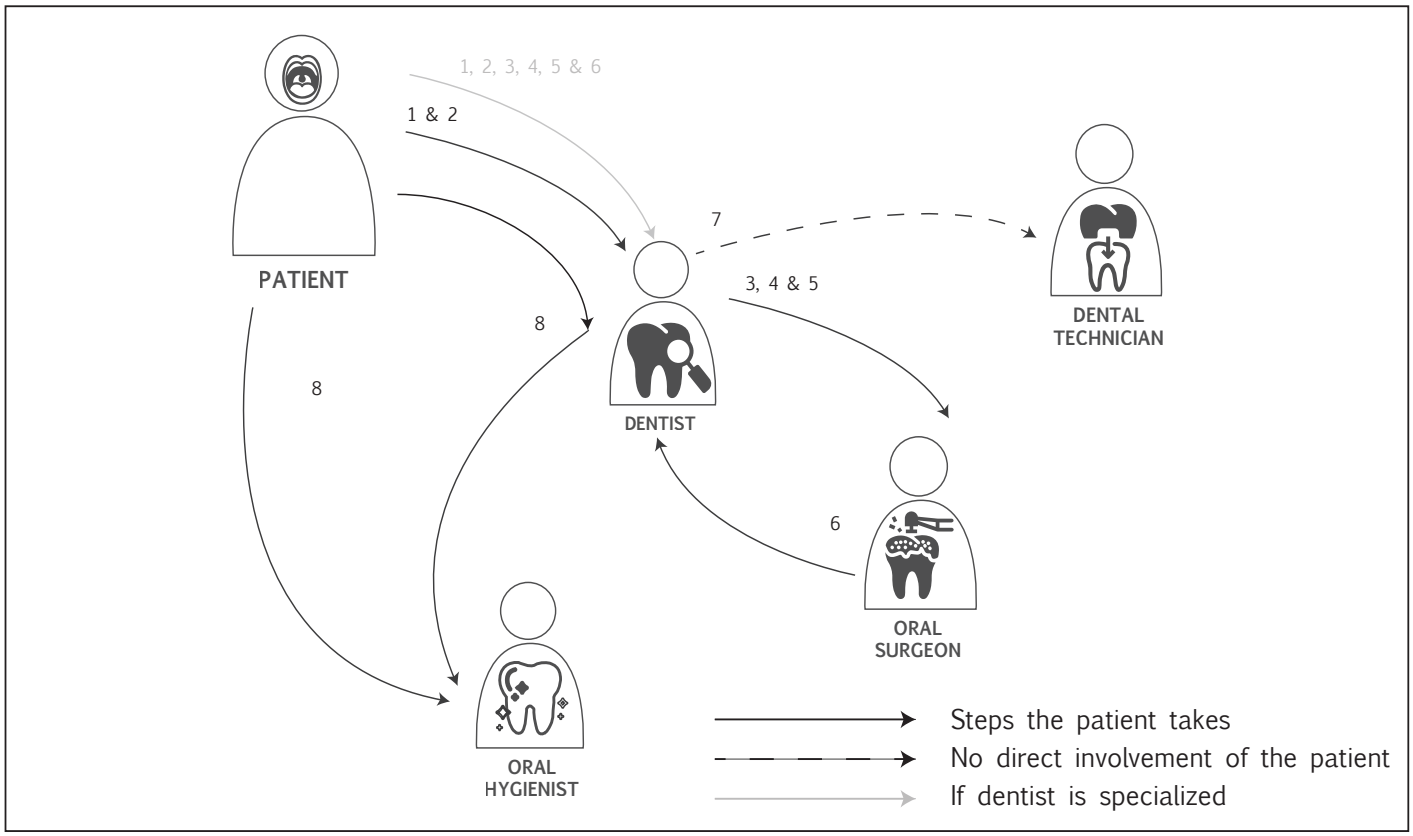
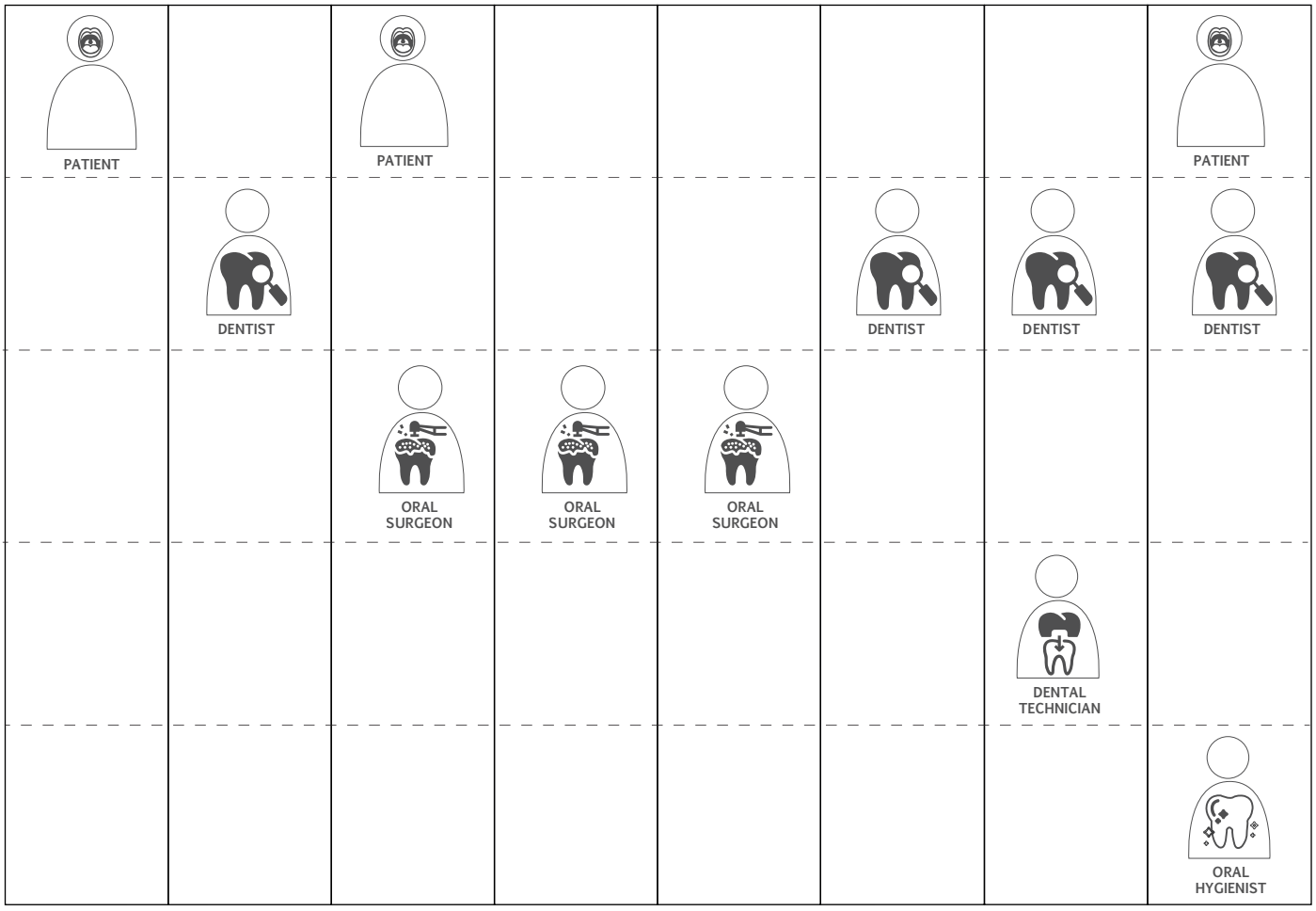


Figure 12: Diagnosis and treatment steps form a patient perspective

STEPS AND EXPLANATIONS

1. AWARE OF PROBLEMS	2. DENTIST APPOINTMENT	3. REFERRAL	4. EXTRACTING TEETH	5. IMPLANT PLACEMENT	6. SUTURE REMOVAL	7. DENTAL PROSTHETIC	8. ORAL HYGIENE
Trauma Bad hygiene Periodontitis Problems are experienced.	Check the teeth. X-ray Cone beam CT scan	Explanation of procedure. Treatment options are discussed. Costs will be listed.	Extracting of teeth. Bone healing	Implant placement during a surgical procedure. Bone healing and osseointegration.	Check the implant and sutures are removed.	Dental technician makes a perfect fitting dental prosthetic. Dentist places the prostetic on the implant.	Regular visits to oral hygienists. Check ups.

MOST IMPORTANT STAKEHOLDERS



NEXT STEPS

Go to the dentist. →	Treatment-plan or referral to oral surgeon or specialized dentist →	Agreement and signing of the document to continue the treatment. →	Bone healing. Back to dentist/oral surgeon. →	Bone healing and osseointegration. Back to dentist. →	Oral hygiene is important from now on. Back to own dentist. →	Oral hygiene care. Back to dentist →	Continue with oral care. Regularly consult by the oral hygienist. →

Figure 13: Dental implants diagnosis and treatment steps

Patient expectations and outcomes

Patients have a big influence on the dental implant procedure. People themselves decides if they want to have an implant or not. Therefore, it is very important that patient satisfaction is high and that the expectations are realistic.

In order to find out what patients experience during teeth loss and what their expectations are of dental implants a literature study is conducted. What should be taken into account in this chapter is that the studies are from all over the world and not specifically focused on one country.

Missing teeth or bad teeth can have a disastrous influence on a person's life. Bad teeth can lead to a decreased quality of life. People do not dare to go to social events because of a low self-esteem. They are afraid that people see their bad teeth.

Missing teeth does not only have psychological effects it also affects the persons in a physiological way, by not being able to chew and this has impact on the nutrition of the body (Johannsen, Westergren, & Johannsen, 2012).

Receiving a dental implant can have a significant positive influence in people's life. A dental implant lead to improved function and aesthethitcally good teeth. This can give people more confidence. (Johannsen et al., 2012).

From different research articles, it is stated that people have high expectations of dental implants. They believe that implants can last a lifetime (Atieh, Morgaine, & Duncan, 2016; Hof et al., 2014; Johannsen et al., 2012), that the total treatment time is around 4 months (Hof et al., 2014), and that no special hygiene care is needed after implantation (Johannsen et al., 2012).

However, these expectations and assumptions are all incorrect. A dental implant last around 15-20 years, the total treatment time is at least 6 months in most cases, and it is important to treat the dental implants with special hygiene care to prevent failure of the implants (Johannsen et al., 2012). Because the patients have such high expectations, the level of satisfaction is low. The information sources are mainly relatives and the internet. These sources do not always provide evidence-based details.

To overcome these misunderstandings, leading to too high expectations, it is advised to stimulate patient-centered communication between the patient and the dentist. This means that the decision is not only dependent on the expertise of the dentist but also by considering expectations, feelings and opinions of the patient. This communication should be verbal and nonverbal to ensure that a realistic forecast of the outcome is given. It is also important that the patient is accompanied by a relative. (Abrahamsson et al., 2017; Atieh et al., 2016; Hof et al., 2014; McCrea, 2017; Al-Dwairi et al., 2014).

People should also be informed in a way that stress and anxiety will be minimized. Anxiety and stress can affect the way in which the information is received. If people have a higher anxiety level the chance to undergo the procedure is lower than for people with lower anxiety levels (Lalabonova, 2015).

A low level of anxiety and stress is preferred for patients that proceed with the procedure, because stress and anxiety can suppress bodily functions which will negatively influence the recovery (Lalabonova, 2015).

The main reason for choosing a dental implant is the restored function of the teeth. However, there are reasons not to choose for an implant. The main reasons for not receiving an implant is the high costs (45%), the fear of unknown side effects and surgical effects (27,3%) and the long treatment times the procedure requires (24,7%) (Al-Dwairi et al., 2014; Hof et al., 2014; Atieh et al., 2016). A complete procedure can take around one year. This is mainly due to the long healing times in between surgical procedures.

In Figure 14 an overview of the patients expectations is given.

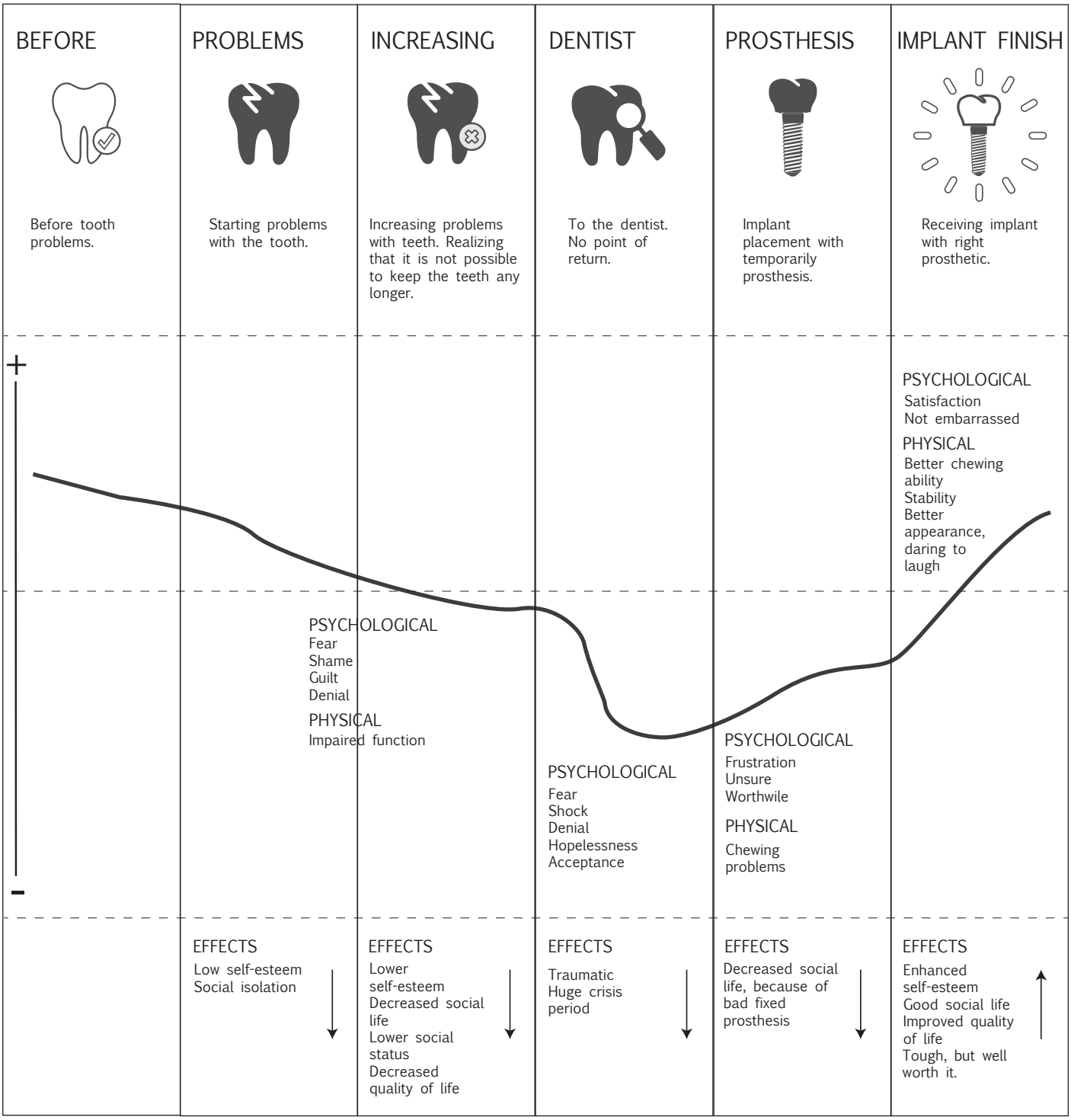


Figure 14: Dental implants from a patient perspective

Conclusions

Realistic expectations are required for high satisfaction levels for patients. Good personal communication between the dentist and the patient lead to this as well as reduced stress and anxiety The main concerns of implants are the high costs, fear, and long treatment times.

An opportunity lies in designing new implants that will reduce the treatment times and lower the negative side effects.

2.4 Surgical procedure

This section focuses on the surgical procedure of placing a dental implant. First all the different procedures are described, followed by the surgical tools that are needed during surgery.

Surgical procedure

A dental implant is placed in the jawbone during a surgery. There are two main surgical procedures to place the implant; one-phase and two-phase procedure.

Before implant placement surgeries.
Before every surgery the toot that should be replaced is taken out. Thereafter the wound is sutured and the bone needs to heal for 3-6 months to close the gap.

One-phase procedure
The most common procedure is the one-phase procedure and the main principle of the surgery is as follows (Figure 15):

- The gingiva is opened and flaps are created.
- A pilot hole is created in the bone.
- With a small diameter drill a hole is created in the bone.
- A larger diameter drill is used to make the hole bigger. (4-6x)
- The implant is screwed into the hole.
- A healing cap is placed to close the implant, which punctures through the gingival tissue.
- The gingiva flaps are closed and sutured.
- Bone should heal and integrate with the implant for 2-6 months.

Placement of the dental prosthetic:

- Healing cap is removed.
- The abutment is placed on the implant.
- Dental prosthetic is placed.

During the one stage procedure only one surgical event takes place. (Froum, 2010)

Two-phase procedure
During the two-phase procedure, the implant is placed in two times and two surgeries are needed. In the first phase the implant will be fixed in the bone by the same procedural steps as the one phase procedure except that the healing cap is placed underneath the gingival tissue. After 3-6 months, the next phase starts; the gingiva needs to be opened again and the abutment will be placed on the implant and the dental prosthetic will be placed (Froum, 2017) (Figure 15).

Other procedures
However the surgical procedure is not optimal yet and therefore procedures are developed to decrease treatment time, to preserve most tissue as possible, to reduce pain, to lower the recovery time, to reduce costs and most importantly to reduce the risks of complications.

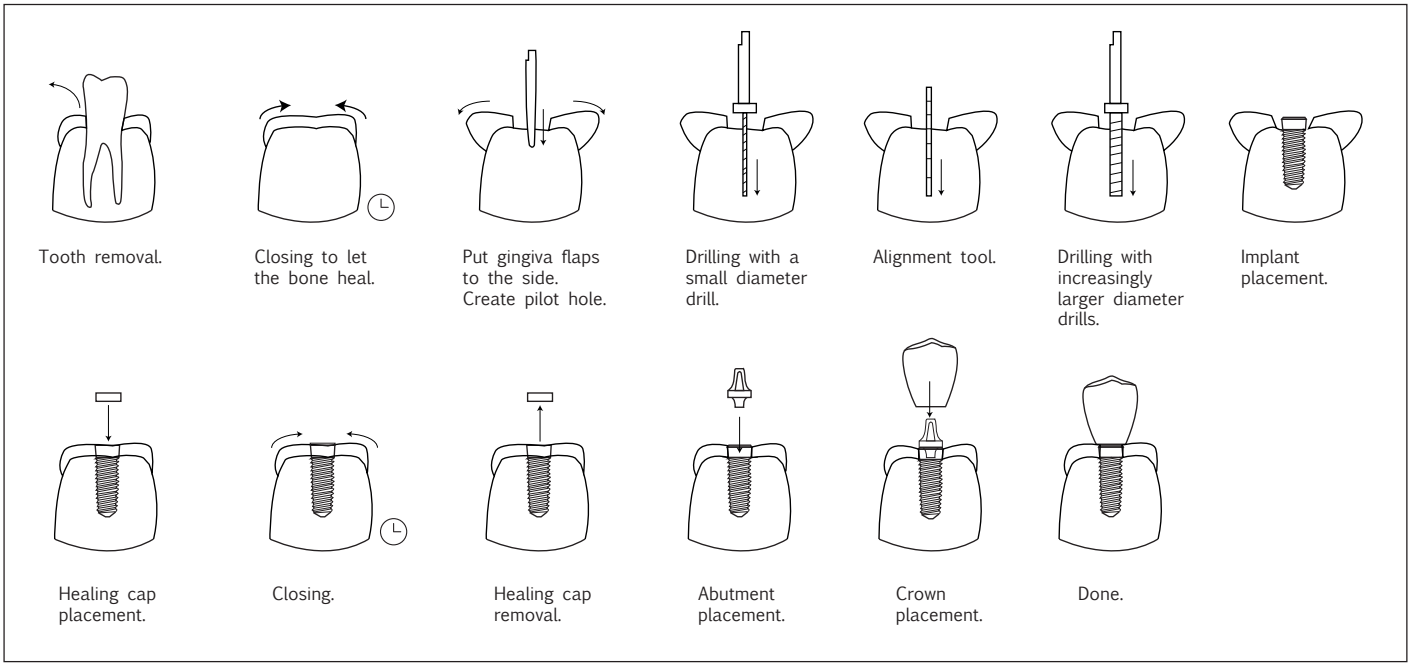
One of them is the *flapless surgery technique.* This is a minimally invasive surgery in which the drilling and implantation is done through the gingiva into the bone (Figure 15).

Another one is the *immediate/direct loading method.* In this method, the dental prosthetic is placed within 72 hours after implant placement. The method is developed to reduce the treatment time (Figure 15).

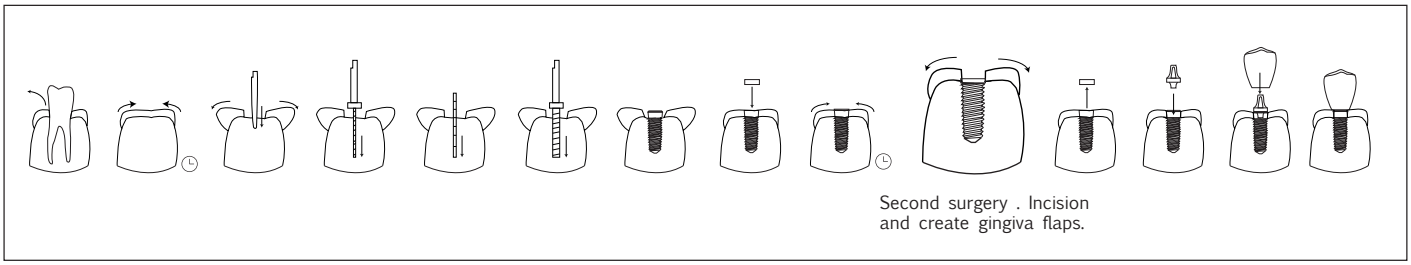
Another alternative method is *immediate implant placement into extraction sites.* In this method, the implant is directly placed after the tooth is extracted, this reduces the amount of surgical procedures, length of treatment, costs, and discomfort (Figure 15).

The type of procedure and the specific steps needed during the surgery are dependent on the patient's situation. In case a patient is edentate, i.e. does not have any teeth, the position of the implant is less important than a patient who is only missing one teeth.

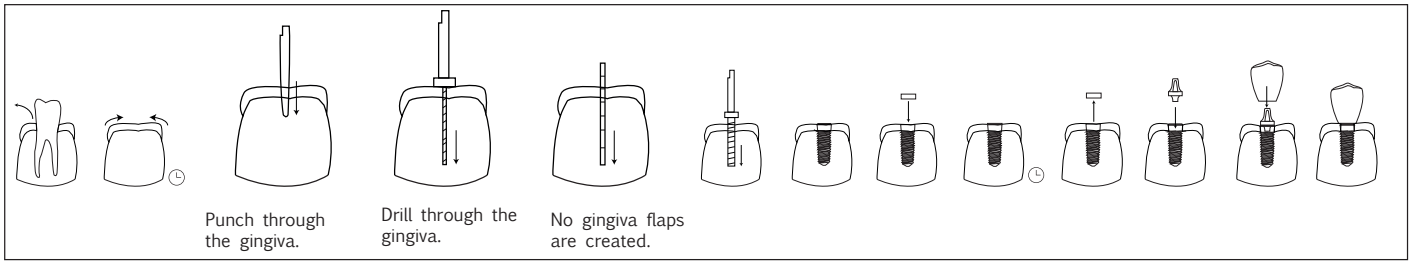
ONE PHASE PROCEDURE



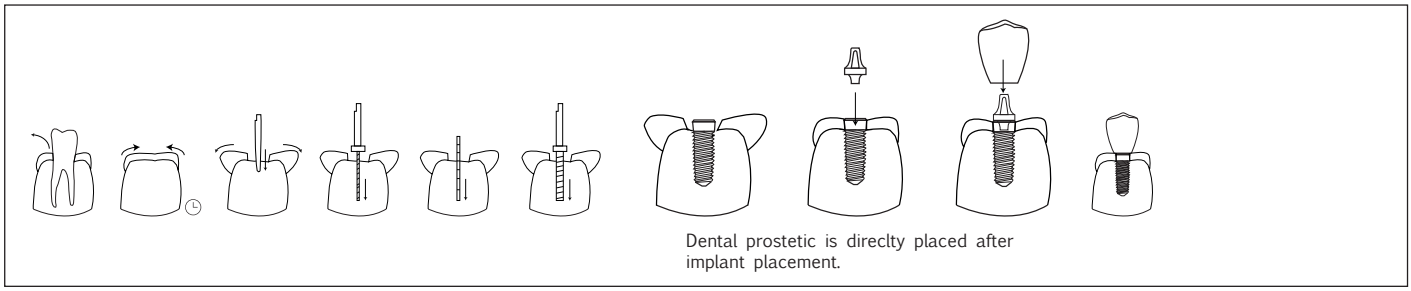
TWO PHASE PROCEDURE



FLAPLESS SURGERY



IMMEDIATE LOADING



IMMEDIATE PLACEMENT INTO EXTRACTION SITES

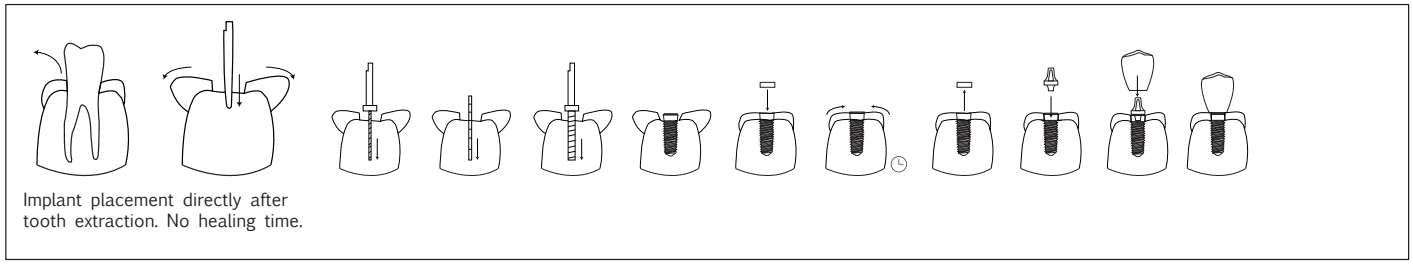


Figure 15: An overview of the different procedures. Larger icons indicate a change in procedure compared to the one-phase procedure.

Surgical tools

The tools needed for surgery a shown in Figure 16 and Figure 17. The main part of the surgery is the drilling of the hole. It is important to drill a hole in such a way that the implant will fit perfectly. The drills are specially created for dental implant procedures.

Straumann offers a surgical cassette to make the surgery easier and smoother. The surgical cassette consists of the drills and related tools needed for surgery. Via color-coding a straightforward and organized workflow is indicated. Figure 18 shows the surgical cassette (Straumann, products and solution, 2017).

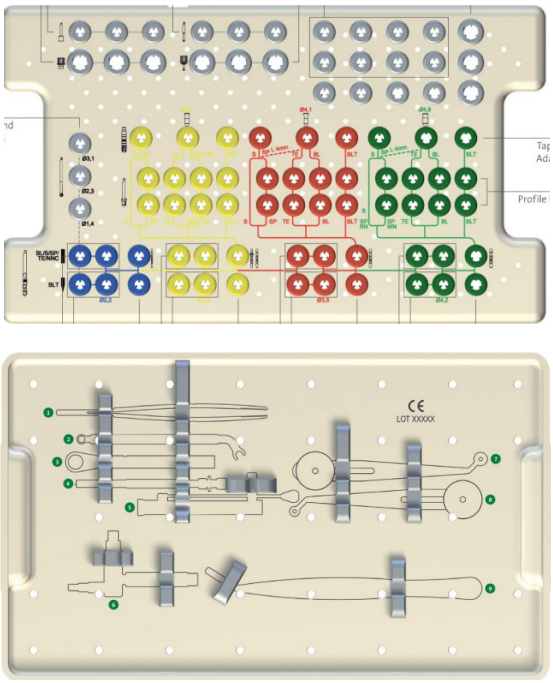


Figure 18: Surgical cassette, Courtesy of straumann.nl (2018)

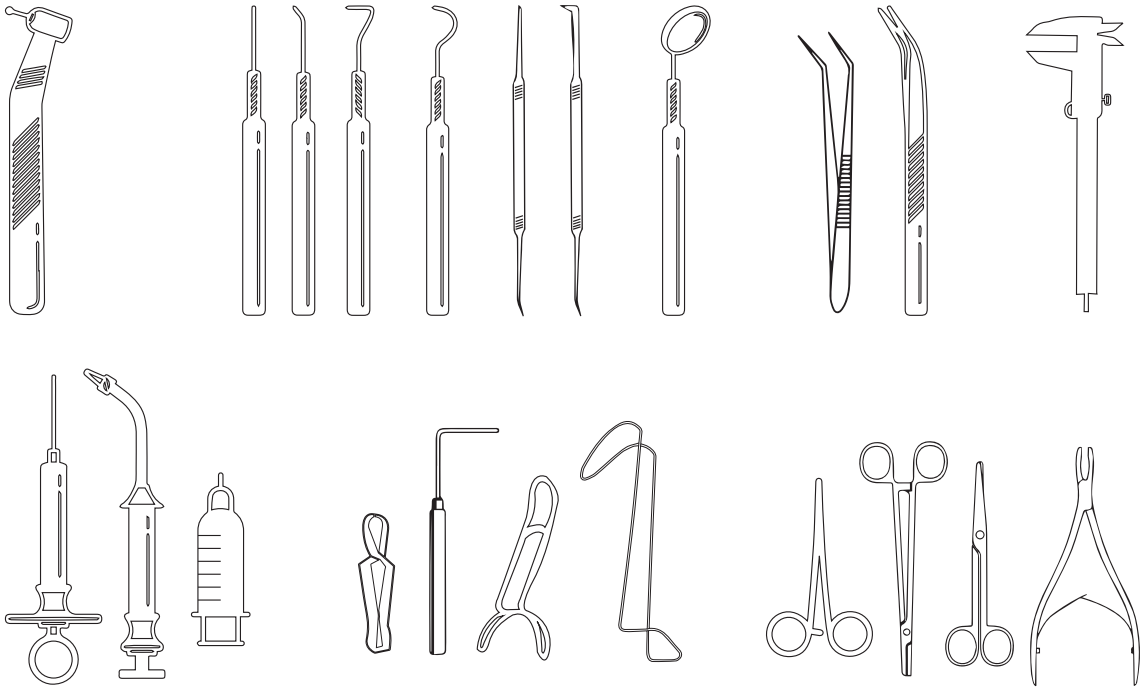


Figure 16: Surgical tools. Courtesy of Adam Zubin, Iconic, Nook Fulloption, Creatica Creative Agency, Oleksandr Panasovsky, Susana Ruelas, Pierre Biome Martin from Noun Project

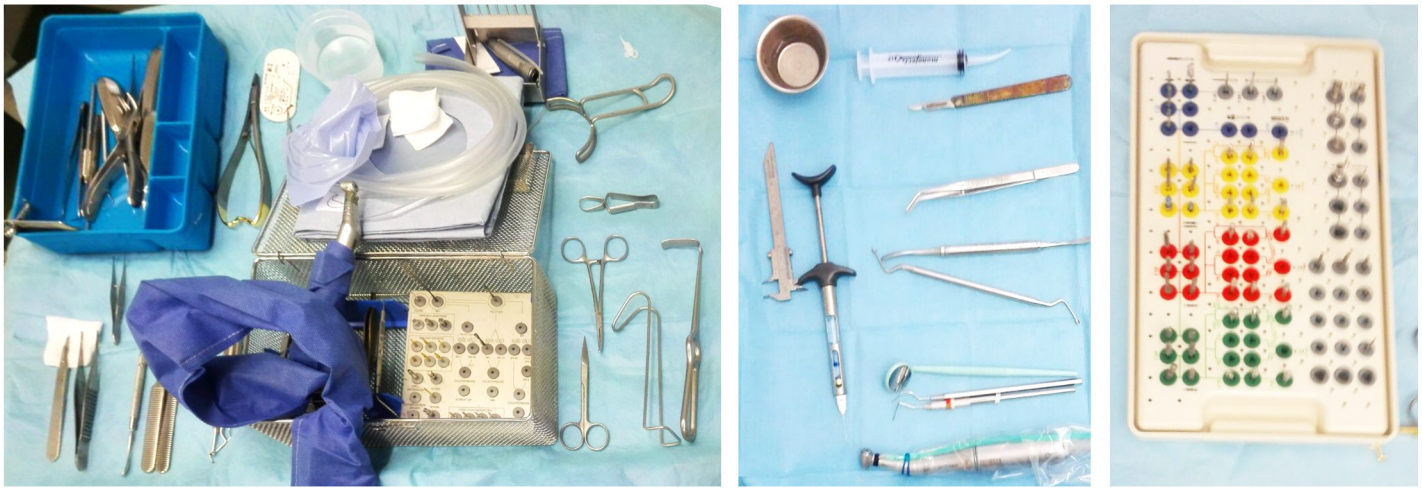


Figure 17: Surgical tools

2.5 Observations - surgical procedures

This section is about the five surgeries that are observed. To analyse the surgeries different types of models are created.

In order to see how the dental implants are used and how a surgical procedure is performed in real life five surgeries are observed. The observations took place in an academic hospital, a general hospital and in a dental practice. In Figure 19 an overview of the observed surgeries is created.

All one-phase procedures were performed on the patients. Edentulous patients as well as patients with only missing one tooth were observed. In one case the dental implant was not placed because two big inflammations were found and these needed to be removed first.

To analyze the observations, the following models are created;
- sequence model
- physical model
- communication flow model
- coordination flow model
- cultural model

In the models, an exclamation mark can be seen, this means that something went wrong.

In the following sections every model is shortly explained and a short analysis of every surgery is shown. In appendix II an elaborate analysis can be seen.

Sequence model

The sequence model shows the steps that are taken during the procedure and by whom this is conducted. In an adjusted sequence model, also the way of thinking and feeling is shown.

In the following paragraphs a short description of every surgery is given.

Surgery 1

Hospital:	Academic hospital case 1
Procedure:	Inflammation treatment
Location of the implant:	-
Dental prosthetic:	-
Complications:	Two big inflammations. No dental implant
Implant brand:	-

Surgery 2

Hospital:	Academic hospital case 2
Procedure:	One-phase
Location of the implant:	4 in the mandible (edentulous patient)
Dental prosthetic:	Denture
Complications:	-
Implant brand:	Nobel Biocare

Surgery 3

Hospital:	General hospital case 1
Procedure:	One-phase
Location of the implant:	1 in the maxilla
Dental prosthetic:	Crown
Complications:	-
Implant brand:	Straumann

Surgery 4

Hospital:	General hospital case 2
Procedure:	One-phase
Location of the implant:	1 in the mandible
Dental prosthetic:	Crown
Complications:	-
Implant brand:	Straumann

Surgery 5

Hospital:	Dental practice
Procedure:	One-phase
Location of the implant:	2 in the maxilla (edentulous patient)
Dental prosthetic:	Bridge
Complications:	-
Implant brand:	Straumann and Nobel Biocare

Figure 19: Overview of the observed surgeries

Surgery 1: Academic hospital case 1

The first surgery in the academic hospital was performed by an oral surgeon assisted by an oral surgeon in training and a circulating assistant. The patient was a woman who would get a dental implant as a replacement for a lateral incisor in the maxilla.

This surgery was quite hectic, because it did not go as planned. Two big inflammations were identified and were directly treated. Also some inattentive moments during the preparation phase have led to irritations during the surgery.

What can be concluded is that a good preparation is essential for a good surgery and that complications can occur at any time. All medical professionals should be trained to deal with unforeseen circumstances and to directly react on it.

In the further analysis of the procedures this surgery is not taken into account, because no implant was placed.

Surgery 2: Academic hospital case 2

The second surgery in the academic hospital was performed by the same oral surgeon was assisted by a surgical assistant and a circulating assistant.

Four implants were inserted in the maxilla of an edentulous patient. All implants were placed according to the one-phase method. Overall the surgery went well.

The patient had to cough many times, because too much water came into his mouth during drilling.

The surgeon wanted to change the amount of water but he did not know exactly how it worked. This caused some irritation.

Another point; according to the surgeon, the assistent opened the packages in a wrong order. Good communication is important and it is very important that the surgeon can work with tools he is familiar with. By providing tools that people don't know how to use, dangerous circumstances can be created. In the thinking and feeling scheme it is visible that the surgeon was irritated by not knowing how the device exactly worked. The surgery went very good, and according to plan.

Surgery 3: General hospital case 1

The third surgery was performed in a general hospital by an oral surgeon and a surgical assistant and assisted by the circulating assistant. The patient was a young man who had one tooth replaced in the maxilla. Different from the other surgeries observed was that the medical professionals were all standing during the procedure. Another important observation was that this oral surgeon was turning in the implant manually, in the other observed surgeries the insertion was done by using the drill.

During surgery an extra x-ray was taken in order to check the direction and position of the created hole. The x-ray device is located in a different room. The patient and the surgical assistant had to go to another room during the procedure. After the x-ray was taken it showed that the direction and position was not optimal. The surgeon decided to deviate from the original plan by changing the implant size from 10mm to 8mm. This also affected the thinking and feeling.

Concluded can be that if the equipment is not located in the treatment room, the surgery might be more complex since the patient has to come out of the chair and has to walk with tools in his mouth, which is very uncomfortable. The other conclusion is that adjustments in the planning can be made. Changing went in this case very fast and the new implant was delivered quickly.

Surgery 4: General hospital case 2

The fourth surgery was also performed in the general hospital by the same surgeon and assistant as surgery 3. The anesthesia was given at the same time as the patient in the third surgery went to the x-ray room. At a certain time two patients were treated at the same time in two different rooms.

After opening the gingiva and inspecting the bone, the surgeon saw that the bone was thinner than she had expected. This required more precision and concentration. As was also the case in surgery 3, the patient had to go to another room for the x-ray,

which is undesirable.

During the surgery, the surgeon had to go to do second opinion for another patient. She left for around 20 minutes. Because the surgeon was away for a long time, the anesthesia was not working anymore after she came back, so the patient experienced pain. Extra anesthesia was given.

The circulating assistant directly opened the implant packages, without showing it to the surgeon. The surgeon corrected her. After this, the surgery went well. The surgeon and the assistant were very happy with the good result, because it was not an easy surgery.

It is very important to communicate well and to stick to protocols. By working very careful, good results can be obtained.

Surgery 5: Dental practice

This surgery was performed in a dental practice by a specialized dentist. The patient was a woman who had had already two implants inserted a few years ago by the same dentist. She knew exactly what to expect. However, she noticed some differences and she was positive about this. She saw that there were still developments going on.

The preparation was done by the dentist and the surgical assistant. A good plan was created, and everything went according to the plan.

The circulating assistant was not there at the right time to open the implant packages. The dentist had to search for her. This meant that the dentist had to leave the sterile area. The dentist was irritated and frustrated by this incident.

In the end, the patient looked very happy that the surgery was successful.

Timing and communication between all stakeholders is very important.

For a more elaborate description of the surgeries, visuals and main similarities and differences see appendix II.

Physical model

The physical model shows the floor plan of the treatment rooms including the movements of the stakeholders. Every color indicates a different stakeholder. The rooms are similar to each other and look like normal dentist treatment rooms (Figure 20). In appendix II a more elaborate version of every floor plan is shown.

In all cases a separate room or hallway is present where the preparation takes place.

A main difference between the surgeries is that there is no real sterile area defined. In the general hospital even all stakeholders, including the patient are leavinf the treatment room during surgery. Use of clothing is also different in each situation. No clear rules exists on how to deal with sterile clothing/areas during these type of surgeries.

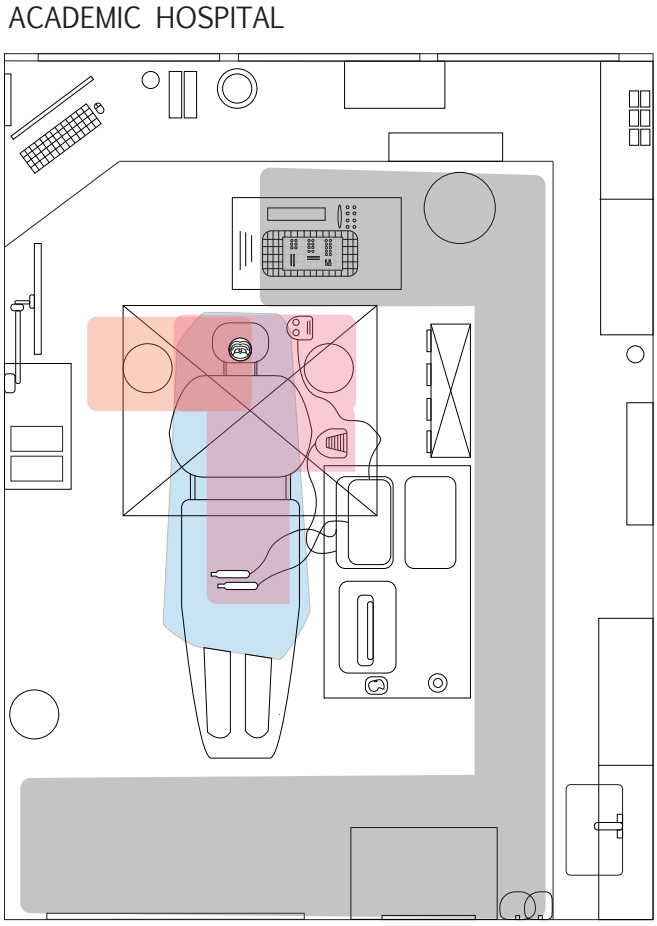


Figure 20: Map of the treatment room in the academic hospital

Flow model: Communication

The communication model describes who communicates with whom and in what kind of way (formal or informal). In Figure 21 the overall communication model is shown, based on the 4 individual models of the observed surgeries. These individual models can be found in appendix II.

All the communication towards the patient is formal. There is no communication between the circulating assistant and the patient in all cases.
Oral surgeon/dentist is explaining the procedure and what he/she is doing to the patient in all cases.
The surgical assistant is there to to reassure the patient.
In almost all cases the communication between the oral surgeon/dentist and the circulating assistant is not smooth. The reason for this can be that the assistant and the surgeon/dentist did not have a clear planning or a lack of experience by the assistent. This should be optimized, by better communication, planning, and to obey the protocols.

Flow model: Coordination

The coordination flow model describes which products are given from and towards which stakeholder and what kind of planning is important and done by whom.
In Figure 22 the overall coordination flow model is shown. This is based on the 4 individual models of the observed surgeries. These individual models can be found in appendix II.

The coordination between the different stakeholders are in every case the same. All actors have a specific role and they know what is expected from them.

In the general hospital not all the equipment is located in the treatment room, this leads to a more complex procedure. The circulating assistents do have to follow protocols in order to let the process go well. This coordination needs to be improved in some cases.

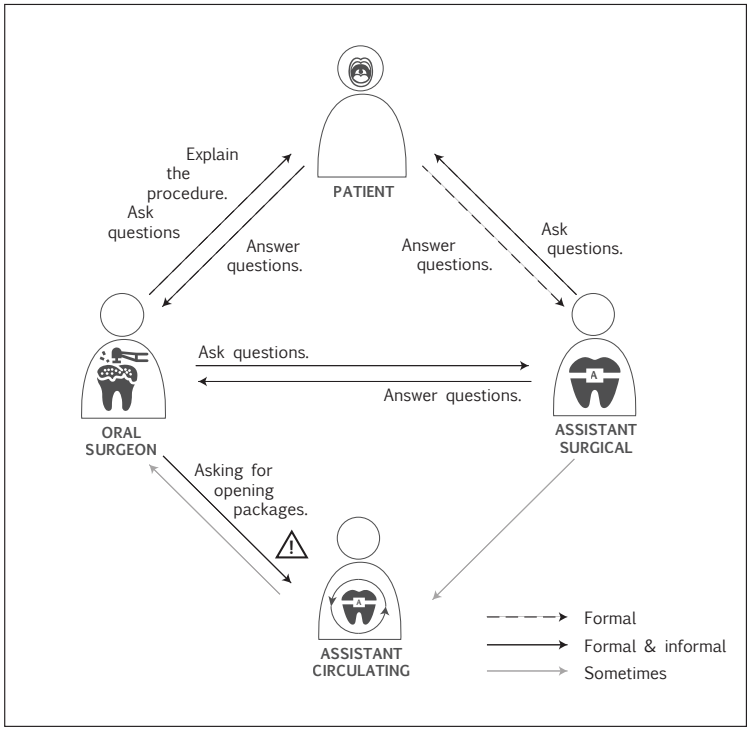


Figure 21: Flow model: communication

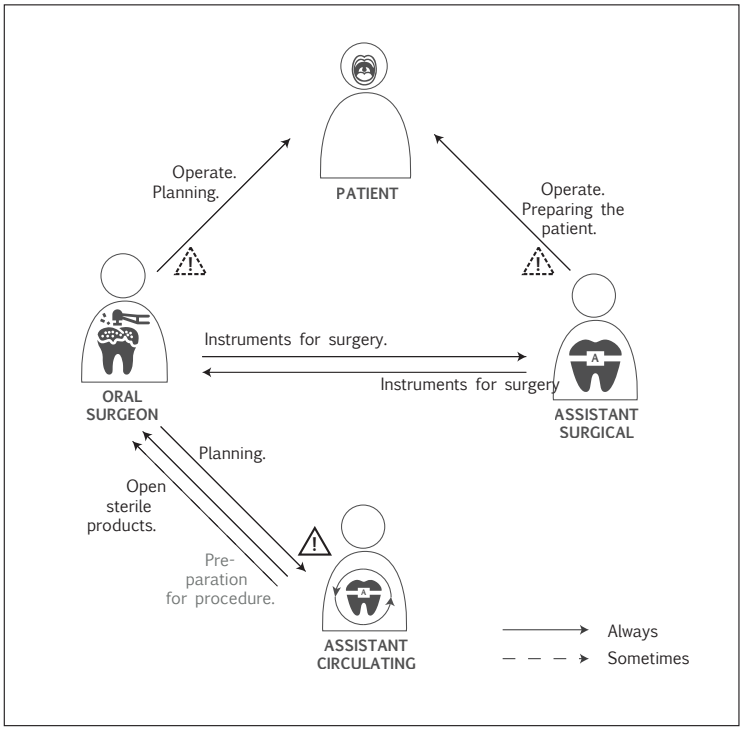


Figure 22: Flow model: coordination

Cultural model

The cultural model shows the hierarchy within the group of stakeholders and who influences who. The size of the circle visualizes the hierarchy of the stakeholder, so a bigger circle means more power. The thickness and the arrows show who has the power to influence the others. See Figure 23 and appendix II.

Dentist/oral surgeon has the highest hierarchy in all cases. The oral surgeon/ dentist determines what is happening and has the lead, because all the responsibility is on them. However, the patient is in every case on top of all stakeholders. If the patient does not want something to happen then the other involved stakeholders should accept that. So, in the end, the patient is the most important player.

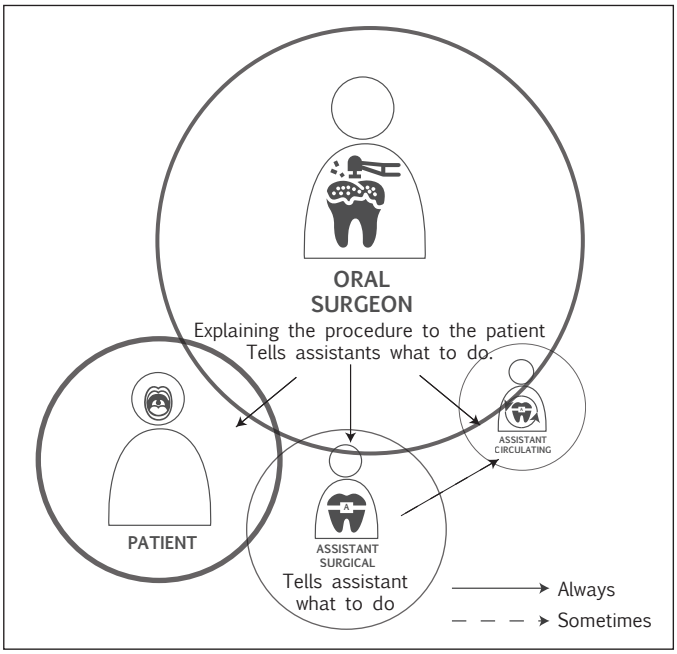


Figure 23: Cultural model

Conclusions

Dental implants are placed into the jawbone by a surgical procedure performed by a dentist or an oral surgeon. Different surgical procedures are used depending on the situation of the patient. The surgical procedure is not optimal yet and therefore procedures are developed to decrease treatment time, to preserve most tissue as possible, to reduce pain, to lower the recovery time, to reduce costs and most importantly to reduce the risks of complications.

It is surprisingly how much tools are needed for one surgery. The drills are only used for one-time use and are thrown away afterwards.

Five surgeries were observed at three different locations. During these surgeries the one-phase procedure was always performed. The main steps were followed every time, only some small steps differed during the procedures in different hospitals. Two edentulous patients came for a surgery and two with only one missing tooth. This led to slight changes in the procedure. According to the surgeons the most difficult part is the drilling of the hole to create such a hole that allows perfect position and direction of the implant. During a surgery plans can be adjusted, for example the size of the implants can be changed. If a good planning is made less changes are required during surgery. A good planning also means that everybody knows what he/she has to do and at what time. This is essential for a good surgery.

Coordination between all stakeholders can be improved, especially between the surgeon and the circulating assistant.

During surgery the oral surgeon decides what is going to jhappen in all cases.

2.6 Complications and challenges

This section focuses on complications that can occur during and after implant placement. The complications described here are the main complications that occur and on which will be focused during this report.

Dental implants are not free from failure. During surgery some complications can occur. The main complications are caused by stress shielding, a lack of osseointegration and infection (figure 23). In about 3-5% the implants will fail. (Buser et al., 2012; Sridhar et al., 2015; Gosau et al., 2016; Trindade et al., 2015; Cheng et al., 2015) In the following paragraphs these terms will be explained as well as how they lead to implant failure.

Complications

Stress-shielding

Stress shielding is a complication that occurs in all implants. It is a phenomenon in which the bone density is reduced because of stress removal from the bone by the implant. Bone does remodel by being influenced by loading according to Wolff's law. After implantation load is performed on the implant. If the implant has higher mechanical properties, such as a higher Young's modulus and strength the load will be distributed over the metal implant. The bone is than not triggered by the loading and the remodeling phase will not be optimal.

It leads to reduction in bone density and bone loss around the implant because the bone properties do not match with the mechanical properties of the implant. (Cheng et al., 2015; Ichim et al., 2016, Lee et al., 2012, Moin, Hassan, & Wismeijer, 2016; Niinomi et al., 2016; Pérez-Pevida et al., 2016)

A lack of osseointegration

A lack of osseointegration is another reason for implant failure. In the case of poor osseointegration, bone is not optimally grown onto the implant surface. If this occurs the implant is not well fixated within the bone and the implant is loosened.

Infection

Infection is another cause for failure. Infection in the dental implant is called peri-implantitis and is caused by bacteria (Sharma et al., 2016).

The main bacteria causing problems for dental implants are: Streptococcus gordonii, Streptococcus mutans, Streptococcus mitis, Streptococcus oralis, Streptococcus sanguinis, Lactobacillus salivarius, Porphyromonas gingivalis, Fusobacterium nucleatum, and Aggregatibacter actinomycetemcomitans (Abdulkareem et al., 2015).

The principle is as follows; bacteria will adhere to the implant surface and will grow and multiply. Bacteria create biofilm on the surface and they generate extracellular matrix. This matrix protects bacteria from antibiotics and adaptive immune cells, so the bacteria have the chance to grow and proliferate further without disturbance.
In the end, the bacteria can adhere onto the entire surface of the implant and create biofilm all over it. Because the implants are then fully covered by bacterial cells. Bone cells, such as osteoblast cannot adhere to the surface anymore, which leads to loosening of the implant by a lack of osseointegration. (Cheng et al., 2012)

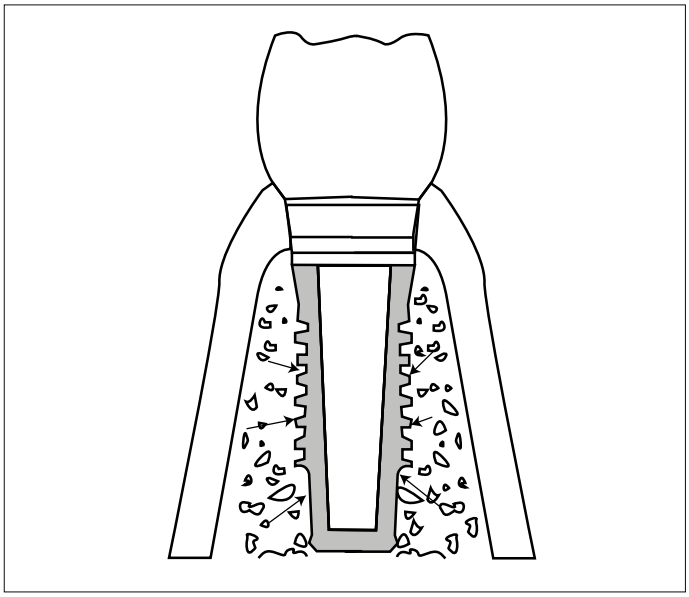
Infections are difficult to treat, because biofilm is formed and antibiotics are not able to reach the bacteria in the biofilm. Bacteria can grow and spread to other parts of the body. It can lead to bacteria differentiation into resistant types. The only option to remove the infection is by taking out the dental implant as well as affected tissue around the implant. (Lin et al., 2013; Wang et al., 2013)

An overview of the complications can de seen in Figure 24.

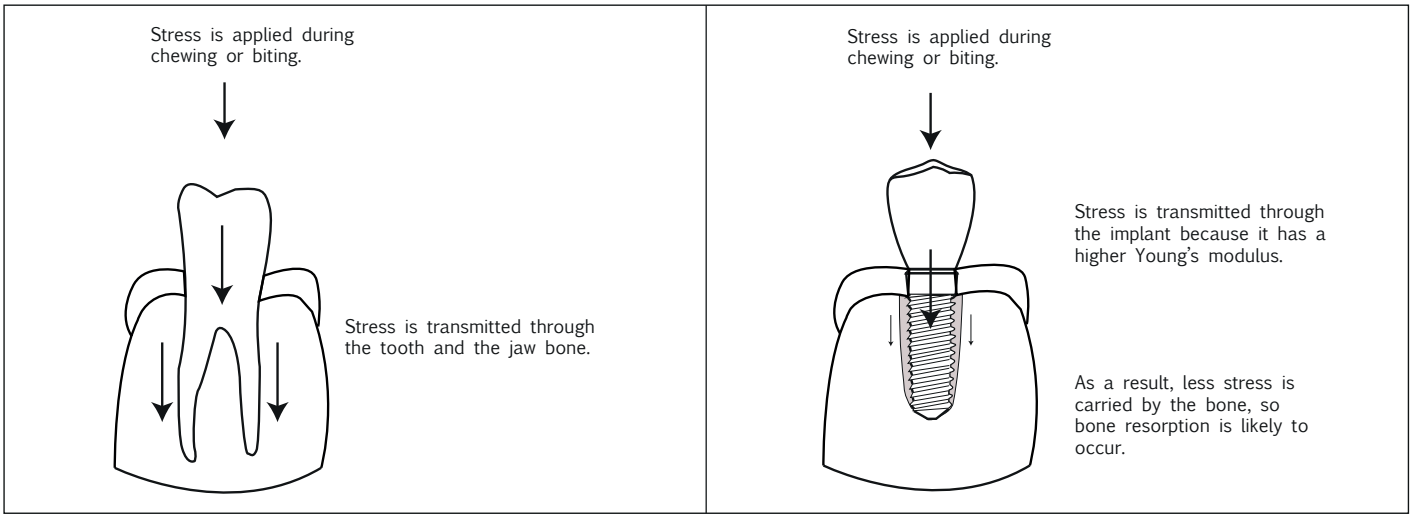
Conclusions

The main complications that lead to implant failure are loosening of the implant by a lack of osseointegration and infection. These two main problems can lead to the decision to take out the implant. In the design phase ways to minimize the risk of these complications are given.

OSSEOINTEGRATION



STRESS SHIELDING



INFECTION

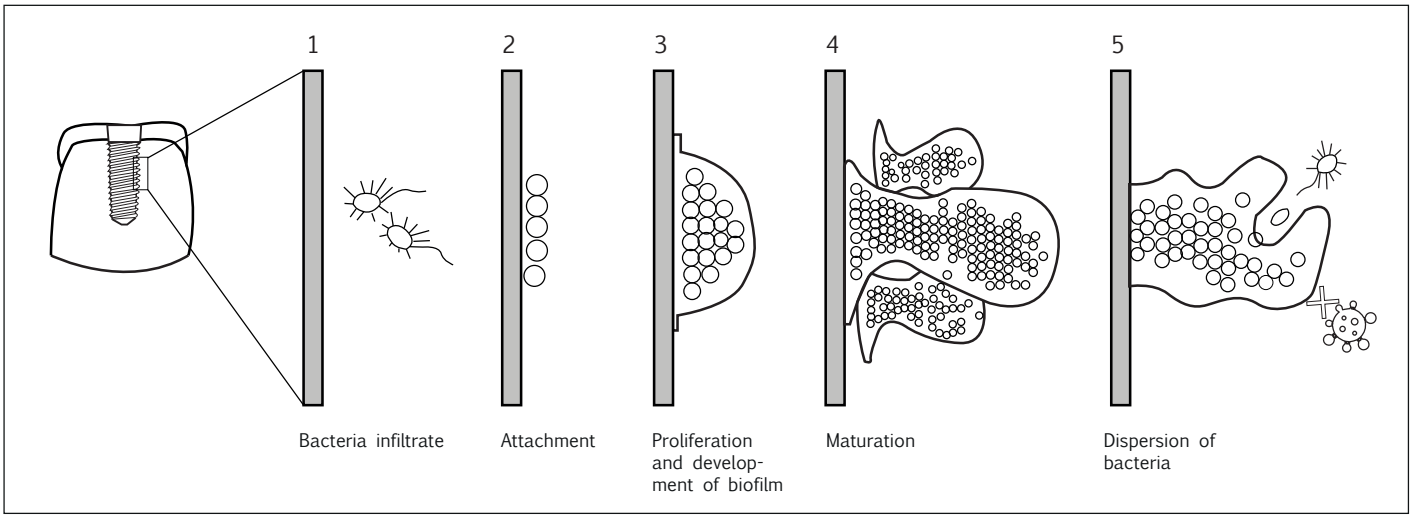


Figure 24: Causes for complications of dental implants

2.7 Developments in the dental implant industry

This section describes the developments that are taken place to overcome the challenges descirbed before. Focused is on additive manufacturing and on antimicorbial surfaces.

In order to overcome these complications, developments in the dental industry are taking place. The developments that are taking place have mainly to do with lowering treatment times, reducing implant failure by creating different types of implants, different materials for better stability and for better aesthetic results.

One of the developments is additive manufacturing of dental implants. Last decades a considerable amount of developments of additive manufacturing have taken place. Nowadays it is also used in the healthcare industry, mainly because of the high accuracy and the possibilities to print biomaterials and to create patient-specific products for patient-specific purposes. Without additive manufacturing personal products would have been difficult or even impossible to make.

Additive manufacturing in dental industry

Personalized products are not new in the dental industry. Crowns and dentures are already made in a patient-specific manner. For dental implant procedures, personalized tools are used, namely the surgical guiding molds to support and guide the surgeon during drilling and implant placement (Rathi et al.,, 2014; Gia et al., 2017; Louvrier et al., 2017, Torabi et al., 2015).

Additive manufacturing of dental implants

Dental implants can also be improved by using additive manufacturing. Additive manufacturing can be used to create a porous structure to promote osseointegration properties and to lower the negative stress-shielding effect, because the implant will be less stiff. Another advantage is that the porous structure mimics natural bone and that natural bone can grow into the pores, which leads to a better fixation.
Creating a porous structure, a larger surface area is there onto which more osteoblasts can adhere and form bone.

Based on literature studies, we can say that a pore size between around 300-1000µm is preferred. (Itälä et al. 2001; Kuboki et al., 2001; Bai et al., 2010; Taniguchi et al., 2016)

The unit cell type is dependent on the type of loading that is applied. A diamond structure is often used, because of its high Poisson's ratio and it can withstand load in different directions. (Wang et al., 2016; Tunchel et al., 2016; Basalah at al., 2012; De Jong, 2018)

Additive manufacturing can be used to create patient-specific implants as well. The main benefit of this is that implants can be created that matches perfectly with the patient's anatomy.

In the literature it is found that additive manufactured implants are made, either patient-specific or with a porous structure.

Additive manufactured screw-type dental implants

Additive manufactured dental implants are in development and are studied by Mangano et al., (2012) and by Tunchel et al., (2016). Those implants were solid screw-type additive manufactured implants (Figure 25). A start-up company Amber implants is developing screw-type dental implants with a porous core and solid thread shapes using addititve manufacturing.

Additive manufactured patient-specific dental implants

Patient-specific dental implants that mimic the rootshape of the natural tooth are also developed. These types of implants adapt to the anatomy of the patient instead of changing the anatomy of the patient to the implants. Studies are experimenting with these so called root-analogue-implants. See appendix III and Figure 25.

The main advantage of root-analogue implants is that they can be immediately placed after extraction in the exact same position of the original tooth in a way the bone socket will be preserved, and tissues are damaged as little as possible. No drilling is needed. This procedure reduces the total treatment time significantly and less surgeries are needed which is beneficial for the patients. (Mangano et al., 2013)

Conclusions

Additive manufacturing of dental implants is possible and it has advantages over standard implants. However, not all benefits that additive manufacturing has to offer are used in generating dental implants. From the studies, none of the additive manufacturied implants had a controlled porosity or a specific pore size. While a porous structure has benefits for better osseointegration.

The root-analogue-implants are also a type of implant that makes good use of the possibilities of additive manufacturing however no porosity is added to these type of implants. Opportunities lie in the field of designing and manufacturing patient-specific implants with porous structures to promote bone-ingrowth and good fixation and stability (Figure 26).

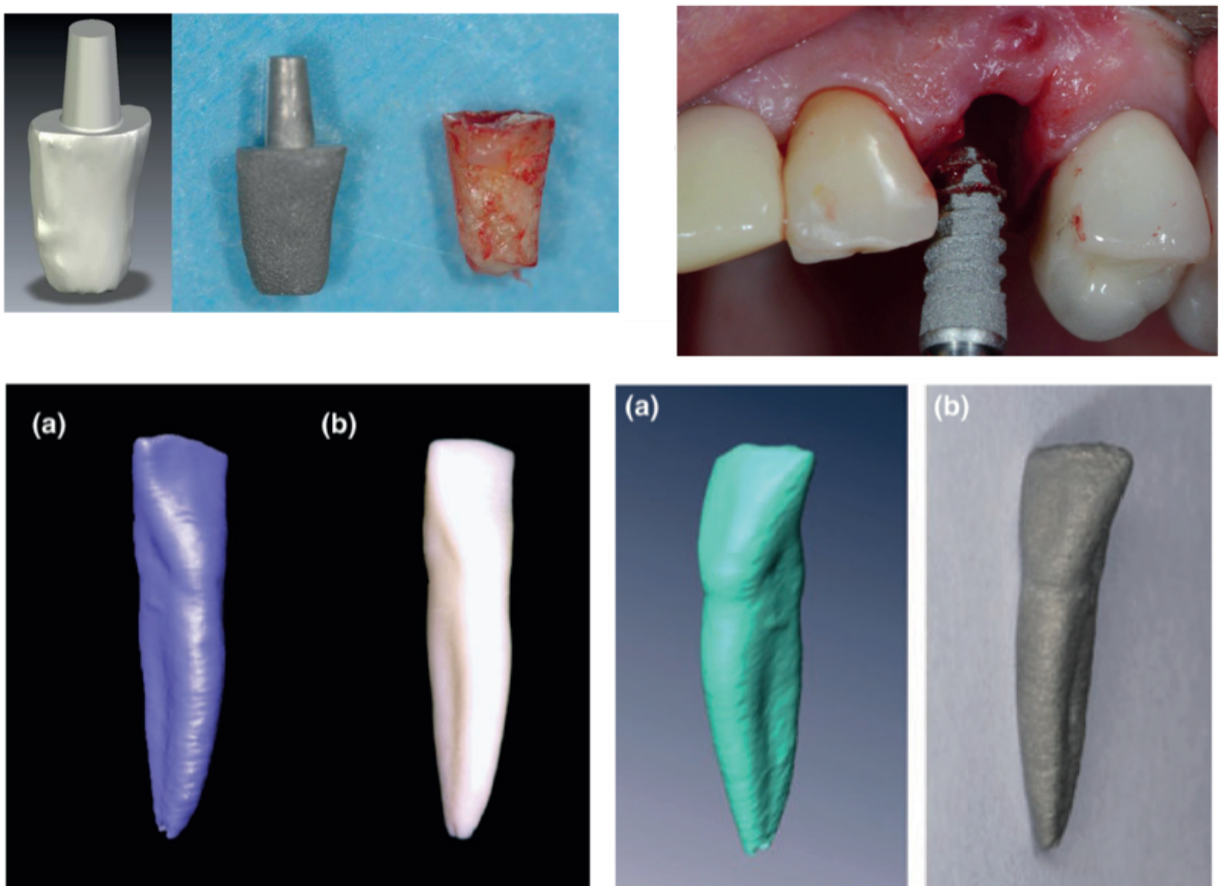


Figure 25: Additive manufactured implants. First row: RAIs form the study of F. G. Mangano et al., (2013) and Figliuzzi et al., (2012) Additive manufactured dental implant Tunchel et al., (2016). Second row root analogue implants (a) CAD Models (b) printed models, zirconia and titanium form the studies of Moin (2014 & 2017).

	DENTAL IMPLANT TYPE 1	DENTAL IMPLANT TYPE 2	DENTAL IMPLANT XANDRA
PATIENT-SPECIFIC			
POROUS STRUCTURE			

Figure 26: Additive manufactured dental implant types. New opportunity is to create a patient-specific porous dental implant.

Infection prevention

Creating porous structures for better osseointegration by having a larger surface area for cells to adhere has also a downside. Since it is not only attractive for bone forming cells, it is also attractive for bacteria cells to adhere to. Infection, caused by bacteria, is one of the main reasons for implant failure (1.1%). (Yue et el., 2015)

Antimicrobial surfaces

Infection can eventually lead to loosening of the implant and to implant failure. To overcome this problem of infection a way to prevent bacteria adhering to the surface is developed. Antimicrobial surfaces are able to kill bacteria or prevent bacteria to adhere on the surface.

There are two different ways to alter the surface of dental implants to prevent adhesion of bacteria. The first principle is to create an antimicrobial surface that will damage the bacteria by releasing antimicrobial agents into the surroundings to kill bacteria. This is called an active coating. The second principle is to create and anti-adhesive surface onto which no bacteria can adhere, also called passive coatings. These coatings are inhibiting bacterial adhesion or kill bacteria when they come in contact with the surface (Figure 27).

Antibacterial compounds and surface modification methods

A certain compound with antibacterial properties should be incorporated on this surface. Different types of compounds can be used. A clear division is made between organic and inorganic compounds.

Organic particles can be incorporated such as antibiotics and antimicrobial peptides. Antibiotics are released in the surroundings to kill bacteria. It is a type of active coating. All studies showed good antimicrobial activity against tested oral bacteria. However the main problem with antibiotics is that the release is fast and later on the release can come below the minimum inhibitory concentration leading to bacterial resistance (Figure 28). Bottino et al. 2017; Lv et al., 2014; Kim et al., 2011; Cortizo et al., 2012).

Antimicrobial peptides have a lower tendency to become bacterial resistant, however there is still the risk. More and more natural peptides are losing the antimicrobial effectivity against some bacteria strains. In order to keep antimicrobial peptides as a solution to prevent infection, synthetic peptides can be created. However, this is a more expensive method (Figure 28) (Zhou et al., 2015; Chen et al., 2014; Liu et al., 2016; Godoy-Gallardo et al., 2014; Godoy-Gallardo et al., 2015).

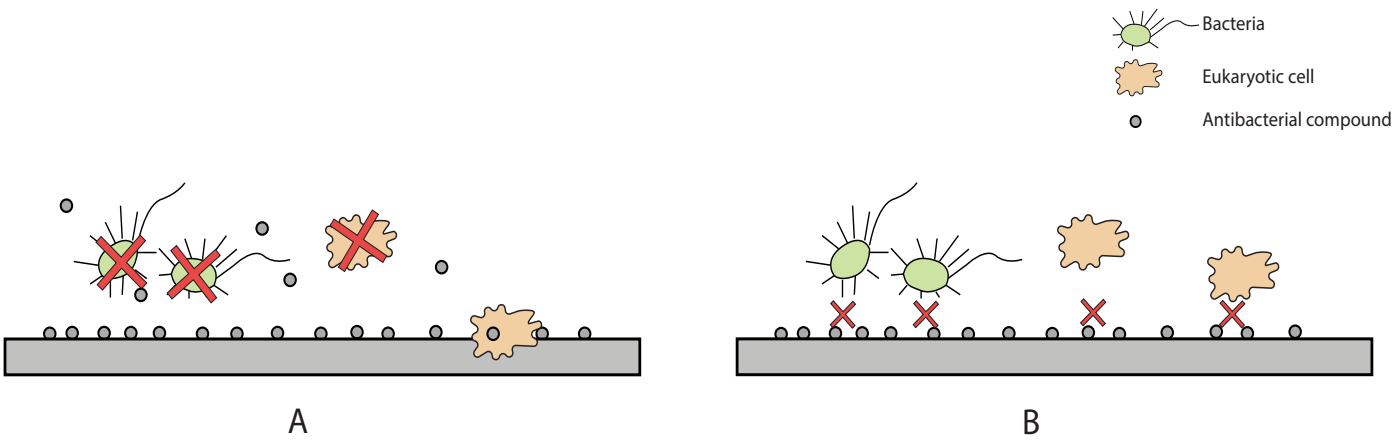


Figure 27: Active and passive layers

Zinc and silver

An alternative is to use less bacterial resistant inorganic particles, such as zinc, zinc oxide and silver. The main concern for these particles is that they can be toxic if a large amount is used. Nanoparticles are preferably used since more ions can then be released. If silver is immobilized on the surface the particles itself cannot spread into the surroundings, lowering the cytotoxic effects. This can be realized if the plasma-electrolytic oxidation method is used (Figure 29).

All studies regarding silver on the surface show antibacterial effects against oral bacteria (Hu et al., 2012; Besinis et al., 2017; Chang et al. 2012; Lin et al., 2013; Abdulkareem et al., 2015; Memarzadeh et al., 2015; Yu et al., 2017; Qiao et al., 2015).

Antimicrobial surfaces on additive manufactured implants are studied by Van Hengel et al., (2017). They created an antimicrobial surface on additive manufactured wires by using plasma electrolytic oxidation.

Conclusions

Complications can occur during the surgeries that result in implant failure. The main causes for implant failure are infection and a lack of osseointegration.

Developments in the addtive manufacturing industry can help to overcome these problems.

Research into antimicorbial surfaces is done to lower the risk of infection.

Silver seems to be a good antibacterial compound that can be added on titanium surfaces.

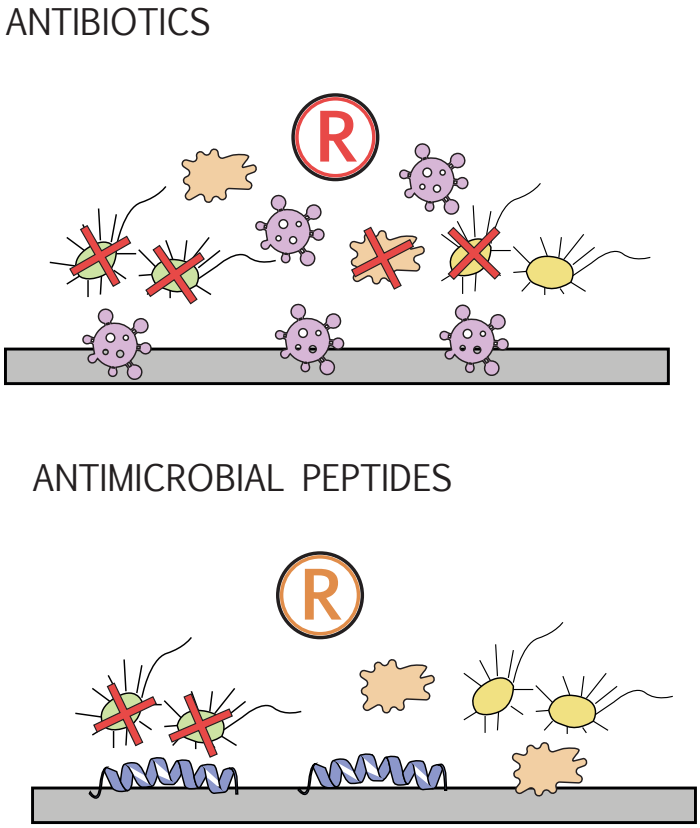


Figure 28: Organic loaded surfaces

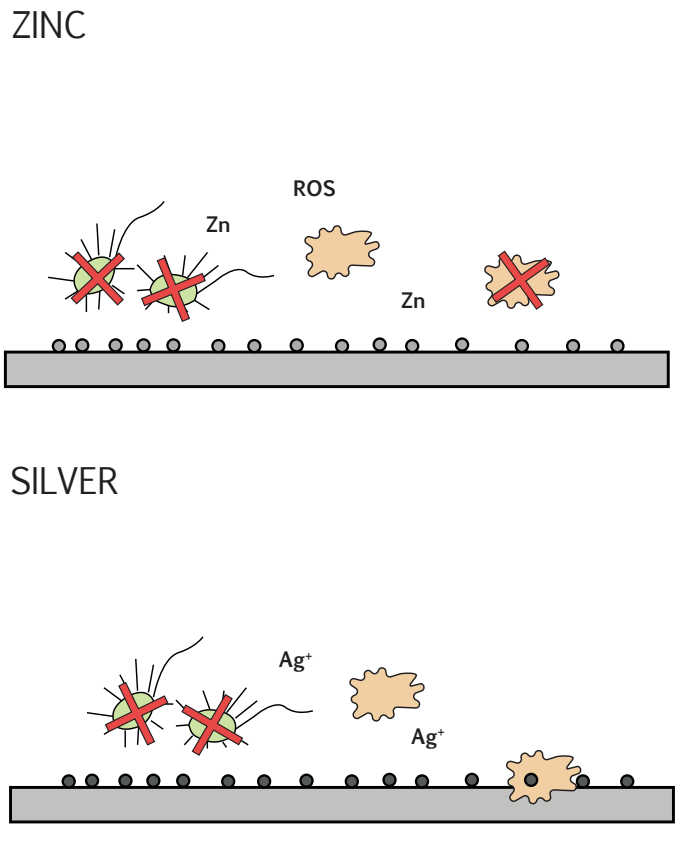


Figure 29: Inorganic loaded surfaces

2.8 Rules and regulations

Introduction

A dental implant is a medical device and therefore it needs to be approved by the FDA in the United States and in Europe according the medical device directive. The FDA has a categorization system in which they have class I (low risk devices), class II (medium risk devices) and class III (high risk devices) devices. In Europe, in the medical device directive there are class I, class IIa, class IIb, and class III categories. These classes are based on the level of control for safety purposes. Class I, least regulatory control devices to class III most regulatory control needed. (Wikipedia, medical device 2017)

Current classification

The FDA classified dental implants in 1980 as a class III device. However, in 1998 they reclassified dental implants as class II devices. The only exception is the blade-form dental implant, that still belongs in class III according to 21 CFR 872.360. (Rutkowski, 2013, FDA medical device, 2004, FDA medical device II, 2004)

According to the European categorization, dental implants fit in class IIb. This is according to rule 2.4 Rule 8 from the directive (Figure 30). The implant is placed inside the bone and will therefore be in the "surgically invasive long-term use and implantable devices". (Medical Device Directive)

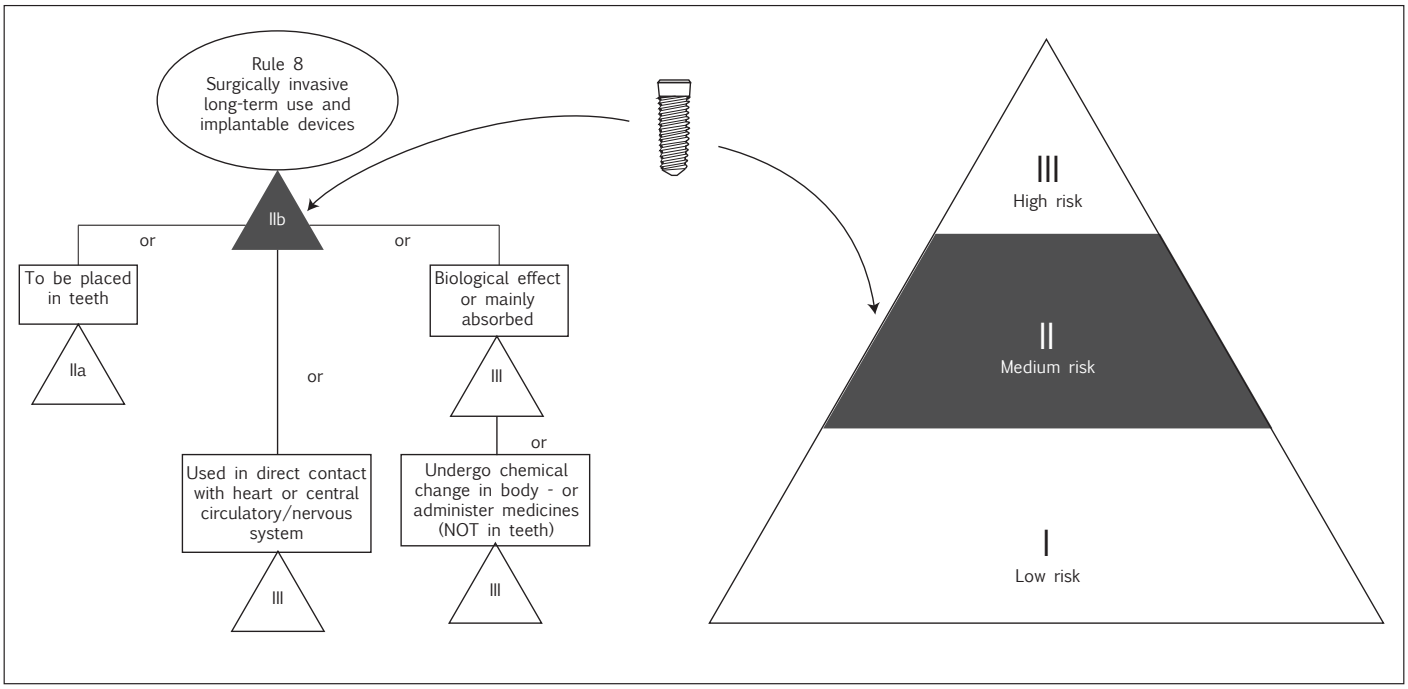


Figure 30: Medical device classification according to Europe (MDR/CE) and the USA (FDA)

2.9 Conclusions analysis phase

From the analysis phase conclusions can be drawn.

Implants are made from titanium and are screw-like implants. Based on the analysis, it can be said that during the last decade no large innovations have taken place. Small innovations such as changing dimensions, length, diameter, change of internal structure and the thread dimensions have taken place. Coatings that are applied are mainly applied to promote osseointegration. Materials are made stronger to allow for shorter implants to reduce the damage to the bone and surrounding tissue. However, not a lot is changed over the last 10 years.

The reason that not a lot is changed can be because the survival rate of dental implants is 95-97%, which is high. The main reasons for the 3-5% that failed are complications due to loosening of the implant and infection. Trying to create an even higher survival rate for dental implants should focus on promoting osseointegration and diminishing the risk of an infection.

The surgical procedure can differ based on the preferences of the surgeon, the situation of the patient, and quality of the bone, the costs and the available time. Developments regarding the surgical procedure are mainly focused on reducing treatment times and reducing damage of tissues. Still the preferred option is the one-phase procedure.

One of the reasons for not choosing a dental implant is the long treatment time. An opportunity lies in reducing treatment time. Focusing on reducing the treatment time and simplification of the procedure will help oral surgeons and patients.

Developments in the addtive manufacturing industry are able to create dental implants which will support the osseointegration. Porous patient-specific implants can be created.

However creating such a porous-structure induce the risk of infection, since a larger surface area is created. Developments in the field of antimicrobial surfaces can play a hugh role in making those implants less risky for infection.

Based on the analysis phase and the conclusions retrieved from it a design vision is created. After the design vision a list of requirements and wishes is created in order to have a clear overview of what should be achieved in the new design.

2.10 Design vision

"Design a patient-specific dental implant which is able to improve the succes rate by increasing bone-ingrowth and lowering the risk of infection and which is also able to reduce treatment time."

Explanation

The additive manufacturing of dental implants is a promising option for perfect fitting of the implants in the jaw, because it makes the implant congruent with the anatomy of the patient. This can lead to perfect positioning of the implant. The best option to achieve this seems to be to design an implant which has exactly the shape of the root of the natural tooth. To promote the osseointegration onto the implant a porous surface can be created. To lower the infection risk, antimicorbial surfaces are helpful. It would be valuable, from a patient perspective, if the total treatment time can be reduced.

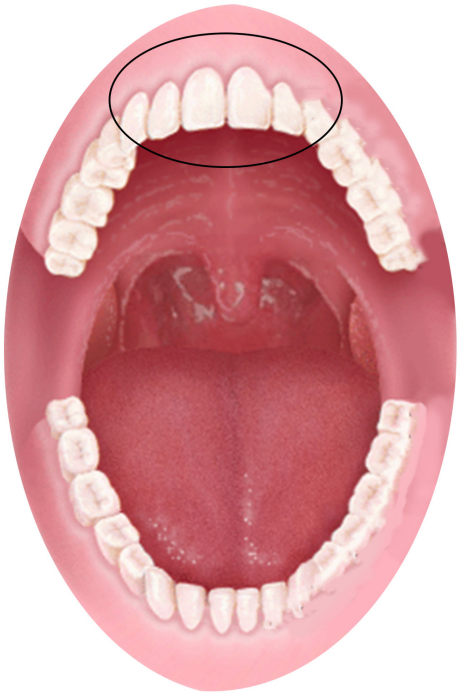


Figure 31: Focus on teeth in aesthetic zone

Focus on incisor tooth

Replacing of teeth happens in three different situations; a situation in which the patient patients miss only one tooth, in a situation in which the patient miss several teeth or in a situation in which the patient is edentulous, which means the patient does not have any teeth left.

The focus of this project is on the patients with only one missing tooth. More specific, the focus will be on patients with a missing tooth in the aesthetic zone, which means missing an incisor or a canine (Figure 31).

This focus is chosen, because during the treatment the patient will have an empty space in the mouth. It is most undesirable if this is in the aesthetic zone and is visible to everybody. This can lead to social and psychological issues. The challenge is to shorten the time of having this empty space for the patients. This can be achieved by the patient-specific implants which can be directly placed after tooth extraction, the 3-6 months healing time are not required anymore.

List of requirements and wishes

A list of requirements and wishes is formed for the new implant design.

1. Function

1.1 The implant must function as a root. (R)
1.2 The implant must provide a reliable attachment in the bone. (R)
1.3 The implant should fit in the jawbone without changing the anatomy of the patient. (R)
1.4 The implant should fit perfectly in the extraction socket. (R)
1.5 The product should be placed with at least the same precision as the current implants. (R)
1.6 The implant must ensure that a dental prosthetic can be attached. (R)
1.7 The implant should improve osseointegration properties. (R)
1.8 The implant should lower the risk of infection. (R)
1.9 The implant must have sufficient mechanical properties to withstand insertion
1.10 The implant must have sufficient mechanical properties to withstand repeated mechanical loading. (R)
1.11 The implant must be able to withstand the same loads as current dental implants. (R)
1.12 The implant must allow for loading of the implant during chewing. (R)
1.13 The implant must apply to the ISO standards. (R)
1.14 The product should have a lifetime of at least 15 years. (R)
1.15 The product must be visible on x-rays. (R)

1.16 The implant must fit with the current ways of attaching dental prosthetics. (W)

2. Context

2.1 The new design should not increase the treatment time compared to the standard way of implantation. (R)
2.2 Insertions of the new implant should not take longer than a normal implant insertion. (R)
2.3 The product has to be handled sterile. (R)
2.4 The surgeon and the assistant should not touch the implant outside of the sterile field. (R)
2.5 The implant must be transported to and inside the hospital in a sterile way. (R)
2.6 The implant must be stored in the hospital or a dental practice. (R)

2.7 Insertion of the implant should take less time than a normal implant insertion. (W)
2.8 The total treatment time should be reduced. (W)
2.9 The amount of surgeries should be reduced. (W)
2.10 The implant should lead to higher patient satisfaction. (W)

3. User and ergonomics

3.1 The implant must be used by an oral surgeon or dentist. (R)
3.2 The implant should be easy to use with gloves. (R)
3.3 The implant should be opened by the assistant and given in a sterile way to the surgeon. (R)
3.4 The implantation should be done by press-fit using the thumb without using extreme forces. (R)
3.5 The surgeon/dentist should be able to know if the position is correct. (R)

3.6 The direction of insertion should be indicated on the implant. (W)
3.7 It should be clear to the user how the implant is supposed to be implanted without the need of a manual. (W)
3.8 The surgeon/dentists should be able to understand when the implantation is wrong. (W)

4. Manufacturing

4.1 The implant should be able to be manufactured by additive manufacturing. (R)
4.2 The implant must be able to undergo surface treatment by plasma electrolytic oxidation. (R)
4.3 Implant should be able to be attached to the power supply. (R)
4.4 Implant should withstand current values, up to 500mA. (R)
4.5 Minimum printing thickness of 300 micrometer. (R)
4.6 Pore size between 300-1000 micrometer. (R)
4.7 Cell type: diamond. (R)

4.8 The implants should be made by a company to make it a cost-efficient implant. (W)

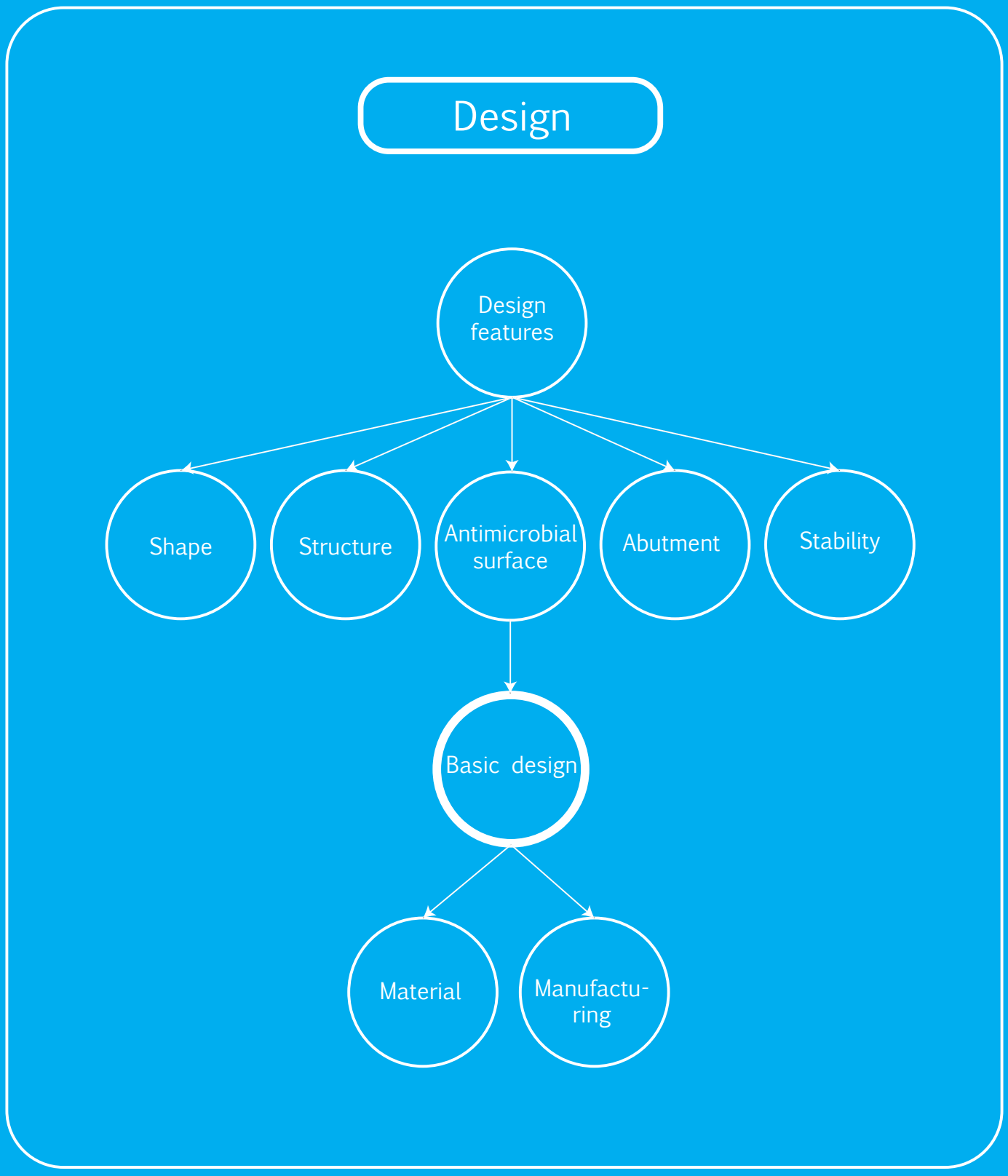
5. Medical rules and regulations

5.1 The implant has to meet all the regulations required for a CE mark. (R)
5.2 The implant should be made of biocompatible approved medical materials. (R)
5.3 Fulfill ISO norms 14801 and 10451. (R)
5.4 The implant should be protected against antimicrobial activity. (R)
5.5 The implant should induce minimal local cytotoxicity. (R)
5.6 The implant should induce minimal systemic toxicity. (R)
5.7 The implant should be protected against a broad spectrum of bacteria and biofilm-forming microbes. (R)
5.8 The implant should not induce bacterial resistance. (R)
5.9 The implant should not impair bone healing and remodeling. (R)

5.10 The implant should release silver ions up to 1 month. (W)

6. Safety

6.1 The product may not contain sharp or protruding components. (R)
6.2 The product may not harm the patient or the users. (R)
6.3 Package should provide a sterile area for the implant. (R)
6.4 The product should be able to sterilize without damaging the implant. (R)


Design
Design features
Shape
Structure
Antimicrobial surface
Abutment
Stability
Basic design
Material
Manufactu-ring

3 Design phase- basic concept

This chapter focuses on the design of the new implant. Insights form the analysis phase are used to come up with a design that fits into its context.

3.1 Basic design of patient-specific dental implant

This section is the starting point of the design. The analysis gave insights into interesting design directions that could lead to a new dental implant that would result in an implant with better osseointegration properties and a lower risk of infection.

A basic concept is created with the main functionalities that the implant should have. Several other features were added in order to improve the design. The additional features are integrated with the basic concept.

From the analysis phase it is concluded that there are currently no patient-specifc dental implants with a porous structure. There are also no implants with an active antimicorbial layer on the market. Therefore a possible solution could be to create patient-specific dental implant with a porous structure with an antimicrobial layer.

In the analysis it was also found that a common issue among oral surgeons is that they find it hard to determine the position and direction of the implant during surgery. A good focus and good concentration is required in this step. It would be valuable if this part of the surgery could be simplified.

The key elements for the basic concepts are creating a patient-specific shape, creating a porous structures and application of an antimicrobial surface. The aim was to create a concept which shows the main functionalities of the implant that fits the design vision.

A patient-specific implant will be designed. The shape is determined on the basis of the natural root of the tooth that will be replaced. the porous structure is created to promote osseointegration. The entire surface of the porous part consist of an antibacterial layer to lower the risk of infection. The main aspects of the design are shown in Figure 32.

The elements that are covered in the design are:

- Shape
- Structure
- Antimicrobial surface
- Abutment
- Stability
- Material

Shape

Create a dental implant that has the shape of the original root of the patient. By this the implant will fit exactly into the extraction socket. The design will be made according to the anatomy of the patient instead of changing the anatomy of the patient according to the design.

Structure

The structure of the implant is changed according to the design vision to create better osseointegration properties. This can be realized by creating a lattice structure. This lattice structure is a porous structure which allow bone to grow into it for a good fixation.

Antimicrobial surface

An antimicrobial surface can be created by adding an antibacterial compound on the surface. From literature is became clear that silver is a antibacterial compound against a wide variety of bacteria species. Silver nanoparticles can be incorporated on the surface by a process called plasma electrolytic oxidation, which is a thermal oxidation process.

Abutment

An abutment should be designed in order to allow the connection of a dental prosthetic on the implant.

Stability

Stability of the implant is necessary to make sure the implant is fixated in the bone. Micro-movements leading to loosening of the implants should be prevented, which can be achieved by good primary and secondary stability.

Material

A biocompatible material should be chosen to manufacture the dental implant. Nowadays, dental implants are made of titanium or a titanium alloy Ti6Al4V. This material is also able to be surface treated and to allow to incorporate silver nanoparticles.

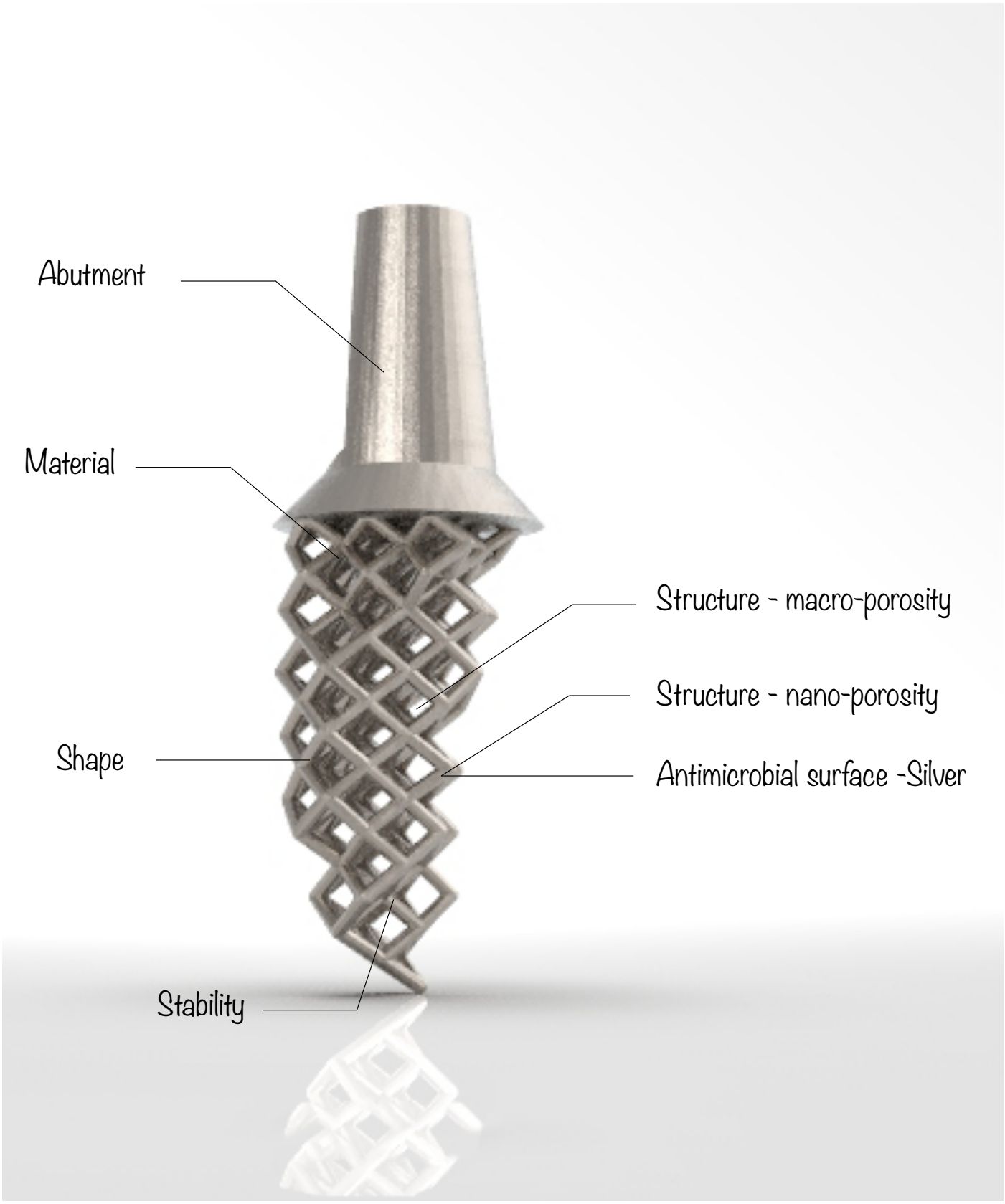


Figure 32: Basic implant with its design features

Surgical procedure

The surgical procedure is changed due to the new implant design. The dental implant is designed in such a way that the surgical procedure is simplified. The most difficult part of the procedure is removed, which is the drilling of the hole in the bone, so the implant can be placed in the right direction and position. Using the new implant design, drilling is not required anymore, since the existing extraction socket will be used.

Concept

The concept integrates all elements that are needed for the patient-specific dental implant. The concept shows all features an functionalities it has (Figure 33).

The concept, a patient-specific implant, forms the basis for development of detailing the design. The main features are:

Patient specific dental implants are beneficial for:
- Root-shape to fit perfectly in the extraction socket
- Preservation of the bone socket
- No extra damage to bone and tissues
- Reduced treatment times. 3-6 months healing time after tooth extraction is not needed.
- No required drilling, simplified surgical procedure
- Less needed surgeries. No separate surgery for tooth extraction, which is also beneficial for bacteria prevention.

Porous structure is beneficial for:
- Lattice structure to allow better bone ingrowth
- Promoting osseointegration
- Reducing stiffness of the implant

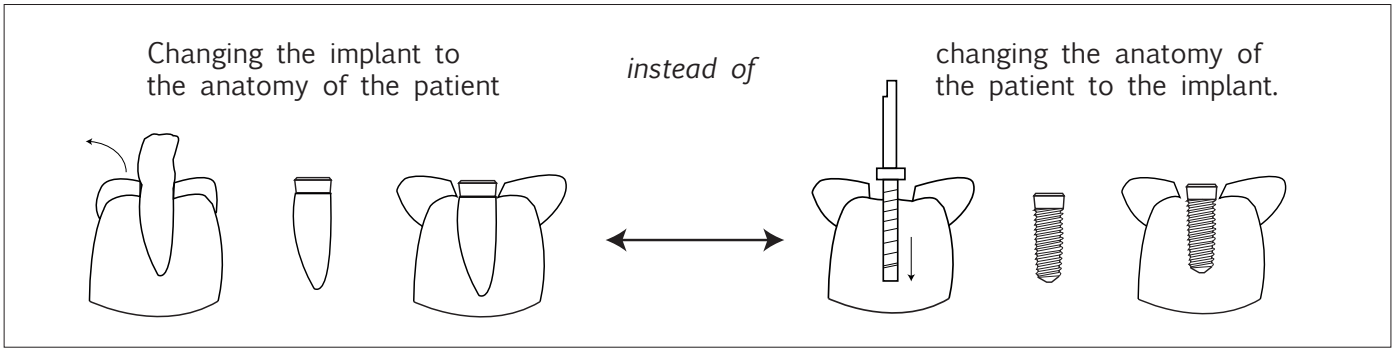
Preferred specifications for the porous structure:
- Unit cell type: diamond.
- Pore size: 300 -800 micrometer
- Porosity: More open/denser towards the outside, more dense towards the inside/core of the implant.

Prevent infection by making use of:
- Use antimicorbial surfaces
- Silver as antibacterial compound
- Antimicrobial structure to limit bacteria adhesion on the implant

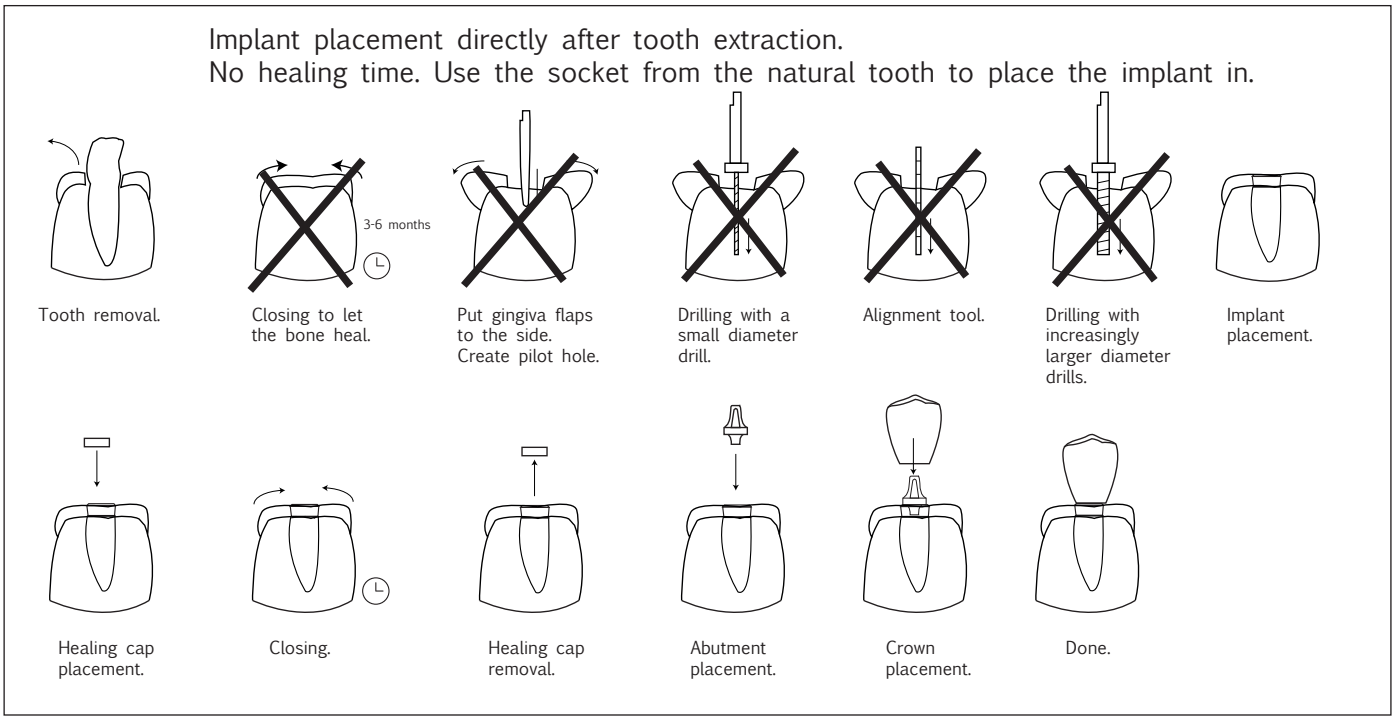
Abutment is used to:
- provide place to attach a dental prosthetic

In the next chapter the design of the implant will be further developed, also keeping in mind the manufacturing process.

PATIENT SPECIFIC IMPLANT



REDUCED TREATMENT TIME



POROSITY

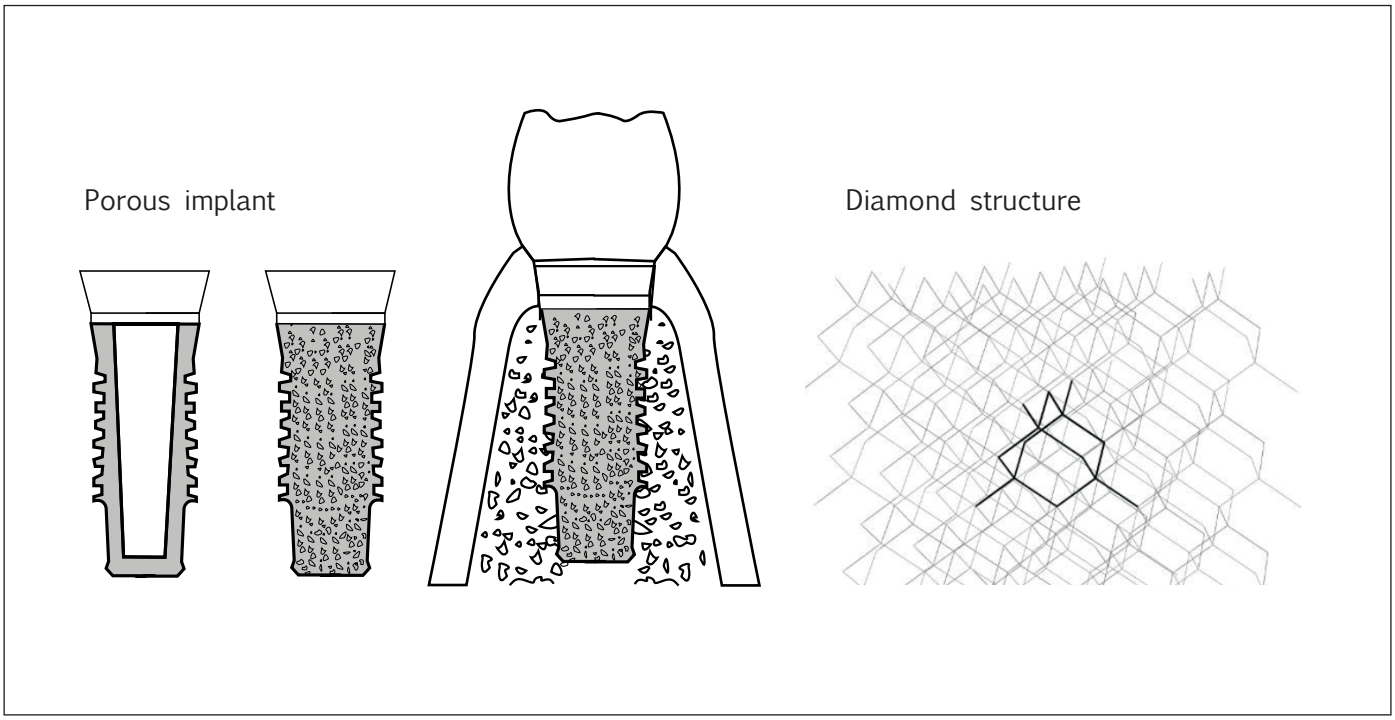


Figure 33: Overview and benefits of concept

3.2 Manufacturing and materials

In order to further develop the concept it is important to take into account which manufacturing processes and materials are used to create the dental implant.

From the analysis phase it became clear that titanium is mostly used in the dental implant industry. Titanium is biocompatible, because it forms a natural oxide layer on its surface. Titanium has also good osseointegration properties. Studies have shown good long-term success rates for titanium dental implants.

Two types of titanium are used for dental implants; commercially pure titanium and a titanium alloy, Ti6Al4V. This is an alloy with 90% titanium, 6% aluminum and 4% vanadium.
Ti6Al4V alloy is corrosion resistant and is stronger than commercially pure titanium with the same stiffness. In this project Ti6Al4V will be used.

Properties of Ti6Al4V
Density: 4420kg/m3
Young's modulus: 120GPa
Tensile strength: 1000MPa

The patient-specific dental implants have a very organic and complex shape. This shape can be additive manufactured. There are several additive manufacturing techniques. The most suitable technique to print metal porous structures is selective laser melting (SLM). This technique uses metal powder in a layer-by-layer approach. A layer of powder is placed on the plate and a laser melts the particles together to make the product. In the end all loose powder will be removed and all lasered powder will form the product (Figure 34 and Figure 37). Ti6Al4V powder is available on the market and can be used for this SLM process. During printing support structures are needed.

The literature search conducted in the analysis phase showed that plasma-electrolytic oxidation is a process that can achieve the application of an antimicrobial surface on implants. Plasma electrolytic oxidation (PEO) is an electrochemical surface treatment suitable for complex geometries, such as porous additive manufactured structures (Figure 35 and Figure 36). This is possible, because during the process a liquid is used. It has access to the complete surface area. PEO provides a bioactive titanium dioxide layer on the surface with macro-porosity and nano-porosity, which is also beneficial for osseointegration. The silver nanoparticles can be included in an easy and fast way by adding the nanoparticles in the electrolyte. This process is applicable for Ti6Al4V materials.

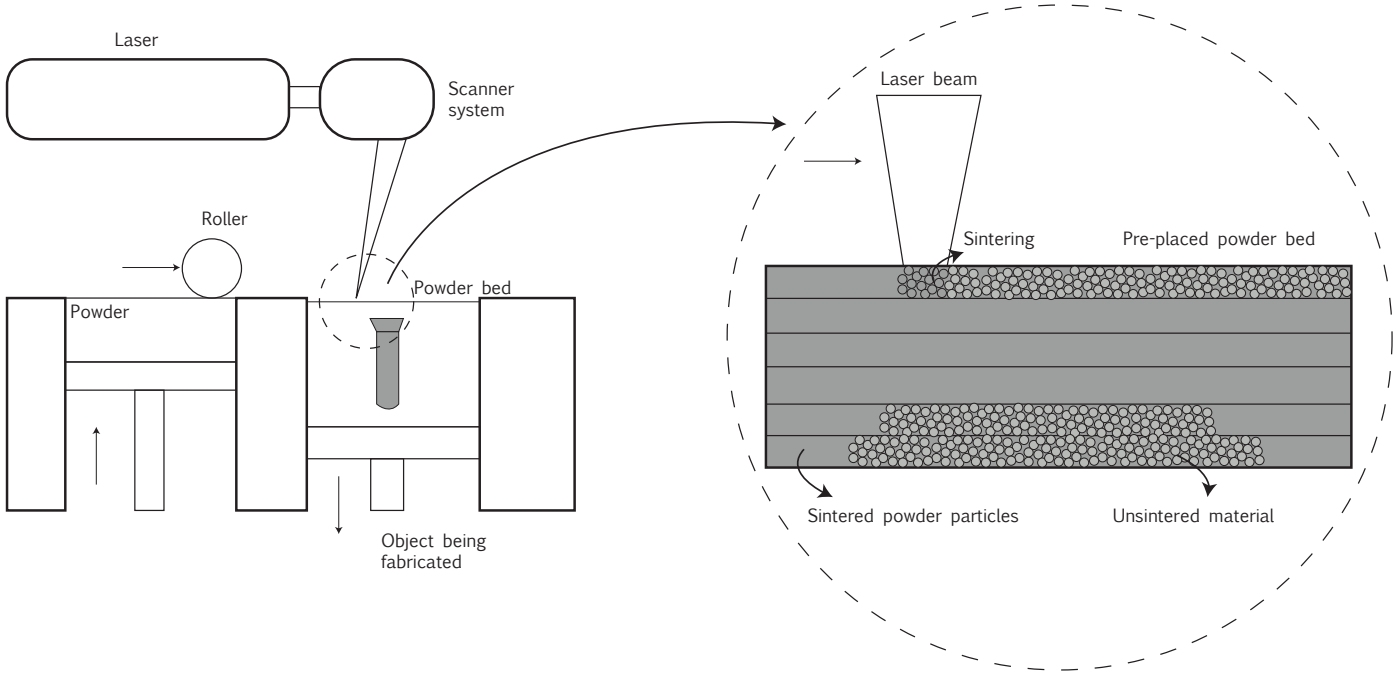


Figure 34: Schematic representation of elective laser melting additive manufacturing principle

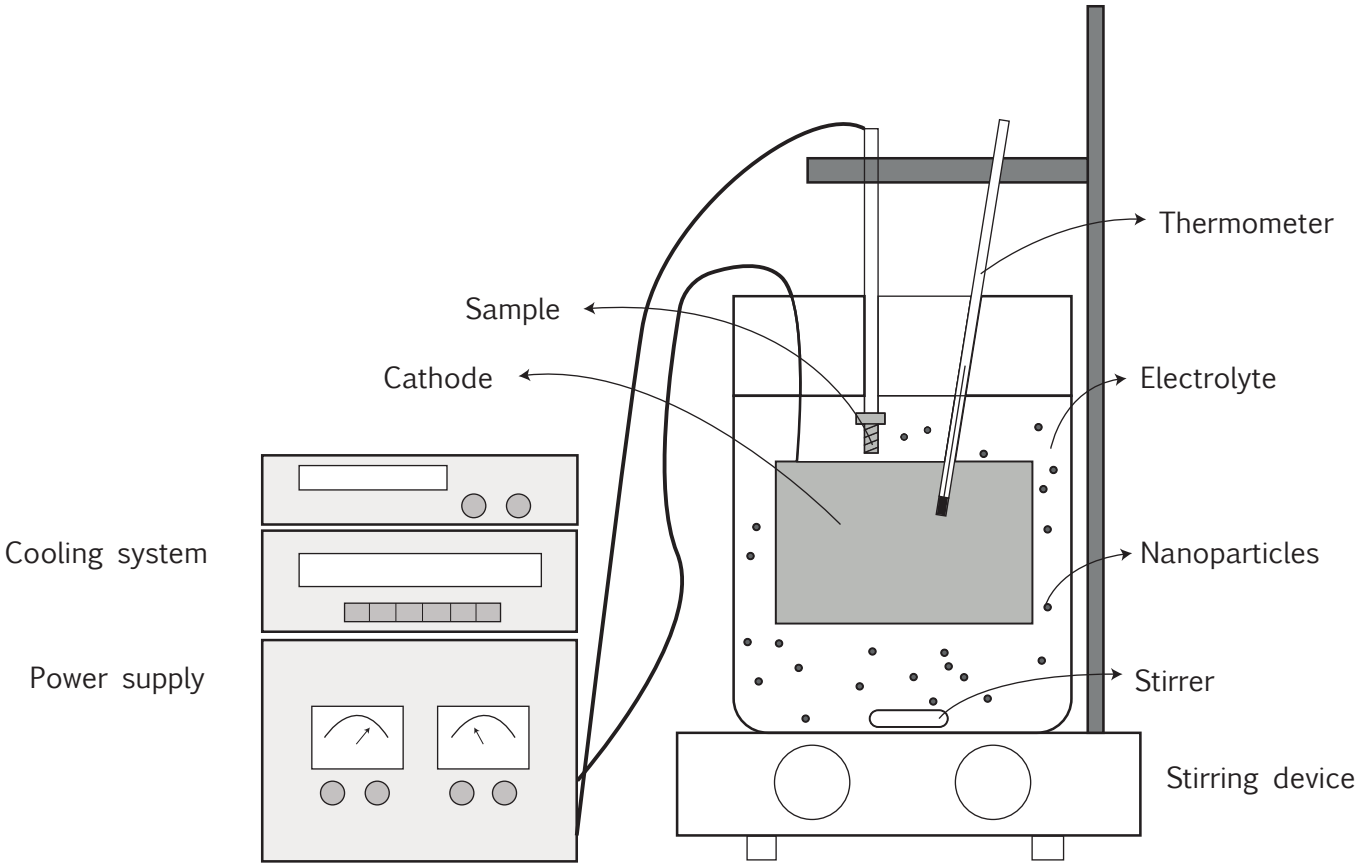


Figure 35: Schematic representation of plasma-electrolytic oxidation process

Figure 37: Selective laser melting set up

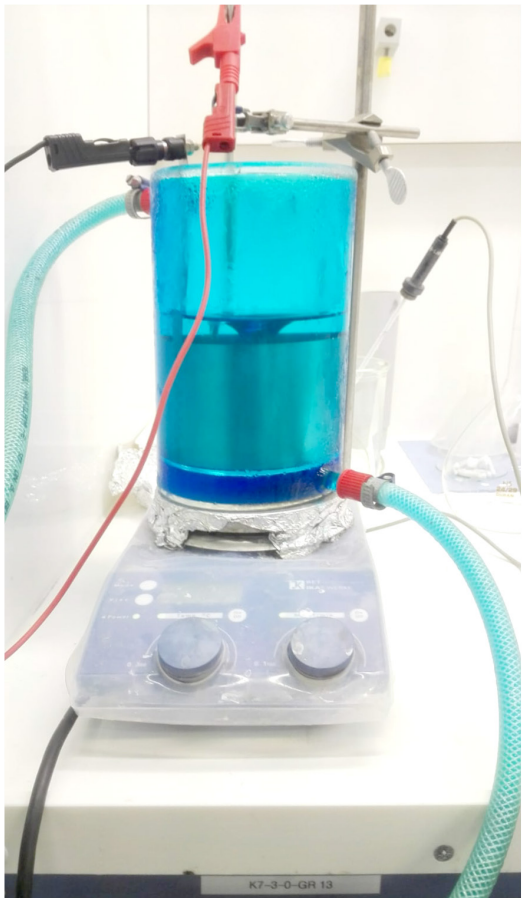
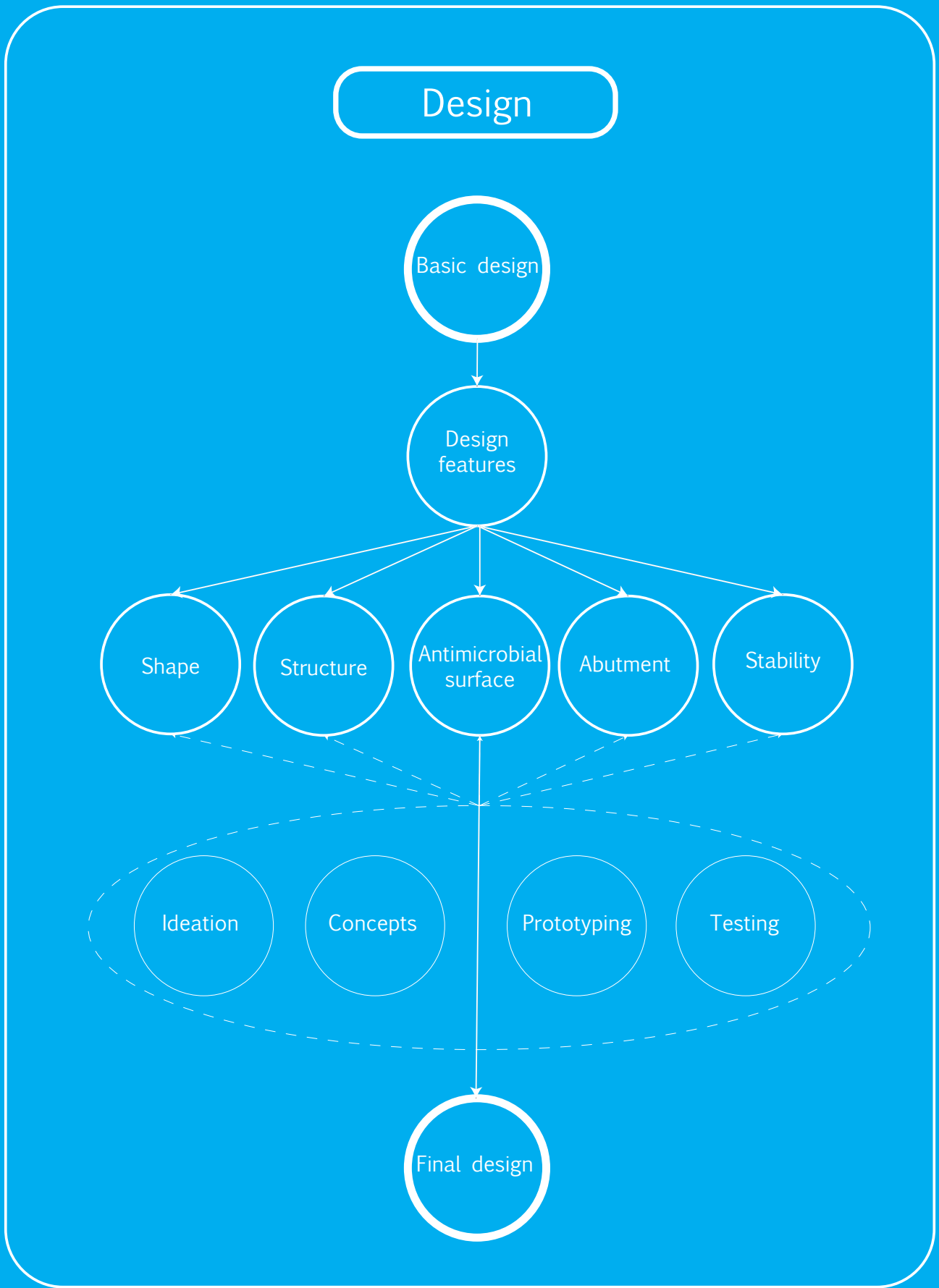


Figure 36: PEO set up


Design
Basic design
Design features
Shape
Structure
Antimicrobial surface
Abutment
Stability
Ideation
Concepts
Prototyping
Testing
Final design

4 Design phase- concept development

In this chapter the design of the basic concept is further developed into a final design.

4.1 Concept development

In this section the concept will be further developed. The concept is mainly elaborated on its shape and its structure. All aspects are integrated into one final design. The chapter provides an overview of the design, including all its features and functionalities. A user scenario is also provided including how the entire process changes for every stakeholder using the new dental implant.

The dental implant is developed up to a point where it can be additively manufactured, can be surface treated and can be tested on antimicrobial activity.

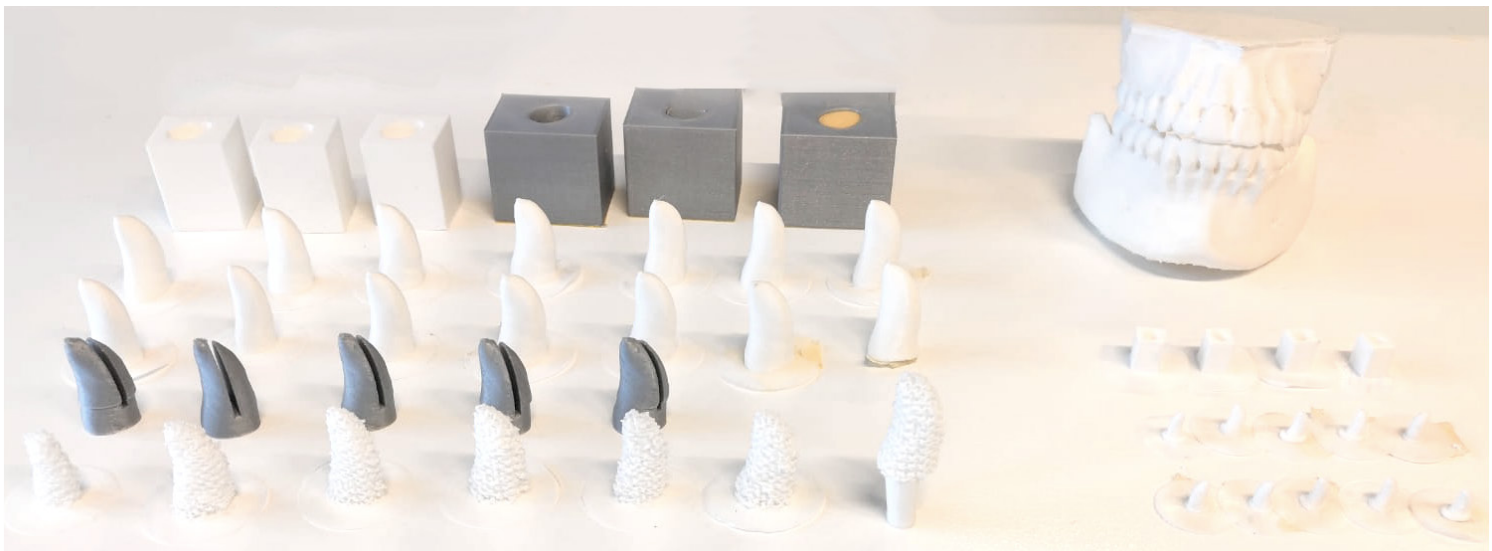


Figure 38: FDM models of implants

Shape

Being able to insert the dental implant right after extraction is the main aim for the shape of the implant. It is important that the implant fits perfectly in the extraction socket.

Requirements:

- Dental implant should be congruent with the shape of the root that will be extracted.
- Dental implant should be made patient-specific

Insights:

Research has shown that it is possible to scan the root of the shape with a CBCT scan when the tooth is still in the human body (Figure 40). Using image segmentation software the shape of the root can be retrieved (Figure 39).

Solution:

Using CBCT software and image segmentation software, 3D slicer, the right shape can be obtained. This creates a highly organic shape that can be further refined in CAD software (Figure 41). Using this method every tooth can be retrieved separately and this process can be used for every single patient.

To test if the shape can fit in exact its same exctraction sockets, FDM printed implants are created (Figure 38 and appendix IV). These show that an implant should be scaled down in either x or y direction by 2% to fit in the extraction oscket. The concept has been proven by inserting the implants perfectly in the socket.

Figure 40: Cone beam CT scan

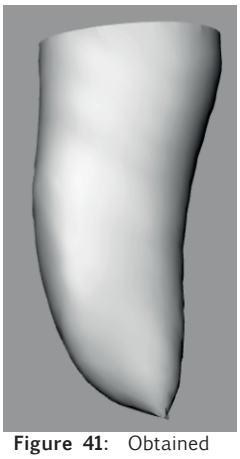


Figure 41: Obtained shape of the root

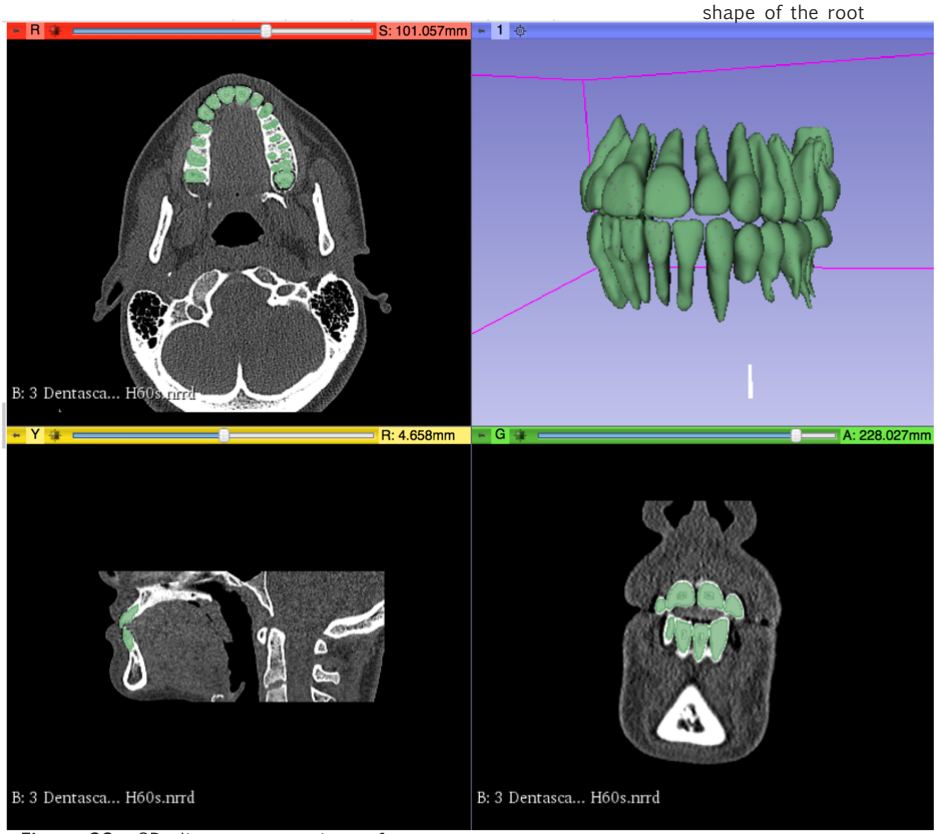


Figure 39: 3D slicer segmentation software.

Structure

The development of the concept consist of refining the final shape of the implant. The porous structure that will be created is changing the overall shape of the implant. The development of the porous shape was in heavy relation to and largely dependent on the printing properties of the SLM printer. Ultimately the shape is a compromise between the exact shape of the root, the porous structure and the limitations of the printing process.

Requirements:

- The porous structure should support osseointegration
- A pore size between 300 and 800µm is desired for bone ingrowth
- Minimal strut size is 300µm due to limitations of the SLM printer
- The design of the lattice structure should be adjustable and designed for specific roots. (Computational design)

Insights:

Making prototypes, analyzing the SLM printing procedure, characterization of the structure using a scanning electron microscope and deviation analyses gave insights in the design of the porous structure.

SLM printing requires support material around the entire implant, it is difficult to remove the metal support material. Using only whole cells, the structure become self-supporting and support material around the implant is not needed.

Characterization of the implant structure using scanning electron microscope showed that the

Figure 42: Design concept with its macro-porosity (lattice structure) and its nano-porosity

desired pore size and strut thickness deviated from the original STL file that was printed. Creating a small pore size around 300 micrometers, resulted in no clear and no structured regular pores in the printed structure. Increasing the cell size resulted in a clear identifiable structured porous structure (Appendix IV).

Using only whole cells, and increasing the cell size does change the shape of the implant. An analysis with 'Geomagic studio' is conducted to analyze the shape deviation of the implant with different porosities compared to the original root. The larger the strut thickness and the larger the cell size the larger the deviation was with the original shape. (Appendix IV)

Solution:

A broad range of iterations (Appendix IV) of the structure led to the final design structure of the new dental implant. The shape incorporates the guidelines from the literature and the possibilities of the SLM printer, with a main focus on maintaining its original shape (Figure 42 and Figure 43).

The lattice structure is a computational design made in 3DXpert. Parameters can be set according to medical relevance and engineers expertise. Strut thickness, cells size in x, y, and z, direction, cell type can all be parametrically changed (Figure 44).

A minimal strut thickness of 0,3mm is used (due to minimum thickness achievable by SLM printer). To clearly identify the a structured porous structure a minimal cell size of 1,2mm is required, which resulted in pores of 550-800µm. A larger cell size does change the shape, so it deviates more form the original shape, which is undesirable (Appendix IV).

Since it is a computational design, the structure can be changed according to the situation and context of the patient. Shapes can be adjusted to different types of teeth, loading of the teeth etc.

Remarks:

Developments are taking place in the printing industry. If better printing facilities will be on the market, the structure can be changed to a more precise shape that follows the function. Structured porosity is not really needed with regards to osseointegration, since bone does grow onto irregular porosity as well, so a lower cell size is possible to use as well.

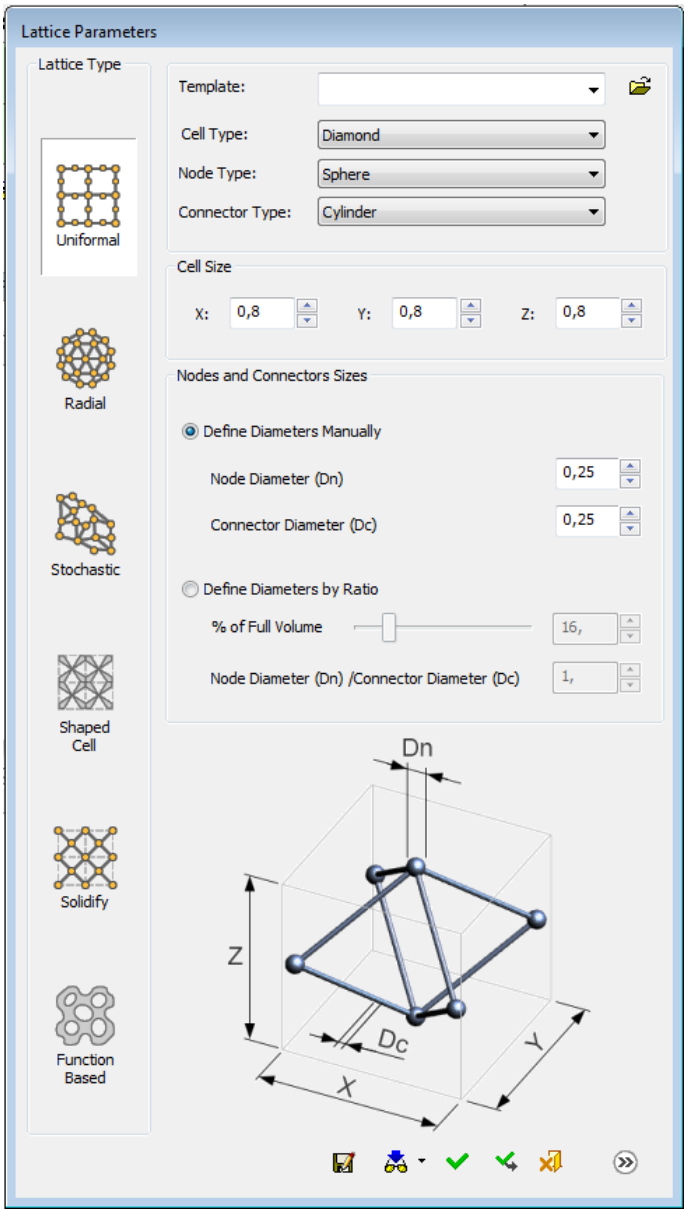


Figure 44: Computational design parameters

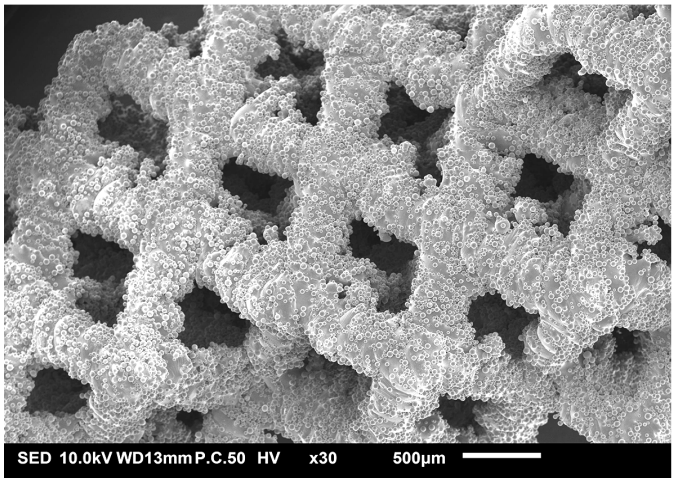


Figure 43: Magnification of porous structure 30x.

Abutment

The abutment is the part that connects the implant in the jawbone with a dental prosthetic, in this case a crown.

Requirements:
- Provide place for attaching a dental prosthetic
- Should be made of a biocompatible material

Insights:
In normal dental implants the abutment is a separate part which is mounted on the implant when the crown will be placed. The abutment is mainly used to adjust and correct the position of the crown regarding the implant position if needed. In this project a patient-specific implant will be designed, in this case positioning can only be done in one way, i.e. the right position. So slightly adjusting the position while placing the abutment is not necessary.

There are two ways in which the crown can be placed on top of the abutment. The first method is to cement the crown on the abutment. The other method is to screw the crown onto the abutment into the implant with a retaining screw (Figure 48).

There is no consensus about which method is better, the cement or the screw-retained crowns. For aesthetic reasons, cemented crowns will be better. (nobelbiocare.com, 2018; Garg, Shenoy, & Shetty, 2014; Wittneben et al., 2017)

In order to perform the plasma-electrolytic process in the right way, a connector piece should be added to the implant to let the current go through. It is necessary that many struts are connected to the connector to let the current flow to the complete structure.

Possible solutions:
Abutment
- Separate abutment that can be screwed on the implant
- Connected abutment

Crown attachment
- Cement-retained crown
- Screw-retained crown

Connector
- Adding an extra part on the implant at the end part of the porous structure (too less connections)
- Adding an extra part on the implant which goes through the entire implant, such that there is a solid core of the implant.
- Adding an extra part which connects all struts at the starting point of the implant and will gradually be one string.
- Make the abutment part of the connector (appendix IV)

Solution
Since patient-specific implants will be designed, the positioning can only be done in one way. Slightly adjusting the position of the abutment is not necessary. That is why the decision is made to design the abutment in a way that it is directly connected to the implant, so the implant and the abutment are one part. This reduces the risk of failure, because of less moving parts and so micromovements, and less open areas for bacteria to adhere.

It is feasible that the abutment can function as the connector to the power supply during surface treatment. In this way many struts of the porous structure are connected, which will guarantee that the current can flow through the entire structure. The abutment can also be placed in the standardized holder for PEO treatment. No extra parts need to be added in this way, and later on needs to be removed (Appendix IV and Figure 49).

Since we are focusing on teeth in the aesthetic zone, the crown will be cemented onto the abutment. Cementing shows better aesthetic results than screw-retained implants.

All decisions taken here keep the design simple, because no threads are needed inside the porous structure to attach the abutment. The implant does not need to withstand torques that are needed to screw in the abutment, which would have been a weak point of the implant.

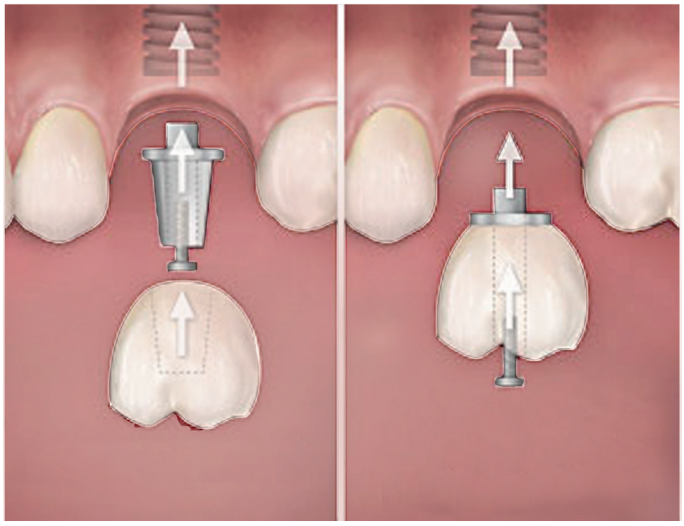


Figure 48: Cemented crown and screw retained crown. Courtesy of optincompanies.com (2018)

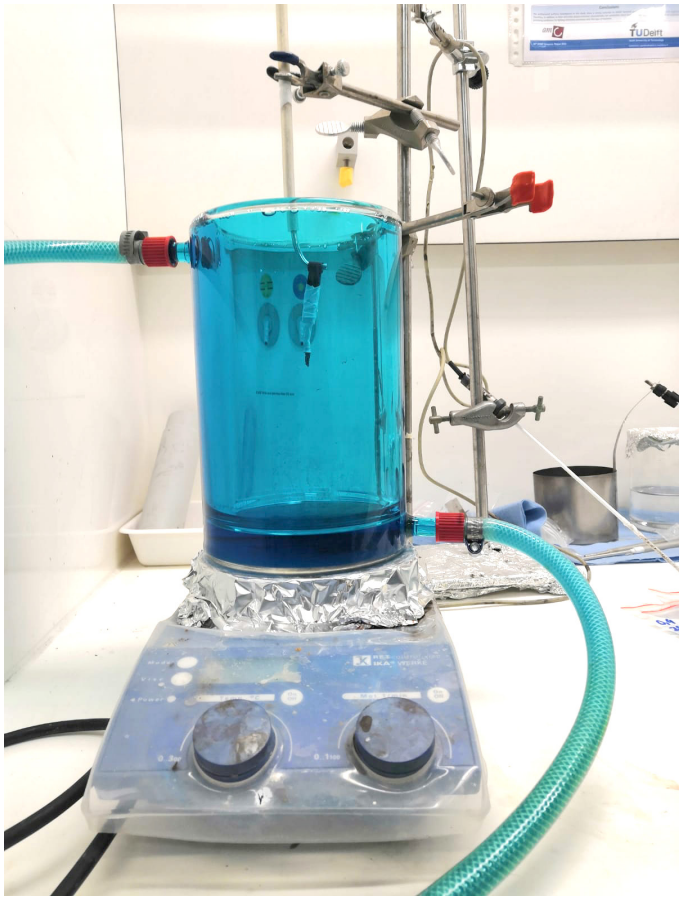


Figure 49: Holder for PEO connected to abutment

Stability

A good fit of the implant is dependent on primary and secondary stability of the implant. The stability of the implants is important since movements in micrometer range can induce stresses or strains. (Javed & Romanos, 2010).

Primary stability is the stability right after insertion. It is related to the congruence between the bone and the implant before any biological process have taken place. Secondary osseointegration happens after primary stability, after 4 weeks of implant placement.

Requirements:

- Implant should fit exactly in the extraction socket
- No micromovements should occur
- Surface should be rough
- Bone should grow onto the surface to allow secondary stability

Insights:

The main primary stability factors are bone quality, bone quantity and the type of implant. Rough surfaces enhance primary stability, because they have a larger surface area which creates a better mechanical link to the bone. (Javed & Romanos, 2010).

Secondary stability is dependent on the primary stability, on bone remodeling and on the implant surface condition. Good bone-to-implant contact enhances secondary stability.

Possible solutions:

- Extra protruding parts can be attached on the implant
- Use press-fit mechanisms
- Create threads on the implant
- Use the Poisson's ration so material will expand if a load is applied
- Attach implant to surrounding teeth to maintain its position
- Heat or cold treatment after implantation to change the shape
- Plug design, squeezing implant to insert in the socket

Extra stability and strength:

- Create a solid core of the implant
- Create a more dense core of the implant (appendix IV)

Primary stability is generated if the implants are fixated well in the bone. Tests were done with FDM printed implants and extraction socket models, in which all parts were upscaled by a factor 3 (appendix IV). 3D-printed implants showed that it is possible to create implants with the root shape and put them back in the modelled extraction socket. So the main principle is proven. Press-fitting worked as well as a plug design that was created with a small upscaling factor, in which the implant were squeezed before putting them in. Extra extruded parts on the implants were difficult to manufacture and did not fit into the extraction socket.

Solution:

With the new design, the implants have a perfect bone-to-implant surface contact, because of the shape that fits perfectly in the extraction socket. Implants are inserted using press-fit mechanism, because this is for now the most ideal solution. It should be tested in real bone to test for primary stability. One porosity in one implant is created, (no variable porosity), because of limited software possibilities. It would be beneficial to have a denser core and a more porous outside layer of the implant.

Stability will also be achieved by the larger surface area created with the porous structure and nano-porosity which makes it rough, which is beneficial for both primary and secondary stability.

Patient-specific implants are only used in patients with good and high bone quality. This is also related to a good primary stability. To know beforehand what kind of quality bone the patient has CBCT scans can be used to analyze the properties of the bone. (O'Sullivan, Sennerby, & Meredith, 2000; Gill & Rao, 2012)

4.2 Comparison between old and new implant

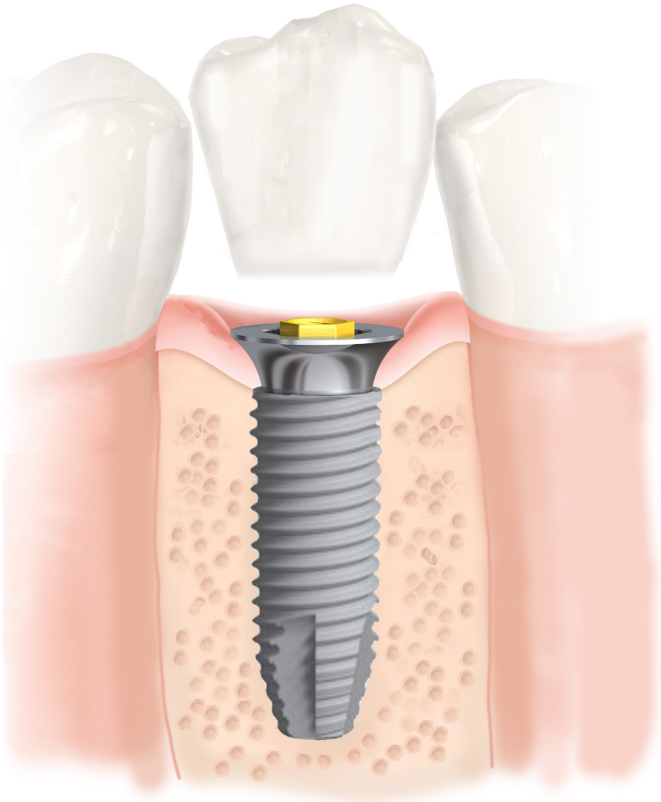


Figure 50: Standard screw-type implant

Material: Ti6Al4V
Type: Screw-type
Structure: Solid
Abutment: Separate
Manufacturing: Subtractive
Production: Mass produced
Availability: In stock
Patients: All

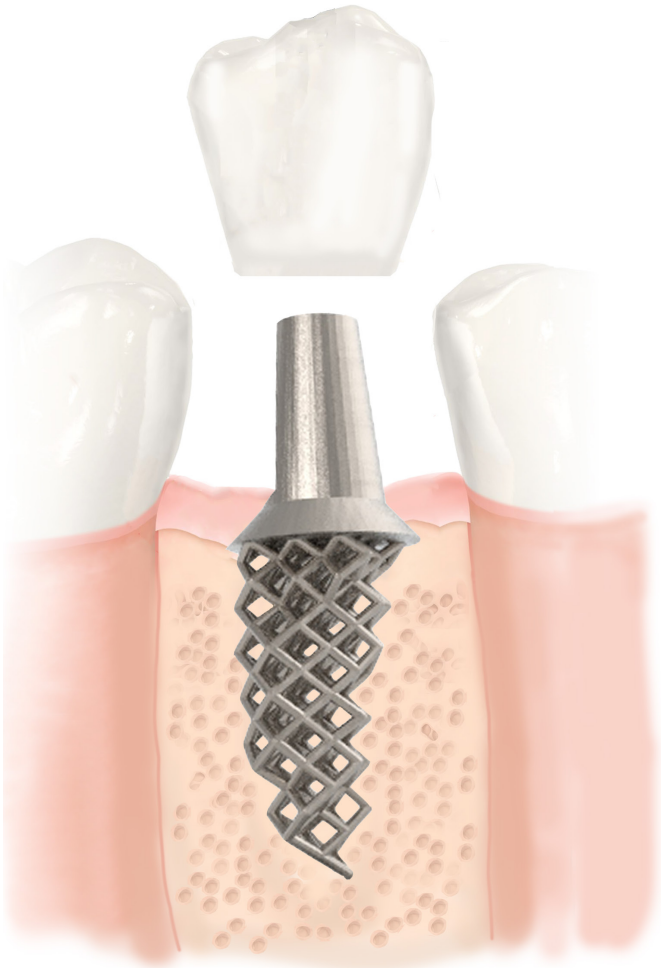


Figure 51: Patient-specific implant

Material: Ti6Al4V powder
Type: Patient-specific
Structure: Lattice
Abutment: Connected
Manufacturing: Additive
Produced: one by one
Availability: Order
Patients: Limited

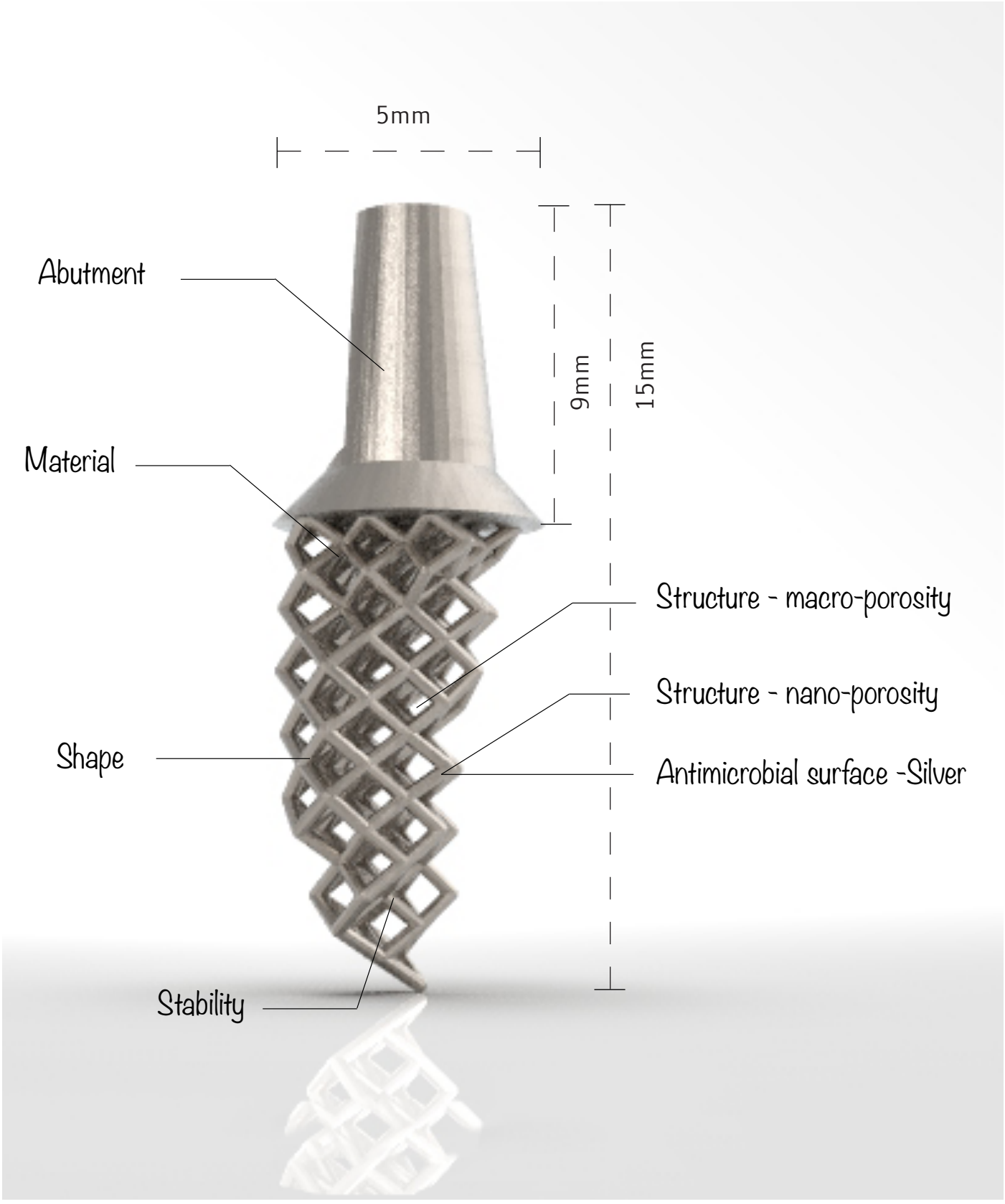
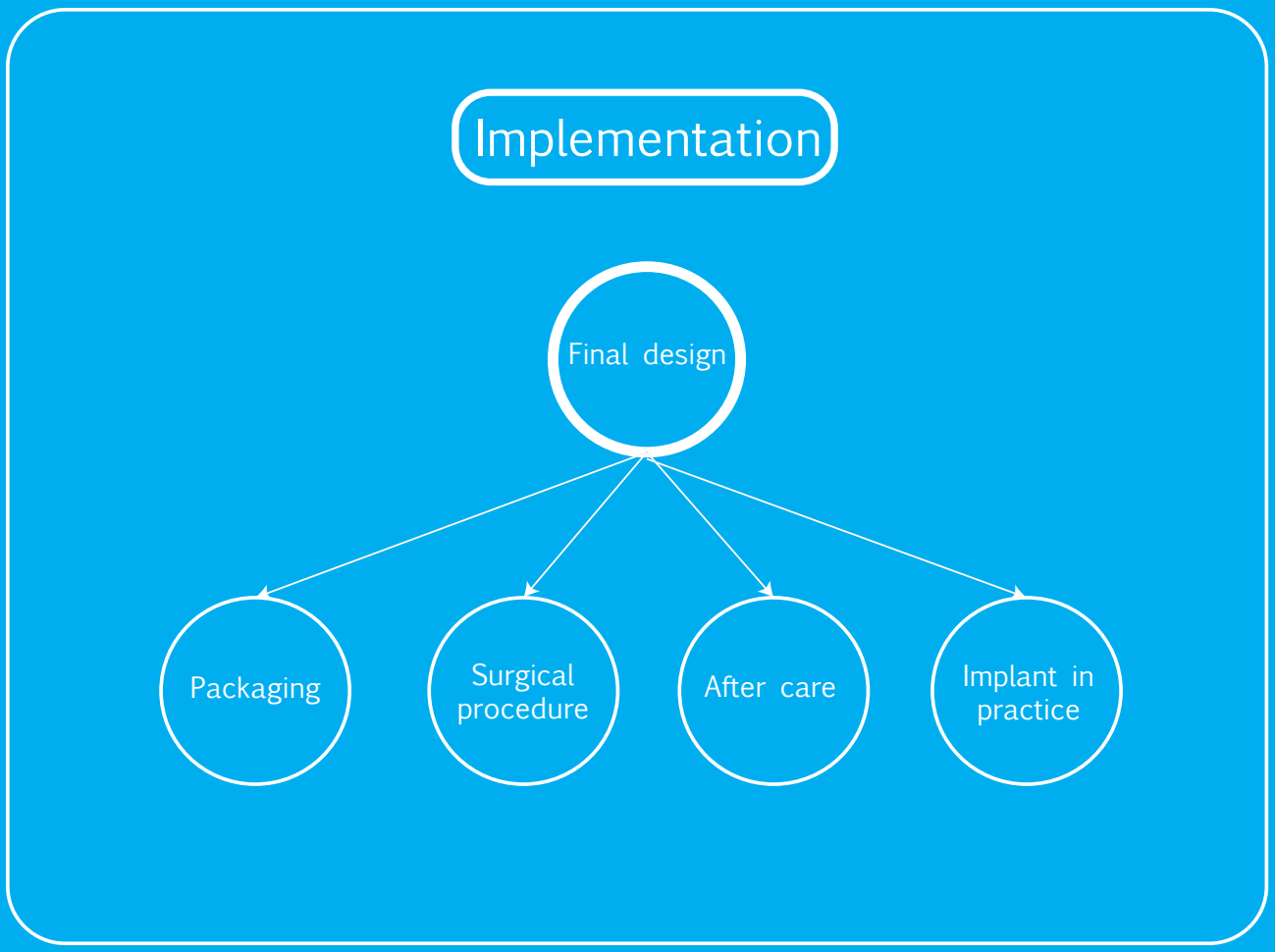


Figure 52: Patient-specific implant with its design features


Implementation
Final design
Packaging
Surgical procedure
After care
Implant in practice

5 Implementation phase

In this chapter the packaging of the implant, the new surgical procedure and how the new implant affects the entire procedure are discused.

5.1 Packaging

It is important that the implants will be packaged in a safe and sterile way.

A packaging is designed for the new implants, which is similar to existing screw type dental implant packaging (Figure 53). After sterilization the implants will be packaged in an ISO Class 7 clean room.

Packaging

The implants will be inserted in a vial in which a titanium structure is present. The implant will be attached on this titanium structure in a way that it touches only titanium and no other material.

The vial is placed inside another tube to prevent any contamination and closed with a cap.

User scenario

During surgery the cap of the tube can be opened by the circulating assistant and the inner vial can be placed on the sterile table. The surgeon can use an insertion tool to get the implant out. (Tool should be designed to do this). When the surgeon takes out the implant, it can be directly inserted in the jaw. The implant does not need to be touched or come in contact with any other material. After insertion the extra titanium part stays on the tool and is removed (Figure 55).

Materials

The vial is made of glass or methacrylate and is placed inside a tube made out of polyethylene terephthalate (PET) the cap is made of polypropylene (PP). A label will be placed on the outside of the tube which provide all necessary implant details. Stickers on the label are present as well, these stickers are later on used to put on the right document and implant passports. Materials are selected based on existing dental implant packages.

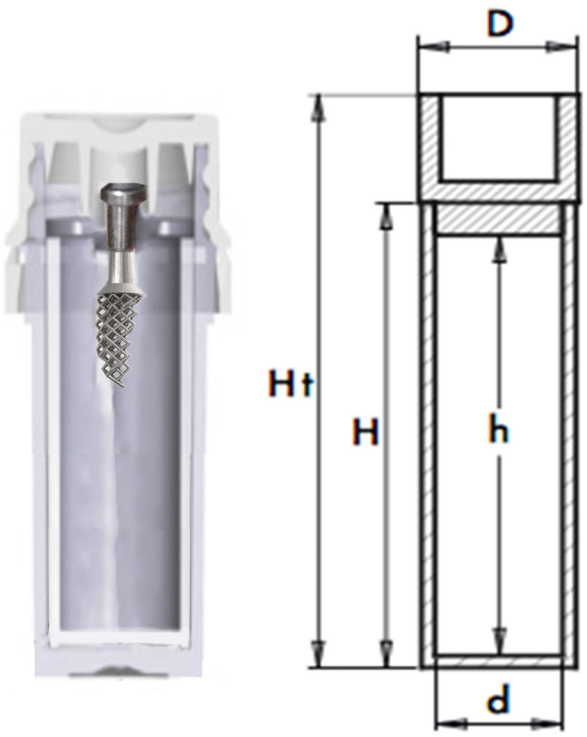


Figure 53: Packaging

5.2 Surgical procedure

The new implant affects the surgical procedure. The surgical procedure itself will be shorter.

Drilling is the most time-consuming and difficult part of the old procedure, because position and direction is very important for the final result. High accuracy is required. Using patient-specific implants, drilling is not required, the implants are pushed in directly after extraction in the extraction socket. This way the most time-consuming step is removed from the procedure. This procedure is only possible in healthy patients with good bone quality and quantity (Figure 54) How the implant will be inserte during surgery is shown in Figure 55.

Bone healing after tooth extraction is not needed either, since the implant is direclty placed after extraction. This saves 3-6 months of treatment time and an extra surgery. Less surgeries/cutting into the human body leads also to lowered risk of bacteria entering the body.

Other benefits of patient-specific implants regarding to the surgery are:

- Perfect positioning
- Preservation of the bone socket
- No extra damage to bone and tissues

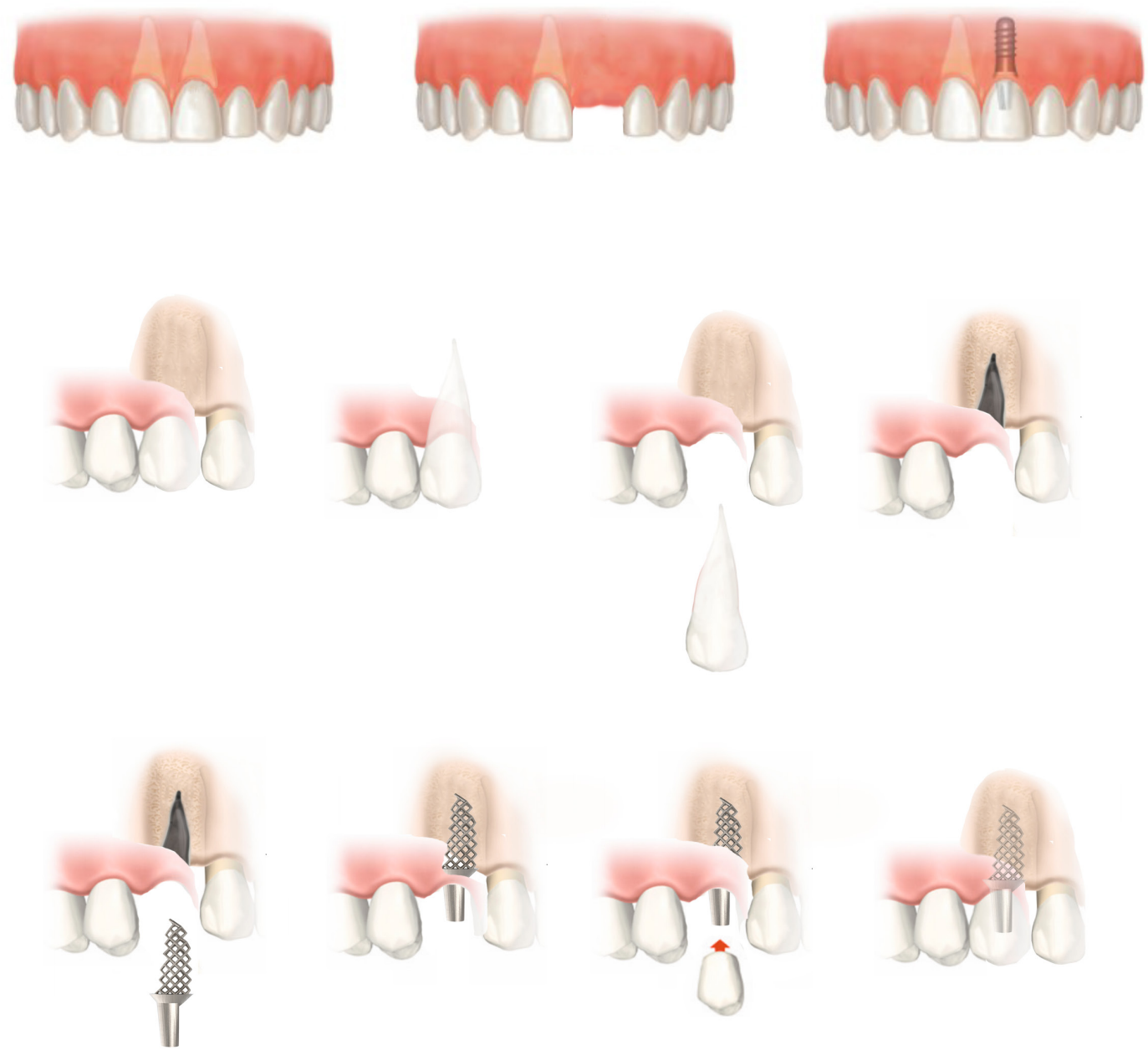


Figure 54: Representation of surgical procedure

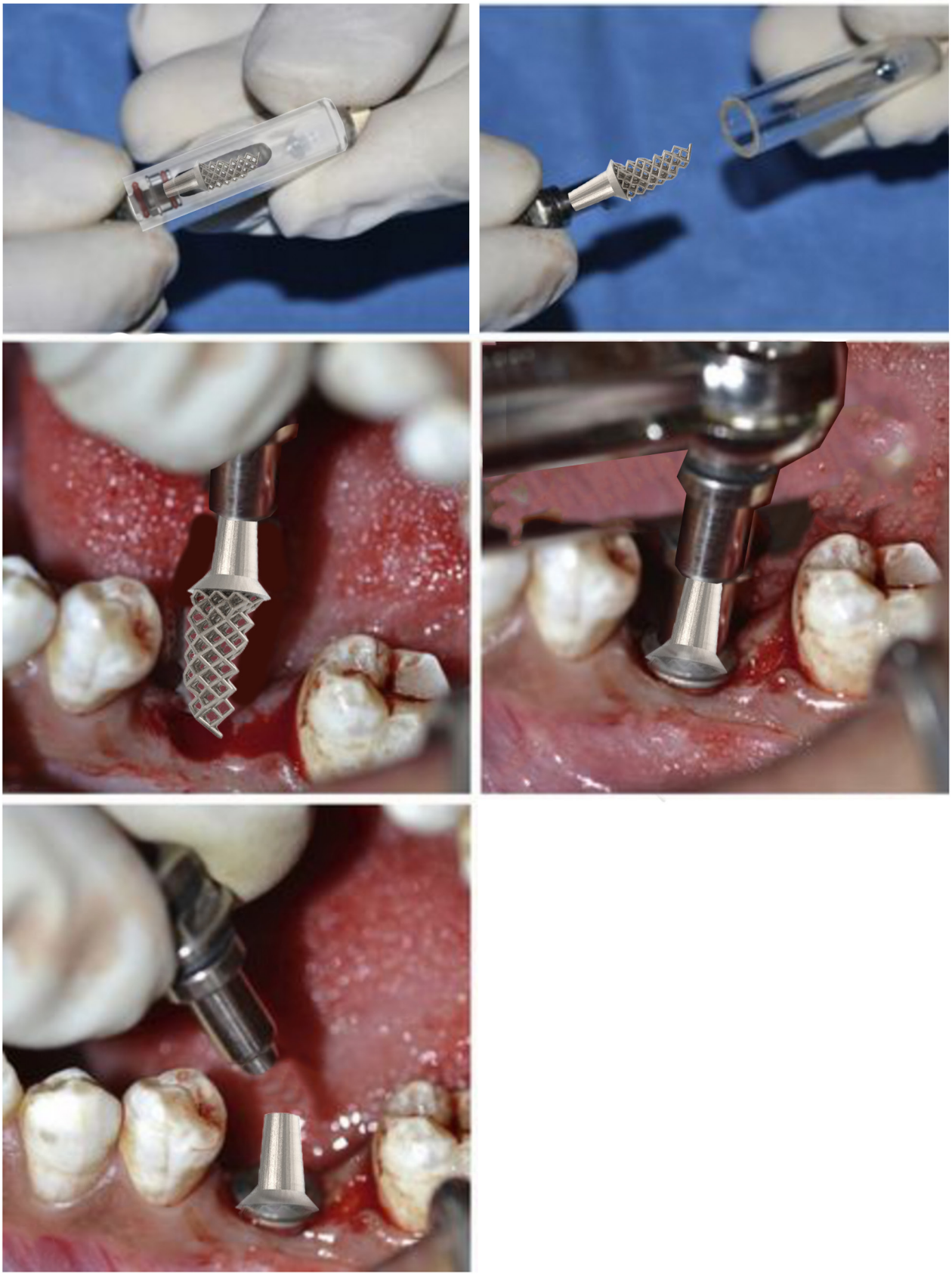


Figure 55: Packaging and implant placement in use

5.3 After care

After the implant is placed a similar process will follow after insertion compared to a normal implant placement. The wound will be sutured and bone healing will take place. Right after surgery a swelling can occur as well as discoloration of cheek and lips. A cold compress and painkillers can be used to relieve the pain. Chlorhexidine is provided to clean the mouth and kill bacteria. It is also possible to provide the patient with antibiotics that the patient should take before and after treatment to prevent infection. However, prescribing antibiotics as prevention is controversial in the medical world.

Sutures will be removed after one or two weeks and can be done by a dentist.

Bone healing requires 3-6 months. In the meantime the implant should not be loaded. A temporary crown can be placed on the abutment to cover the open space in the mouth. The crown needs to be designed and placed in a way that it is shorter compared to surrounding teeth. The temporary crown is also used to protect the abutment.

Regular check-ups are needed, the patient should go to the oral hygienist to clean the teeth and to brush the gingiva around the implant. It is important to take good care of the implant to prevent inflammations. During the first consult the oral hygienist will give instructions how to do this. After the first consult, it is still needed to have regular checks (every month/3months) to prevent early failure of the implants.

After bone healing is done, the dental prosthetic can be placed. The dental prosthetic is designed and manufactured by a dental technician. A dental technician is specialized in making dental prosthetics. The crown will be cemented or screwed on the abutment.

Also after crown placement, it is important to take extra oral care around the implant. Regular checks are advised.

In any case the patient should not smoke before during and after treatment in order to have a successful implant.

Other steps that are needed after implantation are dependent on the oral surgeon and dentist. This is not covered in this report.

5.4 New implant in practice

The new implant does not only affect the surgical procedure, it affects the entire procedure, from diagnosis, to design, to manufacturing, to transportation (Figure 53).

Diagnosis
The diagnosis of getting a dental implant is made by the dentist and oral surgeon. After the diagnosis a treatment plan is made. In this phase the decision for a standard screw-type implant or a new patient-specific implant is made.

The aspects for good decision-making are: Health of the patient, bone quality, place in the jaw, reason for replacement and urgency.

The paths after decision-making differ between the two types of implants.

If a standard-screw type implant is chosen, the treatment can start right away, since all equipment is directly available.

If a patient-specific implant is chosen, the treatment should be carefully planned in order to have all the equipment and the implant ready at the right time. The CBCT scan to analyze the situation and to retrieve the shape of the root should be made as soon as possible. The waiting time between the diagnosis and the actual treatment will be longer, compared to the standard-screw type implants, because the implant needs to be designed and created, which will take up time. If a treatment should start soon, then the patient-specific implant is not the right solution.

Contact between supplier and hospital should be optimal, to create a good treatment plan.

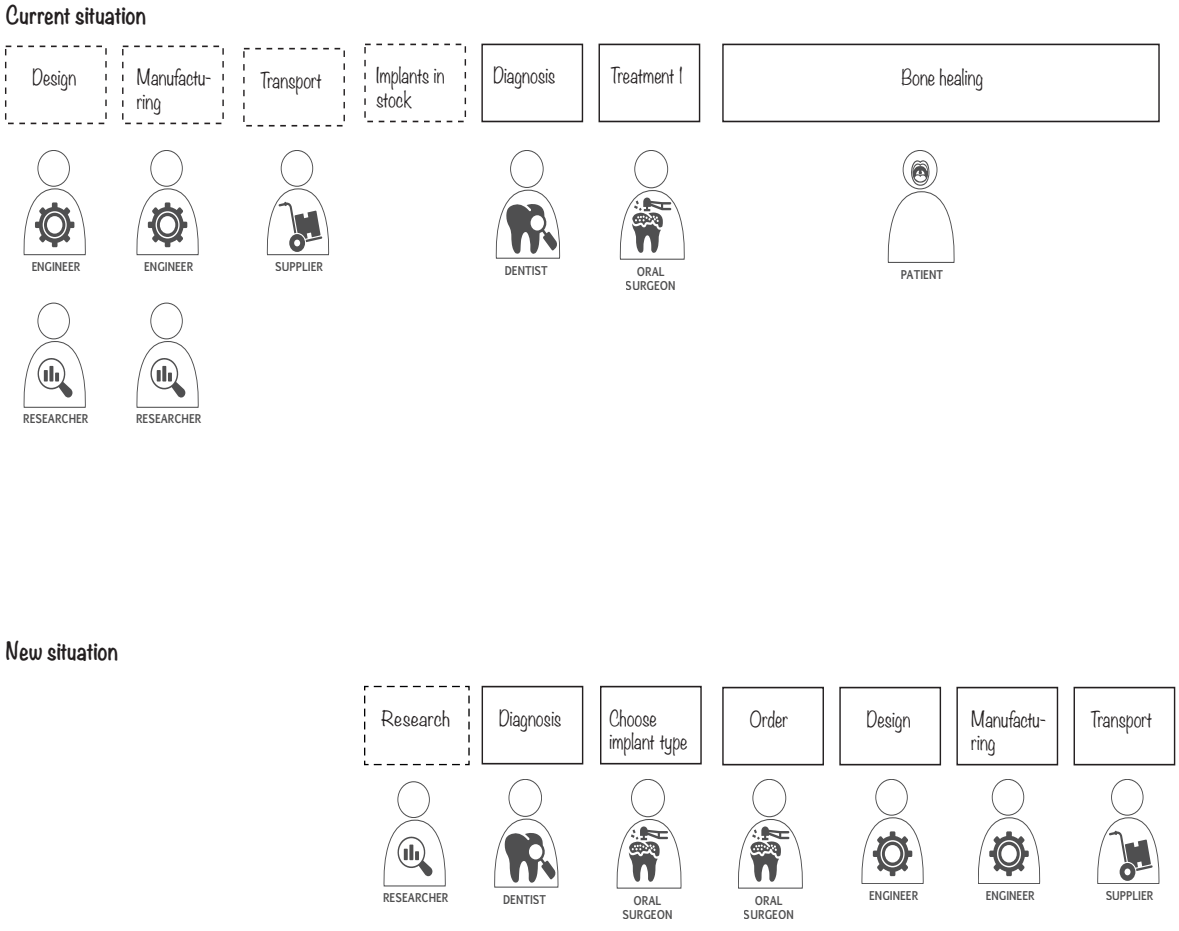


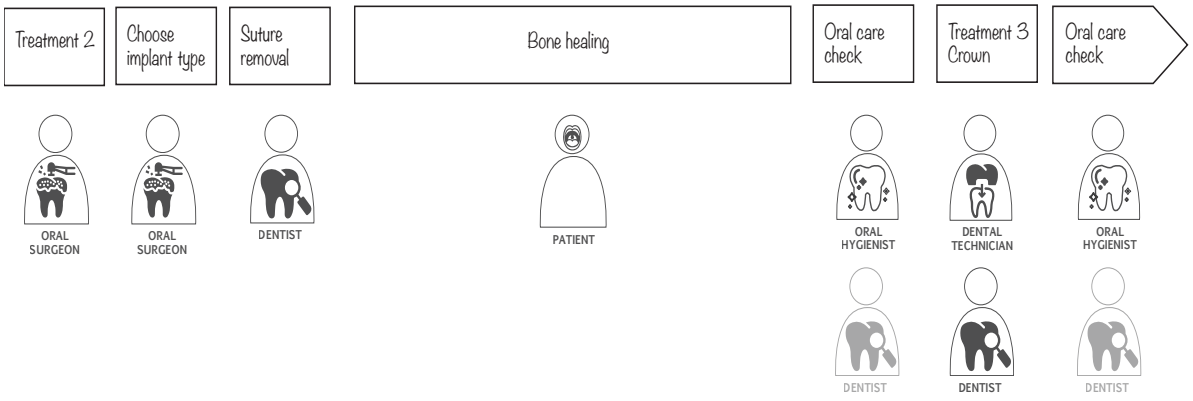
Figure 56: Schematic representation of all process steps and stakeholders involved

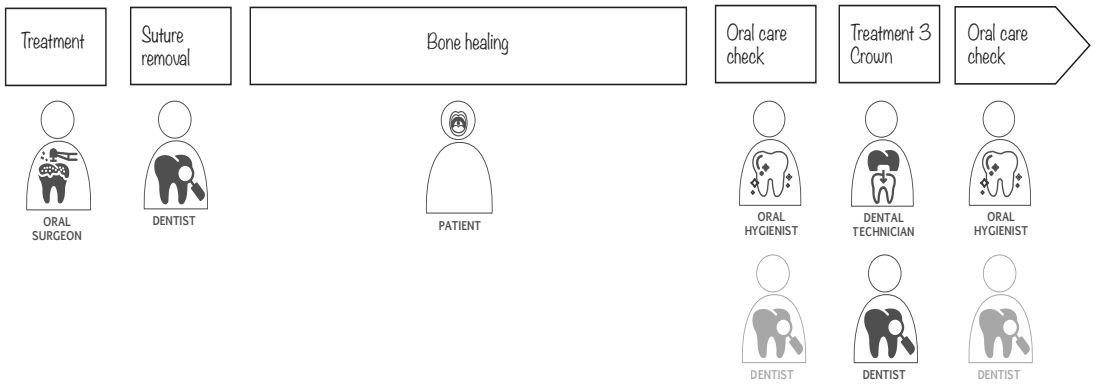
Ordering

If a patient-specific implant needs to be made, an order should be send out to the specific party who is designing the implants. In comparison a current screw-type implant is mass produced and is in stock at hospitals. Large orders are done in one go. For patient-specific implant the ordering process is important to get the implant at the right time.

Design

Design of the implant should be done case specific. This requires engineers and good software programs to achieve this. Since the implant structure is based on the computational design, the design specifications change for every patient and so for every implant. The engineer should be able to determine the right parameters for an optimal design.





Manufacturing

The production of the implants will done by additive manufacturing, one at a time. This is more time consuming than the subtractive mass manufactured current implants.

Manufacturing of current implants is done by dental implant suppliers. There are several options to manufacture the patient-specific dental implants. Three options will be highlighted here (Figure 57):

1, Existing dental implant manufacturer will create patient-specific implants.
2. A new company is set-up to create patient-specific implants (start-up).
3. Patient-specific implants are manufactured in the hospital and collaborations between hospital in certain areas are created in order to all benefit from this new innovation.

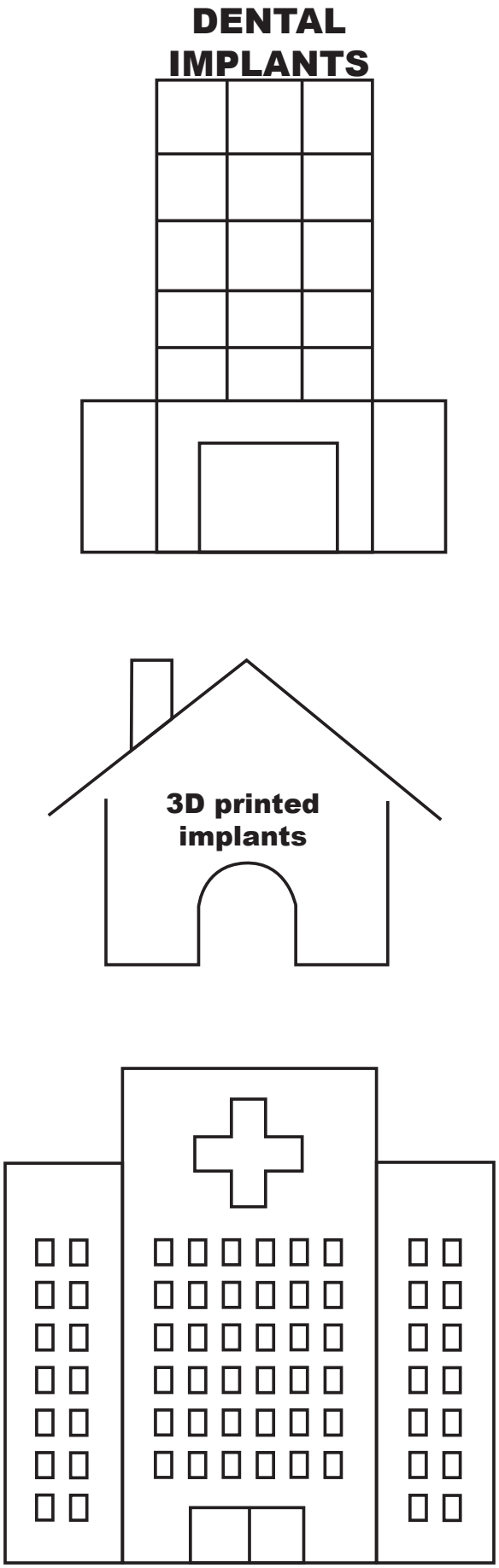


Figure 57: Options where to manufacture dental implants

All options have their own advantages and disadvantages.

Option 1: Existing dental implant manufacturers

Advantage: The companies have already their customers and the new implants could be brought to their attention in a direct way. The relationship is probably already good and relies on trust. Customers can order the two types of implants from the same company, which makes it easy for them.

The disadvantage could be that a lot of engineers must be retrained or they have to hire new engineers. They have to invest a considerable amount of money in new equipment.

Option 2: A new company to create the implants

Advantage: A specialized company that will only focus on these type of implants. A lot of expertise and knowledge will be gathered. A lot of freedom to experiment with the implants and to innovate are possible, without restrictions from a large company. An own vision can be created.

Disadvantage: Difficult to compete with current dental implant suppliers. High investment costs are needed. It is possible to set-up a company and create patient-specific implants. A main goal of a start-up compant can be to be bought by a large company. Many medical start-ups have this strategy, because it is difficult as a start-up to compete on the market and to deal with the risks.

Option 3: Design and manufacturing facilities in the hospital.

Advantage: In-house production. Will reduce costs, because no commercially oriented company will be involved. Nowadays, hospitals are also making their own medicines to reduce the price. Hospitals in a certain area can work together, knowledge will be spread and gained together. Research can be conducted at the same time. Feedback from surgeons, patients and other stakeholders is directly available, which can be used for product development. A large collaboration network between several hospitals can be created. This way, the whole process will be internal, and it can reduce the costs significantly.

Disadvantage: high investment costs to purchase the necessary equipment. Attract new employees, such as engineers to work there. No expertise within the hospital at the moment.

Transportation

The logistics should be optimal for the new design, since the surgery can only start when the implant is delivered at the treatment room.

Treatment

As discussed in the previous section, the surgical procedure is affected by the new design. Also the risk related to the surgery are different for this new implant. The main risk is that if something unforeseen happens with the implant (e.g. it falls on the ground) the surgery needs to be postponed, because no second version will be available If this happens after the tooth is already extracted, it is not possible anymore to follow the patient-specific treatment plan and a new plan should be made.

Costs

This section is about the costs related to dental implants. An overview of the costs of current implants are given followed by a description of how the costs of the new implants would be implemented.

Current implants

The costs for current dental implants are between €1200 and €2000. This includes the material costs for the implant, the working hours of the dentist and the oral surgeons, scans and x-rays, analyses, research, diagnosis and overhead costs. The costs for the total procedure are mainly costs related to the working hours of the dentists and surgeons and the scans that need to be made. The costs for the implant itself are around €300. So only 15-25% is devoted to the implant costs. Implant costs include material costs, manufacturing costs, research and development, transportation costs etc (Figure 58).

New implants

The main costs for the new implant will be the same, since all the steps in the costs overview will remain if the new implant will be used, except for the implant costs.

It is difficult to determine the price, this is mainly dependent on the place where the implants will be made. If this will be at a dental engineering company, the costs will be higher than if it will be produced inside the hospital. Titanium powder itself will costs about per €200-600 per kg. The purchase of an SLM printer is a large investment. No cost estimation could be made on the antimicrobial surface on the implants, since plasma-electrolytic oxidation is not developed in a way that it can be used on a large scale. Working hours of engineers and researchers needs to be taken into account as well. Two hours work for designing and manufacturing per implant will be calculated (€60). The additional second research for diagnosis and treatment planning (Figure 58) will always be needed in case of the patient-specific implants.

Implementation

In the first phase of implementation of patient-specific dental implants on the market, the costs for the implants will be higher than the standard implants, however this can change over time, if printers are produced cheaper, better software programs are created.

Overall, the costs of the entire procedure can be lowered. The failure rate of the implants will be lower, the implants aim to prevent failure. Prevention is always cheaper than curing. So in the long run, the implants would be cost-efficient (hopefully).

Removal of implant costs

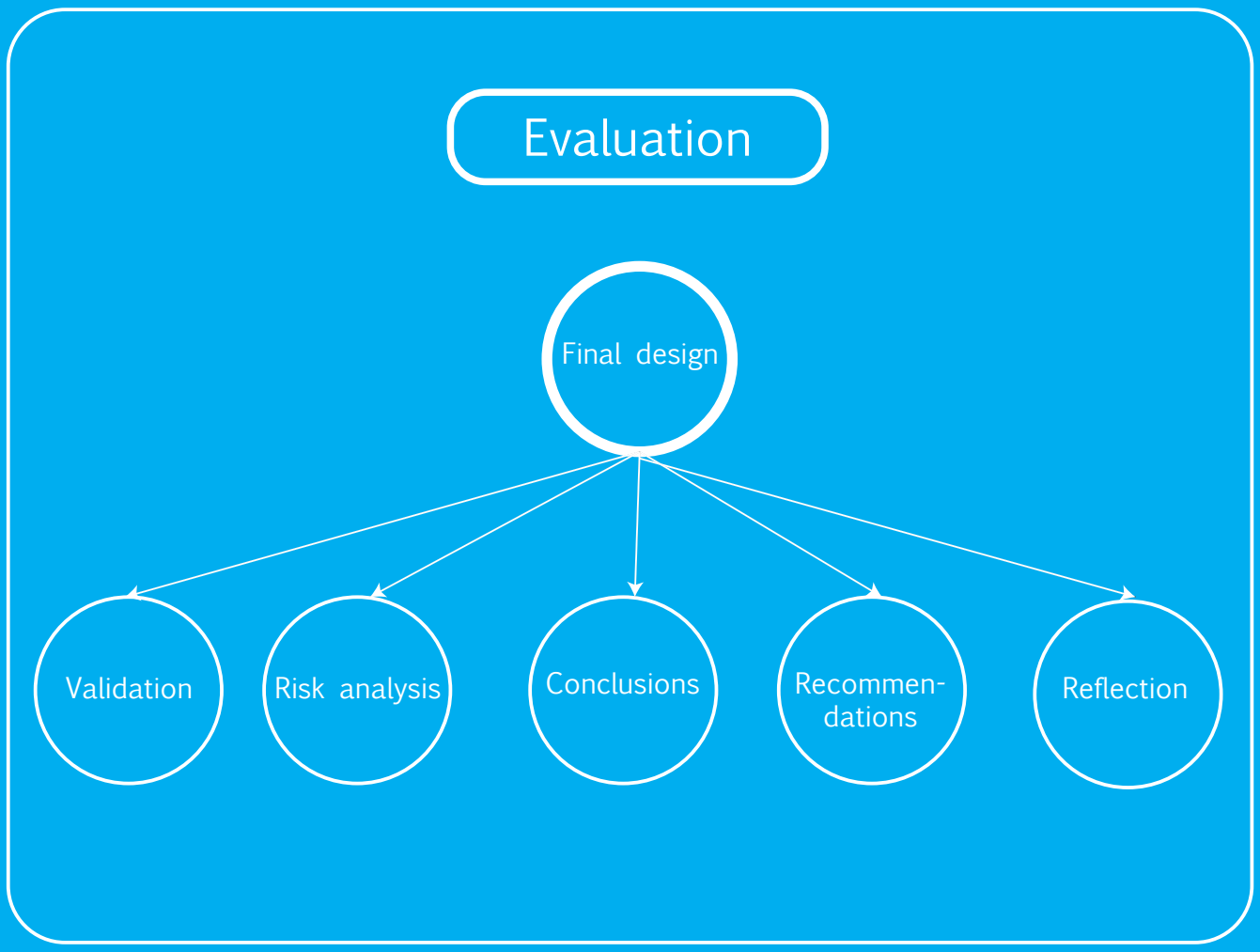
The costs if the implants will fail are higher than if a normal implant would fail. Removal of the implant will be more difficult. The costs for removal of difficult standard implants is €161,35 compared to easily removed implants od €32,27. The removal of patient-specific implants will be more difficult, so the costs will be even higher than €161,35.

Anesthesia	€14,33
Overhead costs implants	€171,85
Research, diagnosis and treatment planning	
First research	€63,56
Additional second research	€97,79
Set up treatment	€132,01
Surgical procedure	
Positioning implant based on cbct scan	€44,00
Placing implant	€223,44
Extra costs for aesthetic zone	€63,56
Placing healing abutment	€73,34
Costs for implant	**€314,04**
Determine stability based on ISQ-testing	€9,78
Crown	
Preparation for creating a crown	€24,45
Crown	€252,17
Aftercare	
Specific consult	€53,78
Elaborate consult	€88,01

Figure 58: Costs current dental implants based on tandartstarieven 2019 code J and code R, independer.nl

Insurance of dental implants

The costs for the implants are only covered by the basic insurance in the Netherlands for two specific groups; For people under 18 who are missing lateral incisors due to medical reasons or if a person lost a tooth when he/she was under 18 and wants to have it replaced before the age of 23. For all other people dental implants are not covered by the basic insurance. Having an additional insurance for dental care might reduce the costs. An amount between €250 and €1000 is insured by several insurance companies, depending on what type of insurance you have. So in all cases the patient itself needs to invest their own money in the treatment.


Evaluation
Final design
Validation
Risk analysis
Conclusions
Recommen-
dations
Reflection

6 Evaluation phase

The validation and risk analysis of patient-specific implants is described in this chapter. The chapter ends with an overall conclusion, recommendations and a reflection on the process.

6.1 Validation- prototype

During the project several prototypes were made of the implant. The prototypes were made of Ti6Al4V manufactured with selective laser melting. The implants were surface treated by plasma-electrolytic oxidation with silver nanoparticles to create an antimicrobial surface.

Experiments and test were done with these samples to evaluate the shape, structure, characterization, phase composition, antibacterial activity and the manufacturing process. Four different porosities were designed and four different groups of porous implants were tested.

Three groups were able to undergo surface treatment with plasma-electrolytic oxidation with silver particles. Only one group did not succeed in getting an antimicrobial layer. This is probably due to a defect in the connection of the struts due to printing.

Creating real prototypes of the implant, in the way that they will be manufactured helped in making the right decisions for the design process and for recommendations to further develop the implant.

Pictures of the prototypes can be seen in Figure 59, Figure 60, Figure 61.

Figure 60: Implant with different porosities.

Figure 61: Implant non treated, PEO treated, PEO+silver treated

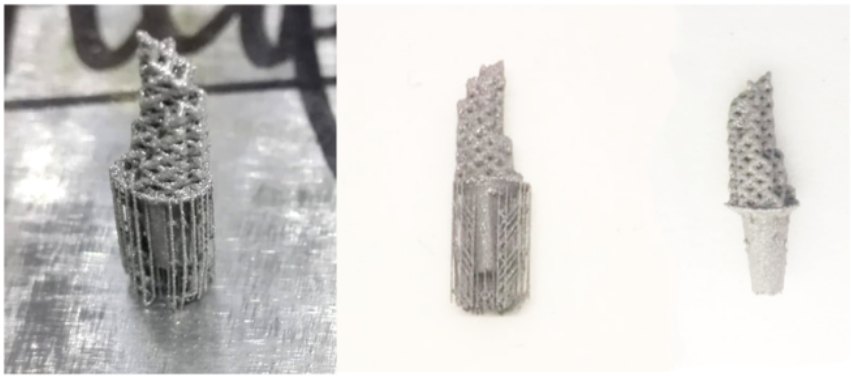


Figure 59: Implant right after printing on printing plate, implant with support material, implant with removed support material

6.2 Validation- oral surgeons, dentist

To validate the new type of implant, the design is presented to four oral surgeons in the Netherlands. They filled out a questionnaire with questions about patient-specific implants, the porous structure and the antimicrobial surface. An interview with a dentist who also researched patient-specific implants is interviewed. However this interview was conducted early in the process.

Oral surgeons questionnaire

All surgeons are working in a general hospital. One surgeon is already retired, one is working for more than 20 years as an oral surgeon and the other two are working in this field for 5-10 years. They all believe that the dental implant industry has changed in the last 10 years and they are all open for new innovations in this industry.

Two out of four oral surgeons had ever heard of patient-specific implants before, the other two did not.

The one who had never heard about it before (retired) totally agrees on the statement that patient-specific implants is a good research field. He also believes that the implant is highly innovative and he sees future in these type of implants. According to him this type of implant can be used in 25-50% of the cases. About the porous structure he is neutral. About the antimicrobial layer he is sceptic, he does not see any value of it.

The other surgeon (5-10years) who had never heard of patient specific implant before, is also positive about research going towards patient-specific implants. He sees it as an innovation, but he is neutral about the question if the implants will be used in the future. He believes it can be used in 5-10% of the cases. He sees more potential in the macro-porosity than the nanoporosity. He is neutral about the antimicrobial surface.

The oral surgeon (20+ years) who has heard of patient-specific implants before. He is very positive about it and sees much potential for it. He thinks it can be used in 25-50% of the cases. About the macro-porosity he is neutral, he sees a risk in more bacteria adhesion, because of the larger area. He is not sure if the antimicrobial surface with silver is sufficient to prevent bacteria adhesion. The nano-porous structure is valuable according to him. The antimicrobial surface is perceived as neutral, because he worries about the effects of silver on osseointegration.

The other oral surgeon (5-10 years) who has heard of patient-specific implants before. He is neutral about the patient-specific implants because he thinks it will be too costly for the advantages it will have. The macro-porosity seems also as a problem for him, because he sees it as a larger surface on which bacteria can adhere and other biological complications can occur. The nano-porous structure is very valuable according to him, he says that it is very compatible and inductive with the right receptors. He knows a research group in Utrecht that is working on it and they show good results. He also sees potential in the antimicrobial surface, but he wonders if it does help to overcome the extra risk of the macro-porous structure.

Interview dentist/researcher

An interview is conducted with a dentist who is also a researcher and promoted on patient-specific implants. He sees potential in patient-specific implants. He is aware of the fact that these type of implants can only be used in a small patient group. So it is only for limited use. He sees opportunities in the porous structure to allow better bone ingrowth. He thinks it would be time-consuming to make every implant for every patient in the right way, with the right porous structure to perform in the best way with the technologies that are available now. He is now focusing on improving segmentation software to make stl models from CBCT scans in an easier and even automated way using artificial intelligence. He is also positive about the antimicrobial layer, since it will prevent infection.

All answers on the questionnaire can be found in appendix V.

6.3 Risk analysis

A risk analysis is made to analyse which risks are relevant for this new implant. Next to the risk analysis, a new classification for medical device approval.

Classification

The new implant will have an antimicrobial coating. This is an active component. Because of this active component the implant will be classified as a class III medical device. This is a higher classification than current dental implants (class IIb) (Figure 62). Medical device approval will be more difficult and extra tests are needed to get the CE mark.

Risk analysis

For the new implant design a risk analysisis made to identify specific risks related to the new device. The analysis can be found in Figure 63. Highest risks are found for moving of the implant in the bone, bacteria adhesion leading to implant failure. If this happens the implant needs to be taken out/ Another risk might be released loose powder from the implants in the body. If this happens, it will have large consequences for the health of the patient. This should be prevented from happening.

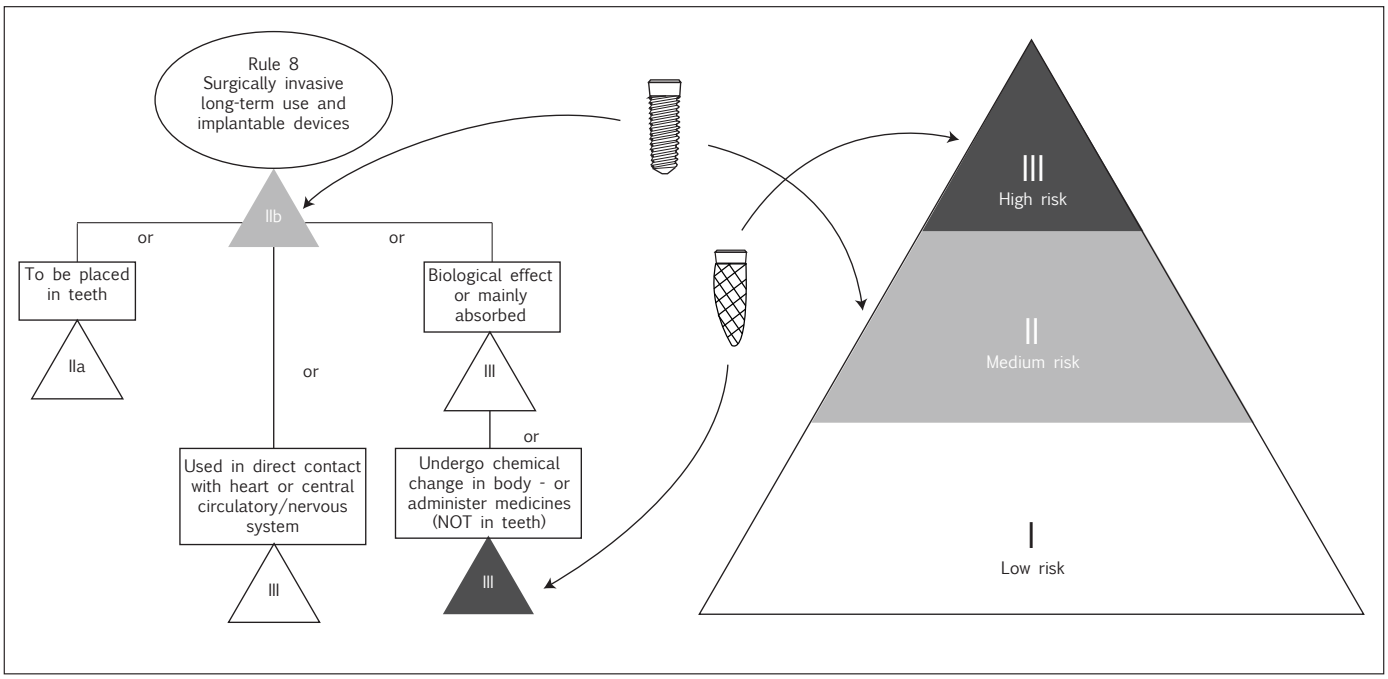


Figure 62: Medical device classification according to Europe (MDR/CE) and the USA (FDA)

Hazards	Possible failure	Possible harm	Possible cause	Probability (P)	Severity (S)	Risk (P*S)
Energy hazards						
Mechanical energy: Falling	Implants drop on the floor.	Implant cannot be used anymore. Postponed surgery.	Inadequate packaging. Unexperienced assistants.	1	2	2
Moving parts	Micro-movement of the implant in the socket	Implant failure. Loosening of the implant	Incorrect positioning, shape not correct.	3	3	9
Torsion, shear and tensile forces	Placement of the crown, chewing	Too high stresses	Incorrect positioning. Inadequate design	3	3	9
Biological and chemical						
Bacteria infection	Bacteria adhere onto the implant	Biofilm formation. Implant failure.	Unsterile working environment	2	4	8
Biocompatibility						
Toxicity of chemical compounds	Patient gets sick	Silver can be toxic if high amounts are used	Too much silver added in production process	1	5	5
Allergenicity	Patient gets allergic reactions. Inflammations.	Implants needs to be taken out.	Metal allergy	1	3	3
Surgical hazards						
Sterilization risks	Implant is touched by non-sterile people while unpacking	Implants is not usable, surgery should be postponed	Inadequate packaging	1	3	3
Packages are opened too soon	Increase change of infection.	Increase risk of infection	Unclear procedure	2	4	8
Operational hazards						
Insufficient positioning	Loosening of the implant	Implant failure	Unexperienced surgeons, severe user mistake	2	4	8
Production hazards						
Insufficient quality of CBCT scan	Implant does not fit	Implant failure, postponed surgery	Insufficient quality of CBCT scan or software to read the data	2	3	6
Insufficient quality of AM implant	Implant does not fit	Implant failure, postponed surgery	Inexperienced engineer, incorrect data transfer	2	3	6
AM hazards						
Loose particles	Loose particles are left on the implant	Particles migrate into patient's body	Inadequate removal of loose powder particles	2	5	10
Change in material	Not the right mechanical properties	Implant failure too soon	Printer with multiple material types	1	3	4
Not fitting implants	Implants does not fit	No surgery to place the implant	Inaccurate printing	2	3	6
Use error						
Attention failure	Placing the implant in the wrong direction	Implant failure	Not paying attention. Distraction	1	4	4
Information hazards						
Incomplete instruction for use	Misalignment of implant	Inadequate position	Incorrect placement	1	4	4
Logistical hazards						
Implants sent to wrong patient	Implants are sent to the wrong hospital/patient	Postponed surgery	Error in logistics	1	3	3
Implant is not labelled correctly	Used for wrong patient	Implant does not fit.	Error in logistics	1	4	4
Production capacity is insufficient	Implant cannot be delivered on time	Postponed surgery	CBCT scan planned too close to surgery	2	2	4

Figure 63: Risk analysis overview

6.4 Conclusions

The final conclusions and the evaluation of the design are based on the design vision and the list of requirements.

Design vision

It was envisioned that dental implants could be improved by making them patient-specific. This would reduce the failure rate, because a perfect fit would be realized, resulting in a perfect bone-implant contact. Thereby osseointegration is supported by creating a macro-porous as well as a nanoporous structure. Reducing infection is achieved by adding silver nanoparticles onto the surface.

In order to design this, multiple aspects of the implant needed to be designed and were all dependent on each other. It was not easy to come up with a good solution since some requirements contradict with each other. For example, the decision to make a porous structure to improve osseointegration contradicts with the vision to make implants less vulnerable for infection. By creating a porous structure you create a larger surface area on which bacteria can adhere. So adding silver nanoparticles on the entire enlarged surface area might seem as a good solution and is highly recommended.

The production of the implant by additive manufacturing and applying the antimicrobial layer were also of large influence of the design. Those techniques have its limitations, and the design should be adjusted based on these limitations. In the end a good prototype with the right materials, right dimensions, and right manufacturing method including the antimicrobial surface is created.

However it was not possible to test the implant on all its facets due to time constraints, and lack of resources. Tests are conducted on some basic principles of the design, such as the shape, printing, applying the antimicrobial surface, characterization of the shape and the antimicrobial layer, the presence of silver and the antibacterial activity in vitro. Next to the tests, literature forms a strong basis of the design. Literature studies show that the use of macro and nanoporosity is creating better bone-ingrowth

The prototype, the literature, the tests, the validation with oral surgeons show that these type of implants are a meaningful alternative and have potential to be further developed and to be on the market. It is a good solution for the current complications that can occur for dental implants.

While designing it was found out that not only these complications could be solved with this design, also the treatment time could be reduced. The total treatment time can be reduced by 3-6 months, which is an advantage for the patient. The actual surgery time is also lowered, because by implementing the new implants the most time-consuming and difficult part of the surgery is omitted. Both the patient and the surgeon/dentist will benefit from this new dental implant design.

Even though the design and the proposed solution suggest that the total treatment time will be reduced, extra time will be added by designing and manufacturing of the implants.

The time in between the diagnosis and the actual treatment will be prolonged. This because a patient-specific implant needs to be designed, based on an analysis of the CBCT scan, image segmentation, designing, printing, linking to the right patient, sterilizing, packaging, labeling, delivery. This is now all personalized and cannot be done in mass production as it was done before. So in this part of the process more time is needed. However the extra time spend here is later saved in the operating room.

Conclusion

The design is evaluated against the design vision and the requirements. The final design is a prototype of a dental implant that can be used by oral surgeons to implement in a patient. The foundations of the design are based on qualitative research, testing and a considerable amount of scientific literature.

Qualitative testing in the form of interviews and questionnaires has shown positive responses on multiple aspects of the design. It gives a bright future perspective on patient-specific implants. Doubts are still related to the costs of the implant and the antibacterial surface layer. Long term testing and clinical testing is needed to further validate the implant, which can also show more benefits to the users, to convince them that the extra features are valuable.

In conclusion, the design shows large potential to positively impact the dental implant surgical procedure by adding benefits for both the patient and the surgeon/dentist.

The dental implant is not ready for use. This report shows the first steps towards these patient-specific implants. A lot needs to be developed and improved. Therefore the following chapter gives an overview of the recommendations that are important for futher development.

6.5 Recommendations

This chapter describes the recommendations for future developments of the implant.

The design should be developed further, to fully function. The main steps that needs to be taken are improving the microporous structure, improving 3D-printers, improving of computer software, do mechanical testing, do biological testing, do clinical trials, create a marketing and strategy plan and design a new packaging.

Microporous structure

In this design the microporous structure is a main feature of the design. The porous structure can be further developed by looking at creating different types of porosity in the structure. In this design, one type of unit cell size is chosen, but it would be better if a changing porosity is created within the implant. A more denser structure on the inside, and a dense structure on the outside, will improve the strength of the implants. To take it one step further, the porous structure can be designed using optimization software. In this case the porous structure is designed for a specific patient for specific loading scenarios. Material is added only where it needs to be The developments in the 3D printing industry are very important to also realize these recommendations (Figure 64).

The porous structure allows bone to grow through the pores into the entire structure of the implant. If the implants needs to be taken out for a particular reason, it is in this case very difficult to get it out. Tools or good solutions to do this should be generated.

Improving computer software

To create the perfect shape for the implant, image segmentation is used to obtain the right dimensions from the CBCT scan. However, this process is manually done and is vulnerable for mistakes. Especially for the segmentation of teeth it is difficult, because both bone and teeth are made from the same material. It is difficult for the software to distinguish between the two. Developments to improve image segmentation software should be helpful in the design process for the implant. If the software can automatically select and separate the particular root, and does the geometric modeling right after, then the process would be way faster.

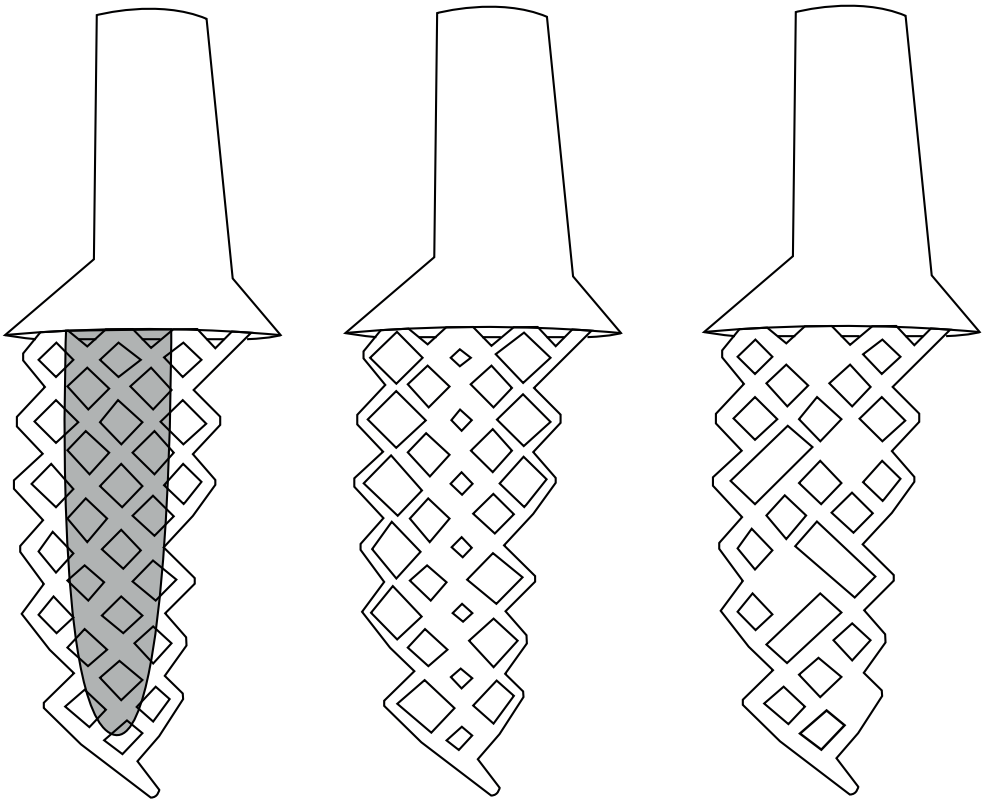


Figure 64: Developments of the porous structure. Solid core, more dense towards the inside, shape optimized structure

Marketing and strategy plan

A marketing and strategy plan needs to be developed to get these new implants on the market. It is therefore important to know where the implants will be manufactured. At existing dental implant companies, a start-up, or inside the hospital. For every situation a marketing strategy with a different focus have to be created.

For what price the implants will be on the market is dependent on the manufacturing process. The added values above current implants should be clearly marketed to find a proper market. A good price-quality should be guaranteed (Figure 67).

Logistics

The logistics of transportation of the implants needs to be thought of as well, since the implants will be personalized and cannot be made by mass-production. The sending of the implants should also be done individual.

Packaging of the implant

Packaging of the implant can be improved. The current design is based on existing packages of current dental implants. Probably there would be a better way to pack the implants in a specific way for the new implants.

Other materials

The implants are now made of titanium. A big disadvantage of titanium implants is that they are grey. For people with thin gingiva it is possible that the grey implants shine thought the gingiva. This is aesthetically unpleasing. Using different type of materials might solve this problem, for example zirconium, a white ceramic. However a lot more research is needed if a patient-specific porous implant with an antimicrobial surface can be made out of zirconium.

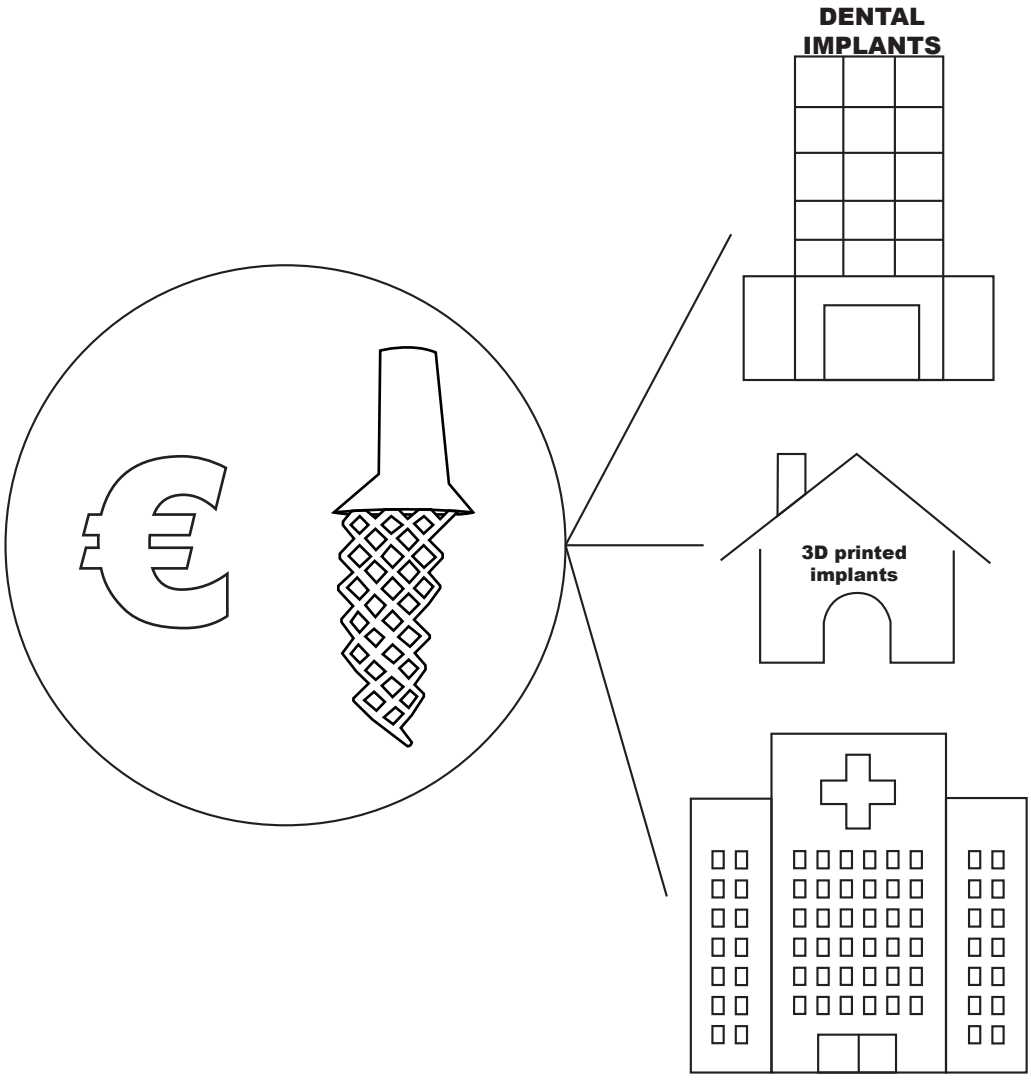


Figure 67: Marketing and strategy is based on where the implants will be manufactured

6.6 Reflection

I started this graduation assignment knowing that this project was a good combination between the Integrated Product Design master and the Biomedical engineering master. I was happy that I was able to find a project in which the two masters could be combined. I wanted to learn more about additive manufacturing in the medical industry. During both of my masters I learned about implants, mostly hips and knees. This project is focused on dental implants, which was completely new to me.

The way of approaching a graduation project is different between the two masters. The biomedical engineering project was more directed towards a desired direction, which was the application of an antimicrobial layer on dental implants. The expertise on how to do this was already there within the research group. However, they had never done something with dental implants before.

An elaborate literature study is compulsory for the biomedical engineering program. This was very helpful in analyzing which developments of antimicrobial surfaces on dental implants had taken place. I also looked into the additive manufacturing of dental implants for this literature study. I came across the root-analogue-implants during this literature study and this was very interesting. I contacted the author of the articles and met with him. This meeting helped me to gain more understanding about these type of implants.

This literature study took long, because finding the right literature, interpreting all the information, and making a report out of it was challenging. However, the literature study gave me a lot if insights and gave me a clear direction, also for the designing part of the implant.

The integrated product design part of the project was focused more on the entire context of dental implants. It was a more open project. Because dental implants were knew to me, and I did not know anything about the procedure, I decided early in the process to contact hospitals and dental practices to ask them if it was possible to observe a dental implant surgery. Il got three positive answers from oral surgeons and a dentist that I could visit them. In total I saw five surgeries on four different days at three different locations. Being able to see oral surgeons and dentists during their daily work was interesting and helpful. I appreciated that the oral surgeons and dentists were open to let me observe the surgeries and to provide me with a lot of information. During the observations I saw which steps were the most difficult and time-consuming. This resulted in the focus on reducing treatment times and more looking into this field during the project, next to the directions based on the literature study.

I also went to a dental implant company, Dyna dental engineering, to get more information about dental implants form their perspective. They also provided me with 25 dental implants that I could use for my research.

The start of the project was, mainly due to all the visits and meetings that I had very insightful, and I learned a lot in a short time. I really value this part of the project, I really enjoyed it.

In the designing phase I learned how to work with a lot of software programs I never had used before. 3D slicer, 3DXpert, Grasshopper in Rhino, Ansys, Geomagic studio, adobe premiere pro, adobe after effects. I am happy that I have learned how to use these programs, because it will always be helpful for my future career.

Not only I learned to work with new computer programs, I also learned how to work in a lab, mainly for the biomedical engineering part of the research. I had never done this before, and for this graduation project I wanted to know how it is like to work in a lab. I did many experiments and used a lot of machines and devices to do these tests. I had to contact several people to help me and to teach me how to use certain devices. I know how to do PEO, how to pipet, how to do ion-release tests, how to do SEM analyses, how to do EDS analyses, how to prepare for XRD analyses, how to embed samples in resin. I learned how to visualize raw data in a clear and scientific way.

Combining the relevant information I gathered from the industrial design part and the biomedical part was challenging, but also gave a lot more value towards the design. It was a good fit between the two masters and expertise which resulted in a design that has potential for future implementation.

Looking back at the process I would have done some steps differently.
First of all I had a quick start, thereafter the process was slowed down. I did not expect that the biomedical tests would take so long. If I had knew it before, I would have started earlier with the printing and the testing. Now I waited until the final design was ready. By having done this before, I could have made decisions earlier in the process, and I could have done probably more validation tests of more aspects of the design.

In the beginning of the design phase I was focused on having the design ready, before printing. I had some ideas which would make the design very complex, in the end it was not possible to produce it with the methods I could use. The final design is a very simple design, which is able to test the main principles. Further details and improvements can be made later on if the implant will be further developed, for example the stability of the implants.

The approach of the biomedical engineering part was straightforward, I think this has limit me to explore more possibilities to challenge the problems from a different perspective. This is also the reason why a different design approach is taken and not the process in which several different concepts were created and finally one is chosen and further developed. This process is based on a basic concept which was designed based on the literature and insights gathered and extra features were designed later on. In the process several small design cycles are taken and different ideas and concepts were generated. I liked this way of working, because it gave me a new view on the design process. I never had done a project in this way. It would be interesting to also approach this project different and to create different concepts which would deviate from each other to come up with a completely new innovative way for the future of dental implants. For example making use of bone material, instead of titanium, creating another antimicrobial effect etc.

For the project management I would have given more structured updates on a regular basis to my supervisors. This could be a point of improvement for my next graduation project.

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8 Appendix

Table of content

Appendix I- 2.3 Patients

The steps that a patient needs to undertake during the dental implant procedure are described in this section.

Step 1: Patient is aware of missing teeth or limited function of the teeth.

The indication of receiving a dental implant can differ per patient. One of the indications is a trauma, whereby the patient has lost a tooth or teeth or part of it. Other indications can be bad hygiene, that has led to plaque formation, gingiva diseases, periodontitis, tooth decay, root canal failure, and excessive wear and tear. Deterioration of the teeth limits the function.

The patient is most important in this first step, because the patient will know whether teeth are missing or fractured or if they experience pain. The patient will go to the dentist, who will do a check and will treat the patient. A next appointment should be made.

Step 2: Appointment with the dentist and diagnosis.

The second step is the appointment with the dentist. During the appointment, the dentist will check the teeth and will make an x-ray and/or a CBCT-scan. The dentist will look at the problems the patient experience and will take the first short term actions to relieve pain.

Step 3: Referral to oral surgeon or specialized dentist

The dentist will refer the patient to an oral surgeon or a specialist implantology dentist to continue the procedure.

During the appointment, the dental implant procedure will be explained. The best treatment options will be discussed as well as the advantages and disadvantages.

The procedures can differ for every patient and different treatment options are possible: fixed dental tooth implant, a bridge, a fixed denture on four implants, a fixed denture on six implants, a removable denture with push buttons or a removable denture with a bar. However, before treatment the patient should be checked on three main aspects; bone quality, gingiva quality and inflammations.

It is important that the quality of the bone is sufficient. If there is not enough bone the implant will not fully integrate and will not be fixated in the jaw. Extra bone, by means of allograft, autograft or artificial bone, can be inserted to improve the quality. Another requirement before starting the procedure is having healthy gingiva. Good gingival tissue treatment options are available. In case of an inflammation, the inflammation should be removed before starting implantation.

Before the treatment can start any oral health problems, such as tooth decay, and gum disease should be managed and solved first.

The costs of the procedure will be listed and the patient has time to think about the all the gathered information and to make a decision. After signing an agreement document, the process can start.

Step 4: Next appointment: Removing teeth that needs to be replaced by oral surgeon.

In case of fractured or rotten teeth the dentist will remove the still existing part of the teeth form the jaw. In most cases, the patient has to wait for three to six months to let the bone heal.

Step 5: **Next appointment at the oral surgeon**: **Implant placement by oral surgeon**.

In this step, the implant is placed. The dentist or oral surgeon will implant the implant during the surgical procedure. This is the most important step of the complete procedure. After placing of the implant, the bone has to heal and has to integrate with the implant for about 3 months.

Step 6: **Next appointment**: **Removal of the sutures by dentist**.

Sutures will be removed after a week. Oral care and hygiene is essential from this point onwards. Not needed in case of resolving sutures.

Step 7: **Next appointment**: **Crown placement, made by a dental technician**.

During the healing of the bone, the dental technician will create a personalized crown, bridge or denture with a perfect fitting. This is done by using a gypsum print or a digital 3D scan of the teeth. During the dentist appointment, the patient will receive the dental prosthetic, i.e. crown, bridge or denture, in a next appointment.

Step 8: **Next appointments**: **Regular check-ups by oral hygienist to check the oral health**.

Good oral hygiene is essential to have healthy teeth. The patient needs to take care of the teeth and regular visits to the dentist or oral hygienist should be made.

The most important role in this step is the patient. The patient has to take extra oral hygiene for the dental implant by flossing and brushing. Smoking should be avoided and a soft food diet for 7 days is recommended. This is essential to prevent the implant from infections and inflammations. Regular visits to the dentist or oral hygienist are needed to clean the teeth.

Appendix II- 2.5 Observations- Surgical procedures

Five surgeries are observed during this project. Every surgery is analysed by making use of models; physical model, sequence mode, flow model and cultural model. All models for every procedure are shown in this section.

Surgery 1

Hospital:	Academic hospital case 1
Procedure:	Inflammation treatment
Location of the implant:	-
Dental prosthetic:	-
Complications:	Two big inflammations. No dental implant
Implant brand:	-

Surgery 2

Hospital:	Academic hospital case 2
Procedure:	One-phase
Location of the implant:	4 in the mandible (edentulous patient)
Dental prosthetic:	Denture
Complications:	-
Implant brand:	Nobel Biocare

Surgery 3

Hospital:	General hospital case 1
Procedure:	One-phase
Location of the implant:	1 in the maxilla
Dental prosthetic:	Crown
Complications:	-
Implant brand:	Straumann

Surgery 4

Hospital:	General hospital case 2
Procedure:	One-phase
Location of the implant:	1 in the mandible
Dental prosthetic:	Crown
Complications:	-
Implant brand:	Straumann

Surgery 5

Hospital:	Dental practice
Procedure:	One-phase
Location of the implant:	2 in the maxilla (edentulous patient)
Dental prosthetic:	Bridge
Complications:	-
Implant brand:	Straumann and Nobel Biocare

Physical model

The physical model shows the floor plan of the treatment rooms including the movements of the stakeholders. Every color indicates a different stakeholder (Figure app. 1).

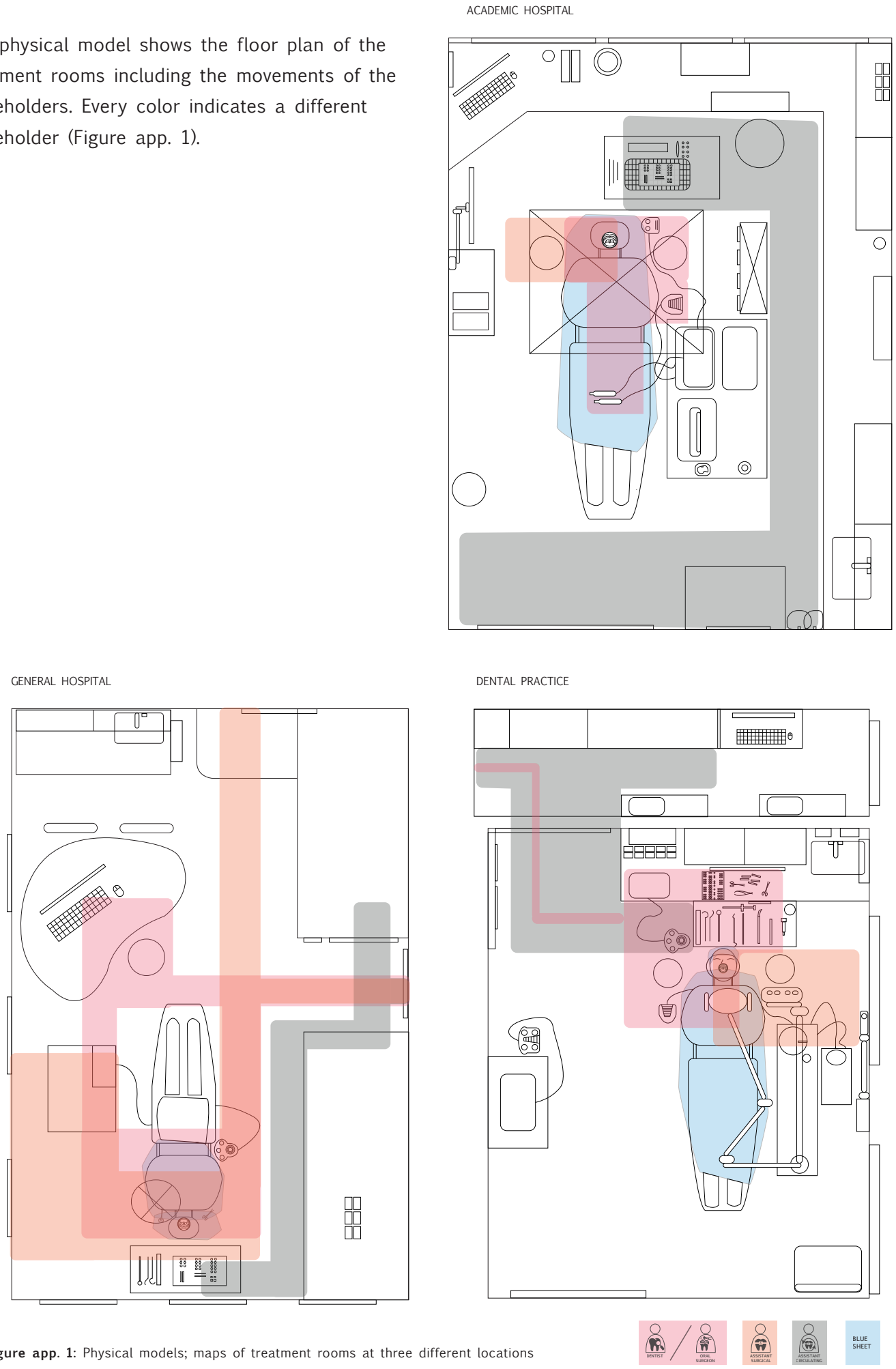


Figure app. 1: Physical models; maps of treatment rooms at three different locations

Similarities

- Circulating assistant walks the most and in the largest area.
- In all cases there is a separate room or hallway where the circulating assistant can work and where instruments and products are stored. In two cases these were connected with the treatment rooms. These areas are kept clean and are not accessible for patients and people from outside.
- Tools are always located near the head of the patient, because the place is logically close to the mouth on which the surgery is performed.
- Implants are placed on a table in the treatment room. The right implants are prepared and some extra are placed there.
- A computer is always located in the treatment room, so the dentist or oral surgeon can easily access the required information during the procedure.
- Administration is done on the computer in the treatment room or on another computer in another room. In the general hospital, the oral surgeon performed two surgeries at the same time.

  The administration was done in between the surgeries on one computer. In the dental practice, the computer where the dentist and assistant did the administration was located in the sterile hallway.

  Administration is done on one central computer. The computers in the treatment rooms are used to get the right information and details during a surgery, not to do the administration.

Differences

Academic hospital

- In the academic hospital, the surgical assistant/oral surgeon in training and the oral surgeon are not leaving the sterile area.

Dental practice

- In the dental practice the dentist is leaving the sterile area, because the circulating assistant was not there. So, this was out of emergency reasons.

General hospital

- In the general hospital, no clear sterile area could be indicated. The patient, surgical assistant and the oral surgeon were moving in between different treatment rooms, the hallway, the waiting room and the x-ray room. Not because of an emergency but out of habit.
- In the general hospital, no chairs or stools are visible. The oral surgeon and the assistants are standing during the entire procedure. In the academic hospital and the dental practice everybody is sitting.

Sequence model

The sequence model shows the steps that are taken during the procedure and by whom this is conducted. In an adjusted sequence model, also the way of thinking and feeling is shown (Figure app. 2, Figure app. 3, Figure app. 4 and Figure app. 5).

ACADEMIC HOSPITAL CASE 1

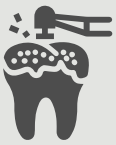
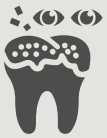
	 ORAL SURGEON	 ORAL SURGEON IN TRAINING	 ASSISTANT CIRCULATING	 PATIENT
PREPARATION	Anesthesia Sterile clothing	Blue sheet over patient Sterile clothing	Room preparation Questions about dental plate Helping with sterile clothing	Entering treatment room
SURGERY I inflammation treatment	Testing anesthesia Incision Bone removal Bone grafting Removal of inflammations	Clamps	Placing pedals Turning on devices	
SURGERY II extra bone	Placing in patient's bone and artificial bone		Providing the surgeon with the artificial bone	
SURGERY III closing	Suturing	Assisting suturing		
AFTER CARE	Next appointment talk Checking fitting of the dental plate	Checking fitting of the dental plate	Picking up the phone	Leaving
CLEANING	Take off sterile coat	Take off sterile coat	Cleaning and removal of the instruments	
ADMINISTRATION	Entering information in the system	Entering information in the system		

Figure app. 2: Sequence model academic hospital case 1


PREPARATION
SURGERY I
creating holes
SURGERY II
implant placement
SURGERY III
closing
SURGERY I
creating holes
SURGERY II
implant placement
SURGERY III
closing
AFTER CARE
CLEANING
ADMINISTRATION
ORAL SURGEON
TASKS
Anesthesia given.
Checks the mouth.
Puts sterile coat on.
Extra anesthesia given.
Incision.
Pilot hole, two times.
Drilling in bone with increasing diameter.
Reduces the amount of water.
Continue drilling, two holes are created.
Turning the implant in, twice.
Healing cap placement, twice.
Suturing
Change position
Incision.
Pilot hole, two times.
Drilling in bone with increasing diameter.
Continue drilling, two holes are created.
Turning the implant in, twice.
Healing cap placement, twice.
Suturing
Checks appointment
Explains next steps
Taking off sterile coat
Administration on PC
THINKING
Is everything ok?
Do I have to give extra anesthesia?
How are the bone properties?
Why is there so much water?
How do I have to change the settings?
Is the position correct?
Where is the circulating assistant?
Is the implant well-fixed?
What is the perfect location for drilling?
Is the position correct?
Where is the circulating assistant?
Is the implant well-fixed?
This was a good surgery.
Is all information in the system?
FEELING
+
-
ASSISTANT SURGICAL
TASKS
Room preparation.
Gets the patient.
Puts sterile coat on.
Sterile cover on lamp.
Checks anesthesia.
Blue sheet over patient.
Retractor is used.
Suction device is used.
Pushes red button for circulating nurse to come
Indicates which implant to get.
Assisting suturing
Change position
Retractor is used.
Suction device is used.
Pushes red button for circulating nurse to come
Indicates which implant to get.
Assisting suturing
Remove blue sheet
Taking off sterile coat
Remove all instruments and cleaning
THINKING
How is the patient doing?
Is the anesthesia woking?
Am I holding the device correctly?
Am I holding the device correctly?
This surgery is completed succesfully.
Do I have all the instruments?
FEELING
+
-
ASSISTANT CIRCULATING
TASKS
Opens implants packages
Opens healing caps packages
Write down numbers on labels
Opens implants packages
Opens healing caps packages
Write down numbers on labels
THINKING
Which numbers do I have to write down?
Is this the right order to open packages?
Which numbers do I have to write down?
FEELING
+
-

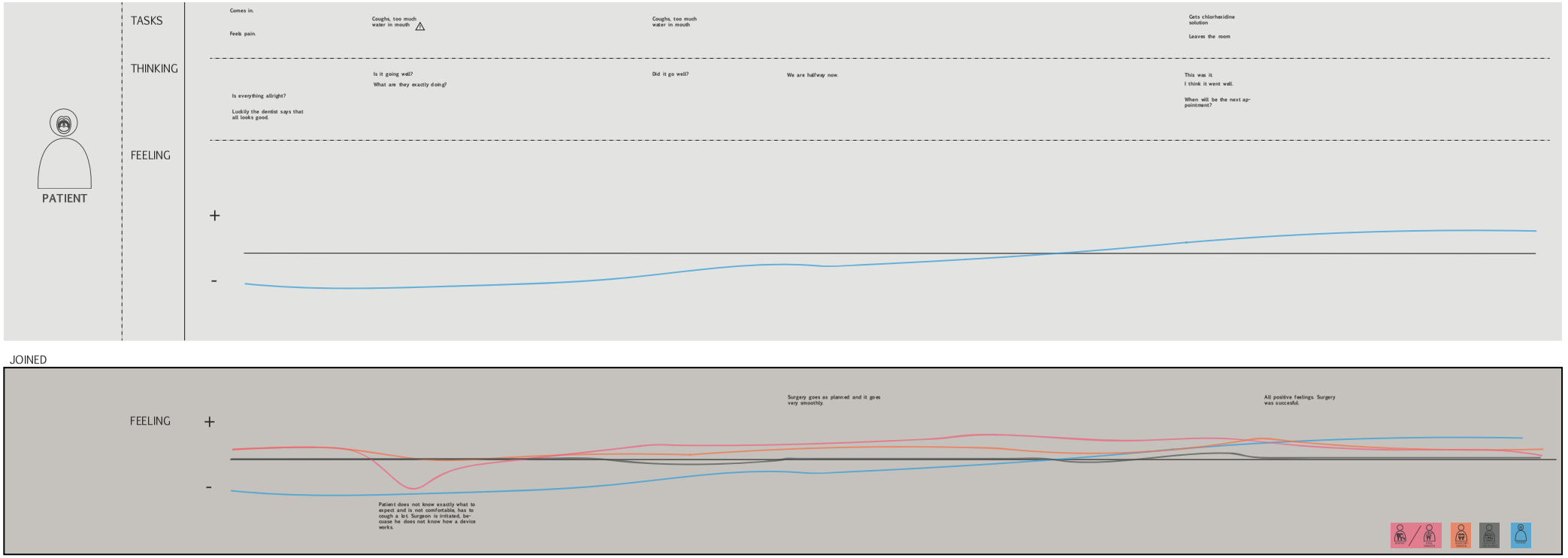


Figure app. 3: Sequence model academic hospital case 2

GENERAL HOSPITAL CASE 1

	PREPARATION	SURGERY I creating holes	SURGERY II implant placement	SURGERY III closing	AFTER CARE	CLEANING
ORAL SURGEON TASKS	NOT OBSERVED	Incision Cleaning Pilot hole Drilling in bone with increasing diameter Alignment tool used Administration Check x-ray Change of implant size Drilling in bone Alignment tool used	Indicating implant packages to assistant Shows implant to patient Implant placement manually Indicating healing cap packages to me Healing cap placement	Suturing	Talk with the patient. Thanked him.	Goes to the next patient. Gives anesthesia to this patient
THINKING		How are the bone properties? How much time do I have for the administration? Did I fill in everything? This is time consuming Is the position correct? The position is close to the sinus. Do I need to change the plan? Change implant size	Where is the circulating assistant? Would the patient be interested to see the implant? Am I applying enough torque? Is the implant well-fixed? Shall I repair the hole in the bone?		This was a good surgery.	Who is the next patient?
FEELING		Change of plans.	Doubts to repair the hole			
ASSISTANT SURGICAL TASKS	NOT OBSERVED	Suction device Making the x-ray Checking the x-ray Pushes black button for circulating nurse to come			Remove blue sheet	Goes to the next patient.
THINKING		Am I holding the device correctly? Do I need to reassure the pateint? Is the x-ray correct? Is the position correct?	Am I holding the device correctly? Do I need to reassure the pateint?		This was a good surgery.	Who is the next patient?
FEELING		X-ray not coorect. Do it over.				

Figure app. 4: Sequence model general hospital case 1

DENTAL PRACTICE

	PREPARATION	SURGERY I creating holes	SURGERY II implant placement	SURGERY III closing	AFTER CARE	CLEANING	ADMINISTRATION
DENTIST							
TASKS	Check patient information. Anesthesia is given. Sterile coats are put on BLue sheet over patient. Extra anesthesia is given Gets the surgery mold	Drilling mold placed Pilot hole Incision Extra anesthesia Gingivia flaps to the side Drilling in the bone with increasingly diameter	Looking for circulating assistant Indicating implant packages to assistant Implants placements Healing caps placements	Suturing	Remove blue sheet New appointment suggestions Providing a cold compress		Scanning documents
THINKING	Do I have all the necessary information What should I print? Patient is allergic to latex, put in other gloves.	How are the bone properties? Is the anesthesia working? Is the patient in the right position? Is the position correct?	Where is the circulating assistant? Frustrated that the assistant is not there. Why does the patient has pain? Is the implant well-fixed?	Do I need an extra suture?	This was a good surgery.		Is all information in the system? This should be automated in the future.
FEELING	+ / -		Frustration				
ASSISTANT SURGICAL							
TASKS	Room preparation Scan of the patient Questions Sterile clothing Blue sheet over patient Cleaning of the mouth	Keeps away the cheek	Talks to the patient to open her mouth further	Assisting suturing		Remove all instruments and cleaning	Updates in computer system Creating implant passports Scanning documents
THINKING	Is it cleaned well enough?	Am I holding the device correctly?	Am I holding the device correctly? Do I need to speak to the pateint?			Do I have all the instruments?	Did I do every step? This takes a lot of time
FEELING	+ / -						Boring and time consuming.

Figure app. 5: Sequence model dental practice

Similarities between all surgeries.

- Procedures are always done in the same order in all cases.
- Main tasks are done by the oral surgeon/ dentist.
- Most difficult part lies in the first step of the surgery. It is very important to get the position and direction right. Also, the emotional level is therefore fluctuating the most in this phase.
- In the phase of suturing and aftercare the emotions are positive in the observed cases. The surgery went well and everybody is satisfied.
- Administration takes time. This is sometimes frustrating.

Differences

General hospital

- In the general hospital, an extra x-ray is taken to determine if the direction and position is right. This is also done because the patient has still natural teeth and the position is more important than in edentulous patients.
- The second surgery in the general hospital took longer than other surgeries. This is because there was a second opinion in between.
- In the general hospital, two patients are treated partly simultaneously.
- In the general hospital, the administration is done during the surgery. Because the assistant has to take an x-ray from the patient, the surgeon has time to do the administration.
- In the general hospital, many times the alignment tool is used to check the position. In the academic hospital and in the dental practice this occurred less. Maybe because the surgeon/dentist are more experienced.
- In the general hospital, the oral surgeon is prescribing painkillers for the patients. In the other 2 cases this did not happen.
- In the general hospital, the oral surgeon was turning the implant in the bone manually. She likes it more in this way, because you can feel when it is far enough. In the academic hospital and the dental practice, they used the drill with a very low rpm to turn in the implant.

Dental practice

- In the dental practice and the general hospital, a cold/warm compress is given to the patients to reduce the pain after surgery.
- In the dental practice the dentist is changing the position of the patient's chair during surgery. In the hospitals, the oral surgeons are moving around the patient to have a comfortable position.
- In the dental practice the surgical assistant is doing part of the administration. In the hospitals, the oral surgeons are doing that themselves.
- In the dental practice, they used a CBCT scan to predict what kind of implant they will be using and they also used a surgical mold, which was made before to determine the position of the implant during surgery.

In the hospitals, they only use x-ray scans and they did not use a mold. This can be due to the fact that the oral surgeons are operating in a hospital and they have to get approval of using new techniques from the board, more people should be involved and there is a budget for every department.

The dental practice stands on its own and can easily afford new techniques and spend money on it.

Academic hospital

- In the academic hospital and dental practice sterile coats are used in the general hospital not.
- In the academic hospital, they give the patients antibiotics before surgery. This is to prevent infections later on.
- In the academic hospital, patients get a chlorhexidine solution to clean their mouth after surgery. This is to prevent infection.
- In the academic hospital, an iPad is used with the Osseocare Pro program. This is used to regulate the drill. It knows how much rpm is needed for every step and you can regulate the water supply. In the end. you can see how much torque was needed for every implant. A sterile cover is placed over the iPad every surgery.

Hospitals compared with dental practice

- In both hospitals, they are aware of showing the packages of the implants to at least to people. This is stated in the protocols of the hospitals. The surgeons are saying this to their assistants.

  In the academic hospital this was done in a bit of a sarcastic way, the oral surgeon said to the assistant I will use this, can you see it? Otherwise I cannot do this.

  In the general hospital, the circulating assistant already opened the package without letting see it to the oral surgeon. The oral surgeon corrected her and said that she had to show it before opening.
- In both hospitals, the next appointments are already made for the patient. In the dental practice the patient has to make a new appointment after surgery at the service desk herself.
- A button in the treatment rooms is used in both hospitals to warn the circulating assistant to come. In the dental practice this button was not there, and this led to leaving the sterile zone from the dentist to search for the circulating assistant.

Flow model- Communication

The communication model describes who communicates with whom and in what kind of way (formal or informal) (Figure app. 6).

Similarities

- All the communication towards the patient is formal.
- No communication between the circulating assistant and the patient in all cases.
- Oral surgeon/dentist is explaining the procedure and what he/she is doing to the patient in all cases.
- Oral surgeon/dentist is asking questions to the surgical assistant and the assistant answers. The surgical assistant is not asking questions to the surgeon/dentist in any case.
- The surgical assistant is asking the patient to open his mouth further or to turn, and says in some cases words to reassure the patient. The oral surgeon is never reassuring the patient.
- In almost all cases the communication between the oral surgeon/dentist and the circulating assistant is not smooth.

  The reason for this can be that the assistant and the surgeon/dentist did not have a clear planning. Another reason, in the general hospital case, is that the circulating assistant did not have many experience.

Differences

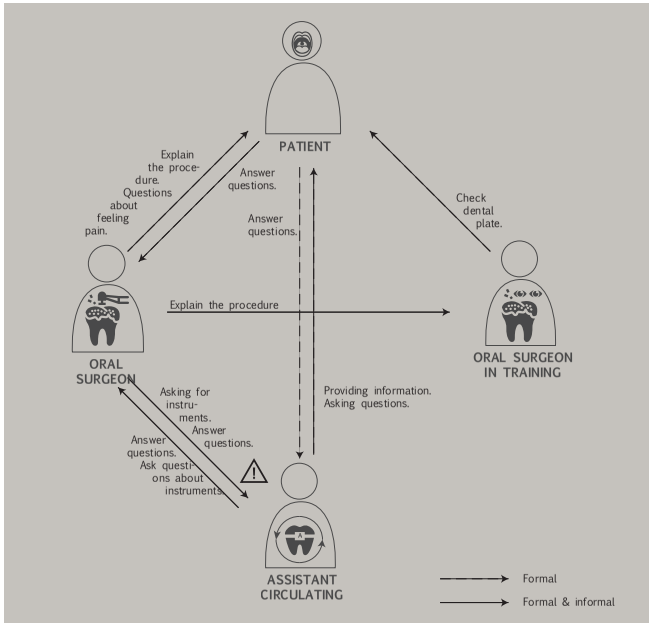
Dental practice

- Only in the dental practice the patient is asking questions to the dentist. In all other cases the patient was only answering questions, and not asking anything.

  The fact that the person in the dental practice was asking more questions could be because the patient is familiar with the dentist, and it is easier to ask questions. Another reason might be that this patient has a different personality than the others, and is more used to ask questions.

  An exclamation mark is shown for the communication between the oral surgeon/dentist and the circulating assistant. This should be optimized, by better communication, planning, and to obey the protocols.

ACADEMIC HOSPITAL CASE 1



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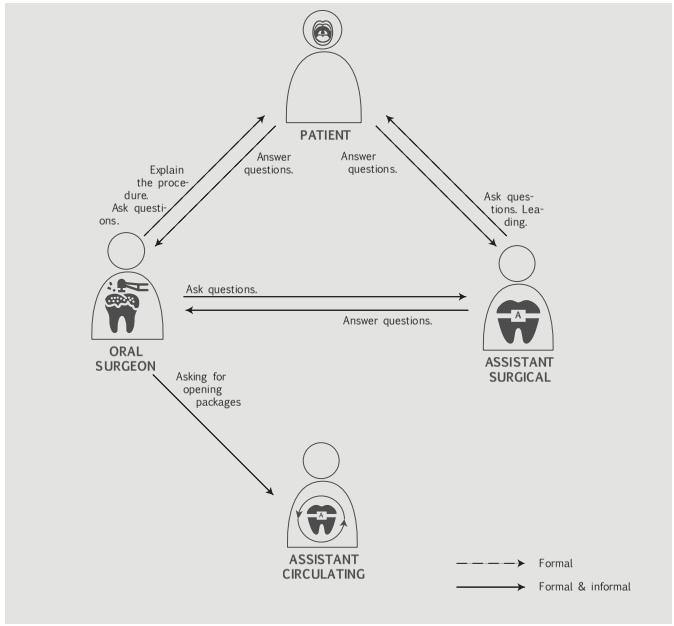
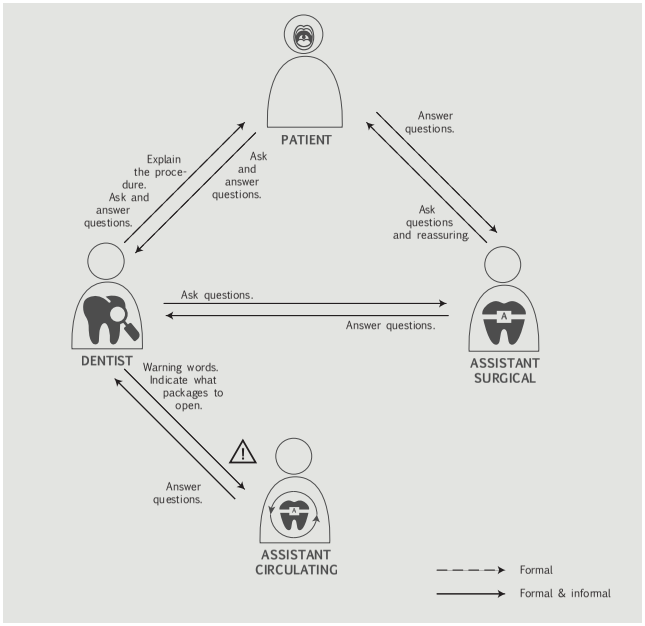


DENTAL PRACTICE



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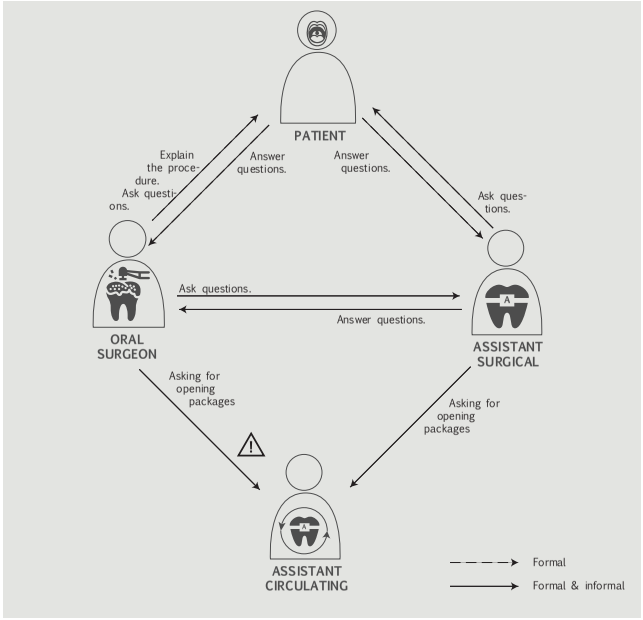

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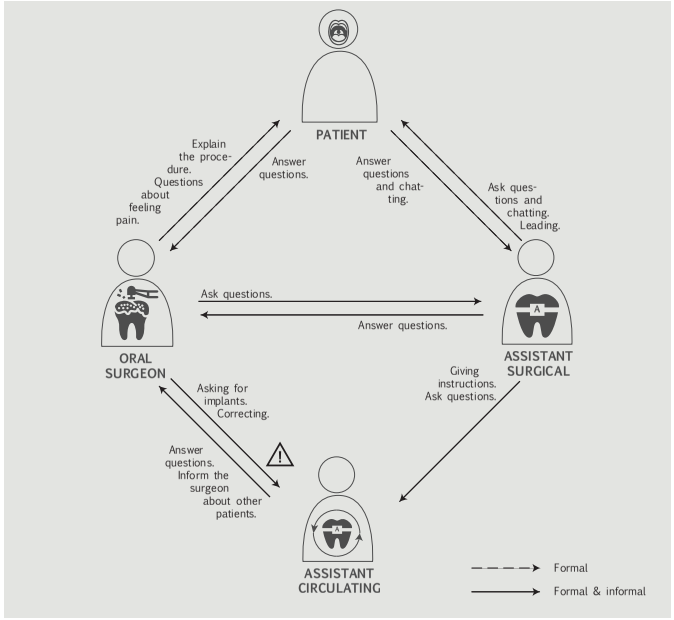

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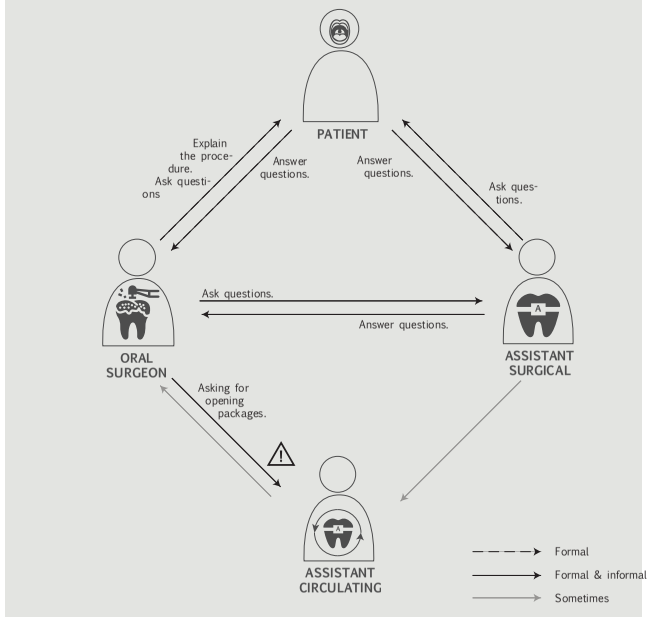

Figure app. 6: Flow model- communication, all cases

Flow model- Coordination

The coordination flow model describes which products are given from and towards which stakeholder and what kind of planning is important and done by whom (Figure app. 7).

Similarities

- The coordination between the different stakeholders are in every case the same. All actors have a specific role and they know what is expected from them.
- The surgical assistant is preparing the patient in all cases. This means to get the patient from the waiting room and to check if the patient has followed the steps correctly before surgery.
- Circulating assistant does not interact with the patient.
- The instruments for the surgery are always provided by the surgical assistant or the oral surgeon/dentist gets it himself.
- Planning is essential for a good surgical procedure.

Differences

General hospital

- In the general hospital, the equipment for taking x-rays is not located in the treatment room, this means that the patient and the assistant have to move to another room during the surgical procedure to take the picture.
- Coordination between the dentist/oral surgeon and circulating assistant is in some cases not smooth. In case 2 of the general hospital, the circulating assistant did not show the packages before opening.

The lack of coordination can be caused by lack of a good planning or by not following certain protocols.

Dental practice

- Coordination between the dentist/oral surgeon and circulating assistant was in some cases not smooth.
- In the case of the dental practice the circulating assistant was not available at the time she needed to be there.

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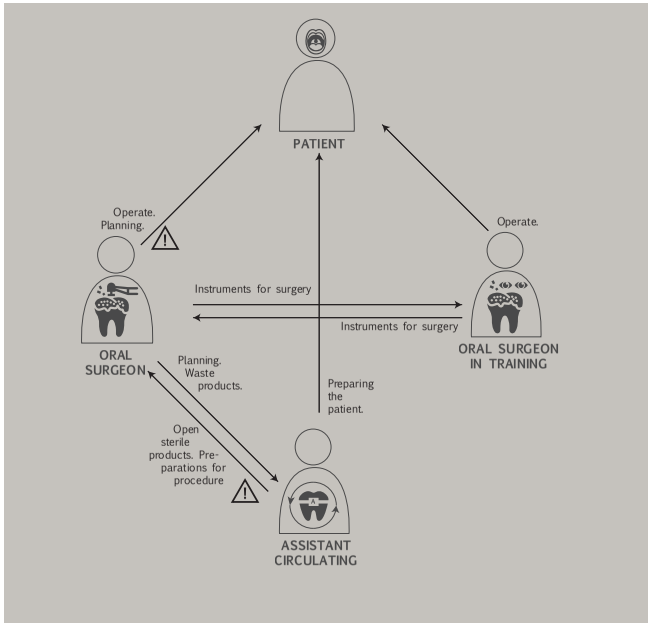

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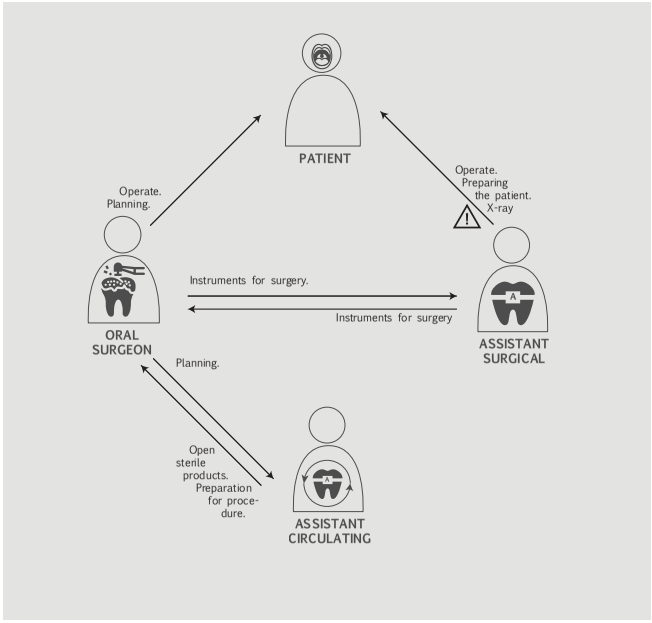

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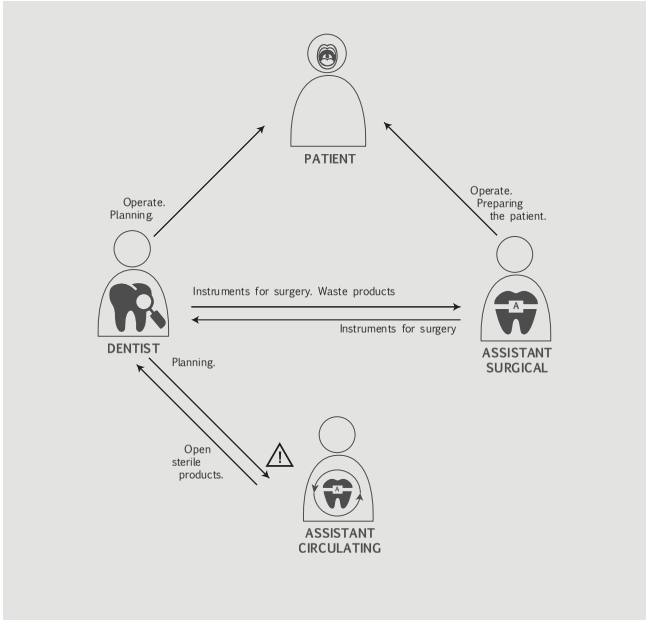

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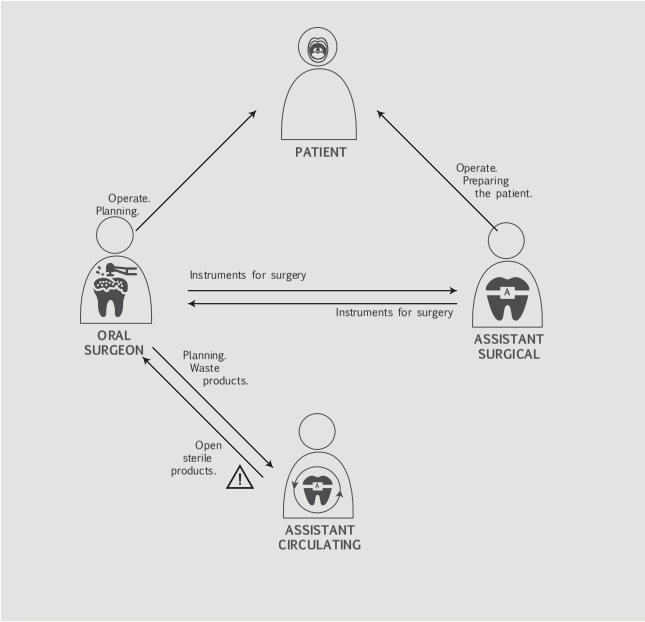

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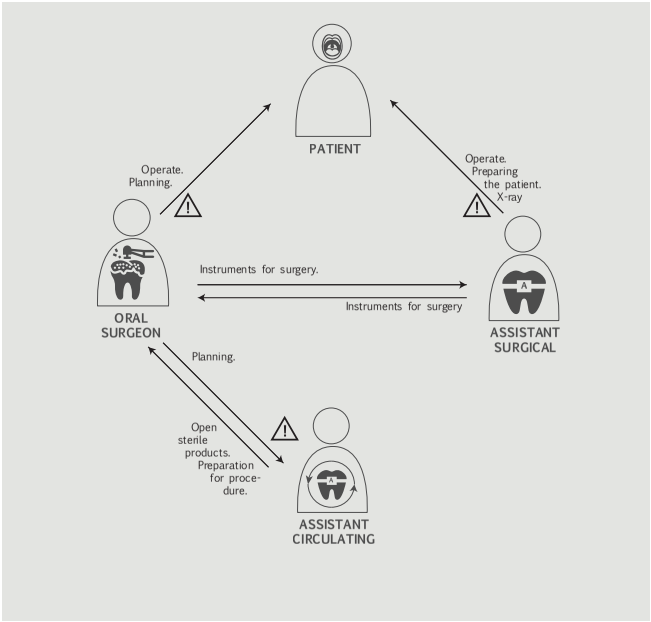

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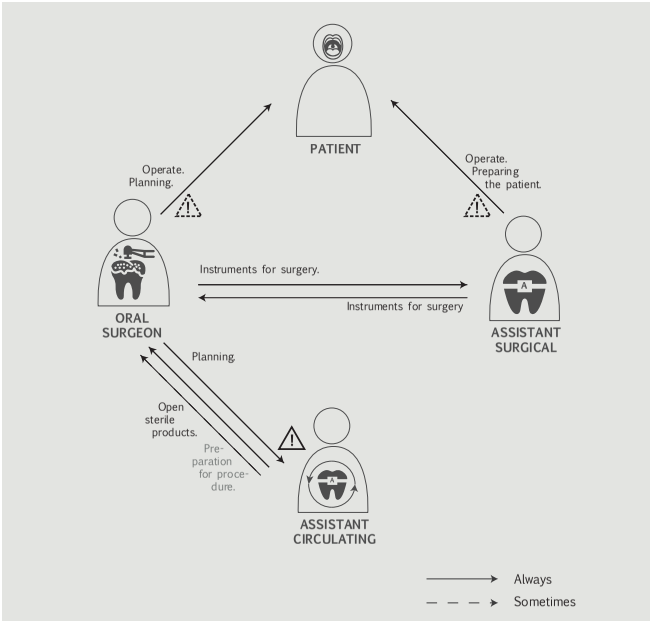


Figure app. 7: Flow model- coordination, all cases

Cultural model

The cultural model shows the hierarchy within the group of stakeholders and who influences who. The size of the circle visualizes the hierarchy of the stakeholder, so a bigger circle means more power. The thickness and the arrows show who has the power to influence the others (Figure app. 8).

Similarities

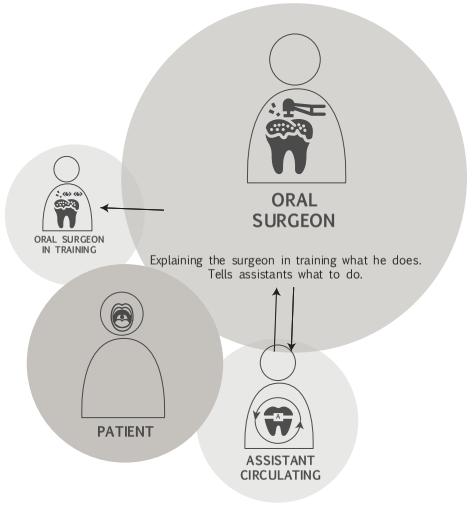
- Dentist/oral surgeon has the highest hierarchy in all cases. The oral surgeon/ dentist determines what is happening and has the lead, because all the responsibility is on them.
- The roles are depending on seniority. The person that is highest in the hierarchy has also the most responsibility. If something new needs to be implemented in the procedure, this is the person that should agree with it and should be willing to use it and is willing to change.
- Dentist/oral surgeon has the overview and gives the instructions to others.
- The patient is in every case on top of all stakeholders. If the patient does not want something to happen then the other involved stakeholders should accept that. So, in the end, the patient is the most important player.

Differences

Dental practice

- In a rare case, dental practice, the assistant can tell the surgeon or dentist what to do.

ACADEMIC HOSPITAL CASE 1



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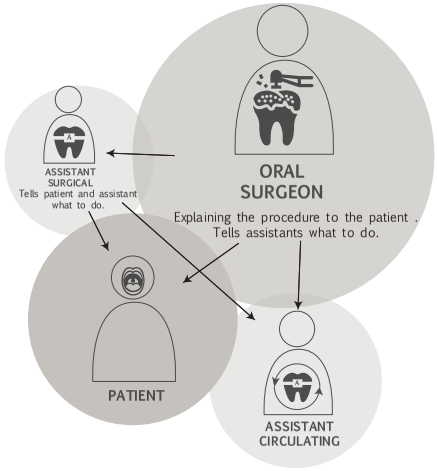
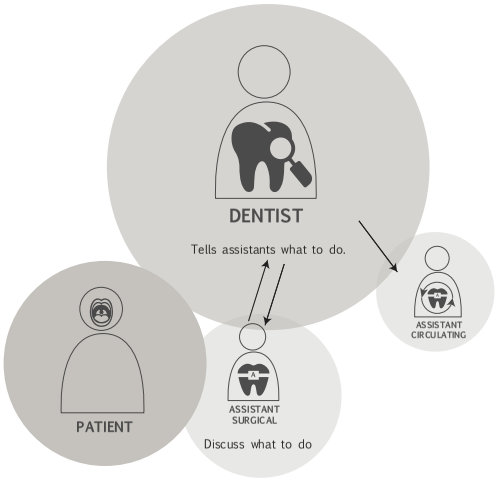


DENTAL PRACTICE



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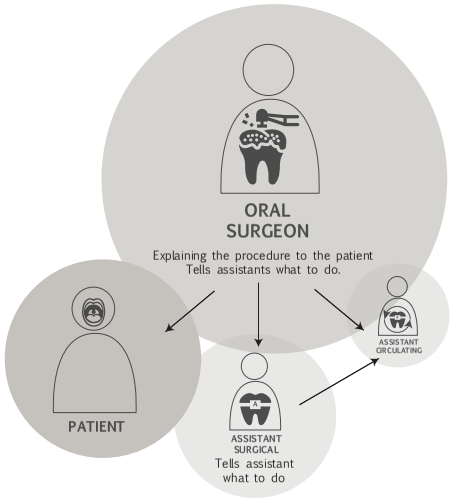

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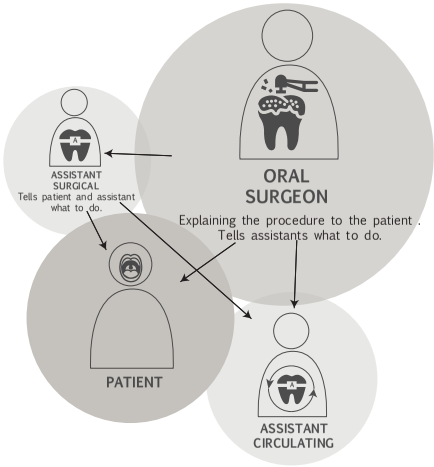

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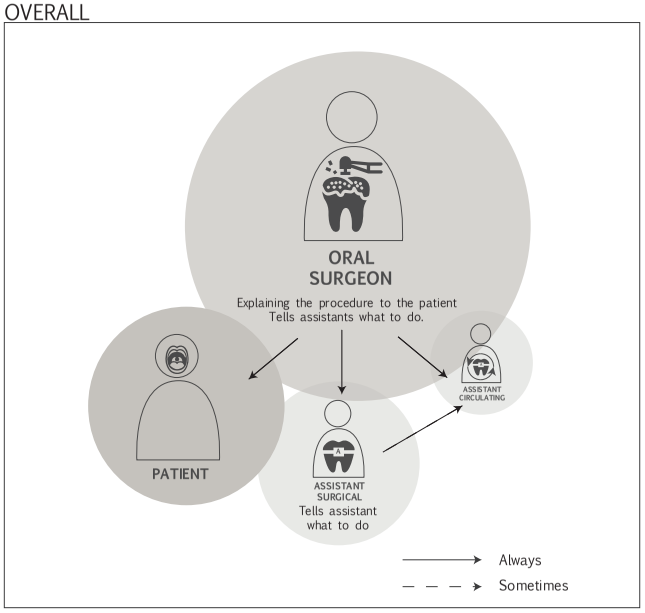


Figure app. 8: Cultural model, all cases

Appendix III- 2.7 Developments in the dental implant industry

A development in the dental industry is additive manufacturing. Using additive manufacturing, patient-specific implants can be made. This section shows which studies are already conducted on these type of implants.

One way of creating these patient-specific dental implants is to make root analogue implants (RAIs). These are implants that mimic the root of the natural tooth that needs to be replaced. These implants are placed directly after tooth extraction. These types of implants are highly patient-specific and adapt the implant to the socket instead of adapting the bone socket to the implant.

Studies are experimenting with root-analogue-implants. Mangano et al., (2013) created Ti6Al4V root analogue dental implants with the additive manufacturing selective laser melting (SLM) technique. Fifteen patients got these dental implants inserted and after one year the survival rate of the implants was 100%. All implants were stable with no signs of infection. Patients indicated no pain or swelling after the treatment. Stability of the implant was achieved after 3-4 weeks (figure 26).

Figliuzzi et al., (2012) used SLM printing technique to create a titanium (Ti6Al4V) root analogue implant. The implant was placed in a 50-year-old woman. One year after placement the patient-specific implant functioned well. The implant was stable with no signs of infection and a good condition of the peri-implant tissues was observed (figure 26).

During the literature study, recent articles were found by D. Ansarri Moin. He promoted in January 2018 on the subject of additive manufacturing of dental implants. He studied root-analogue-implants and he mainly analyzed the printing accuracy of these implants. In one study Moin et al., (2013) created a root analogue implant of Ti6Al4V with the SLM printing technique. The aim of the study was to compare the dimensions of the root analogue implant with the natural tooth. The main difference between the two dimensions was found in the apex region. The surface area was lower for the RAI compared with the natural tooth by 6.33%. In another study (Moin et al., 2014) they placed the implants into nine mandibles of cadavers. In total 11 implants were inserted. Scans were made of natural teeth, RAIs, mandibles with empty sockets, and mandibles with RAIs in the socket. The scans were analysed and the differences of the surface area and volumes were determined. The volume of the socket was always larger than the RAI with a difference of 0.6%-5.9% (figure 26).

In a follow up study (Moin, Hassan, & Wismeijer, 2016) a finite element analysis was done on root analogue implants with different surface characteristics. The surfaces were changed by adding small prisms, fins, plug or bulbs on the surface and were compared with a standard design. In the analysis two loads were applied; an oblique force of 300N and a vertical force of 150N. The plug design of the RAI has the lowest von Mises stress.

From this study, it can be concluded that adding extra protrusions or retentions onto the surface has a positive effect on stress distribution, and a lower stress concentration, and a better primary stability (figure 26). Primary stability is very important for a high success rate when dealing with RAIs. Macro-retentions can help to secure primary stability as well as a diameter reduction of 0.1-0.3mm at the side of the implant that will be closest to the lips (buccal side) (Figliuzzi et al., 2012) (Figure app. 9).

Chen et al., (2014) created two types of root-analogue-implants, one standard RAI and one RAI with threads. The main goal of the study was to analyse the stress distribution and primary stability with FEM analysis and in vitro studies. The threaded RAI showed better primary stability and stress distribution (figure 26).

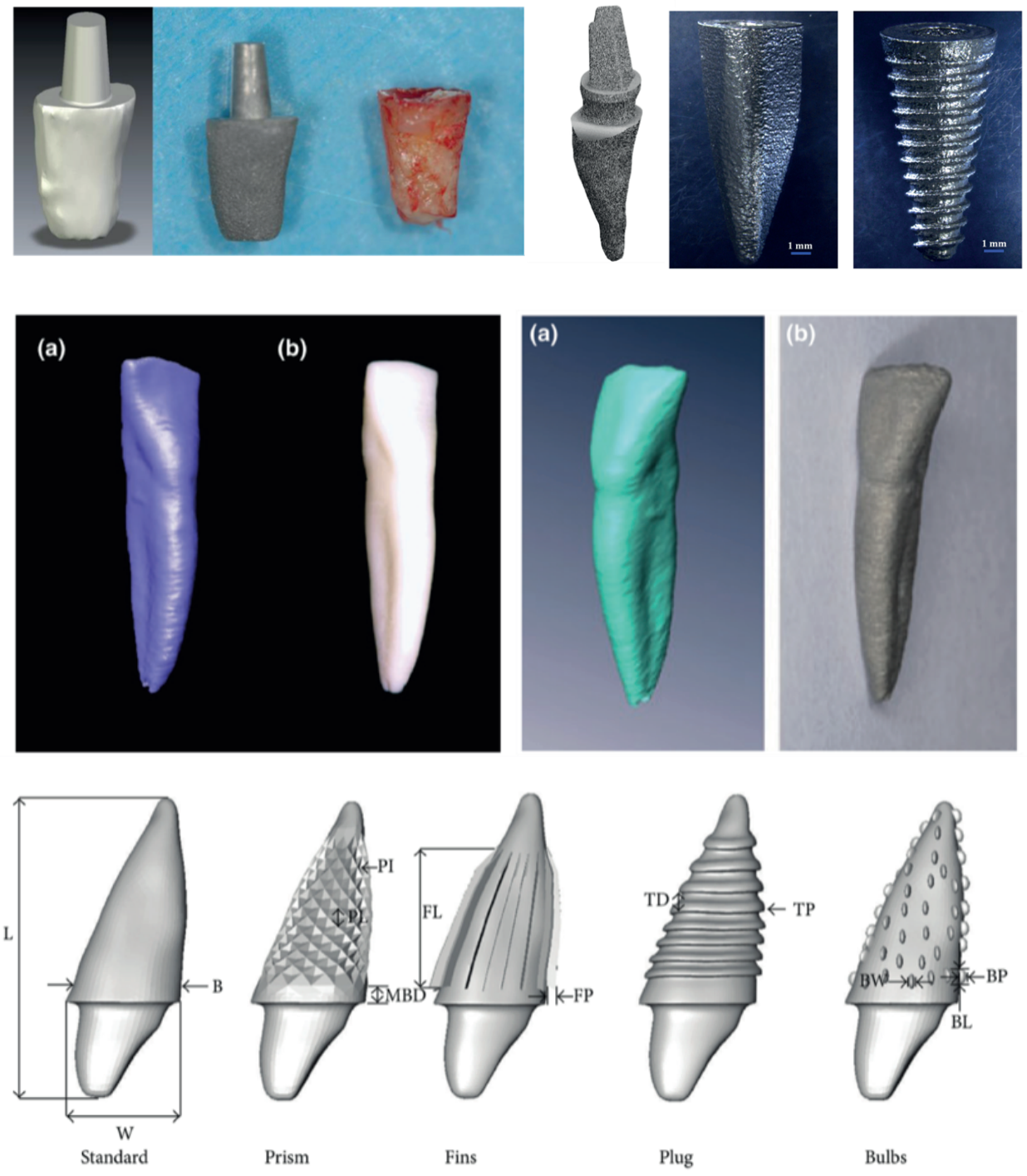


Figure app. 9: Root analogue implants. First row: RAIs form the study of (F. G. Mangano et al., 2013) and Figliuzzi et al., (2012) and Chen et al. (2014). Second row root analogue implants (a) CAD Models (b) printed models, zirconia and titanium form the studies of Anssari Moin, (2017) and Moin et al., (2014). Third row CAD models of root analogue implants with macro-retentions for primary stability from the study of Moin (2016).

Appendix IV- 4.1 Concept development

In this section parts of the design are explained. Models, sketches, tests, results are all shown.

Shape

In order to test in the principle of patient-specific implants, models are printed with an Ultimaker (FDM printer). Simulations of extraction sockets are created as well.

First 3 times scale models were created. From testing with these samples, we can say that the implants should be scaled done by 5% in either x or y direction.

The real size implants were printed later on, for these shapes a downscaling of 2% was needed to fit the implants in the socket.

Porous implants are created to see how this strucutre would look like after printing and how it does affect the shape.

The grey implants are designed to improve the implant stability (Figure app. 10). More about these implants can be read in the next section.

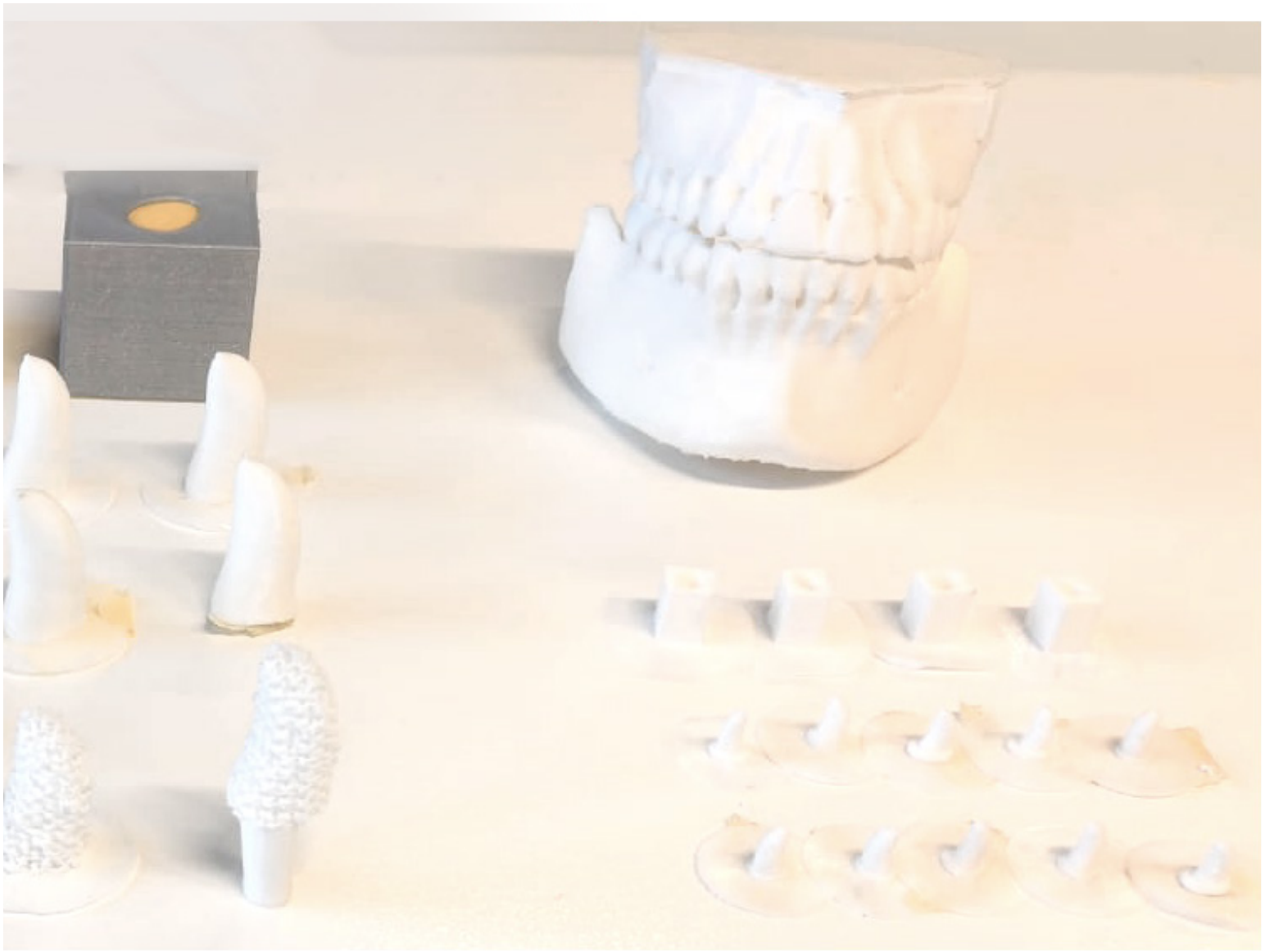


Figure app. 10: FDM models of dental implants.

Stability

To solve the problem of primary stability an idea generation took place. Several ideas were made (Figure app. 11, Figure app. 12, Figure app. 13 and Figure app. 14).

Press fit
Extrusions
Thread shape
Use of Poissons ratio
Shape memory alloys
Heat or cold to change the shape after implantation
Attach implant to surrounding teeth.
Cementing.
Plug design

Some ideas have more potential than others. Shape memory alloys and treating the implants with high or low temperatures to change the structure and dimensions of the implant after implantation is very difficult. It makes the procedure complex.
Cementing, which is also done in implementing hips and knees can be an option. However in the dental implants this has never been done before, so probably this will not works for dental implant. In the hip and knee implants industry they are also shifting more towards cementless options. So this might not be the ideal solution.

Attaching the implant to surrounding teeth to make sure the implant stays in place, also requires a lot of extra material and extra steps which makes the procedure more difficult.

Options with more potential are the press fitting, the extruded parts and the plug design.
The simplest way is to just make use of press-fitting the implant inside the socket. This can be done by creating the implant slightly larger than the socket, i.e. original root.

Extra extrusions around the neck of the implant might also work according to the literature.
Another option is to use some type of threads around the implant to create the stability.
Another option that might work is the plug design shape which can be squeezed while inserting and expands after insertion.

Models
Some of the ideas were made in a CAD model and 3D printed using an Ultimaker (FDM printer).

The plug design implants are printed and showed that they can be squeezed and easily inserted. A strong fit is created.

The implants designed with the extruded parts are difficult to make with the porous structure. Since the parts are small and the Ultimaker FDM printer is not able to create a good porous structure. An option might be to create the standard shape with a porous structure and that the extruded parts remain as a solid.

Solution
Because this is a first try to make the implants in this way, i.e. porous with antmicorbial layer, the decision is made to keep the implants as simple as possible and make use of press-fitting. This is also used in hips nowadays and in the original root-analogue implants.

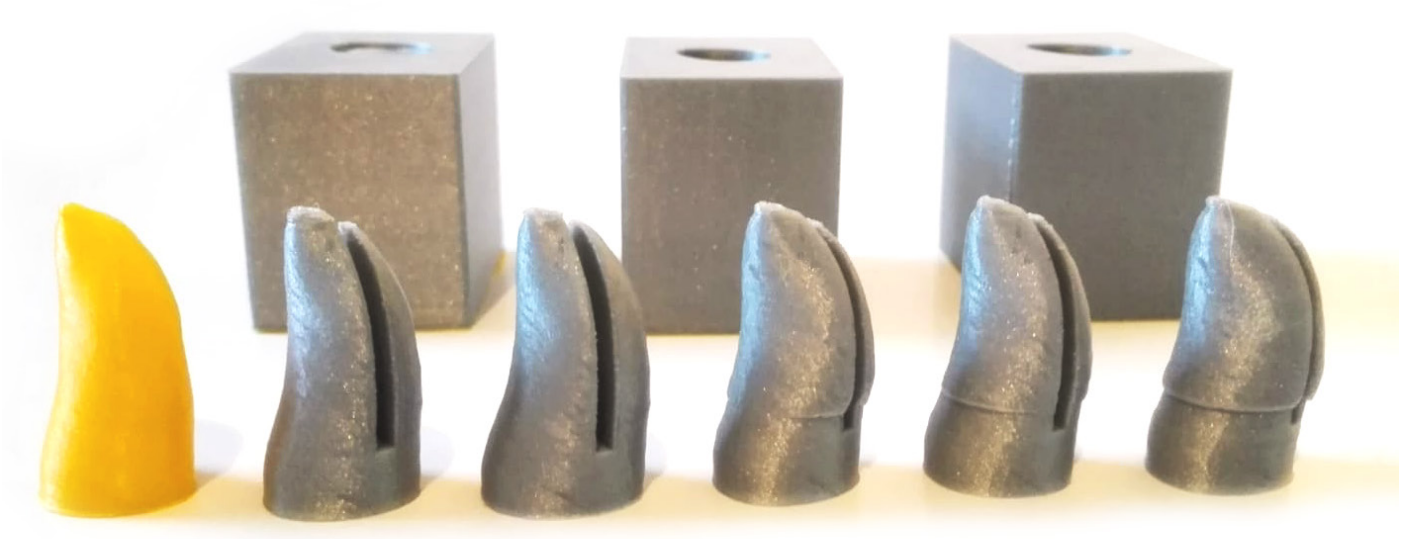


Figure app. 11: FDM models of dental implants for stability

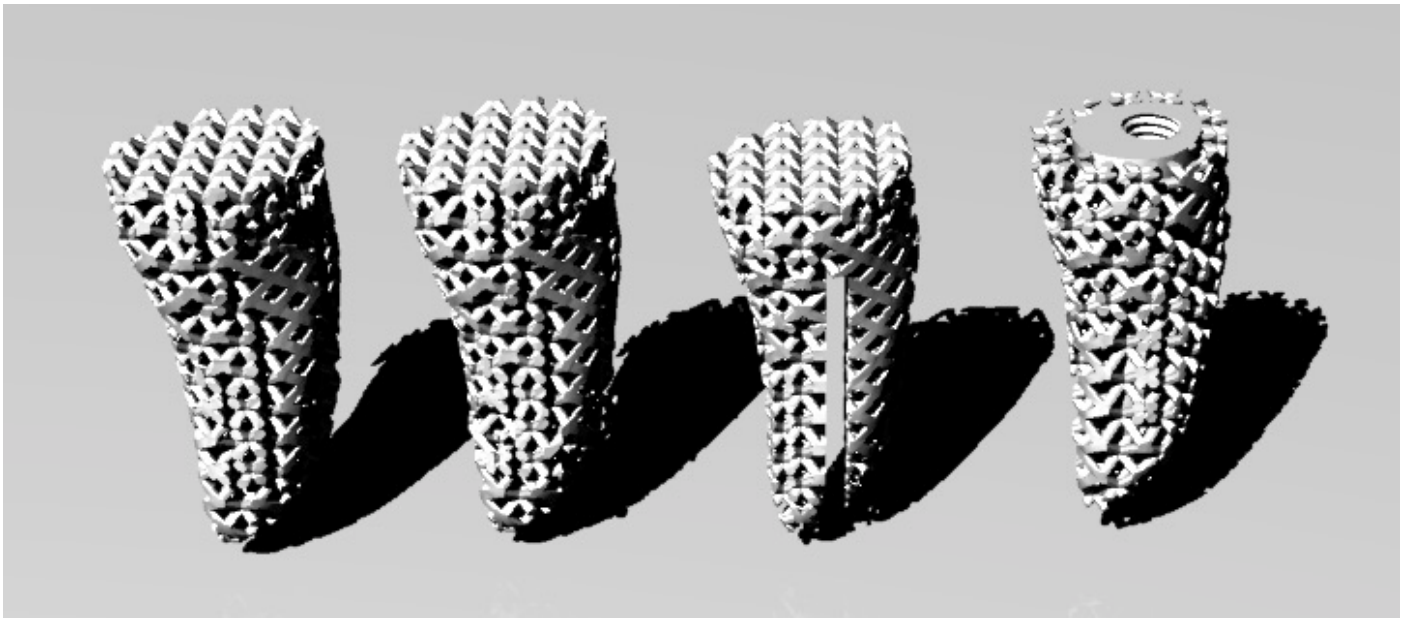
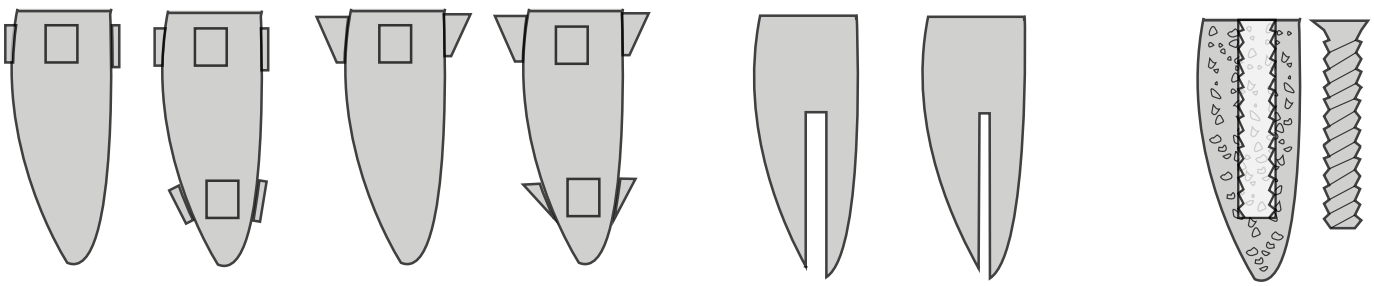


Figure app. 12: CAD models of dental implants stability

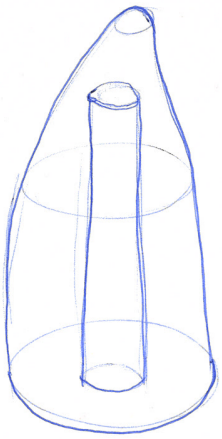


Extrusions on the implant and extrusions only around the neck

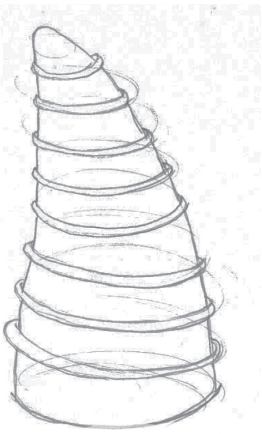
Squeezing the implant, it becomes smaller while inserting and larger if it its not squeezed. Implant is a bit larger than the original shape.

Insert screw, due to the poisson's ratio effect the implant will be larger in horizontal direction.

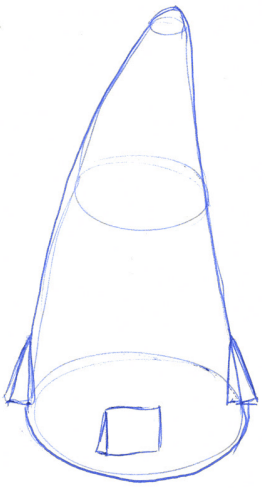
Figure app. 13: Idea generation for stability

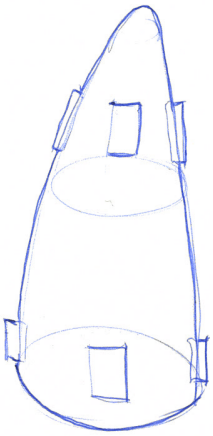


Solid core



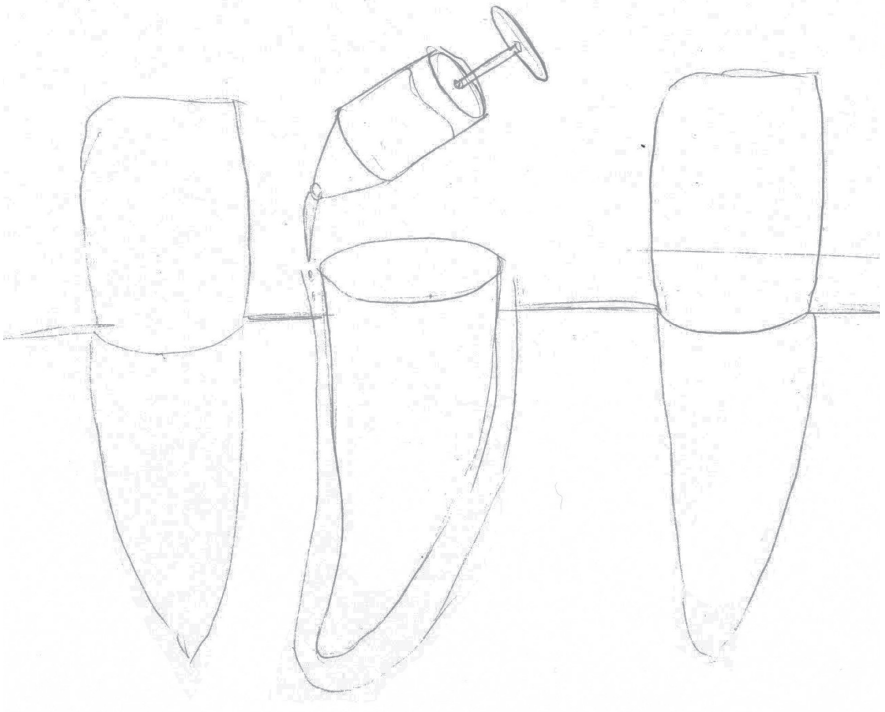
Threads





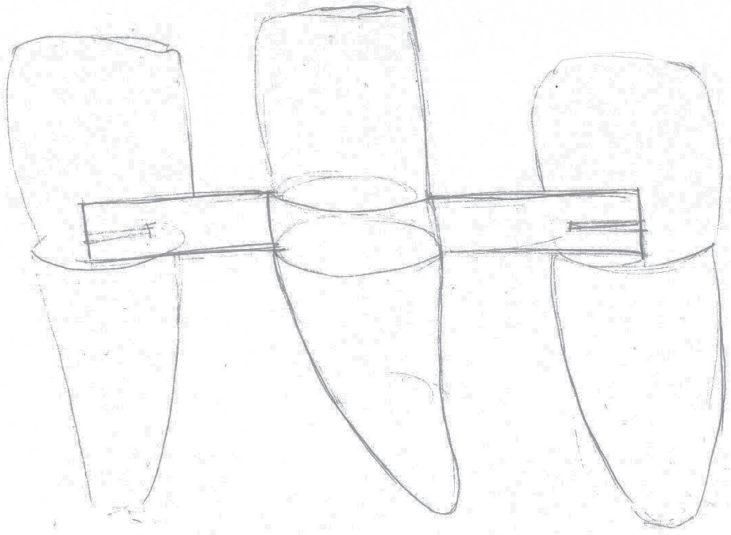
Extrusions

Inside screw

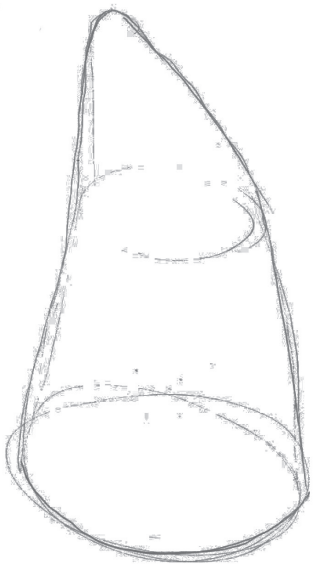


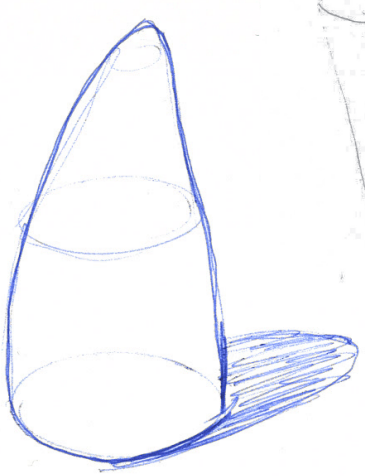
Cementing

Solid inside in different shapes



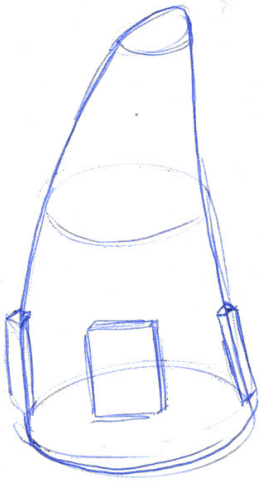
Attaching to surrounding teeth



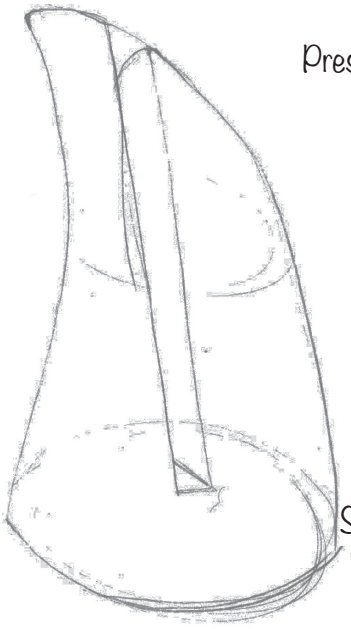


Press fit

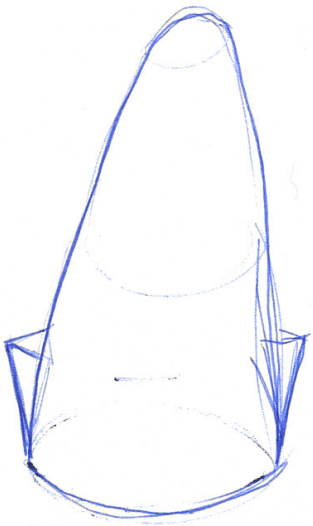
Press fit



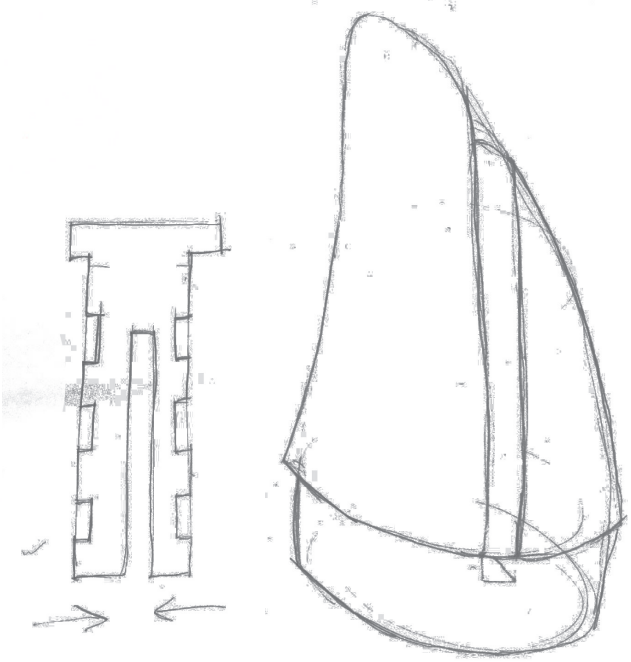
Extrusions



Squeezing in



Extrusions



Squeezing in and change in dimension

Figure app. 14: Idea generation for stability

Strength

To have a high enough strength it would be good to have a denser core and a higher density in the other parts. Even a solid core is an option to provide enough strength and stiffness (Figure app. 15 and Figure app. 16).

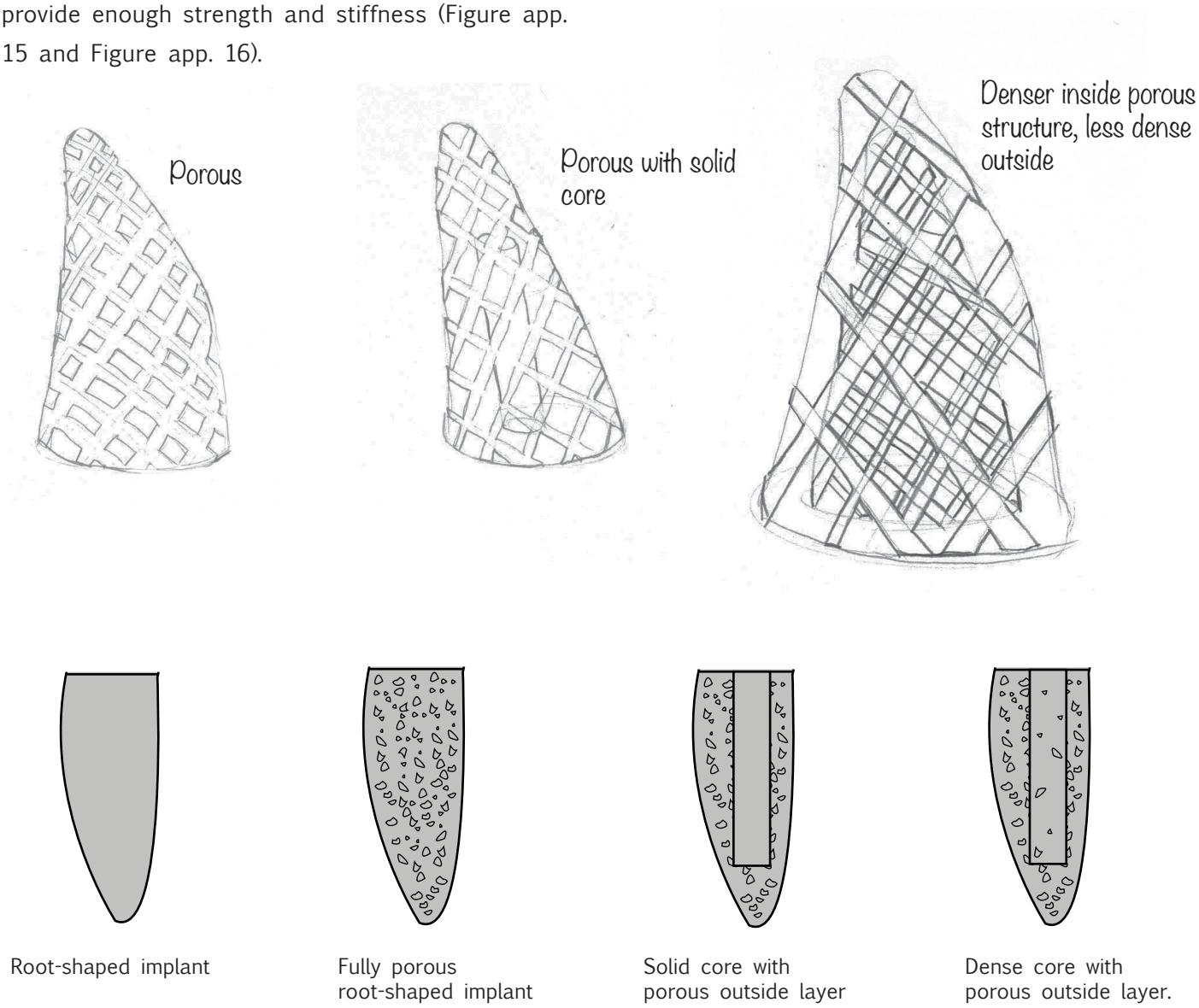


Figure app. 15: Idea generation for strength

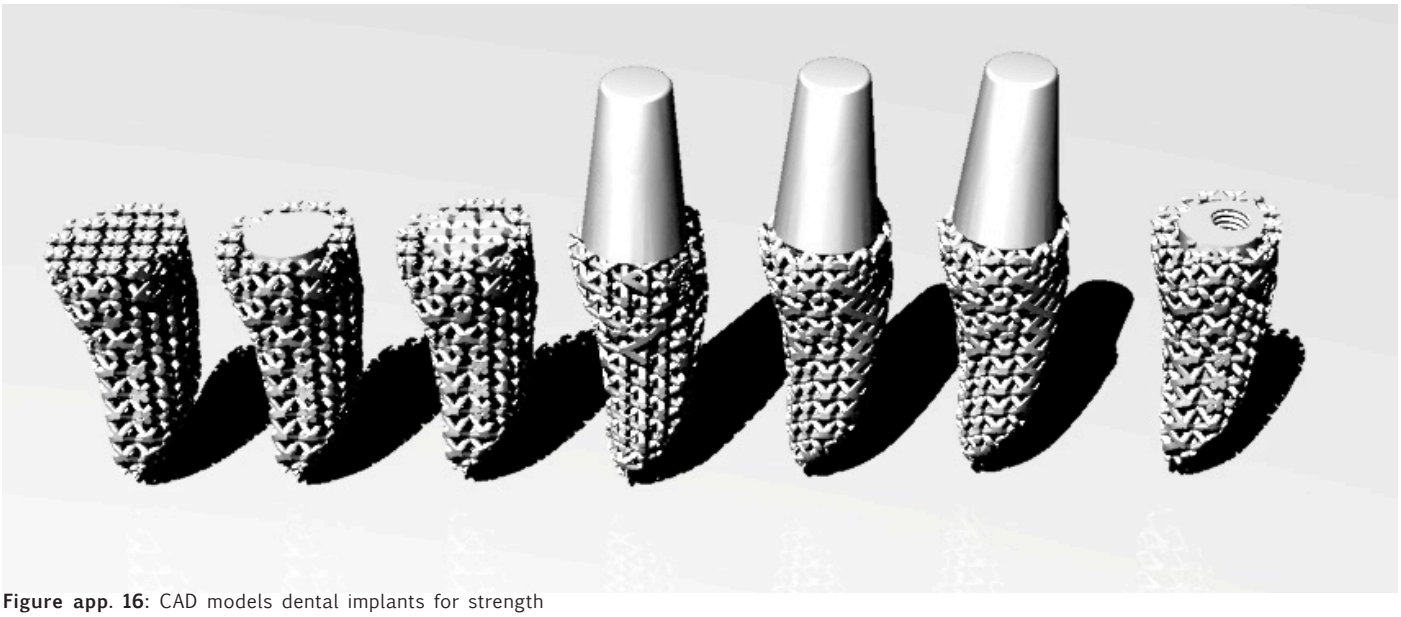


Figure app. 16: CAD models dental implants for strength

Abutment

An abutment has the function to connect the implant with its dental prosthetic. Two types of abutments are available. A connected abutment and implants with a screw thread to turn a separate abutment in.

Both options are available and possible to manufacture. However, screw thread inside a small volume of a dental implant is more difficult to produce than to just create an abutment on top of the implant.

By having an implant with a screw thread inside into which a screw needs to be inserted an extra torque will be applied. For this the implant should be designed in a way that it can resist these torque forces. The torque can also lead to micromovements after insertion of the implant. This is highly undesirable since it can negatively influence the stability of the implant. The choice is made to create a connected abutment.

A screw-retained or a cement-retained crown can be placed on top. In Figure app. 17the advantages and disadvantages of each type is shown.

The abutment functions also for connector piece to the plasma-electrolytic oxidation (PEO) holder to apply the anitmicrobial surface.

In order to let the PEO process work wel, current needs to flow through the structure. A connector piece should be designed that is able to do this. Several ideas were created.

The connector piece should connect many struts in order to let the current flow through the entire structure.

Only attaching it to one strut is no option.

Another limitation was the manufacturing method. The extra part should be additive manufactured, so no larger angles of 45 degrees should be created.

While sketching, the idea came into mind to use the abutment as connector piece (Figure app. 18).

During the experiments with PEO its shows that this worked.

Using the abutment is highly beneficial, since no material needs to be removed later. The abutment is in contact with all struts, so current can go through.

	SCREW RETAINED	CEMENT RETAINED
ANTERIOR REGION		
COMPLICATIONS		
AESTHETICS		
REPLACEMENT		

Figure app. 17: Decision matrix screw retained VS cement-retained crown.

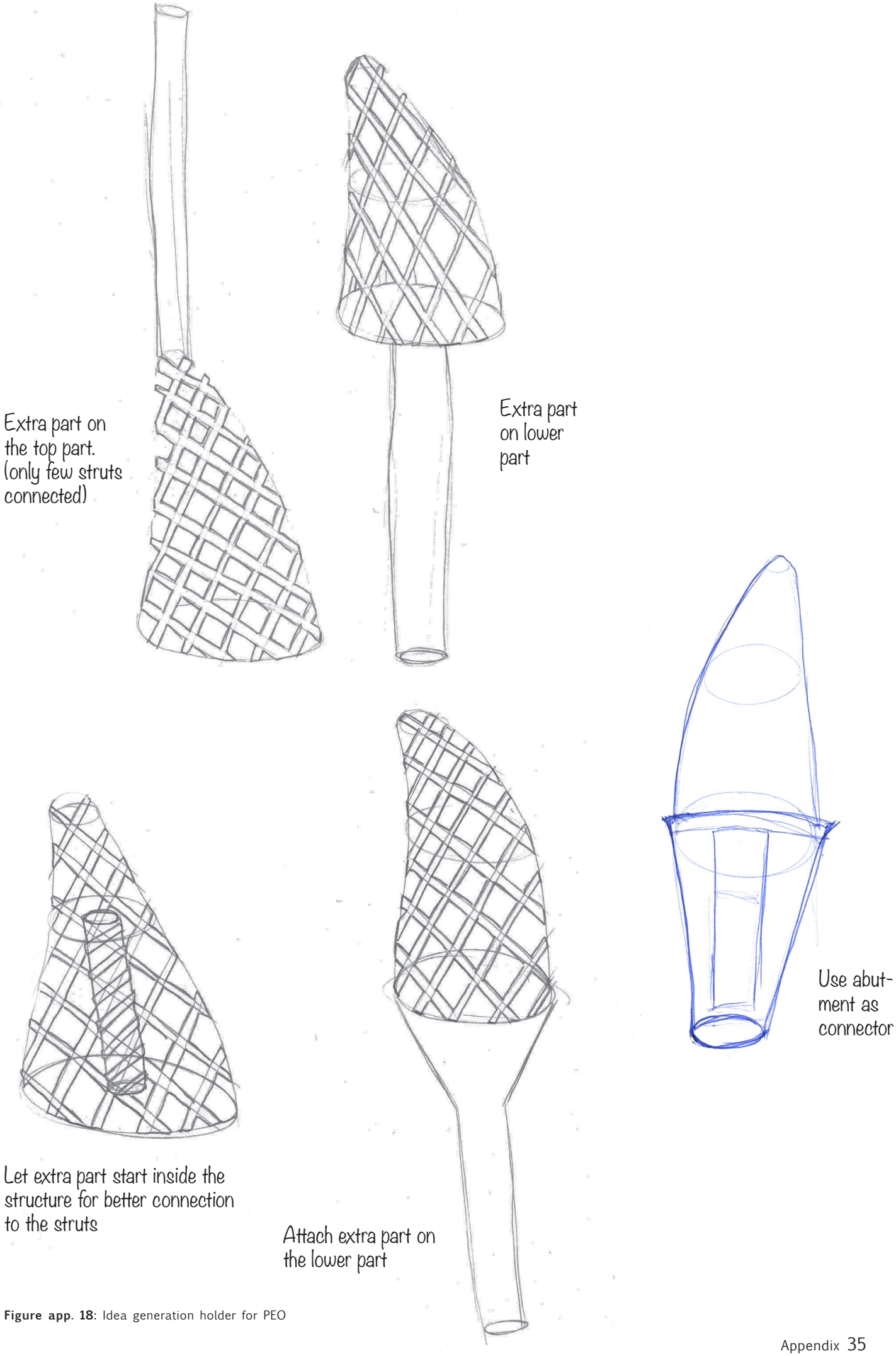


Figure app. 18: Idea generation holder for PEO

Structure

The porous structure is created. However, due to the printing facilities, the choice is made to make only use of whole cells. This way, no extra support structure is needed.

Using only whole cells does affect the shape of the implant. An analysis in Geomagic studio is done to see how much the shape deviates from the original shape (Figure app. 20 and Figure app. 21).

A strut thickness of 0,3 and different unit size cells (1,0 1,1 1,2 1,3 1,4 1,5) are used, as well as a strut thickness with different unit size cells.

In Figure app. 19, the values are shown. The values of the errors indicate that a larger cell size creates a larger deviation form the original shape.

	0,3 1,0	**0,3 1,1**	**0,3 1,2**	**0,3 1,3**	**0,3 1,4**	**0,3 1,5**
Model maximum length	9,166000	9,033272	9,096172	8,171352	8,006187	8,426875
Average error	0,257220	0,359309	0,371000	0,476766	0,478097	0,484913
RMS error	0,283246	0,383630	0,399809	0,511867	0,523835	0,516228
Deviation elimination error	0,708236	0,849087	0,984441	1,201576	1,268998	1,168590

	0,4 1,0	**0,4 1,1**	**0,4 1,2**	**0,4 1,3**	**0,4 1,4**	**0,4 1,5**
Model maximum length	8,89000	9,133272	8,712445	8,687907	8,103395	7,935854
Average error	0,241091	0,284734	0,351641	0,429167	0,431339	0,505519
RMS error	0,272273	0,316215	0,391581	0,465170	0,477117	0,562736
Deviation elimination error	0,700837	0,721638	0,885877	1,137966	1,187987	1,277029

Figure app. 19: Deviation of porous shape compared to the original shape

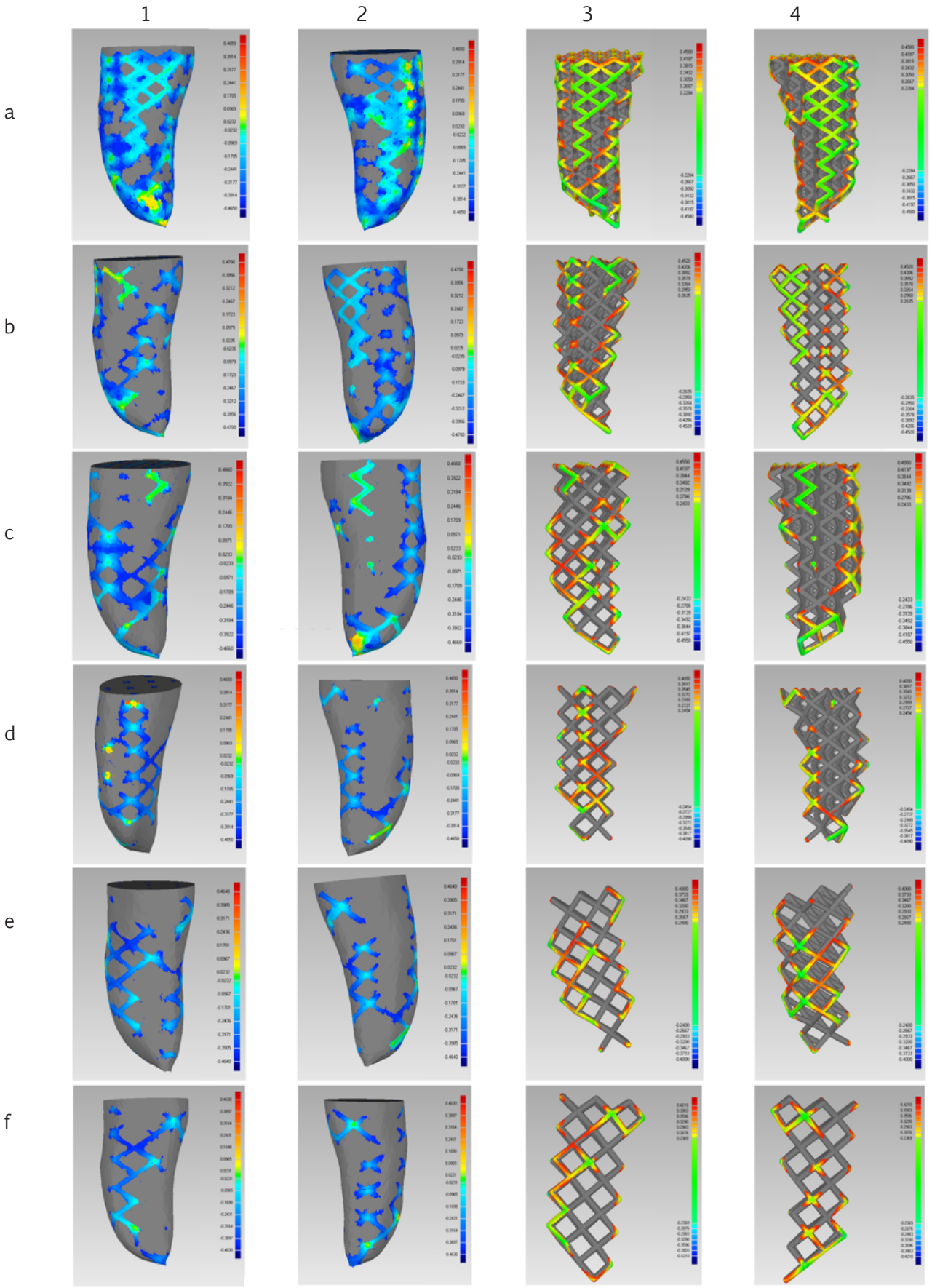


Figure app. 20: Deviation of the porous samples compared with the original shape. Colours indicate the deviation. (a) 0,3 1,0 sample compared with the original root shape. (b) 0,3 1,1 sample compared with the original root shape. (c) 0,3 1,2 sample compared with the original root shape. (d) 0,3 1,3 sample compared with the original root shape. (e) 0,3 1,4 sample compared with the original root shape. (f) 0,3 1,5 sample compared with the original root shape. 1&,2 are the deviations with the original root shape as reference, 3&4 are the deviations with the porous root as reference.

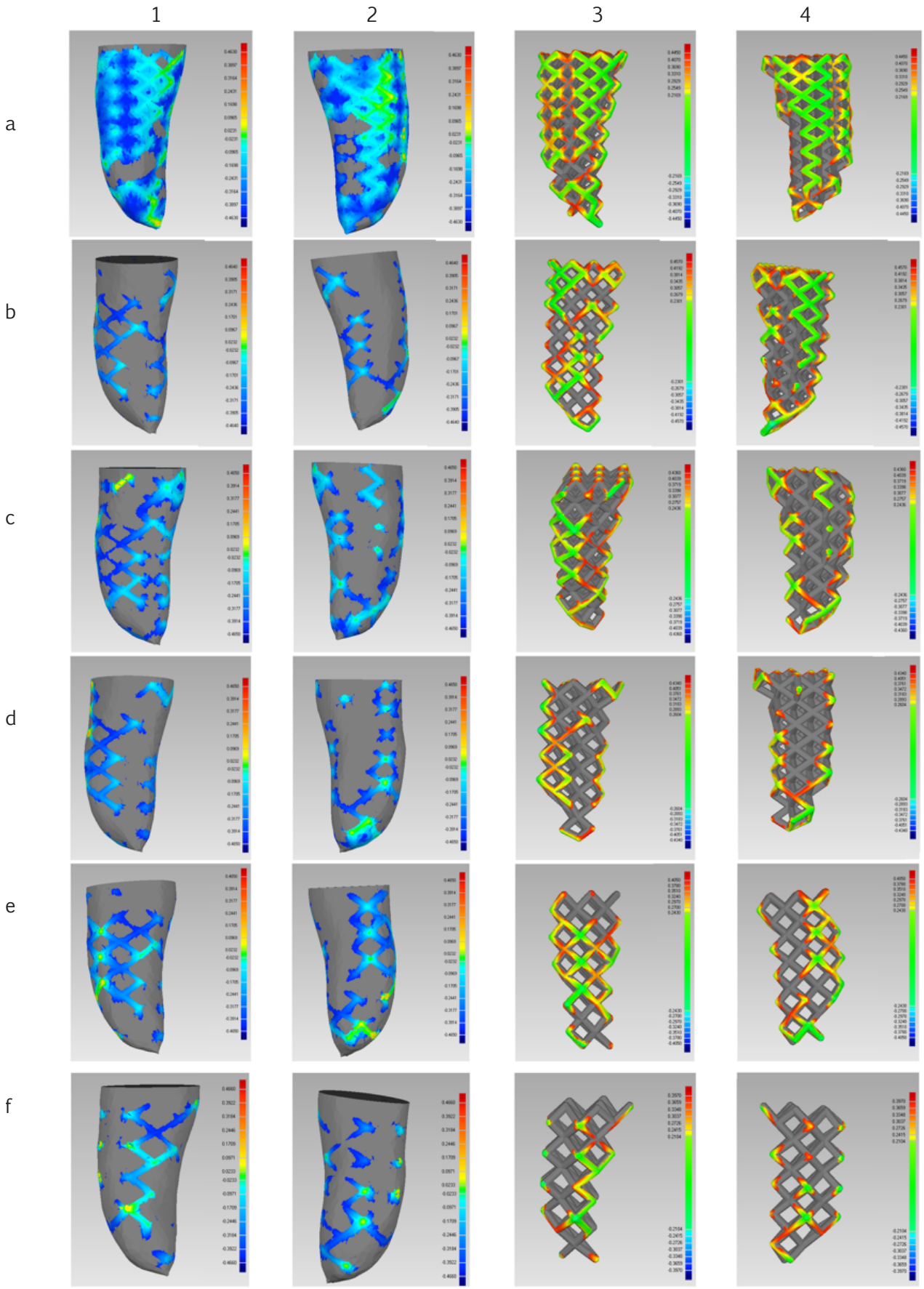


Figure app. 21: Deviation of the porous samples compared with the original shape. Colours indicate the deviation. (a) 0,4 1,0 sample compared with the original root shape. (b) 0,4 1,1 sample compared with the original root shape. (c) 0,4 1,2 sample compared with the original root shape. (d) 0,4 1,3 sample compared with the original root shape. (e) 0,4 1,4 sample compared with the original root shape. (f) 0,4 1,5 sample compared with the original root shape. 1&,2 are the deviations with the original root shape as reference, 3&4 are the deviations with the porous root as reference.

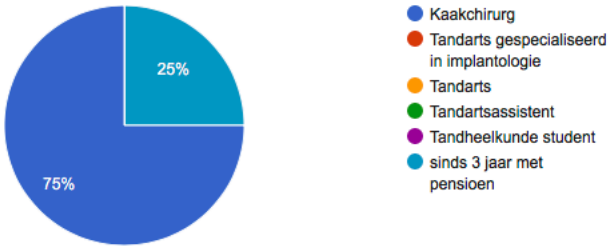
Appendix V- 6.2 Validation- oral surgeons, dentist

During the validation of the design four oral surgeons filled out a questionnaire. The answers are shown here.

1. Algemene vragen (1/5)

1.1 Ik ben een

4 responses

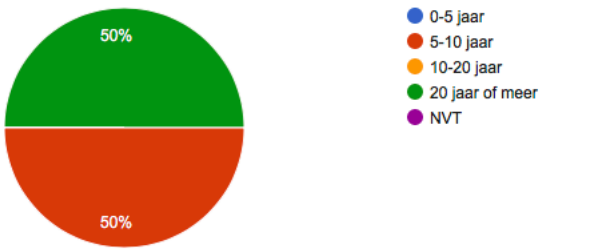


1.2 Ik werk in een

4 responses

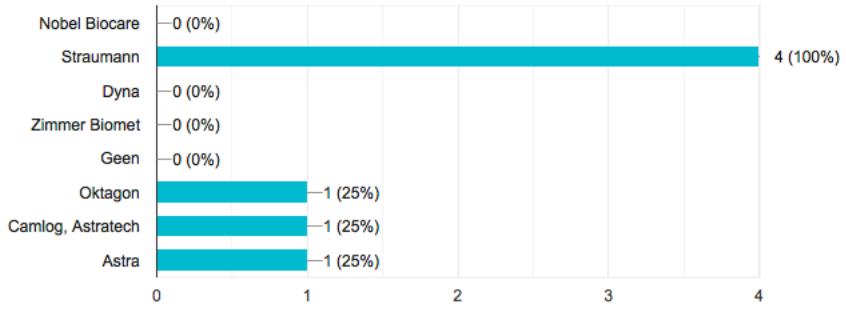
1.3 Ik ben .... werkzaam in dit vakgebied

4 responses



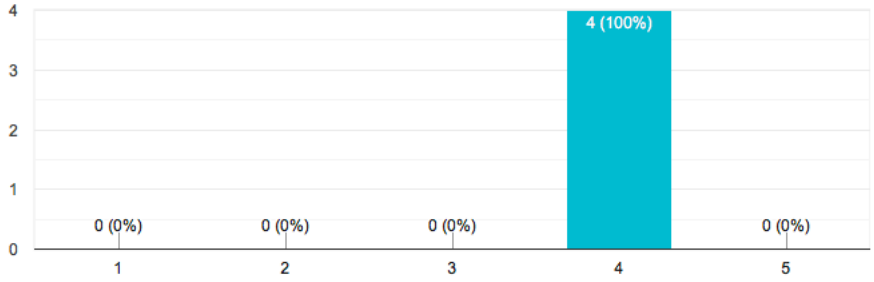
1.4 Ik maak gebruik van tandimplantaten van de volgende merken (meerdere antwoorden mogelijk)

4 responses



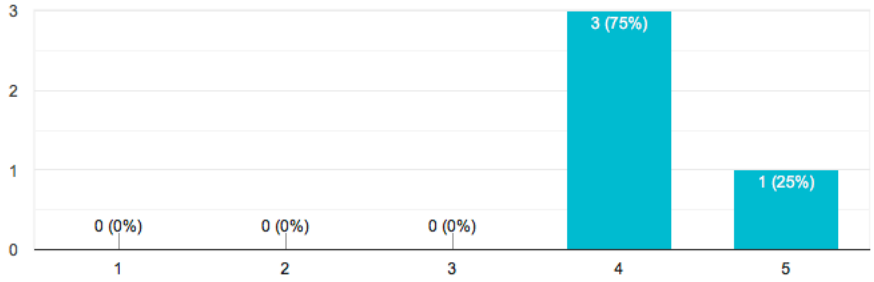
1.5 Ik zie dat tandimplantaten-industrie in de afgelopen 10 jaar is veranderd.

4 responses



1.6 Ik sta open voor innovaties binnen de tandimplantaten industrie.

4 responses



1.7 In welke gebieden in de tandimplantaten-industrie liggen volgens u kansen om te innoveren?

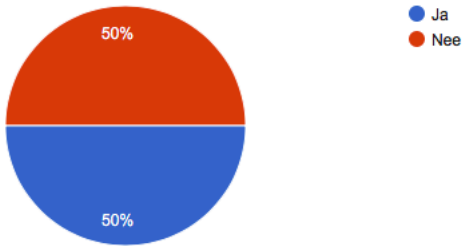
4 responses

Atrofische maxilla
preventie en behandelbaarheid van peri-implantitis
PSI, koppelingen met navigatie,
Volledig compleet behandel traject tegen voorspelbare lagere prijs; 3D innovatieve trajecten binnen de behandelpraktijk

2. Patiënt-specifieke implantaten (2/5)

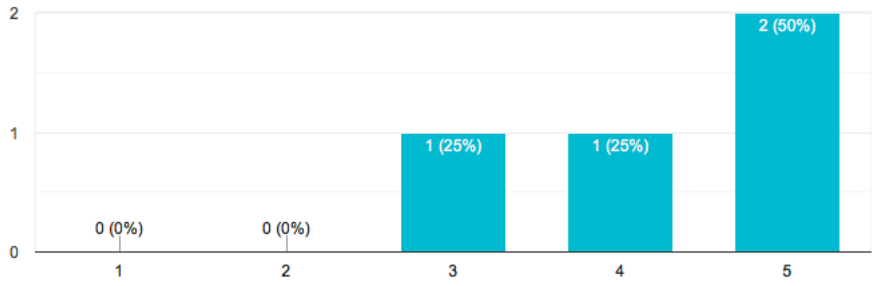
2.1 Heeft u ooit eerder gehoord van patiënt-specifieke implantaten, ook wel root-analogue implantaten genoemd?

4 responses



2.2 Ik vind het goed dat er onderzoek wordt gedaan naar patiënt-specifieke implantaten.

4 responses



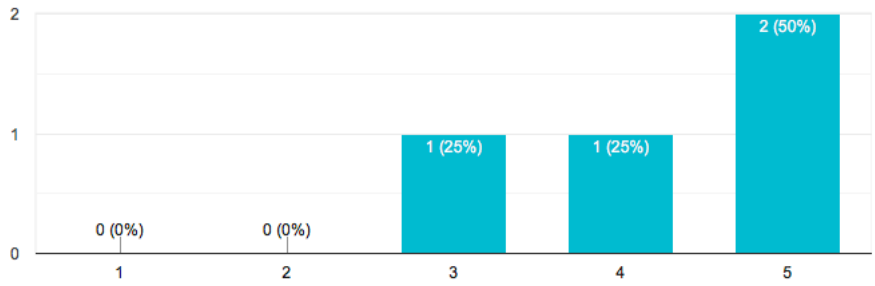
Toelichting

1 response

De toegevoegde waarde tov de huidige producten met oog tevens op kosten lijken mij zeer gering terwijl de risico's niet lijken af te nemen.

2.3 Deze oplossing (patiënt-specifieke implantaten) is innovatief.

4 responses



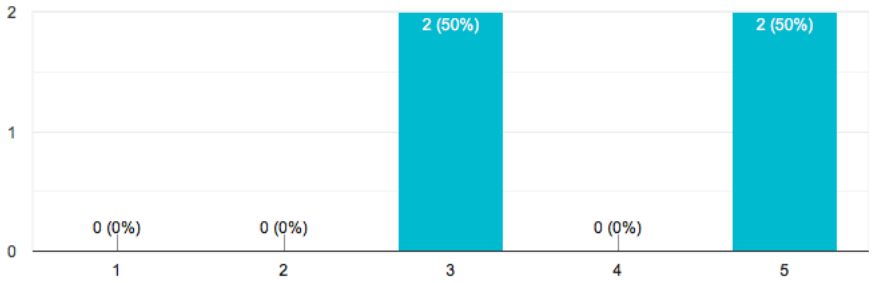
Toelichting

1 response

De structuur oogt vatbaar voor biologische complicaties

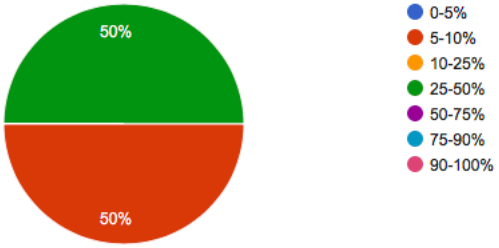
2.4 Ik zie toekomst in patiënt-specifieke implantaten.

4 responses



2.5 In hoeveel procent van de gevallen denkt u dat patiënt-specifieke implantaten gebruikt kunnen worden?

4 responses



Toelichting

3 responses

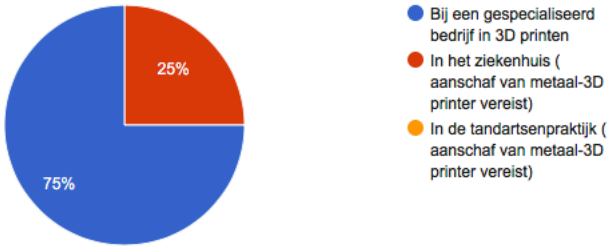
Afhankelijk van de situatie

Ook een PSI houdt geen rekening met resorptie dus past nooit perfect na een aantal weken.
Het lijkt me ook erg lastig bij meerwortelige elementen, m.n. als wortels divergent staan.

Te kostbaar tov de voordelen

2.6 Waar zou de productie van de tandimplantaten moeten plaatsvinden volgens u?

4 responses



Toelichting

2 responses

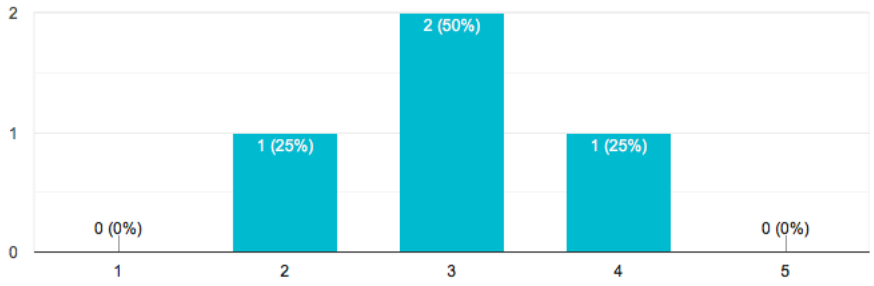
Bij gespecialiseerde bedrijven is de vereiste schaalgrootte realiseerbaar om tegen aanvaardbare kosten aan alle eisen van kwaliteit te voldoen

Per regio in samenwerking tussen kaakchirurgen en inplantologen in de directe omgeving

3. Poreuze structuur (3/5)

3.1 Ik zie een meerwaarde in de macro-poreuze structuur om bot-ingroei te promoten.

4 responses



Toelichting

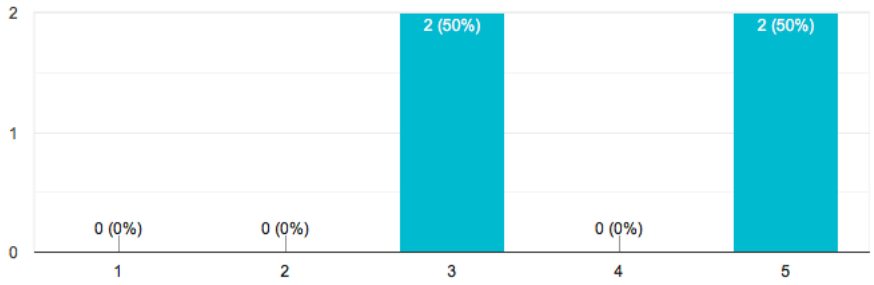
2 responses

Risico op infectie neemt toe, bij eventuele peri-implantitis lastiger te verwijderen of te reinigen

Vergroot ook risico op biologische complicaties

3.2 Ik zie een meerwaarde in de nano-poreuze structuur om bot-ingroei te promoten.

4 responses



Toelichting

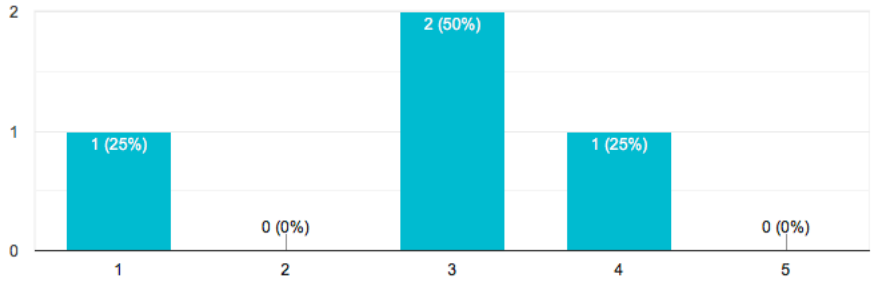
1 response

Zeer compatibel en inductief bij juiste receptoren; zie hiervoor ook regeneratief lab MKA van UMC Utrecht

4. Antibacteriële oppervlakte laag (4/5)

4.1 Een antibacteriële laag met zilver nanodeeltjes op het tandimplantaat is waardevol.

4 responses



Toelichting

3 responses

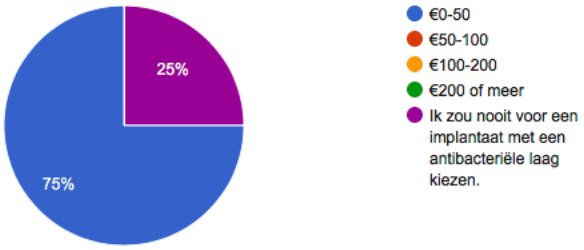
Mij onbekend

Effect op osseointegratie?

Is dat voldoende? Ook als de macrostructuur toch retentie biedt aan micro-organismen in plaques?

4.2 Ik zou kiezen voor een implantaat met een antibacteriële laag boven een implantaat zonder antibacteriële laag als de extra kosten niet hoger zijn dan €...

4 responses



5. Afsluiting (5/5)

Heeft u verder nog opmerkingen, suggesties, kritiek, over patiënt-specifieke implantaten. Laat deze hieronder achter.

1 response

Mooi initiatief! Succes