escola superior de tecnologia e gestão
instituto politécnico de leiria

Product development in custom-made medical devices.

Master in Product Design Engineering

Víctor Quintana Ramos

Leiria, November of 2020

Product development in custom-made medical devices.

Master in Product Design Engineering

Víctor Quintana Ramos

Master's Internship report held under the guidance of Doctor ESTG Supervisor Professor Mário António Simões Correia, Professor of the School of Technology and Management of the Polytechnic Institute of Leiria and co-orientation of Doctor (s) ESTG Co-Supervisor Professor Henrique de Amorim Almeida, Professor at the School of Technology and Management of the Polytechnic Institute of Leiria.

Leiria, November of 2020.

Originality and Copyright

Dedication

Dedicated to my brother, father and mother.
To my grandparents, those who are still with me and those who are somewhere else.
Dedicated to everyone that cared, at least once, about my career decisions and turns.
To myself for at least trying.

Acknowledgements

I cannot express enough thanks to my Supervisors during this Report delivery, Prof. Mário António Simões Correia and Prof. Henrique de Amorim Almeida. I want to mention as well my Masters Coordinator, Prof. Fábio Jorge Perera Simões, who helped me a lot during the first year of this Masters Degree, when I was in deep doubts.

Special thanks to the people that hosted me during my internship, in particular my supervisor Donato Monopoli Forleo, the creative supervisor that I needed, and to Sebastian Deviaenne, Industrial Designer that I spent most of my time with, that taught me how to reach for excellence when designing.

I would like to thank everybody that pushed me to study again and not to be afraid of such a big turn. To Sam, that was there when I started. To family, friends and even certain acquaintances. Thank you.

Abstract

The 21st century presents a revolution in additive manufacturing, and these technologies will continue to grow. Osteobionix S.L., the company where the internship took place, has been designing and producing titanium prosthetic parts for human implantation since 2008.

The company's goal is to design and build parts of the human body tailored for patients in which standard prostheses do not solve the problem. Based on this, the company's methodology was to obtain 3D images of each case, discuss, design and build a final solution. As soon as the solution is accepted by the surgeon, it proceeds to the production phase, mainly using an electron beam fusion machine (ARCAM S12).

The objective in the internship time was to understand the company's workflow, help in the production line and develop some design cases in order to learn and analyze what is a complete design follow-up case.

The main results obtained are the prototypes that are manufactured in EBM. Licensing for human use and implantation of products in humans is a slow process. Animal testing should be the next step to obtain useful data. Finally, several cases developed during the internship will be presented and explained.

Keywords: "Additive Manufacturing", "Electron Beam Melting", "Custom-made Human Prosthesis", "Titanium", "Design".

Resumo

O século 21 apresenta uma revolução na fabricação aditiva, e essas tecnologias continuarão a crescer. A Osteobionix S.L., empresa onde decorreu o estágio, concebe e produz peças protésicas de titânio para implantação humana desde 2008.

O objetivo da empresa é projetar e construir partes do corpo humano sob medida para pacientes em que as próteses padrão não resolvem o problema. Com base nisso, a metodologia da empresa foi obter imagens 3D de cada caso, debater, projetar e construir uma solução final. Assim que a solução é aceite pelo cirurgião, segue para a fase da produção, recorrendo principalmente a uma máquina de fusão por feixe de eletrões (ARCAM S12).

O objetivo no tempo de estágio foi o de entender o fluxo de trabalho da empresa, ajudar na linha de produção e desenvolver alguns casos de design a fim de aprender e analisar o que é um caso de acompanhamento de design completo.

Os principais resultados obtidos são os protótipos que são fabricados em EBM. O licenciamento para utilização humana e a implantação de produtos em humanos é um processo lento. Testes em animais devem ser o próximo passo para obter dados úteis. Para finalizar, vários casos desenvolvidos durante o estágio vão ser apresentados e explicados.

Palavras-chave: (*"Fabricação Aditiva", "Fusão por feixe de eletrões", "Prótese humana customizada", "Titânio", "Design*)

List of Figures

2.1 Orthognatic surgery planification 6

2.2 Temporomandibular current prosthesis 7

3.1 Workflow diagram 8

3.2 ARCAM EBM S12 10

3.3 Kondia B640 11

3.4 Daewoo Puma 240MB 11

3.5 Surgical tray marked with the laser engraver 13

3.6 Metal hardening kiln or oven 14

3.7 TPLO plates 14

3.8 Clean room diagram 15

3.9 3d generated surface 18

3.10 Yellow represents geometric modelling, white freeform and green surface . . 19

3.11 3d surface with artefacts 20

3.12 3d surface without artefacts 21

3.13 3d surface with artefacts 22

3.14 3d surface without artefacts 23

3.15 EBM diagram 24

3.16 EBM diagram 25

3.17 EBM Base plate + printed pieces + unsintered powder 26

3.18 EBM Base steel plate 26

3.19 support structure removal 27

3.20 EBM vs. DMLS surface [8] 28

3.21 EBM vs. DMLS surface 28

3.22 Dremel rotary tool 29

3.23 Sandblast cabinet 31

4.1 Pectus excavatum diagram 34

4.2 Pectus excavatum case 1 (Front view) 35

4.3 Pectus excavatum case 1 (Bottom view) 35

4.4 Pectus excavatum case 1 (section analysis) 36

4.5 Pectus excavatum case 1 (Front view) 37

4.6 Pectus excavatum case 1 (Front view) 38

4.7 Pectus excavatum case 1 (Front view) 38

4.8 Pectus excavatum case 1 (Front view) 39

4.9 Pectus excavatum case 1 (Isometric view) 39

4.10 Pectus excavatum case 1 (Side view) 40

4.11 Pectus excavatum case 1 (Front view) 40

4.12 Pectus excavatum case 2 (BONE + PROSTHESIS) 41

4.13 Pectus excavatum case 2 (BONE+ MUSCLE + PROSTHESIS) 41

4.14 Pectus excavatum case 2 (BONE+ MUSCLE +SKIN + PROSTHESIS) 42

4.15 Mould Design 43

4.16 Lower part mould Design 44

4.17 Upper part mould Design 45

4.18 TPU flexible printed prototype 45

4.19 TPU flexible printed prototype 46

4.20 TPU flexible printed prototype 46

4.21 TPU flexible printed prototype 47

4.22 Technique's diagram 49

4.23 Cube sample 1 (designed with 3dstudio Max 50

4.24 Cube sample 2 (Designed with k3dsurf and Magics) 50

4.25 Cube sample 3 (Designed with k3dsurf and Magics) 51

4.26 Cube sample 4 (Designed with Fusion 360 and Magics) 51

4.27 Cube sample 5 (Designed with Fusion 360 and Magics) 52

4.28 Cylindrical sample 53

4.29 Cylindrical sample 53

4.30 Defect adapted solid 54

4.31 Defect adapted porous structure 1 (booleaned with cube shown in Figure 4.23) 55

4.32 Defect adapted porous structure 2 (booleaned with cube shown in Figure 4.27) 55

4.33 Technique Final Result 56

4.34 Real prototypes 57

4.35 Real Prototypes 58

4.36 Titanium granules used as scaffold for bone growth 60

4.37 8 year evolution with PTG, no improvement evidence was found 61

4.38 Horizontal reabsorption 63

4.39 Horizontal reabsorption, called "knife" crest 63

4.40 DESIGN LINE 3 64

4.41 DESIGN LINE 3 64

4.42 Technique's Diagram 65

4.43 DESIGN LINE 3, Titanium EBM printed prototype 66

4.44 DESIGN LINE 3, Titanium EBM printed prototype 67

4.45 DESIGN LINE 3, Titanium EBM printed prototype 68

4.46 SWOT analysis 69

4.47 Dental Implant macrodesign 70

4.48 3d generated surface 71

4.49 3d generated surface 72

4.50 Dental Implant macrodesign 73

5.1 8L bottle design 75

5.2 Parts to cut from the bottle 76

5.3 Face shield protector 77

5.4 mask 77

5.5 Mask adaptation to a real 3d(.DICOM) 78

5.6 FDM printed Face shield structure 79

5.7 FDM printed Face shield structure 80

List of symbols

ESTG: Escola Superior de Tecnologia e Gestão
S.L.: Limited Society
R+D: Research + Development
ITC: Instituto Tecnológico de Canarias (in Spanish.
English translation "Canarian Institute of Technology")
CEO: Chief Executive Officer
CNC: Computer Numerical Control
CAM: Computer Aided Manufacturing
EBM: Electron Beam Melting
TPLO: Tibial Plateau Leveling Osteotomy
ISO: International Organization for Standardization
STL: Stereolithography (file format)
DICOM: Digital Imaging and Communications in Medicine
CT: Computed Tomography
CAD: Computer Aided Design
NURBS: Non-uniform Rational Basis Spline
SLM: Selective Laser Melting
CE: European Cerficate
PE: Pectus Excavatum
FDM: Fused Deposition Modelling
TPU: Thermoplastic Polyurethane
PTG: Porous Titanium Granules
SWOT: Strengths-Weaknesses-Opportunities-Threats

Contents

Originality and Copyright III

Dedication IV

Acknowledgements V

Abstract VII

Resumo IX

List of Figures XV

List of symbols XVII

1 Introduction 1
- 1.1 About the company . . . 2
- 1.2 Structure of the Internship report . . . 3

2 Osteobionix solutions 4
- 2.1 Why this company? . . . 4
- 2.2 Orthopaedic . . . 5
- 2.3 Trauma . . . 5
- 2.4 Spine . . . 5
- 2.5 Craniomaxillofacial surgery . . . 5

3 Materials, Methods and Equipment 8
- 3.1 Data Acquisition equipments . . . 17
- 3.2 Modelling . . . 17
- 3.3 Production systems (production steps) . . . 18

4 Case studies 33
- 4.1 Case study 1. Pectus Excavatum . . . 33
  - 4.1.1 Design methodology . . . 48
- 4.2 Case study 2. "The crumble" . . . 49
  - 4.2.1 Future drift . . . 62
- 4.3 Case study 3. "Porous chair" . . . 63
- 4.4 Case study 4. Dental Implant line . . . 70

5 Our COVID-19 interpretation 74
- 5.1 Carafe . . . 75
- 5.2 Face Protection . . . 79

6 Conclusions 81

Bibliography 83

1 Introduction

Engineering and design are fields that blend and merge with almost every professional field in modern society. My previous study is a Degree in Dentistry. Dentistry, as many medical fields, needs engineering and design to evolve and adapt. When I started looking for an internship, the activity to be carried on along the internship needed to be something related to my previous studies.
My main goal is to continue a professional line strictly related to the dentistry field. The aim is to drift away from the clinical exercise and apply to the dental product manufacturers. It was extremely important to me to work on medical related implants and medical related designs. This paper will give proof and show what my internship and my duties have been along this past year. My work inside the company leaned towards design related activities, engineering duties inside the company were performed by the senior mechanical engineer only.
My personal goals were to become fluent and skillful in design methodologies and softwares and to develop one or a few products within the company's structure. To prototype them, or produce one or two units of them, and if possible, to test them (even thought I realised that last step is going to be very difficult). The relevance of this period is to become a fully capable junior designer.
Along this report, my role in the company, my design improvements and the relevance of this internship in my work-related objectives will be addressed.

1.1 About the company

About to explain my personal objectives to achieve and learnings to gather along the Internship, I reckon it is important that the company gets a proper presentation.

"Osteobionix S.L." [1] is a Gran Canarian based bioengineering and biomedics company that distributes, currently worldwide, but mainly in the European market. Currently we are developing cases for surgeons and veterinarians in Italy, Switzerland, Spain (Mainland and the islands), but they have collaborated previously with Argentina, the United Kingdom, Mexico, France and Germany among others.

It is a private owned company that was built by the workers from the previous public-owned company, to accelerate certain processes, mainly problems with the supply chain. The original company still remains active. It is the bioengineering wing of a government owned I+D innitiative. The ITC (Instituto Tecnológico de Canarias, or "Technologic Institute of the Canary Islands" translated to english) remains as a public owned company, that started promoting Industry and I+D in the Canary islands back in 1992. We still operate within that benchmark, but it was for logistics and acceleration routes that Osteobionix S.L. opened. Therefore, it can be considered as a half public, half private company.

Activity

The company is specialized in custom-made titanium prosthesis for implantation. Due to tumorous resections, congenital defects, traumas or degenerative diseases, patients need body parts to be removed. Thanks to science and technology, nowadays that does not mean that we have to leave them without shape, aesthetics or function. Standardized products such as femoral heads, knee prosthesis or hip prosthesis are the main market when we talk about biomedics worldwide. But there are cases where tailor made prosthesis are needed, and that is what Osteobionix S.L. does. We focus on specific cases, we handle the planification side by side with surgeons, from the beginning to the surgery in itself in situations where standard products do not reach the millimetric adaptation.

On the other hand, the company developed a standardized line of products for veterinarians and animal surgery techniques under the name "Biosurgex"[2]. We are currently line producing a kit for a particular animal tibia surgery, and studying different techniques to enlarge our catalogue in the animal surgery field.

1.2 Structure of the Internship report

This paper is divided in 5 main chapters. First chapter serves as Introduction, presenting the company chosen for the Internship and the reasons to be chosen.

Second chapter, "Osteobionix solutions" explains in depth the nature of the company, the solutions that they provide and its branches or fields of work.

The third chapter exposes the materials, methods and equipment that make the company's activity possible, and the ones that I personally, have used along the internship

Chapter four depicts a few case studies that I have been able to develop within the company's structure and chapter five exposes results and conclusions.

2 Osteobionix solutions

What the CEO of the company, my supervisor during this period, thought when he started the company (nearly 20 years ago) was that he wanted to solve the cases that the standard prosthesis industry had left aside or behind. He wanted the complicated cases to come to him. And that is what the company has achieved.
One day, along my internship, a peculiar case came into the inbox mail. It was an ankle. The patient was achondroplasic. His/her ankle was fixed with a cement that was placed there 15 years ago. Giving the fact that the patient was achondroplasic, not only he/she measured less than 1'5 meters, but the anatomy was unsuitable for a standard prosthesis. A custom design was needed and there was where my supervisor was excited to work in. That person turn from almost zero mobility to a functional ankle.
We also replaced a dogs half thorax, and the alternative was sacrifice. Along the internship many cases came in and got produced, and solutions were found to all of them. That was what made the company most proud of.

2.1 Why this company?

Since the beginning of this Masters in Engineering, I knew that my field of action would be linked to my previous studies. The aim was to find something directly related to dentistry, but in a poorly developed area, when we speak about industries, like the Canary Islands, that was impossible to find. But along the search for an adequate company, I found this a very interesting opportunity. The day that I contacted and interviewed myself with them, they were working on the design of an Temporomandibular joint, and I felt that that was the closest I could get to mixing both my studies, creating a profile that I was enthusiastic about.

Giving my lack of engineering previous preparation or studies, I felt that this internship needed to cover plenty of , what I considered, basic practical knowledge in the field of design, machinery and techniques. When I visited the facilities, they toured myself around and I made sure that they had what I wanted to learn. A proper CNC machining station and a CNC lathe, with a technician to learn CAM, programming and learn machining in itself from. A multidisciplinary team that encompasses engineers and industrial designers. A wide range of softwares to learn from and achieve the design goals.

Besides these "basics" of design and manufacturing, the technique or machine that can pump my knowledge and my cv, and the main reclaim of this company, was the EBM (Electron Beam Melting), one of only two machines present in the Spanish territory. As we have studied, additive manufacturing is the present and future of manufacturing. Being able to spend months with that machine, understanding its workflow, its possibilities and limitations is a luxury. The machine is an ARCAM S12 (installed in 2008, the 47th machine installed in the world), which signifies that the team working here at Osteobionix has wide and deep knowledge about its proper function. Several examples of the company's past solutions will be presented along the rest of this chapter.

2.2 Orthopaedic

Shoulder and ankle custom made surgeries. We do not focus on hip and knee, because 99 per cent of the prosthesis that are implanted are standard. It is difficult to compete with an industry that produces implants at such a low price.

2.3 Trauma

Partial tibiae implants, ankle fixed and mobile prosthesis, single or multiple rib implants and scapula prosthesis have been performed.

2.4 Spine

Vertebrae substitution and multiple vertebrae arthrodesis are the two techniques the company has been doing over the last decade.

2.5 Craniomaxillofacial surgery

Mainly temporomandibular joint replacements and orthognatic surgery planification.

Orthognatic surgery

Orthognatic surgeries correct severe deviations either in the maxilla, in the lower jaw or in both (as seen in Figure 2.1). Maxillofacial surgeons used to break and attach where they thought it was needed. Nowadays, most orthognatic surgeries require planning. New generations of surgeons rely on computerized techniques more that previous generations did. Rellocation of the bone aiming at an harmonic equilibrium was performed by us, designers, at Osteobionix.

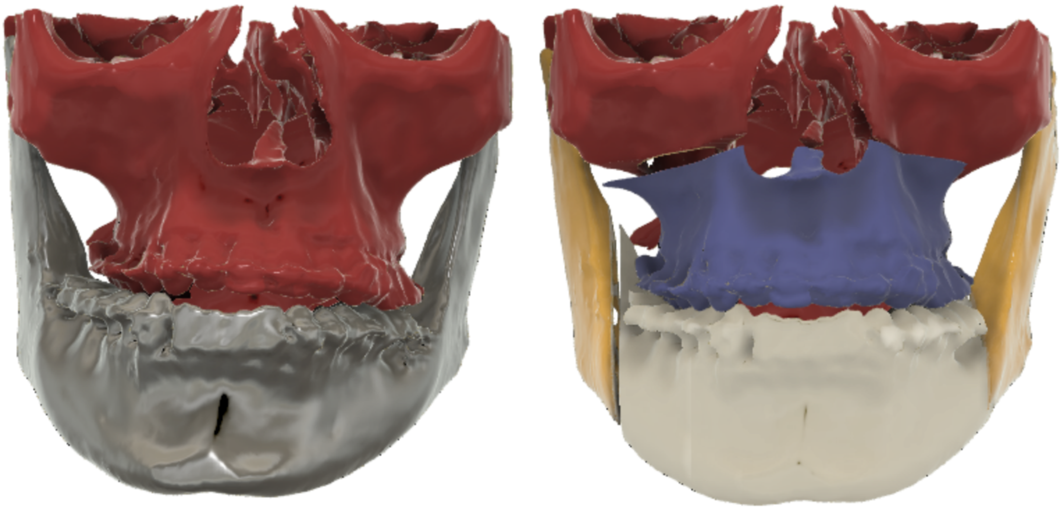

Figure 2.1: Orthognatic surgery planification

Temporomandibular joint replacements

Temporomandibular joint replacements are a 2 part setup, consisting each part in 2 pieces as well. A cranial part and a mandibular part. The cranial part is composed by a titanium box that will be screwed against the Zygomatic process of the temporal bone, and a polyethylene to interact with the mandibular sphere. The mandibular part consists on a Titanium custom made adapted part for the Mandible ramus, that gets screwed and fixed. The other part is a Cobalt-Chromium sphere attached through a screwed cylinder to the previously mentioned part. The polyethylene of the cranial piece articulates with the sphere of the mandibular piece. As it can be seen in the figure 2.2.

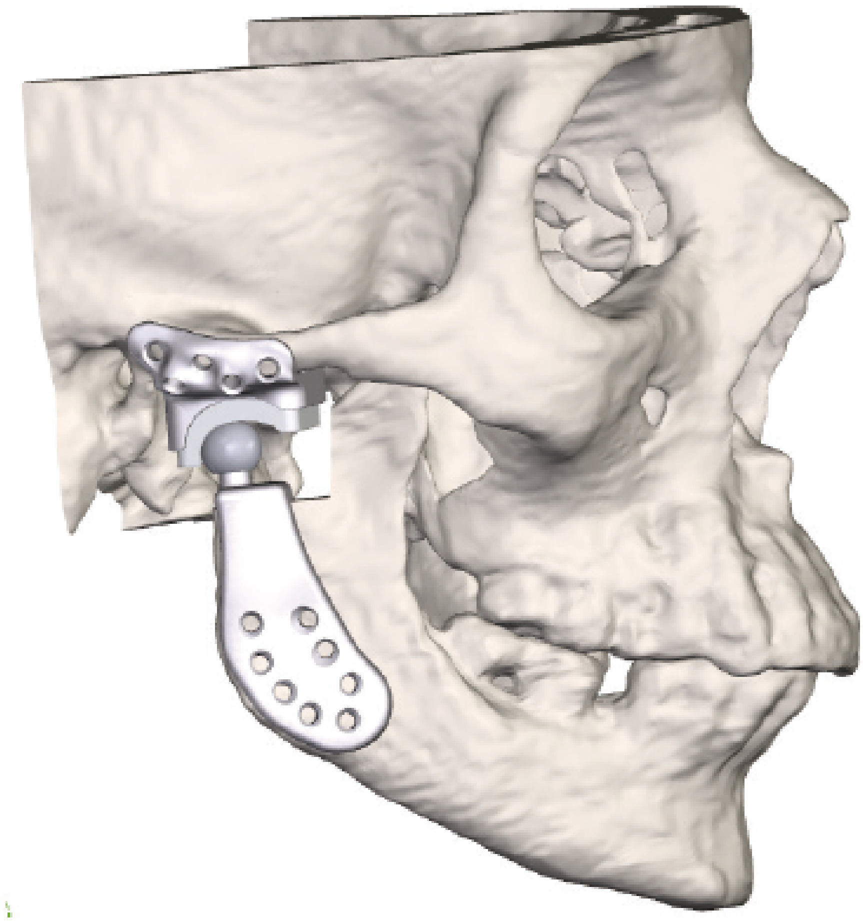

Figure 2.2: Temporomandibular current prosthesis

3 Materials, Methods and Equipment

Methods

The main task once I arrived was to understand the workflow of the company. After a few weeks I understood that each case was custom made, but in the end, the workflow was the same in every case (as shown in Figure 3.1). Further in the document (3.2.1-Production steps, pages 20 to 33) Figure 3.1 will be explained in detail.

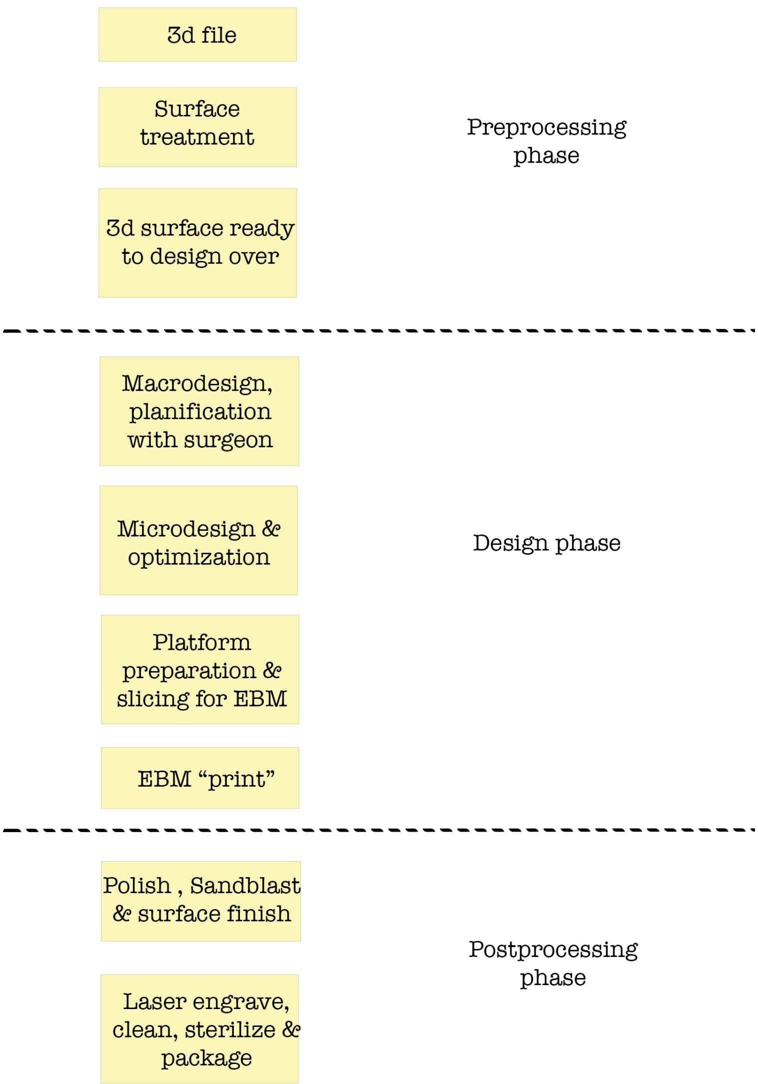

Figure 3.1: Workflow diagram

Materials

Titanium Titanium was discovered in 1790, but humans did not purify it until the early 1900s. Its use for industrial purposes began in the second half of the 20th century. Since that time, its main uses are related to military, aerospace and biomedical fields, due to its incredible resistance to corrosion and its low density[3]. The alloy used in the company to produce implantable, safe and certified prosthesis is Titanium-Aluminum-Vanadium Grade 5 (Ti 6Al-4V). It brings out strength, low weight ratio and outstanding corrosion resistance. This alloy has led to a wide and diversified range of successful applications in surgery and medicine. Ti 6Al-4V, or Grade 5 titanium, is the most commonly used of all titanium alloys. It accounts for 50 percent of total titanium usage the world over. Ti6Al4V ELI (Grade 23) and Ti-6Al-4V (grade 5) both are typically used for medical implants. The main difference between Ti-6Al-4V ELI (Grade 23) and Ti-6Al-4V (Grade 5) is that in ELI (Extra Low Interstitials) the maximum oxygen content is lowered to 0.13 per cent. This gives the material improved fracture toughness. Both options are good enough for human implantation purposes. But again, it is Ti-6Al-4V (Grade 5) what the company works with.

Due to the techniques used (EBM printing and machining), Titanium comes into the workshop in different forms. Powder, slabs and rods. Powder is supplied uniquely by ARCAM (EBM manufacturer), ensuring only high quality powder is used in the machine. Other pieces of Titanium can be produced through machining, that is why Titanium rods and slabs are also available in the facilities.

Stainless Steel Used mainly for plates or parts that belong to the prosthesis but are not going to interact directly with bone tissue, or if they are going to, that linkage will be temporary, as in certain type of screws. There are multiple forms of stainless steel. Type 302 was introduced for its application in orthopedic surgery. Type 316L is the most used in surgeries. The type used in the company is Stainless steel Type 316L. Type 316L stainless steel selected for the purpose of surgical implants contains approximately 17 to 19 per cent of chromium and 14 per cent nickel. The desired propertes are, first, that metal implants are not susceptible to corrosion. That can be achieved by various procedures. And that ferrite is not added because that gives the metal a magnetic property, which would be a problem in future Magnetic Resonance Imaging (MRI).

PLA Polylactic Acid is a biodegradable polymer obtained from the monomer Lactic Acid, which is obtained from the fermentation of sugars. This component is turned into lactide and then into Polylactic Acid. PLA is one of the main filament raw material used for FDM. In Osteobionix it also is used mainly for Fused Deposition Modelling, and for the production of prototypes or bone models.

There are other materials used in small amounts such as **Chromium-Cobalt**, **Aluminium** and **Teflon**.

Equipment

ARCAM S12:The company's activity spins around a central axis. It is through EBM (Electron Beam Melting, seen in Figure 3.2) technology that the majority of the prosthesis are manufactured. The company owns an ARCAM S12 EBM since 2008. Arcam started the commercial production of EBM in the early 2000s. The machine that the company owns was the 47th machine that was produced in the entire world.

Figure 3.2: ARCAM EBM S12

3 Axis-CNC:Prosthesis, or at least parts of each prosthesis need to be machined, drilled or surface treated. The 3-Axis is a Kondia 640B (as seen in figure 3.3).

CNC Lathe: Prosthesis, or at least parts of each prosthesis need to be machined, drilled or surface treated. Also used for screws.The CNC Lathe is a Daewoo Puma 240MB (shown in figure 3.4).

Figure 3.3: Kondia B640

Figure 3.4: Daewoo Puma 240MB

Both machines are used for side parts production as well. In some cases, part of the prosthesis is "3d printed" in the EBM, but other parts such as screws, plates, attachment systems and active parts of the prosthesis are machined from a titanium plate or rod. Each case demands different approaches, forcing us to redesign approaches constantly.

As said above, the company was facing an upcoming expansion. Two major upgrades in terms of machinery were about to happen, until the Covid-19 situation slowed the process down. Company has already in its property, waiting for an industrial warehouse relocation, a 5-axis CNC Machining Station and a Multispindle CNC Lathe. The 5-axis CNC Machining Station is a HAAS UMC750, and the Multispindle CNC Lathe is a HANWHA XE20H.

Several other smaller machines are also owned and have been used by myself along the internship:

CNC Laser Cutting machine (LASAG FLS 352N): mostly used for Surgical kit's lid production

Thermoforming machine

Band saw metal cutter machine

Laser engraver: each prosthesis that leaves the company and every surgical tray that we produce needs to be marked. Whether it is to engrave the company's logo or to classify drill diameters, steel plate sizes, screw diameters, we use a laser engraver. Laser engravers are able to mark a wide range of materials, from soft plastic to titanium. It is through modifying its power that we achieve a certain color and even roughness. In Figure 3.5 reader will be able to see a surgical tray, machined with the CNC station out of a sterilizable plastic slab with numbers laser engraved on its surface.

Surface finishing tools(Dremel rotary tool, Sandblast gun, cabinet and sandpaper rotary belts):

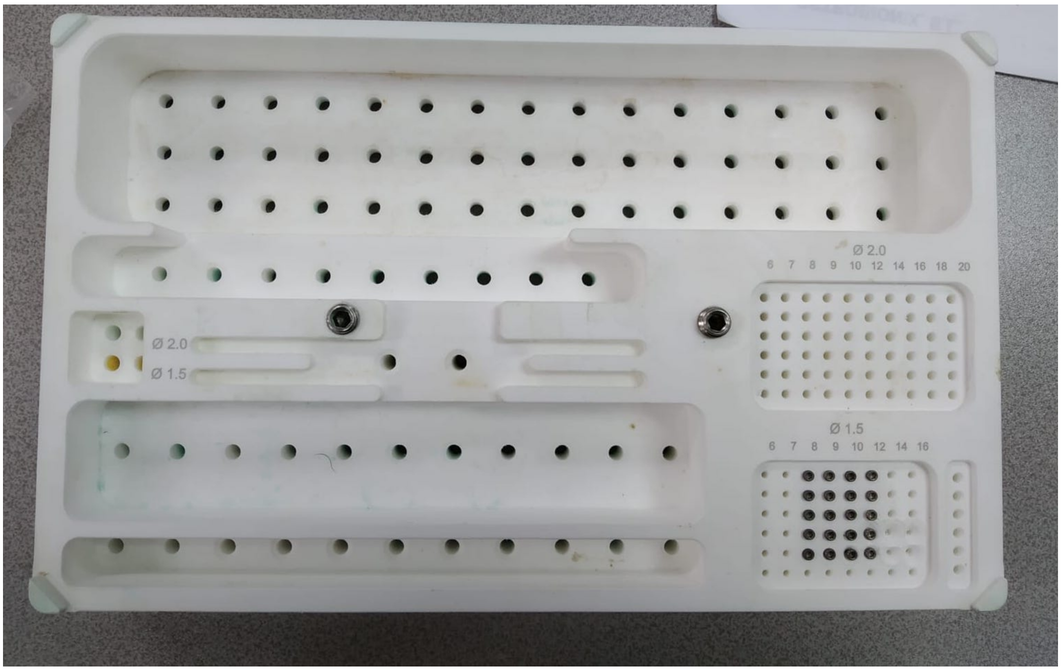

Figure 3.5: Surgical tray marked with the laser engraver

Kiln: seen in Figure 3.6. Mainly used for steel tempering. Sometimes, before machining we had to plan the metal outcome properties needed. As an example, when developing a veterinarian technique called TPLO, we needed to stamp the final plates (seen in Figure 3.7). So we needed the mold's steel to be harder than the plate. We hardened the mold before stamping the plates in the kiln.

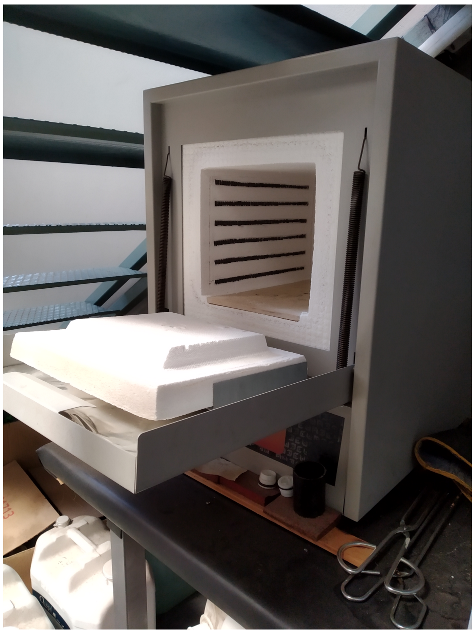

Figure 3.6: Metal hardening kiln or oven

Figure 3.7: TPLO plates

Clean room

It is, technically, not consider a machine, but it is as important as any machine in the facilities. In Figure 3.8, the company's clean room is depicted as a diagram.

According to the ISO [4] "Cleanrooms and associated controlled environments provide for the control of contamination to levels appropriate for accomplishing contamination-sensitive activities. Products and processes that benefit from the control of contamination include those in such industries as aerospace, microelectronics, optics, nuclear, and life sciences (pharmaceuticals, medical devices, food, healthcare)."

EBM printers need to vacuum seal the printing compartment in order to manufacture properly, which means that dust inside and around the machine needs to be properly diminished. A cleanroom was built around the EBM to ensure proper function of the machine. A 3 chamber clean room was built, as seen in the FIGURE 3.8. Room 1 is a transition room, room 2 is where the EBM and the Titanium powder recovery cabinet are placed and room 3 is the cleaning room (used for ultrasonic cleaning, sterilization and metal passivation).

Clean rooms work with pressure differences. Room 1 and 3 have positive pressure, which means they both have higher pressure that the adjacent room. Through ventilation channels, dust and particles will "effortlessly" flow from a positive pressure room to a negative pressure room due to the pressure difference, keeping it particle empty to a certain degree.

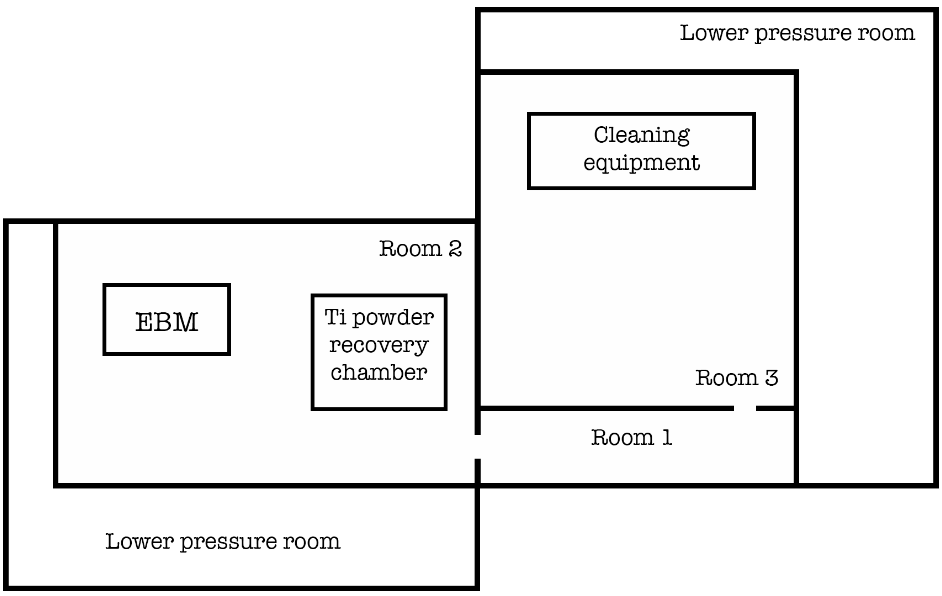

Figure 3.8: Clean room diagram

Softwares

Although not hardware nor machinery, softwares count and indispensable materials for the company and the role of the designer. The following have been used by myself along the internship:

Fusion 360

Parametric, surface and freeform model. Powerful CAD and CAM software. Simulation (finite element generative design) . Render mode.

Extremely powerful software with a sharing and connectivity module ahead of other modelling softwares.

3DS Studio Max

Non parametric modelling software. 3D modeling and rendering software for design visualization, games, and animation.

Meshmixer

Meshmixer is state-of-the-art software for working with triangle meshes along with sculpting mode and slicer.

Invesalius

Open source software for reconstruction of computed tomography and magnetic ressonance images.

Materialise Magics

Materialise Magics is a versatile, industry-leading data preparation and STL editor software for Additive Manufacturing with a specific medical module.

Ultimaker Cura

Powerful slicer.

K3dSurf K3DSurf is a program to visualize and manipulate Mathematical models in three, four, five and six dimensions. K3DSurf supports Parametric equations and Isosurfaces. We used to generate a variety of porous structures.

3.1 Data Acquisition equipments

As it will be explained further in the document (Chapter 3.2.1 Production steps- Preprocessing phase - DICOM management and 3D surface preparation), it all starts with the proper 3D imagery. Computed tomography scan (CT) is the base of our work. A proper CT scan allows us to reconstruct a surface to design over. We, as a company, do not own a CT scan, Doctors in their hospitals or clinics have the hardware needed for the purpose. The case starts as soon as we receive a folder with hundreds of images that compose a CT. The worldwide format used is .DICOM. When a .DICOM folder is shared, user obtains a single folder with hundreds, or perhaps thousands of images (.jpg files).

Hardware is their part, software is ours. As soon as we receive the mentioned folder, we treat the documents. Invesalius is a Brazilian open source software for reconstruction of computed tomography and magnetic ressonance images. There are several other softwares in the market, some of them extremely expensive and perhaps more powerful, but to our objective, Invesalius works perfectly. It works as simple as this: upload the folder with the CT images, twitch the surface limits depending on which tissue you want to obtain (either bone, soft tissue, skin, etc.), and click on generate surface. The outcome is something similar to what is shown in Figure 3.9.

3.2 Modelling

Modelling is where our work takes a more creative and knowledge based direction. Among the company were 3 designers, each of them has its own preferences for softwares. Some of them use CREO proengineer, some of them use Fusion 360, some 3dsStudio Max. I personally focused most of my time on Fusion 360 and a small part of it on 3dsStudio MAX.

Most design or modelling softwares offer various options when designing, and it is up to the designer to choose how to approach each design. The important part is to achieve what you have in mind, the path that you choose to get is entirely up to you. Fusion 360, as an example, offers 3 main modelling approaches. Example of each mode shown in Figure 3.10.

Geometric modelling

First CAD softwares were based on the extrusion or projection of 2D sketches into 3d volumes. The used of geometrical standard figures such as cubes, cylinders and other polygons is common as a starting point.

Surface

Based mainly on nonuniform rational Bezier-spline (NURBS). As opposite to what happens in geometric modelling, when extruding a sketch, a plane or surface is obtained, but it can not be considered a volume. Control points define the curvature of the surface.

Figure 3.9: 3d generated surface

Freeform or sculpt

It is a type of surface modelling. Freeform shapes consist on low-level representations, such as NURBS. Freeform modelling is a very powerful tool for product designers, it is based on a faster and more intuitive modelling approach.[5]

3.3 Production systems (production steps)

This chapter serves as a wide explanation of what was shown in Figure 3.1 (Workflow Diagram).

Preprocessing phase

DICOM management and 3d surface preparation

In order to work over a 3d image that represents as faithfully as possible the patients anatomy, and thereby, the problem he or she is facing in order to redesign the prosthesis that will substitute the malfuction, DICOMS need to be succesfully managed.

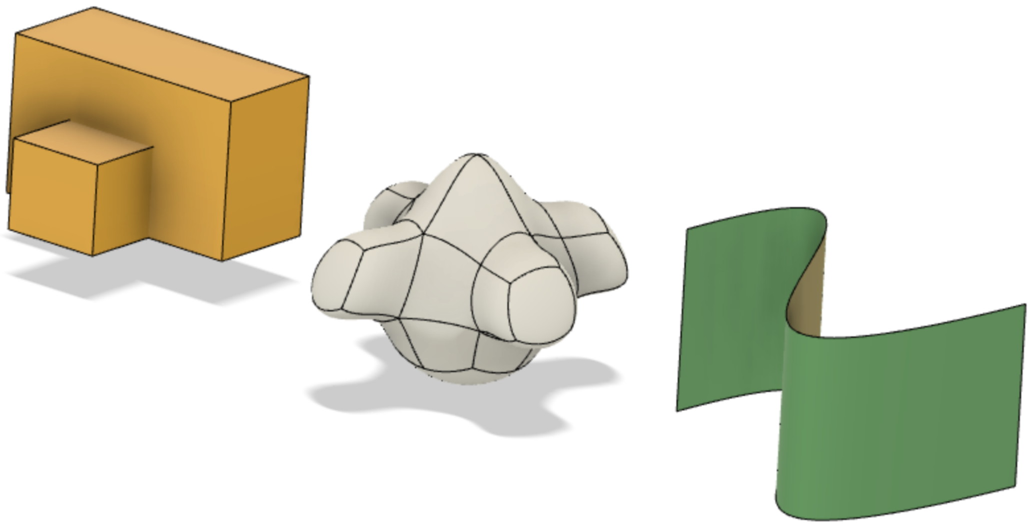

Figure 3.10: Yellow represents geometric modelling, white freeform and green surface

According to their developers[6] DICOM stands for "Digital Imaging and Communications in Medicine", it is the "standard for the communication and management of medical imaging, information and related data. The DICOM Standard pertains to the field of Medical Informatics. Within that field, it addresses the exchange of digital information between medical imaging equipment and other systems."

These standardization has helped the relation between Doctors, engineers, computer scientists, radiologists, designers and many more professionals.

As said before, the first step is the contact that a surgeon establishes with the company. Normally, they pursue a tailor made solution, the market is flooded with standard prosthesis (knee, hip, shoulder among others). Only in Spain, around 30.000 prosthesis are implanted yearly, mostly knee and hip replacements, while worldwide the sum exceeds a million per year. [7] The surgeon provides a digital file that encompasses the mentioned DICOM file. Nowadays, there are softwares that convert a mass of .jpg files into a 3d surfaces, but it has been my duty to specify the exposition limits, in order to obtain a clean artefact-free bone structure, muscular tissue, skin, or even all of them. If we want a clean surface, as the one you can see in figure 3.10, it is important to tune the exposition limits properly.

If exposition limits aren't properly measured, a useless image will result. Check figures 3.11, 3.12, 3.13 and 3.14 to see the how a wrong limit tuning can ruin a 3D surface. Both cases shown in figure 3.11 and 3.13 could be treated to reduce the artefacts, but the finer you work on the first step, the less information you are going to lose along the artefact refinement process.

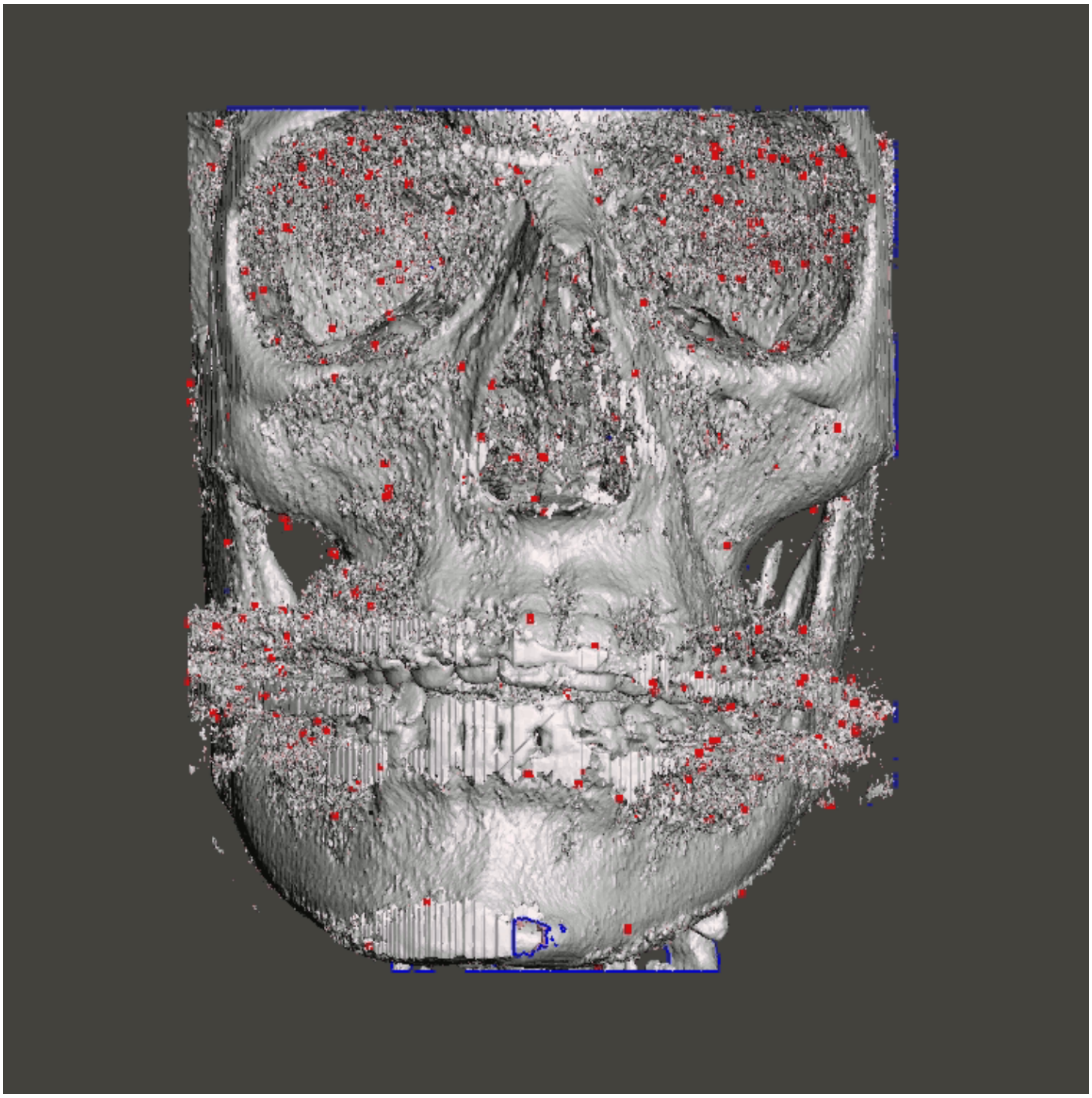

Figure 3.11: 3d surface with artefacts

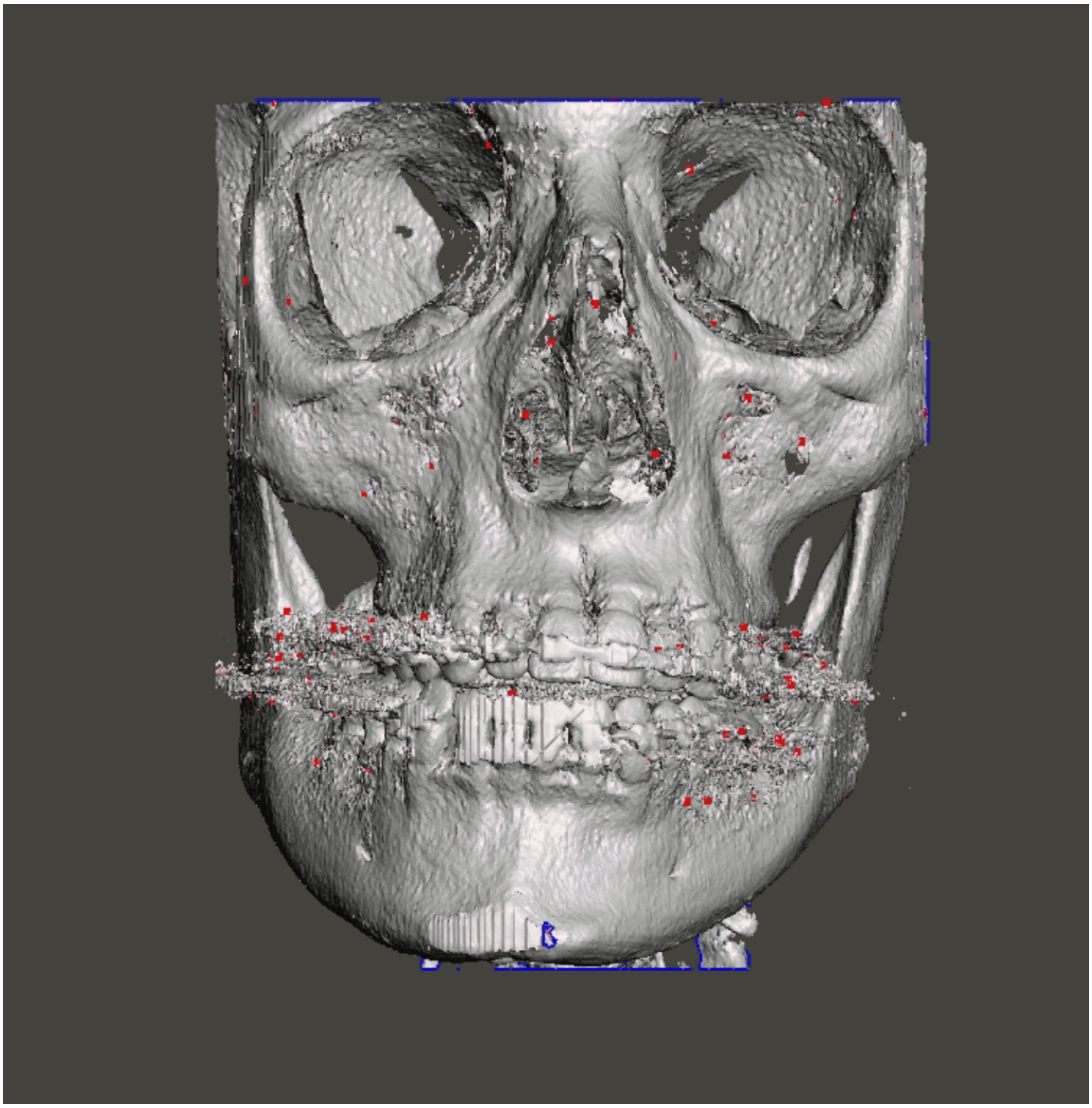

Figure 3.12: 3d surface without artefacts

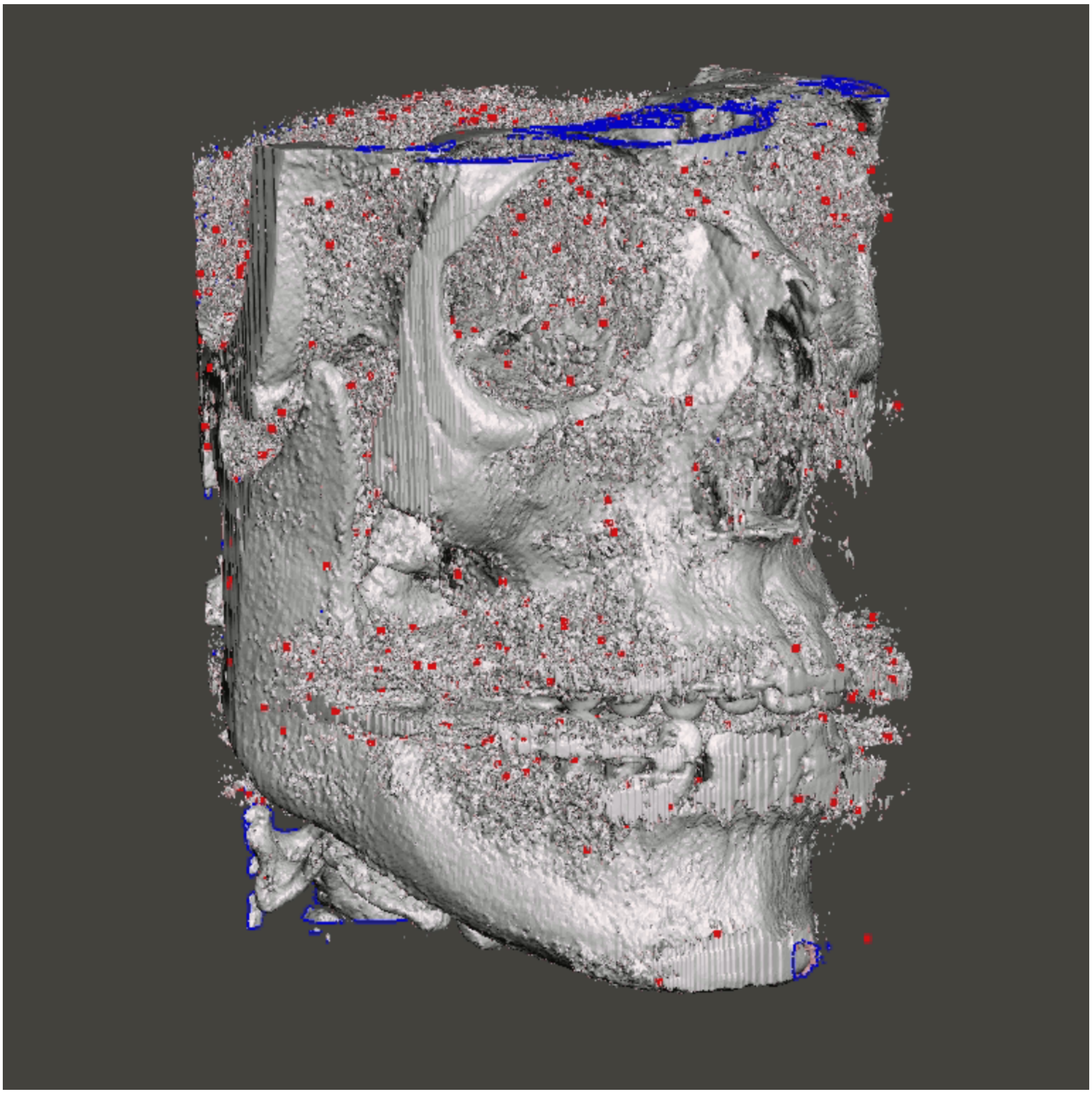

Figure 3.13: 3d surface with artefacts

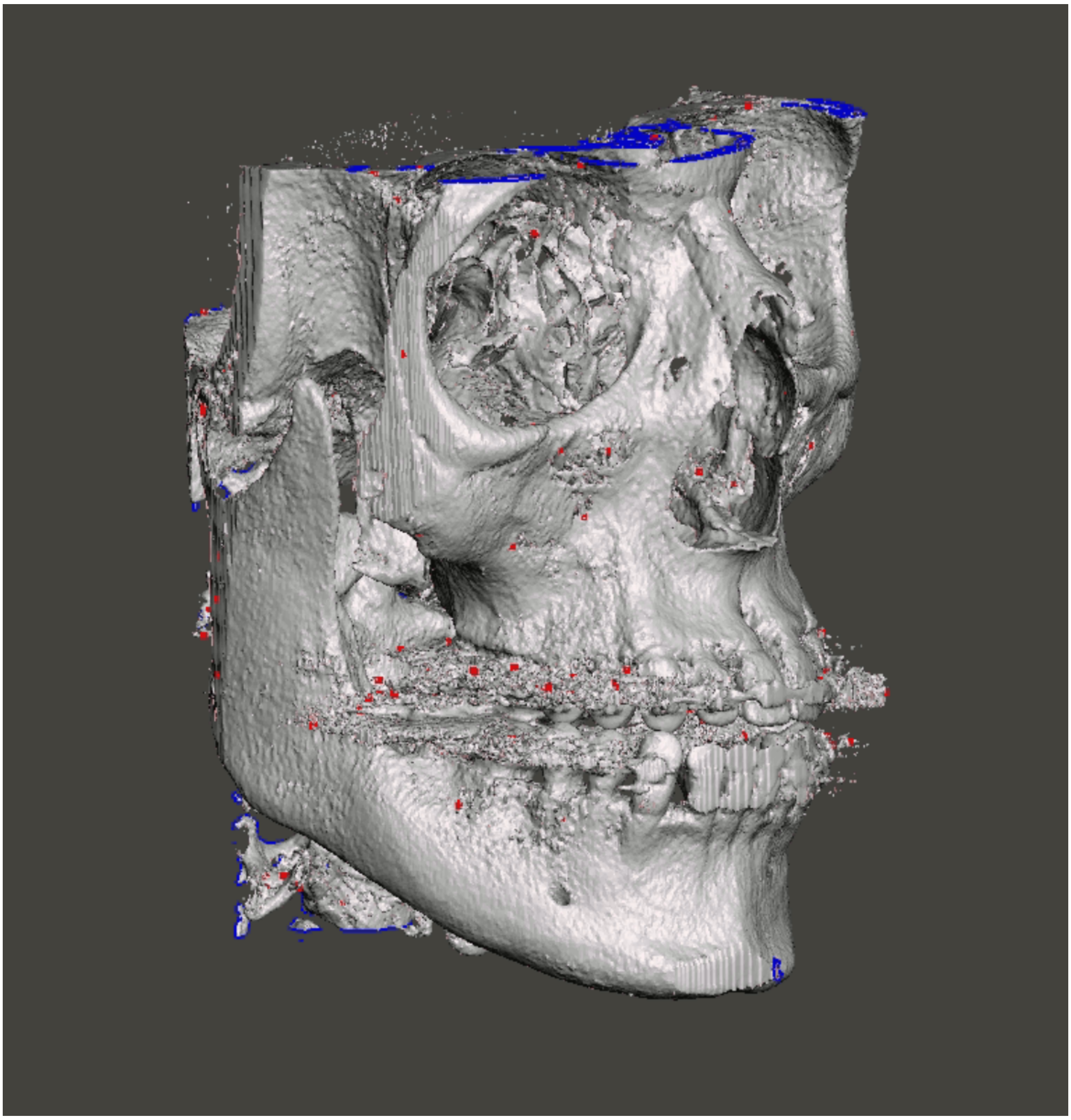

Figure 3.14: 3d surface without artefacts

Design phase

Additive manufacturing technology

The world of additive manufacturing started around 1987 when stereolithography was marketed. Since then it has evolved in many ways, and so many different technologies have been patented and marketed. Electron Beam Melting was patented by ARCAM, a Swedish company, in 1993, but it wasn't until mid 2000's that it got successfully produced and sold.
At the time Osteobionix was founded, EBM was the only metal(Titanium in particular) additive technology considered fully reliable. SLM had already been patented, but it wasn't developed enough and it didn't have the CE that the EBM had at that time. Choices were not that many.
As in any additive manufacturing technology, it all starts with a 3d model, either designed or pre-scanned. Once an .stl file is generated, it is time to send it to a slicing software, also called slicer, which will cut it into physical layers. A G-code file is generated containing all the information that the cnc-driven axis' need to start moving and printing.
Once the file is sent to the EBM, the process starts layer by layer. EBM is a powder based technology. The tanks are filled with Titanium powder (number 3 in Figure 3.15), and they deposit powder gradually. A sliding bar (number 5 in figure 3.15) distributes equally the powder on top of the platform that lowered itself after finishing the previous layer. The Electron beam hits again, passing through a vacuum environment and oriented by a magnetic field (as pictured in Figure 3.16), and the electron beam continues melting the next layer. That process is repeated along the printing time again and again, obtaining a final, solid piece.//
Map Key: 1- Vacuum chamber (ensures tight atmosphere) 2- Electron Beam 3- Titanium powder tanks 4- Platform 5-Sliding Bar

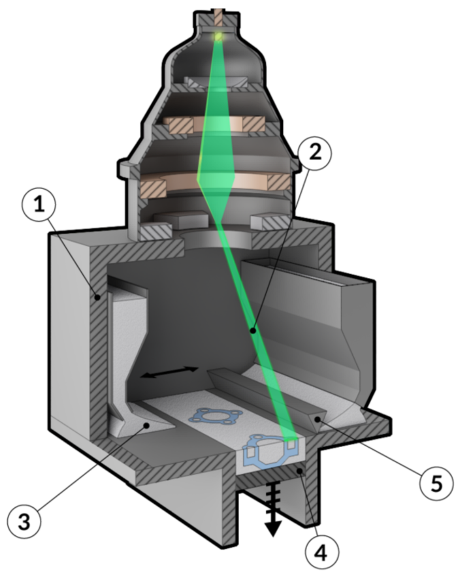

Figure 3.15: EBM diagram

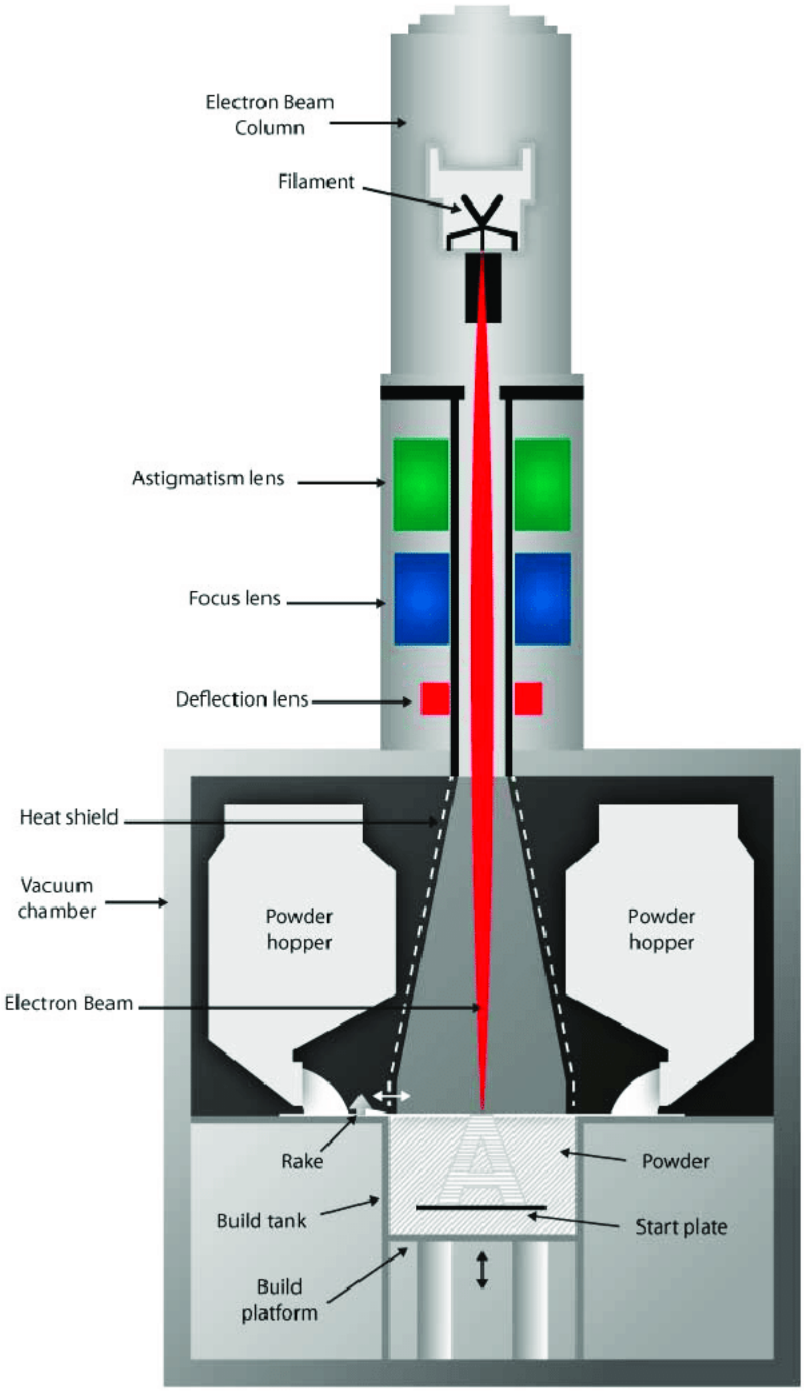

Figure 3.16: EBM diagram

Print recovery

When the printing cycle is finished, it is time to recover the pieces. The ARCAM S12 has a print volume of 250 x 250 x 200 mm. In order to print, a steel square (250mm x 250mm) plate needs to be placed in the base. The first layers of each piece will bond to that base plate (as seen in Figure 3.18). The final result is a base plate, the prints attached to it and plenty of unsintered powder (as it can be seen in Figure 3.17). The first step when recovering prints is to grab the plate and move it to a sandblast cabinet, one specially cleaned inside the clean room that is only used for that purpose. The gun is loaded with Titanium powder and it aims at getting rid of the unsintered powder, and most important, recover it so it can be used to refill the tanks an reused. Then with care, the prints need to be removed from the base plate with a chisel, a hammer and/or tongs.

Figure 3.17: EBM Base plate + printed pieces + unsintered powder

Figure 3.18: EBM Base steel plate

Postprocessing phase

Support structure removal

Even though EBM is a powder based additive manufacturing technique, support structure is needed to maintain the proper geometry while printing. The first step after recovering the EBM printed files is to remove the structural support. As seen in figure 3.19, in this particular piece, the support structure encompasses more material than the piece in itself. The support structure is the area that spans from the bottom till the top of the sticks. Support needs to me removed with strength, it is made out of Titanium as well, but ensuring we do not damage the final piece.

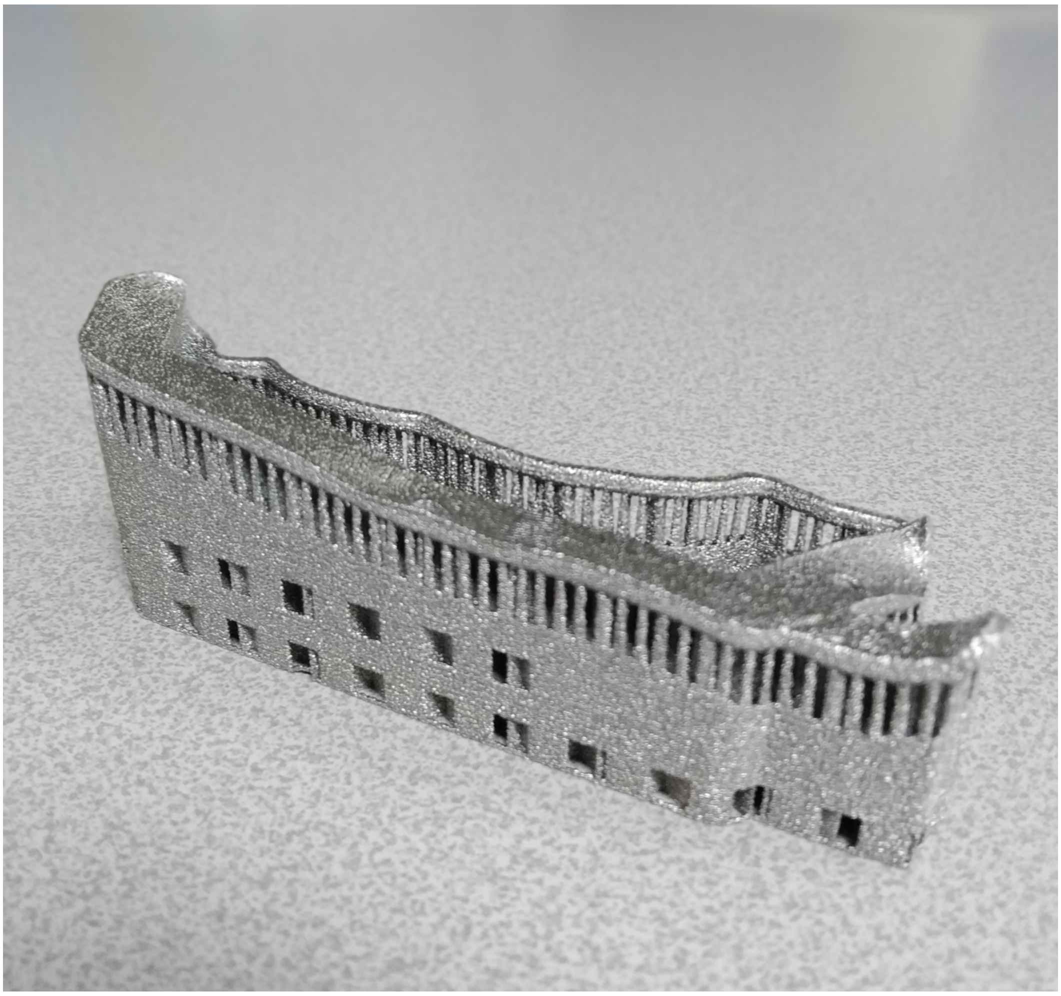

Figure 3.19: support structure removal

Surface finishing

EBM printers, in particular the ARCAM S12 that we were working with allow two modes when printing, 50 and 70 microns. That means that depending on the mode, the electron beam is melting a surface of 50 or 70 microns in diameter. While EBM works within this range, modern SLM printers (Selective Laser Meting) can reach up to 20 microns, ending with a much finer product in terms of surface roughness, as seen in figure 3.20 and 3.21. This means, that our products need to be hand polished and sandblast. For the purpose we use a Dremel rotary tool (seen in Figure 3.22) in order to refine the outer grain.

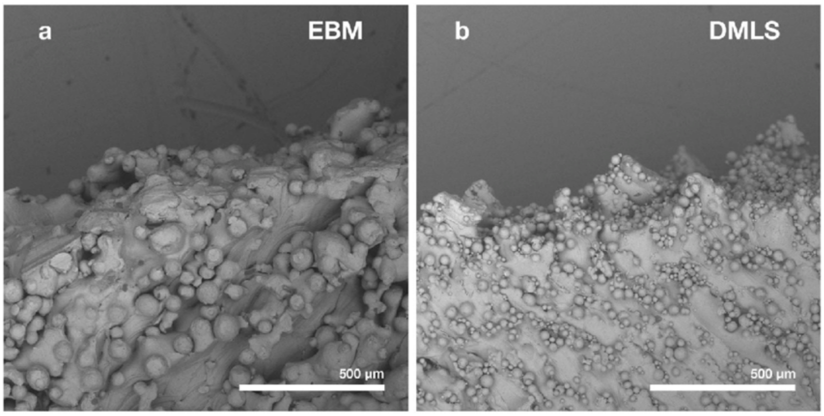

Figure 3.20: EBM vs. DMLS surface [8]

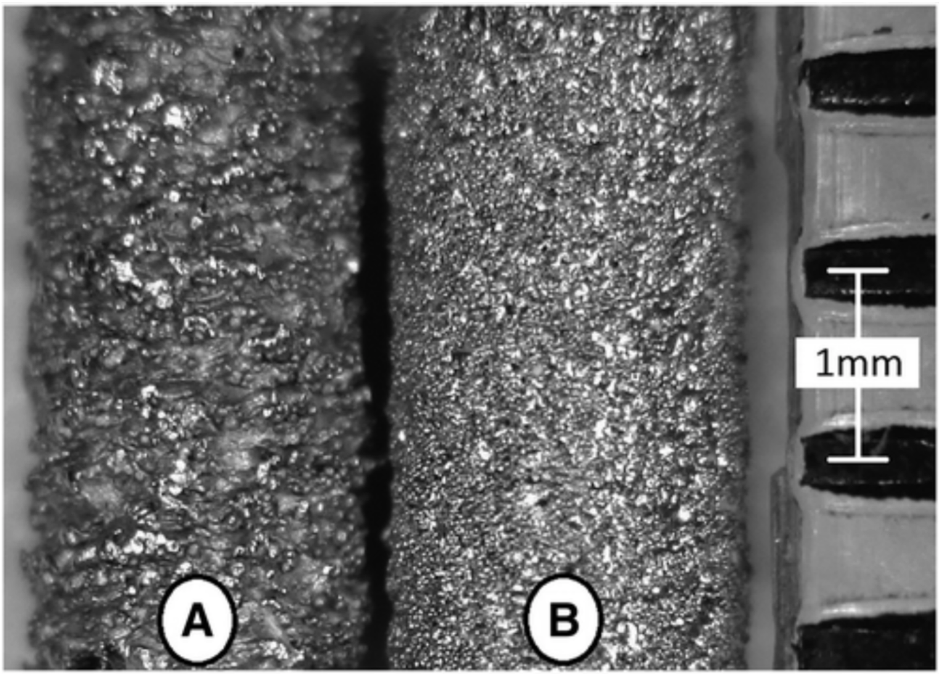

Figure 3.21: EBM vs. DMLS surface

Figure 3.22: Dremel rotary tool

From a manufacturing point of view, it takes time to hand polish every single product. Just as a curiosity, from an optimization point of view, an SLM would reduce postprocessing time considerably, but at the time the machine was bought, SLM had not European certification for human implantation.

Sandblast

According to some authors [9] "fibroblasts and epithelial cells adhere more strongly to smooth surfaces and the ability of osteoblast proliferation and collagen synthesis is greater in surface with moderate roughness". Hence, surface finish of any titanium implant plays an important role in the osseointegration process. There are several surface treatments for titanium implants. Acid etching and sandblasting are the most popular. Many authors, specially in the dental implantology market (field which has plenty of studies published) defend the combination of sandblasting first and acid-etching afterwards. As said, acid etching is too popular in the dental implantology market, which relies on mass production of very small pieces, which means that, with a relatively small amount of acid, a high volume of implants can be treated weekly.

In our case,sandblasting was the treatment chosen, because of the following. First of all, our cases are custom made, which means that one week we might treat 5 different prosthesis, while the next 4 weeks not even one case is treated. Secondly, some of our prosthesis are quite big, which means that a huge amount of acid is required. Thirdly, it would imply having relations with a chemical company that treats the acid after it being used. A situation that would be worth for a mass production company.

A sandblast cabinet that encompasses a sandblast gun is shown in Figure 3.23. The powder used to shoot is zirconia.

Figure 3.23: Sandblast cabinet

Passivation

Passivation happens when an outer layer of shield material is created around the desired material, which protects the material in itself. Normally created by a chemical reaction with the base material. We used to apply this process to the surgical tray's steel lids, in order them not to rust during the sterilization and cleansing cycles. In order to achieve the desired result over steel we passivize it with citric acid. According to some authors, passivation with citric acid is cleaner for the planet than nitric acid[10].

Cleaning and sterilization

After a prosthesis has been surface treated and before it gets packaged and shipped, a proper decontamination process occurs. Firstly, a regular soap wash to get rid of debris and dust that has been produced along the polishing process. We use double-distilled water, to avoid electrolytes to start any undesired effect or process on the surface. Secondly, ultrasonic cleansing. 20 minutes at 65^{o}C sets one cycle. If there is any mistrust in the decontamination process, two cycles can be done. The ultrasonic cleansing, uses ultrasonic vibrations in order to detach any stuck or bonded debris, tiny particles or difficult access remains. Once the cycle/cycles are finished, the prosthesis is dried (inside the clean room) and packaged (airtight normally).

Package

Proper packaging sets the presentation of any product. From my point of view it is an important task, specially when we talk about biomedical products, in which hygiene, cleanliness and even sterilization are key factors. Our packages left the building in air tight plastic, after the piece has been washed and ultrasonic cleaned. Surgeons and their teams do the sterilization process once they receive the prosthesis, to ensure implantation requirements.

4 Case studies

4.1 Case study 1. Pectus Excavatum

A Pectus excavatum is a condition in which the breast bone or sternum appears sunken and the chest concave. According to [11] "Pectus excavatum represents a depression in the anterior chest wall as a result of dorsal deviation of the sternum and the third to seventh rib or costal cartilage, and is the most common chest wall deformity, representing 90 percent of all cases...Although PE in most instances has little or no influence on the function of the inner organs, the cosmetic appearance of the patients leads to psychological impairment which requires therapy." An explanatory diagram can be seen on 4.1.

There are three main surgical techniques to correct a Pectus excavatum case. Two of them involve a full breakage and relocation of the toraxic limits (bone and cartilage).The Ravitch Procedure requires an open surgery, the Nuss Procedure achieves the breakage with through a minimally invasive technique. Curved metal bars are inserted behind the sternum and so, pushing it into a regular position. Last, but not least, we have the prosthesis implantation. A biocompatible silicon prosthesis in placed below pectoral muscles, fat tissue and skin in order to correct the congenital defect. No bone or cartilage breakage is involved, reducing drastically the post-surgical pain and inflammation. We design cases for this last approach.

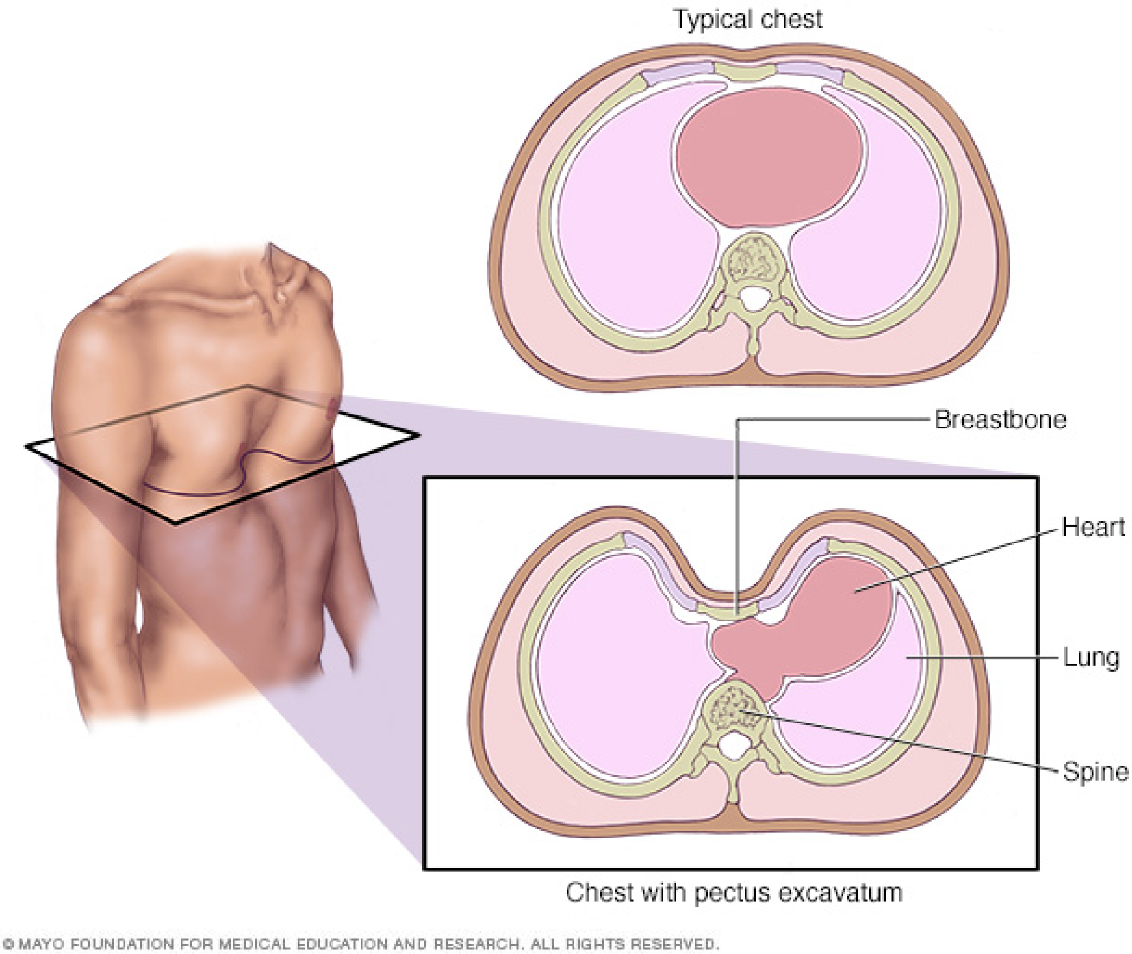

Figure 4.1: Pectus excavatum diagram

I started by reconstructing the 3d surface, task that I had been doing for almost the entire internship for other designers. As it can be seen in figure 4.2, 4.3 and 4.4 the ribs and breast bone draw the same pattern as shown in figure 4.1.

Figure 4.2: Pectus excavatum case 1 (Front view)

Figure 4.3: Pectus excavatum case 1 (Bottom view)

Figure 4.4: Pectus excavatum case 1 (section analysis)

As in any modelling case, there are several approaches. I knew that my supervisor tends to modify to detail what designers do. So I decided to look for an approach in which, modifications were simple to update. I decided to work with surfaces instead of solid and/or booleans.

The prosthesis seen in figure 4.8, 4.9 and 4.10 an 4.11 will come out of the space generated in between the two surfaces (grey and red) and the transversal surface (blue) in figure 4.5, 4.6 and 4.7. Any modification needed is as simple as modifying each surface.

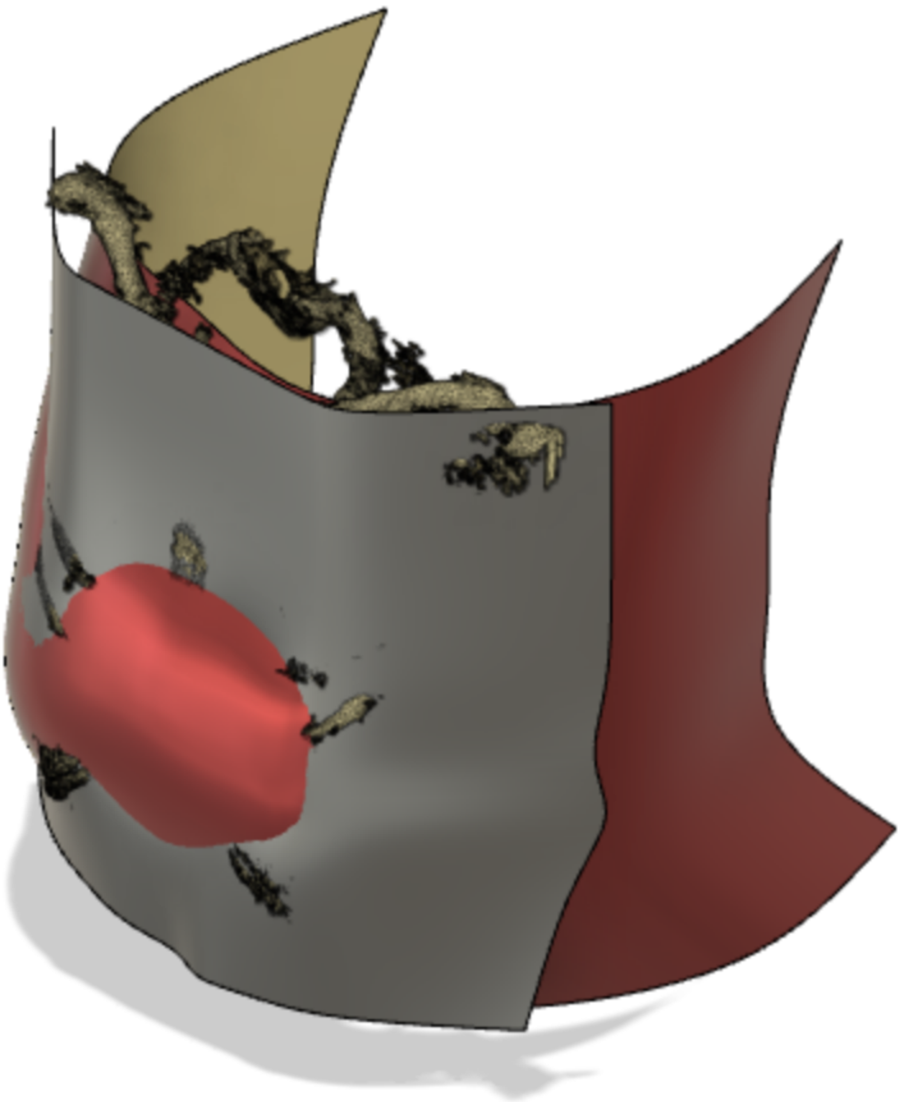

Figure 4.5: Pectus excavatum case 1 (Front view)

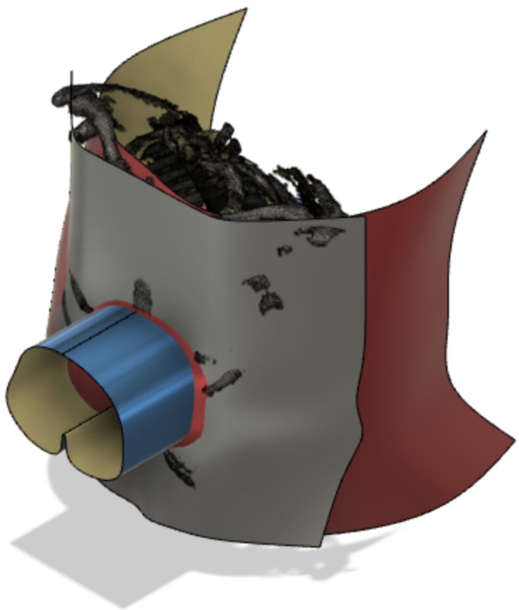

Figure 4.6: Pectus excavatum case 1 (Front view)

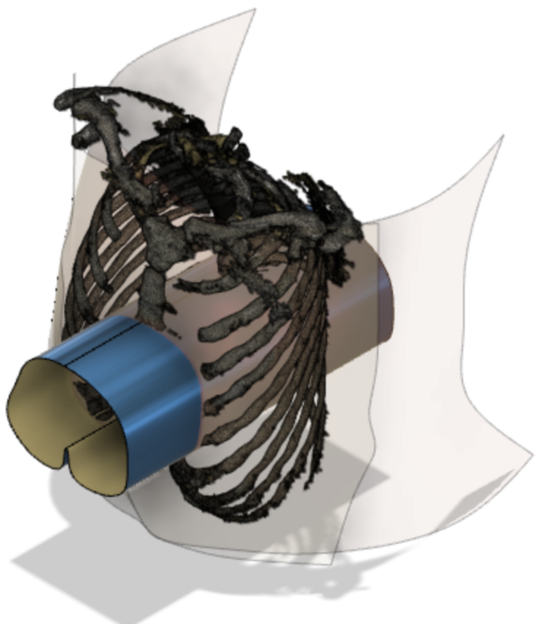

Figure 4.7: Pectus excavatum case 1 (Front view)

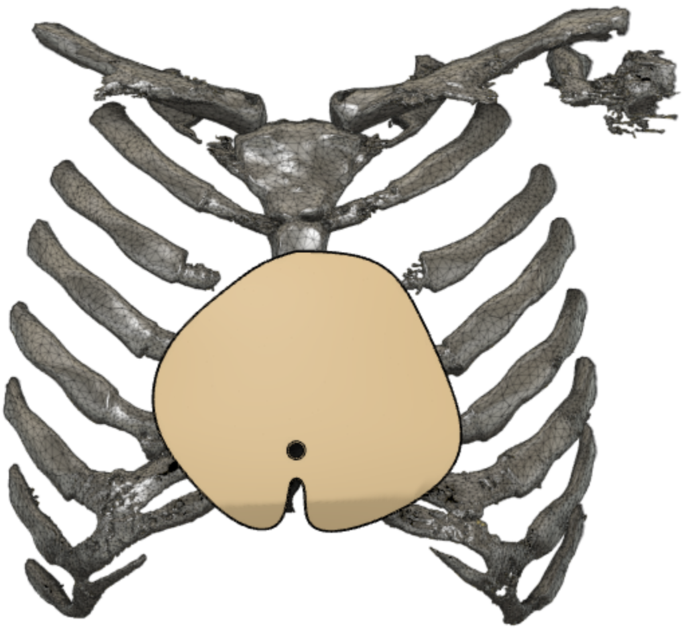

Figure 4.8: Pectus excavatum case 1 (Front view)

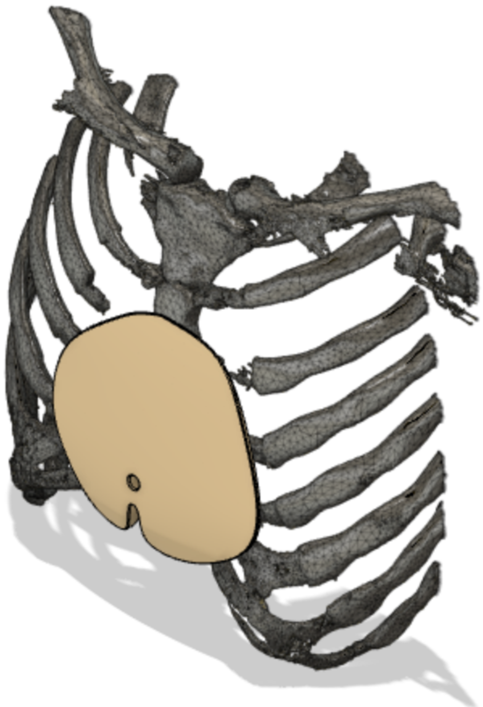

Figure 4.9: Pectus excavatum case 1 (Isometric view)

Figure 4.10: Pectus excavatum case 1 (Side view)

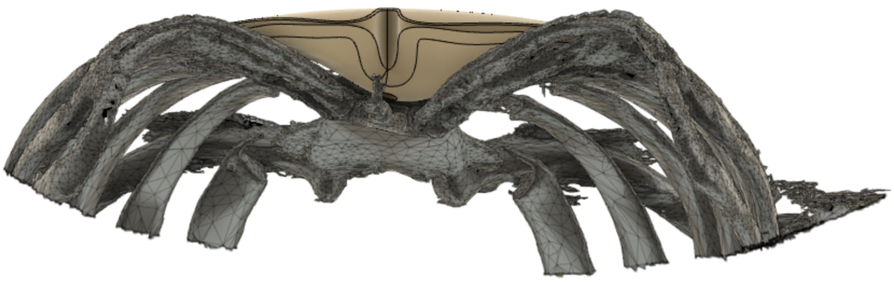

Figure 4.11: Pectus excavatum case 1 (Front view)

By the time I was working on this case, another Pectus excavatum case came in (seen in figures 4.12, 4.13 and 4,14). My boss insisted on me working on both at the same time, so we could develop a methodology for this cases. He wants to promote this product line. We worked together on a methodology, in order to optimize the design process going over the same steps.

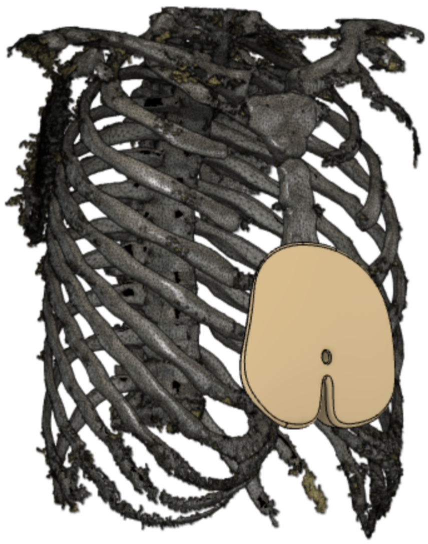

Figure 4.12: Pectus excavatum case 2 (BONE + PROSTHESIS)

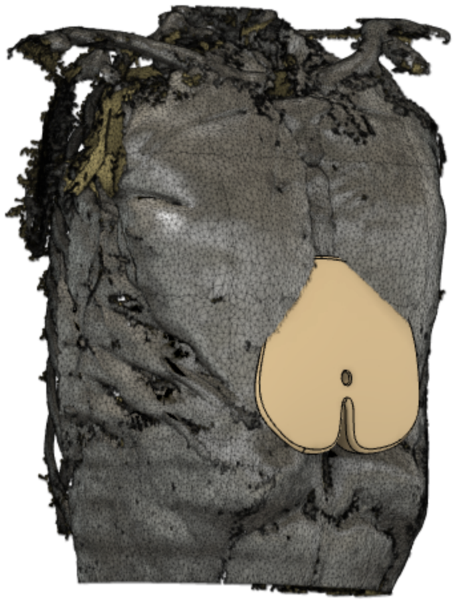

Figure 4.13: Pectus excavatum case 2 (BONE+ MUSCLE + PROSTHESIS)

Figure 4.14: Pectus excavatum case 2 (BONE+ MUSCLE +SKIN + PROSTHESIS)

It was my responsibility to produce a custom made mould per case with FDM (seen in figures 4.15, 4.16 and 4.17), using high quality materials. The sterilizable, biocompatible resin will be injected in it, and later undergo a proper cleansing and sterilization process before implantation

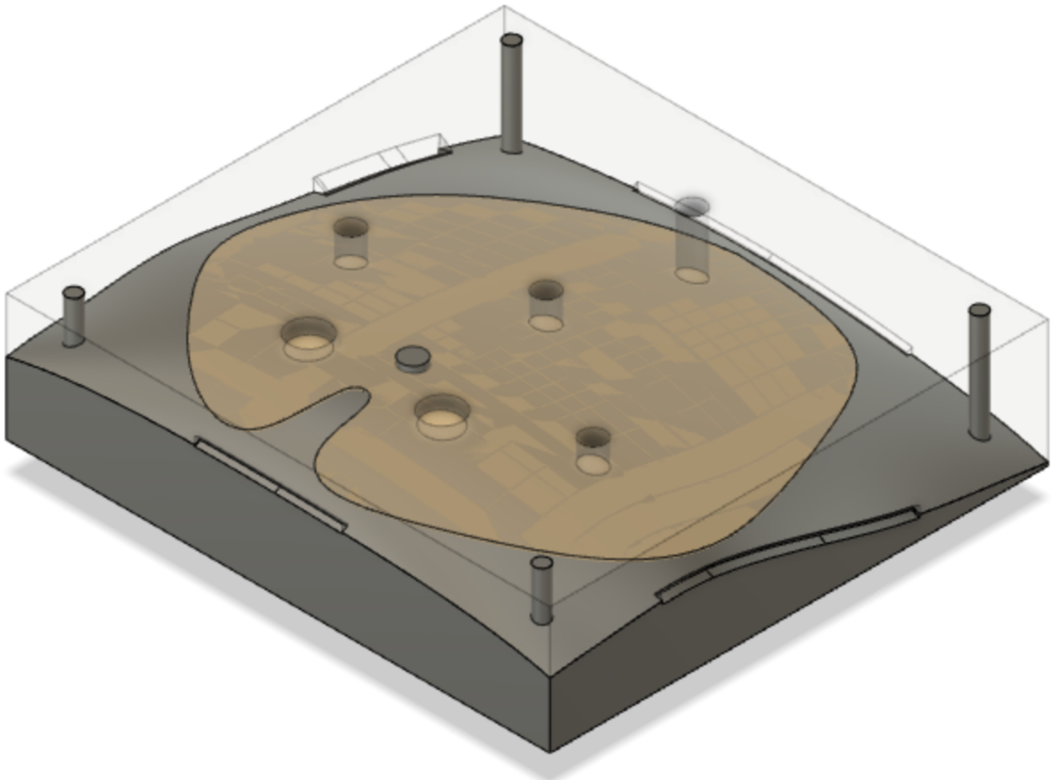

Figure 4.15: Mould Design

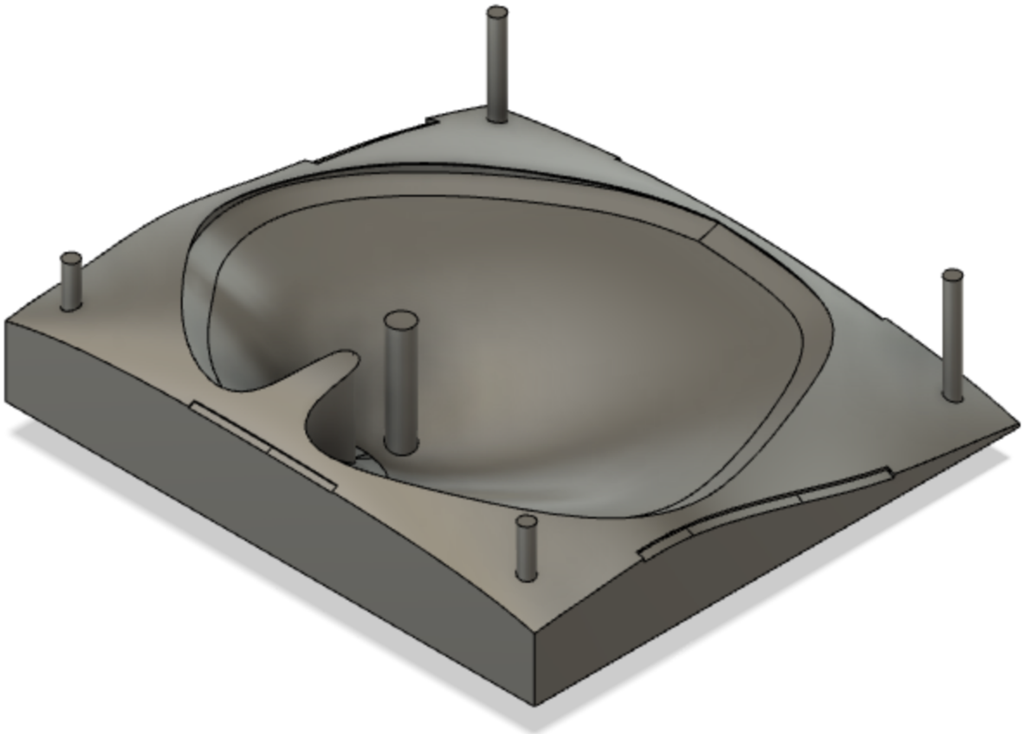

Figure 4.16: Lower part mould Design

Even though the surgeries have been postponed due to the COVID-19 situation, we already printed (FDM) flexible TPU prototypes so the surgeon can check adaptability (shown in Figures 4.18, 4.19, 4.20 and 4.21).

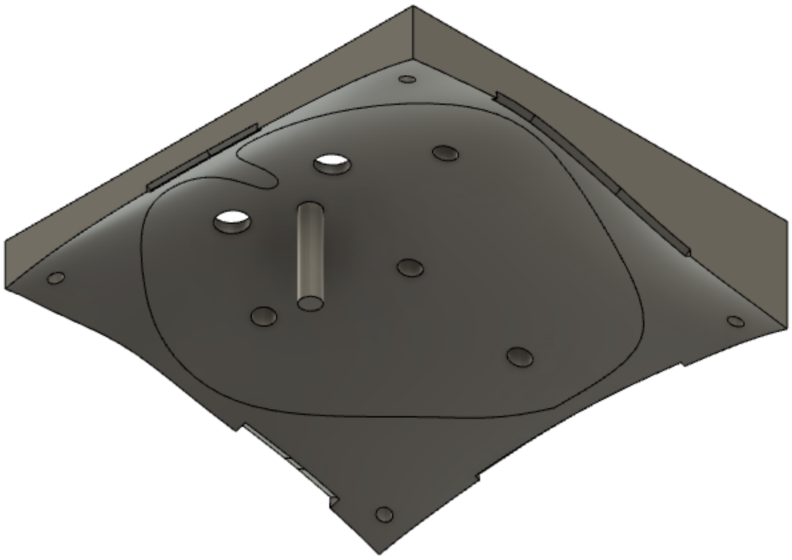

Figure 4.17: Upper part mould Design

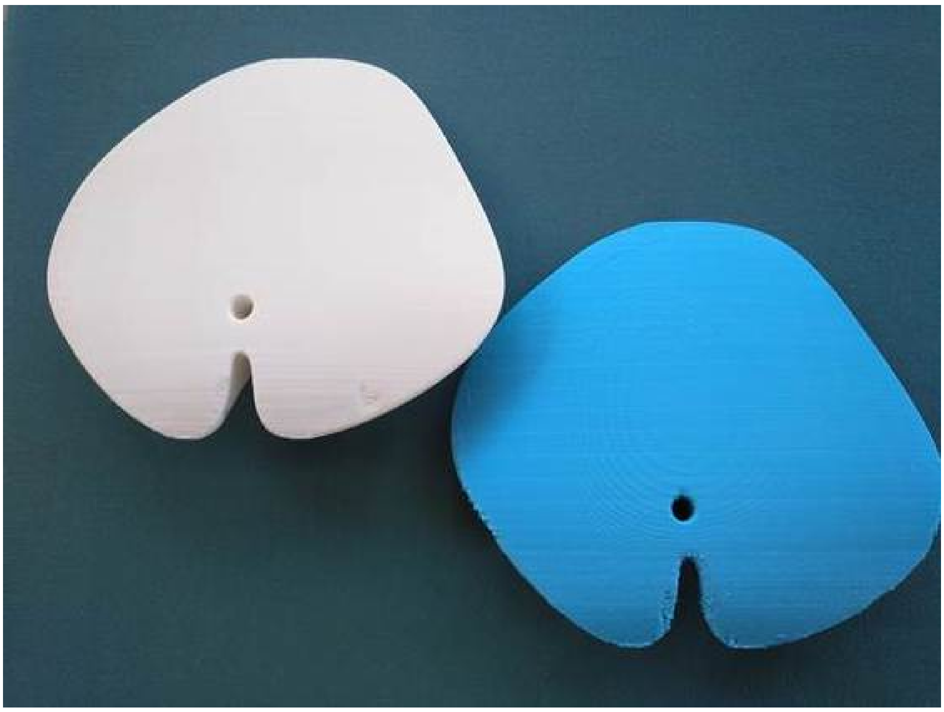

Figure 4.18: TPU flexible printed prototype

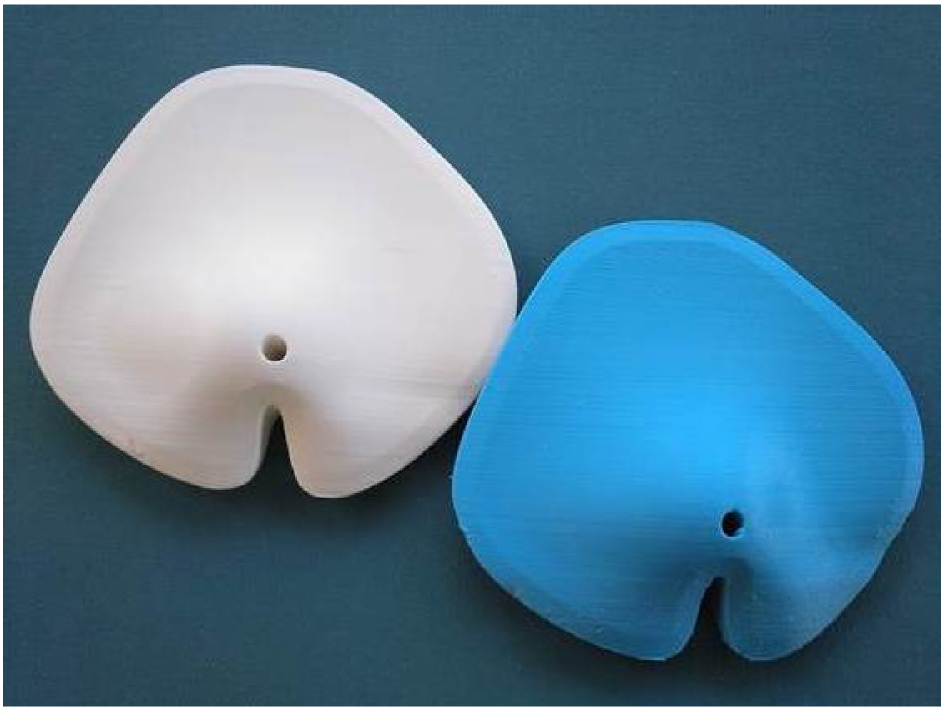

Figure 4.19: TPU flexible printed prototype

Figure 4.20: TPU flexible printed prototype

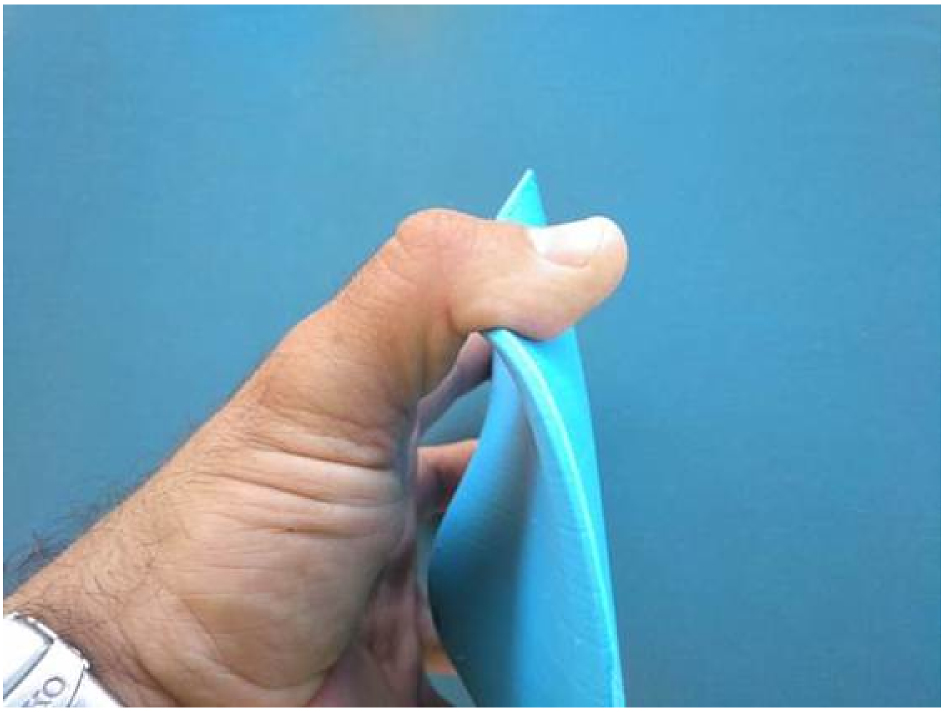

Figure 4.21: TPU flexible printed prototype

4.1.1 Design methodology

What we have done here is clearly a custom made case, an unique piece. But every pectus excavatum prosthesis can be obtained following the same steps, that is why my supervisor wanted me to spend more time and develop a design methodology. It will slow the first case, but accelerate every future case. In 10 steps, the designer will finish the prosthesis:

1- Generate the 3d surface from the DICOM received
2-Import it to the design software.
3-Create a sagittal plane, it will depict the center line of the final prosthesis.
4- Generate a surface and adapt it to the sternum and rib curvature. This surface will define the "back" face of the prosthesis, the side that rests in contact with the imperfection. So, take time to adapt it as fit and close and possible
5-From a front view, fix a point in every rib. Every point should be placed, on the spot that is the most advanced in space, the vertex of the rib. In a normal chest, this point would be in the sternum, but in these cases the sternum is sunken. If we identify the "tallest" points from a bottom view or the most advanced from a side view, they will point a the limits of the prosthesis.
6- Generate a surface that touches the points generated in the previous step. It will define the "front" face of the prosthesis. It will need some adaptation to completely fill the defect as seen in Figure 4.5. Join the points with splines and remember that, at the bottom, centered, we will always need a vertical cut or space to allocate the diaphragm and abdominal muscular insertion.
7- Make sure both surface are crossing and through a "boundary fill" command, obtain the volume trapped between both surfaces.
8- From a front point of view, extrude a surface that matches the splines generated in step 6. And, again, through "boundary fill" command, obtain the desired volume. This surface will define the borders of the prosthesis (as seen in figure 4.7).
9- Smooth borders applying fillets or rounding edges.
10- Extrude a hole, 1 cm above the lower central cut. This hole is a solution, if the patient has a very thick abdominal and diaphragm insertion and the surgeon needs to gain extra space for the insertion.

Every case is unique, but following these steps, and allowing certain adaptation in every new case, they should guide the designer through the easiest and most direct way to success.

4.2 Case study 2. "The crumble"

Before the Internship started, I told my supervisor that I wanted to develop a small product line. And even there, I sent him an explanatory text of what I had in mind. Let me quote myself in that text (..."I propose a thin porous sheet or plate (3-5mm) that allows a guided bone growth through the piece, and avoids the post- surgery horizontal bone loss"...). I came up with this idea before the internship, but after several conversations with my supervisor, and few slight concept adjustments, it did evolve even more.

We wanted to achieve a titanium matrix so fragile, that the surgeon could break parts and adapt it to whichever kind of bone defect he/she was facing. As seen, as an illustrative diagram in Figure 4.22

We wanted to produce a standard line, consisting on a sterile 10mmx10mmx10mm Titanium cube of high porosity. The Titanium would keep its bioinductor properties while its fragility would allow the surgeon to model it to defect during the surgery, and even drill it after 6 months of bone regeneration. It would accelerate the bone regeneration and, most important, would maintain bone volume and avoid marginal reabsorption by giving a structure for guided regeneration.

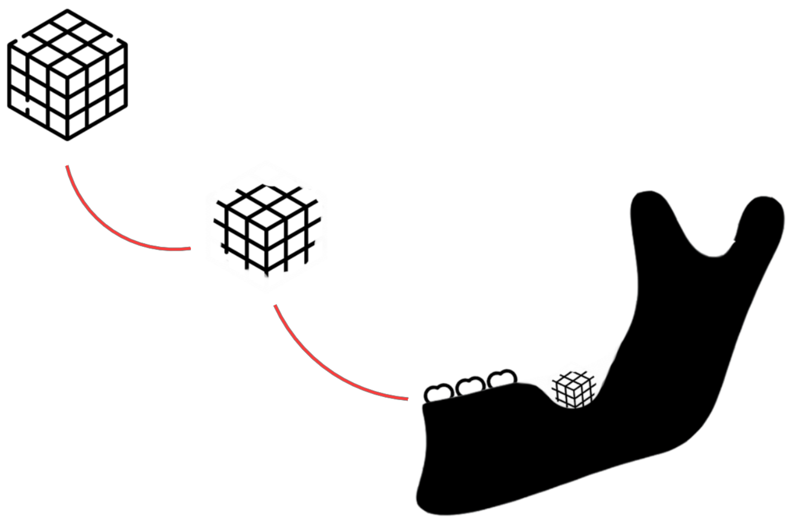

Figure 4.22: Technique's diagram

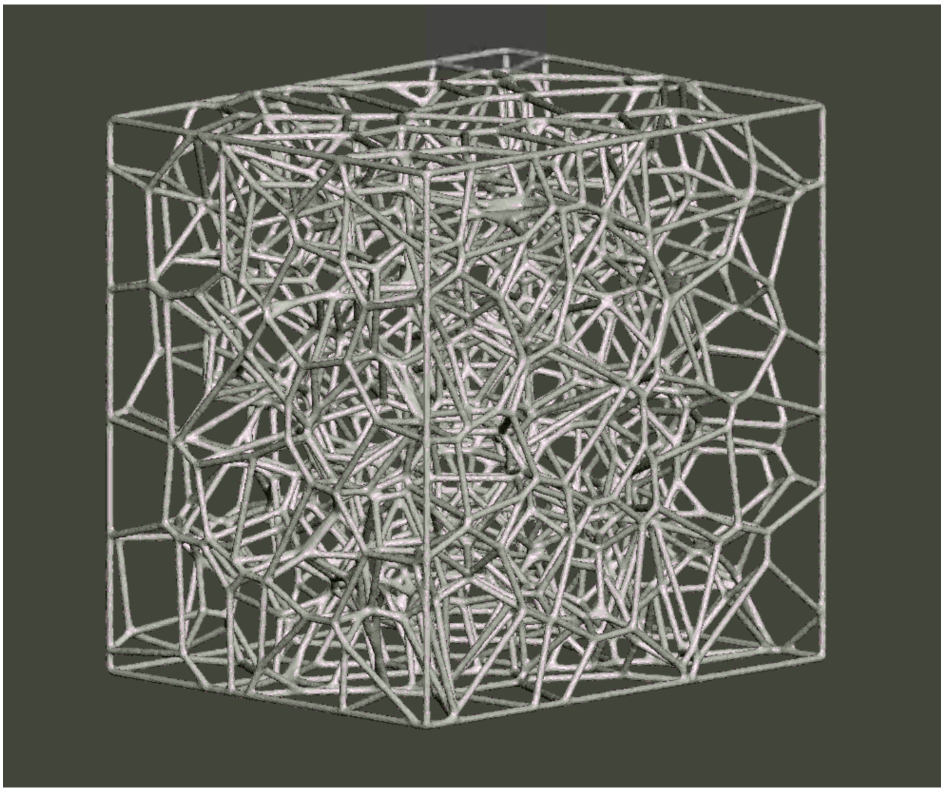

Figure 4.23: Cube sample 1 (designed with 3dstudio Max

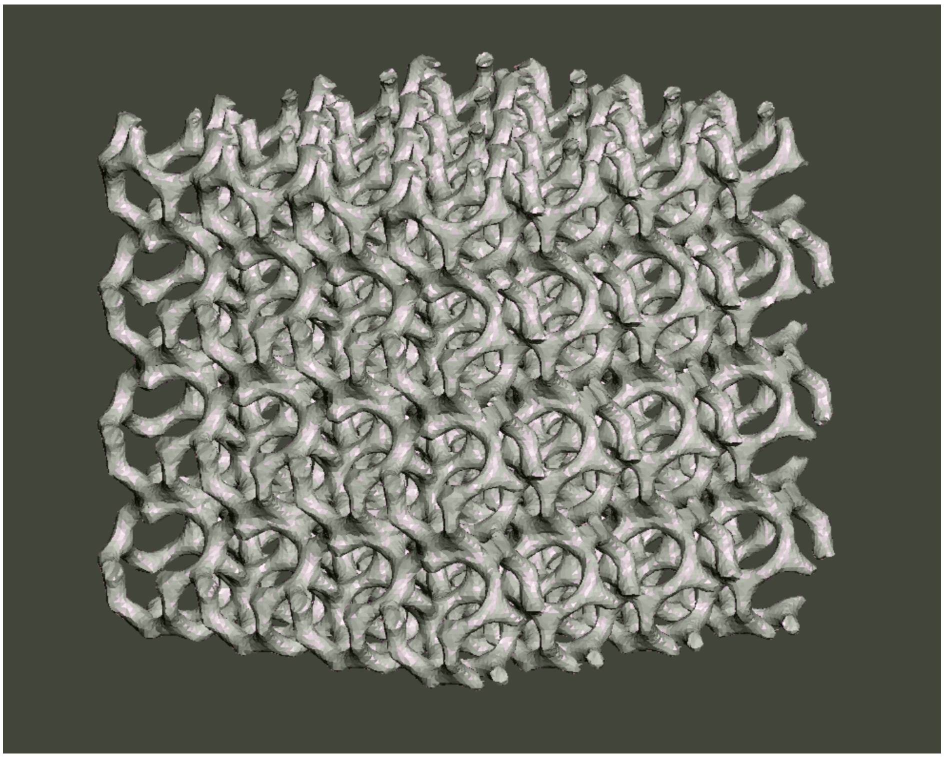

Figure 4.24: Cube sample 2 (Designed with k3dsurf and Magics)

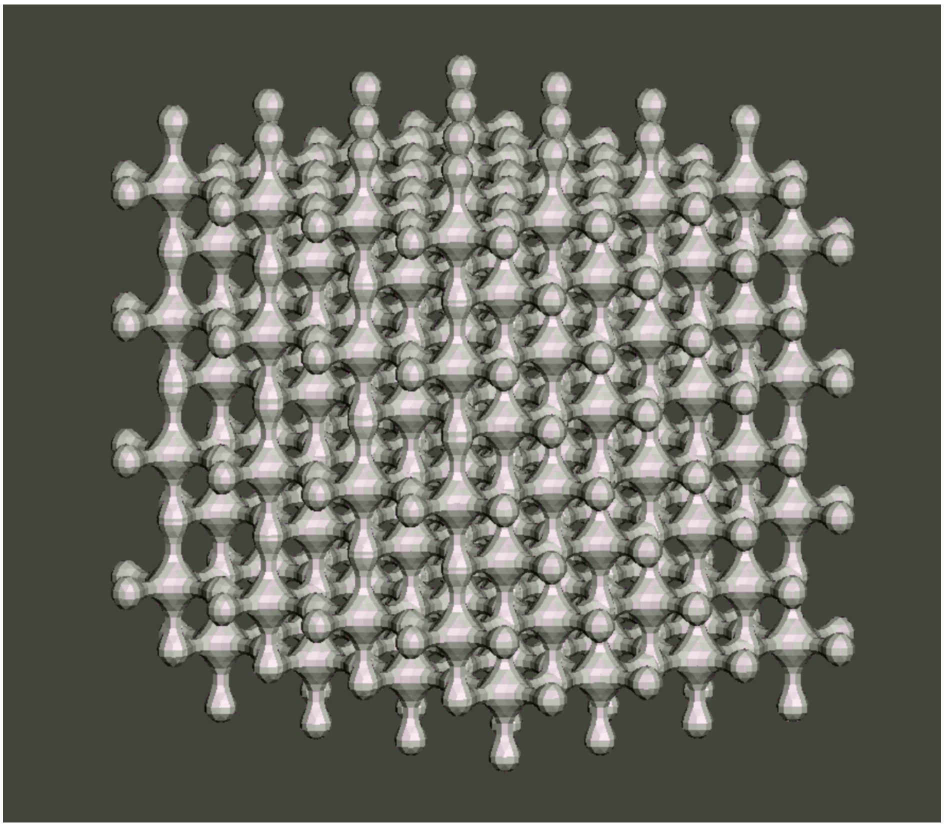

Figure 4.25: Cube sample 3 (Designed with k3dsurf and Magics)

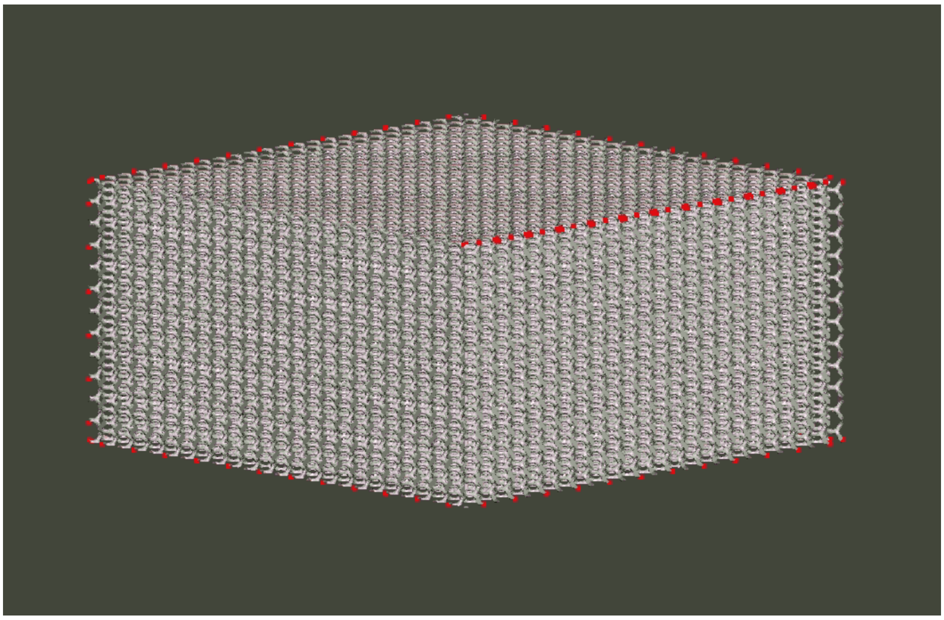

Figure 4.26: Cube sample 4 (Designed with Fusion 360 and Magics)

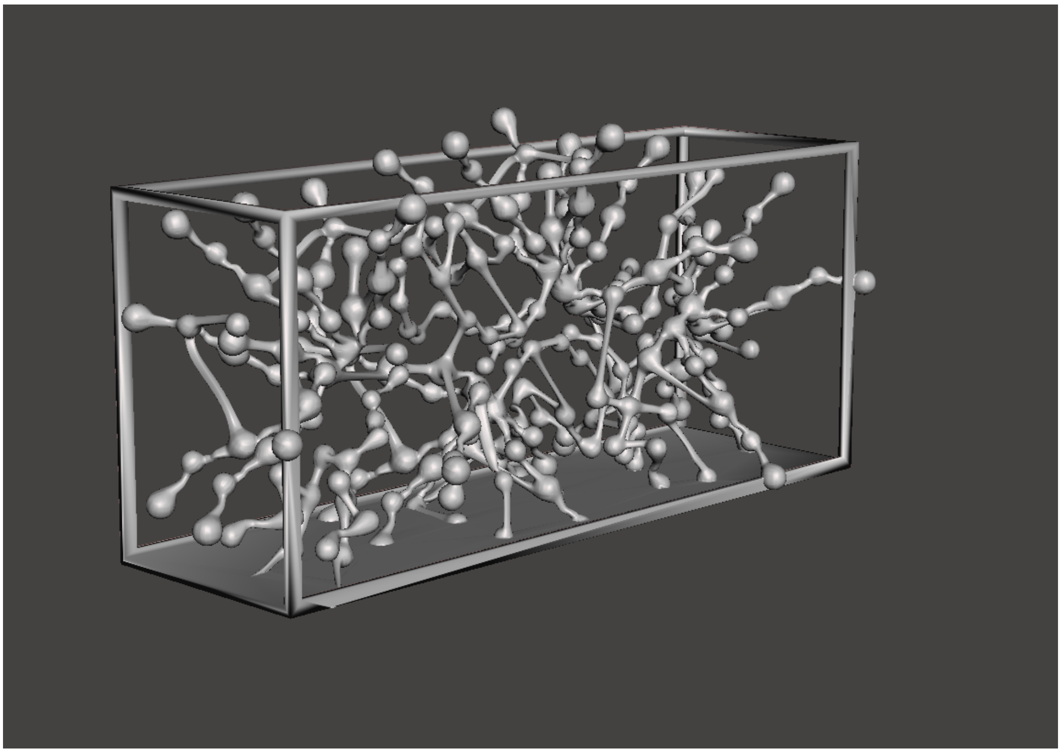

Figure 4.27: Cube sample 5 (Designed with Fusion 360 and Magics)

I designed many different porous patterns and set them for debate due to its achievable characteristics. Some of them are shown in Figures 4.23, 4.24, 4.25, 4.26, 4.27. Some of them were generated mathematically through softwares like k3dsurf (mathematical surface generator softwares) while some others were designed in Fusion 360 and 3Dstudiomax by myself.

At some point, I thought that the cubic structure and the surgeon modelling it during the surgery might not be the best option. There I thought that a cylindrical structure would adapt easier to the defect. A hole in the middle would act as a guided drilling point. I designed the desired cylinder as another option and a design exercise (Figures 4.28 and 4.29). There has been studies along the history of dental implantology of hollow cylinders [12] [13].

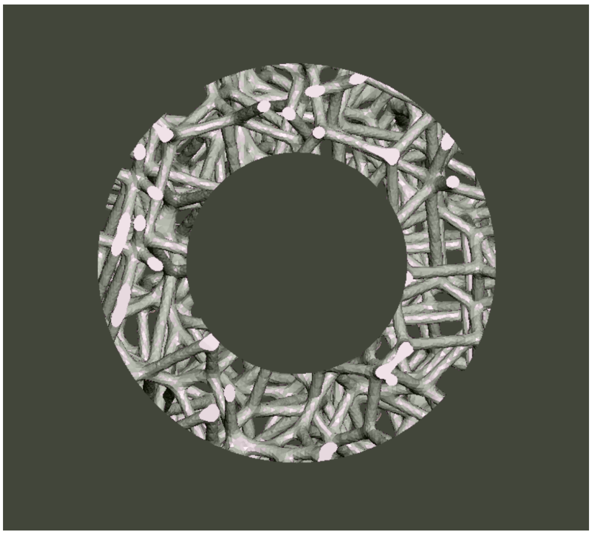

Figure 4.28: Cylindrical sample

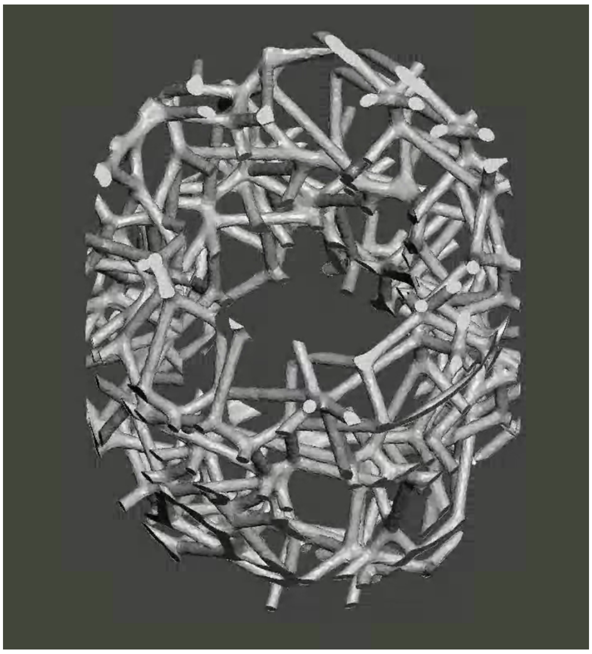

Figure 4.29: Cylindrical sample

I was not completely happy with the technique at that point so I sat and debated with my supervisor, we talked about CE and licensing. The company does not hold a CE for standard line production, only for custom made cases. So I decided to give the technique a twist. Even though the product has its chances both in a cubic and/or cylindrical shape, we had to adapt it to our current license situation.

Adaptation was easy, the purpose of the technique is to solve serious periimplantitis related situations. Periimplantitis rates are increasing due to the increase of implants placed per year worldwide. Which means that cases can be treated individually, as we do with any case, through DICOM files. The crumble would not have to be adapted by the surgeon during the surgery, reducing its contamination possibilities. It would be directly designed and manufactured with the desired shape to fill the post-periimplantitis bone defect.

The design methodology is easy.
1- Treat the DICOM files received in order to generate a quality, artefact-free 3d surface.
2- Create a form that fills the periimplantitis defect (grey form, seen in 4.30)
3- Boolean that form with a porous predesigned structure. Following these steps we obtain the final titanium piece (as seen in figure 4.31 and 4.32)

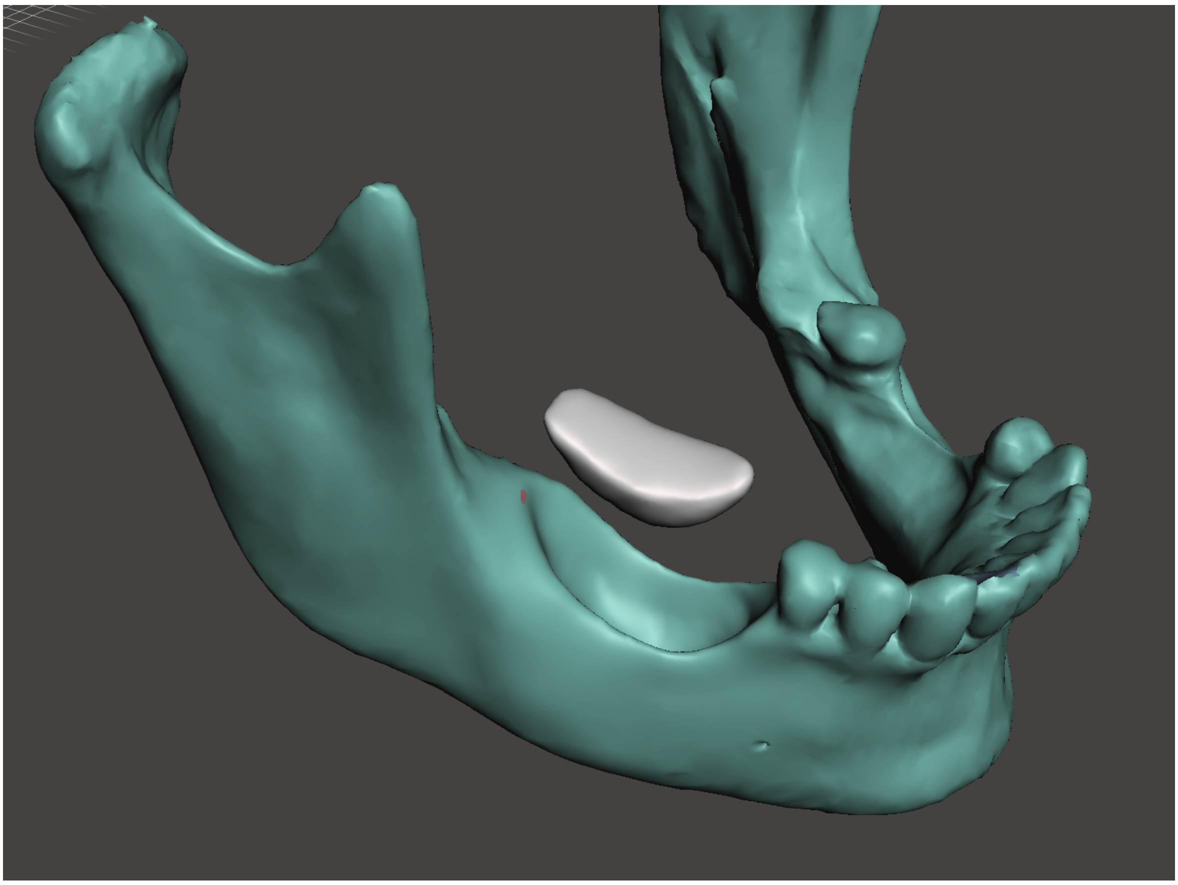

Figure 4.30: Defect adapted solid

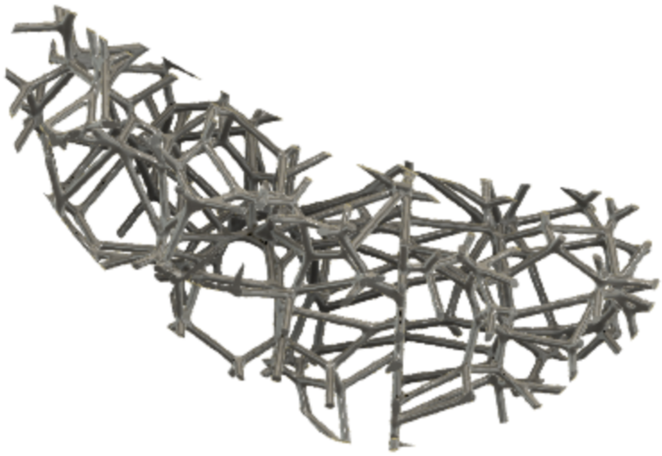

Figure 4.31: Defect adapted porous structure 1 (booleaned with cube shown in Figure 4.23)

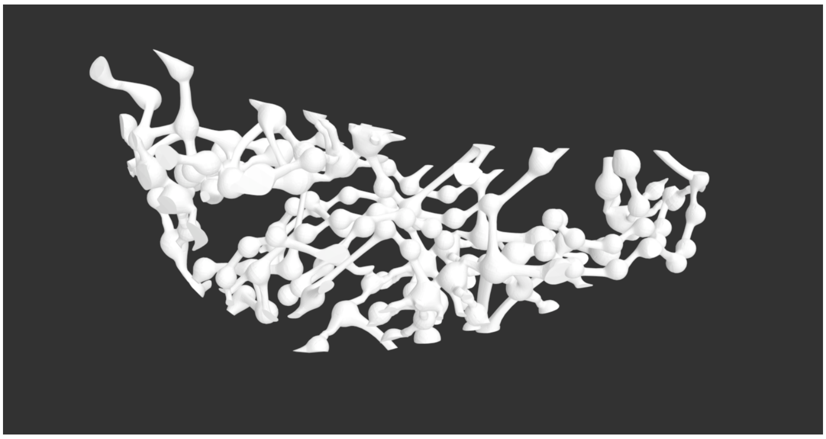

Figure 4.32: Defect adapted porous structure 2 (booleaned with cube shown in Figure 4.27)

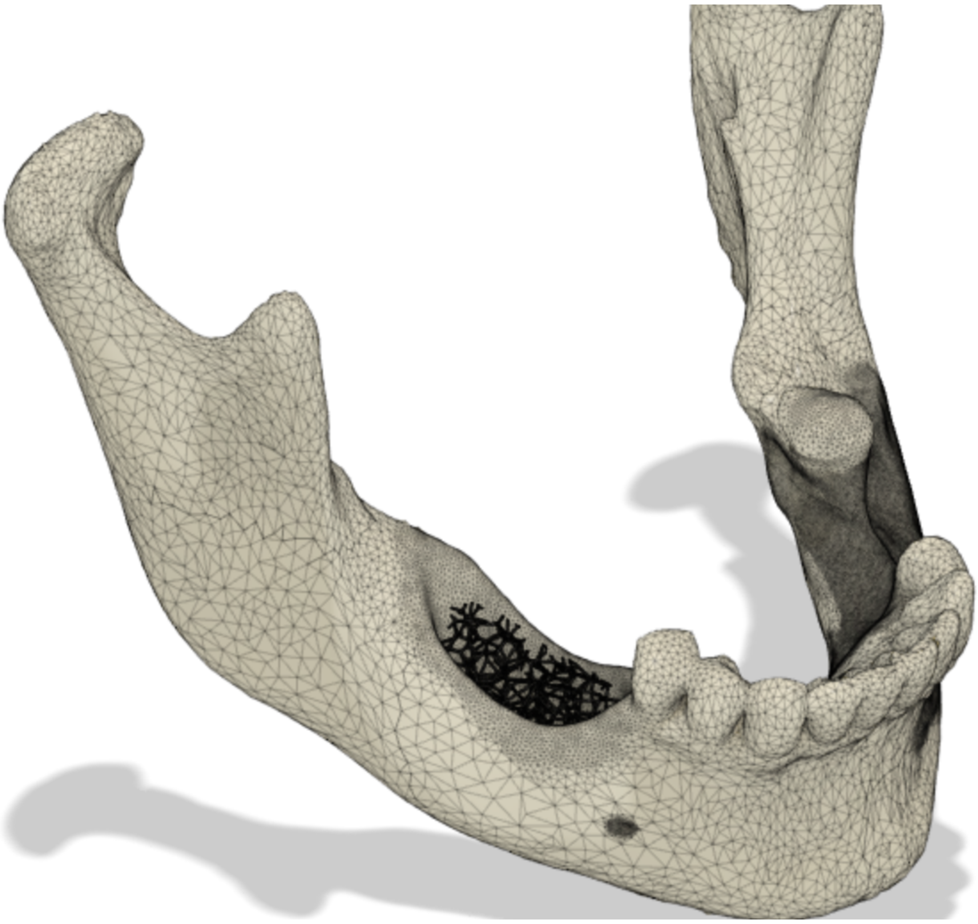

Figure 4.33: Technique Final Result

Figure 4.34: Real prototypes

Figure 4.35: Real Prototypes

My supervisor told me that when they received the ARCAM (EBM) and started tweaking the settings, they had a few prints in which the pieces were weaker than normally. Some of them even collapsed or crumbled when squeezed. At that moment, we realized that we had to look for a "printing failure" in parameters in the EBM. That way, instead of obtaining solid resistant pieces, we would obtain what we started calling "a crumble". On the other hand, we could not exceed ourselves when twisting parameters, or the piece would disintegrate in unsintered fine Titanium powder, which would migrate through vessels all over the host's body. We needed to achieve a balance. When we reached that point, the EBM broke. It was officially, and will be for a long period broken. That situation set a solid limit for my investigations, tests and product development.

Through that "printing failure" would have been an interesting way to obtain what I desired, and learning about EBM settings and Titanium properties. Instead, I had to adapt, and started designing thinner bars, in order to keep the piece fragile. Prototypes are shown in Figures 4.34 and 4.35.

A competitor in the market

A company named Tigran produces a interesting, although different product[14]. The product is called Tigran PTG, and it basically is sterile Titanium granules, that can be compacted in a bone defect, as seen in figure 4.34. It is normally used in periimplantitis defects. Some studies are doubtful about its behaviour in long term and, apparently there might be even some granule migration if we look at X-rays records (as seen in figure 4.35)[15].

Figure 4.36: Titanium granules used as scaffold for bone growth

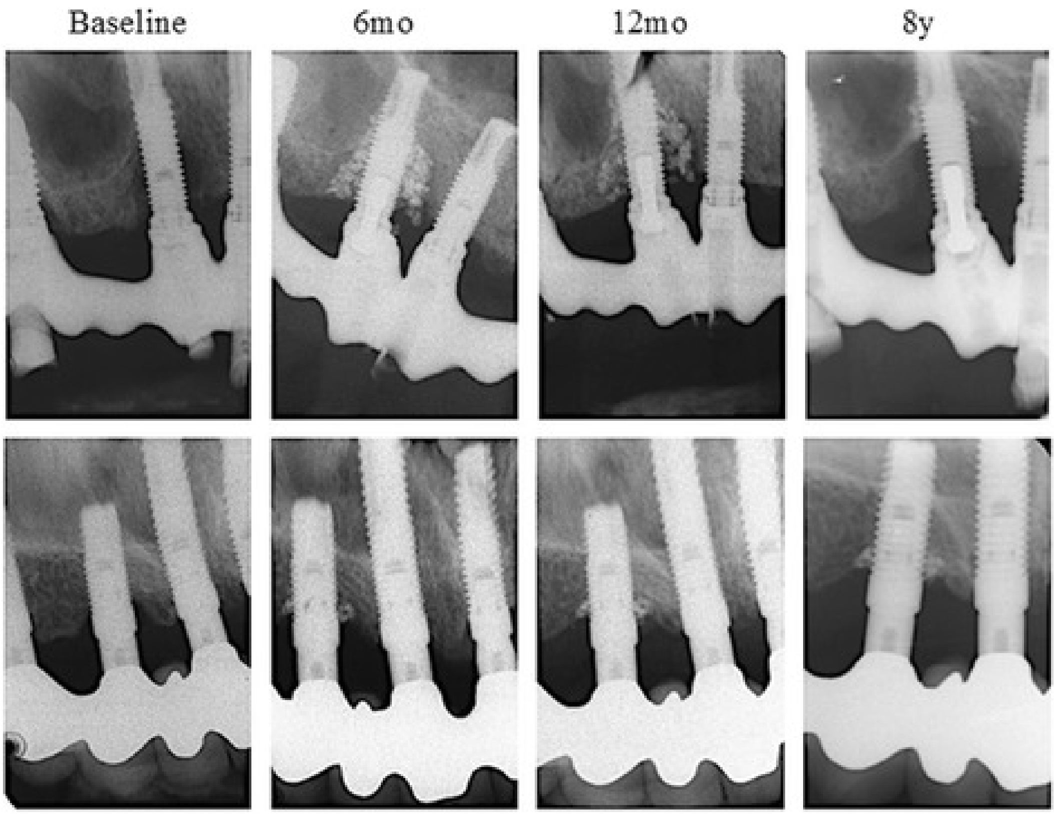

Figure 4.37: 8 year evolution with PTG, no improvement evidence was found

4.2.1 Future drift

The importance of this study, and thereby this technique relies not only on the technique and product in itself, but also on its future possibilities. Now we know that the bone response characteristics that the Titanium will induce are more than positive, but Titanium has drawbacks as well. If an infection appears on such a complex structure, removal would be difficult. On the other hand, if osseointegration occurs with no complication, it will have to be drilled in 6 months. And even though we are designing to achieve the thinnest and most fragile structure that we can design, Titanium is still a metal and it can generate and conduct heat when drilled. If the drill is not performed very carefully heat will be conducted along the structure and pass onto the surrounding bone. Heat while dental implant surgery is one of the main factors for dental failure.[16]

Knowing the weaknesses and strengths of a material like Titanium, we did ponder alternatives. We thought for a while about 3d printing of reabsorbable biopolymers like Polylactic acid and Polyglicolic acid. And even though that would be the easiest to produce, it is known that both biopolymers can release acidic degradation products that can induce inflammatory response [17] [18], which means that in a delicate situation like a post-periimplantitis 2nd surgery, that characteristic would not be helpful. Biopolymers were discarded, but there were other options.

Reabsorbable bioceramics [19] and composites made out of biopolymers and hidroxiapatite are two interesting categories. The most widely used bioceramics are Hydroxyapatite and its related crystalline tricalcium phosphate. According to some authors "hydroxyapatite is a ceramic that allows not only the bioactive fixation, but cells and nutrients invasion to promote the tissue regeneration; however, it presents low mechanical resistance"[20] and Calcium triphosphate helps mantaining horizontal and vertical bone crest volume after tooth extraction [21] [22].

All these materials are wonderful options to explore and investigate, but the truth is that the company the I have worked for along the internship has no experience, nor machinery prepared for bioceramics or composites. Perhaps this paper paves certain paths for future studies.

4.3 Case study 3. "Porous chair"

This design line aims at custom made cases in which the patient experiences an intense horizontal bone absortion. This happens when, a few adjacent teeth were removed a long time ago. Every time a tooth gets removed, bone reabsorption starts. Reabsorption can happen horizontally and vertically. When more than one, adjacent pieces get removed, vertical reabsorption starts, which means we lose 1 mm of bone height per year. If the piece does not get restored, and time passes, along vertical reabsorption, horizontal reabsorption starts, which means that the crest where the teeth were gets thinner and thinner, turning eventually into useless bone for implantology purposes. As seen in Figures 4.38 and 4.39

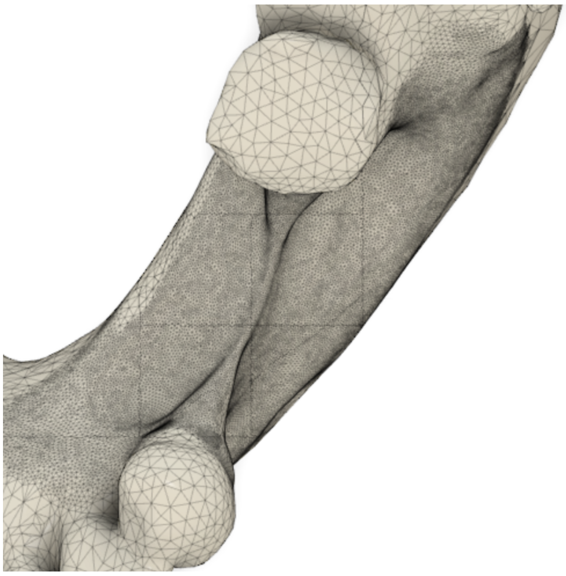

Figure 4.38: Horizontal reabsorption

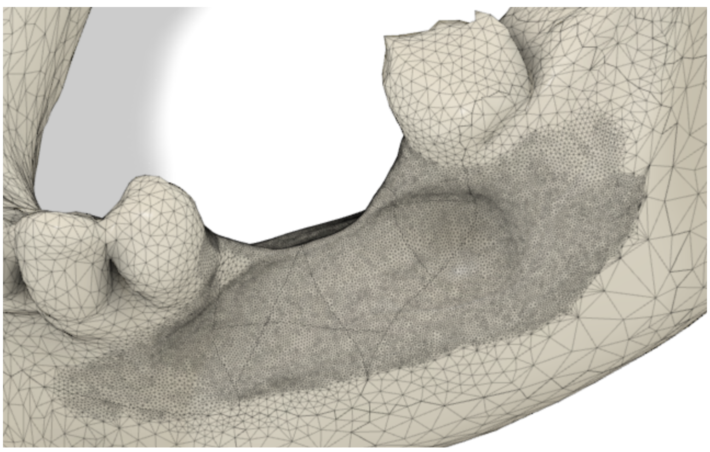

Figure 4.39: Horizontal reabsorption, called "knife" crest

The idea was to use that crest to allow an engineered structure to rest on the crest (as see in figures 4.40 and 4.41).

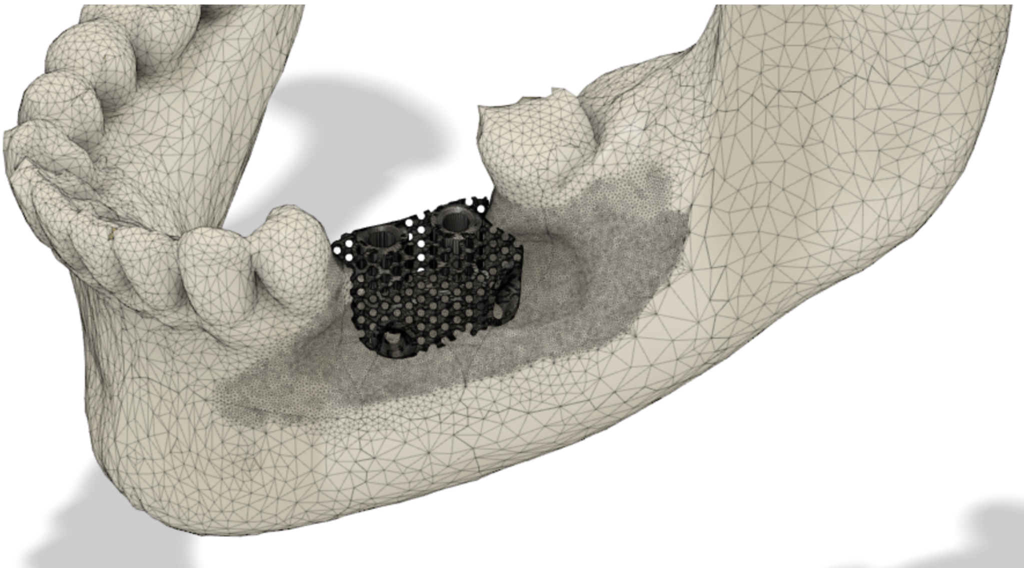

Figure 4.40: DESIGN LINE 3

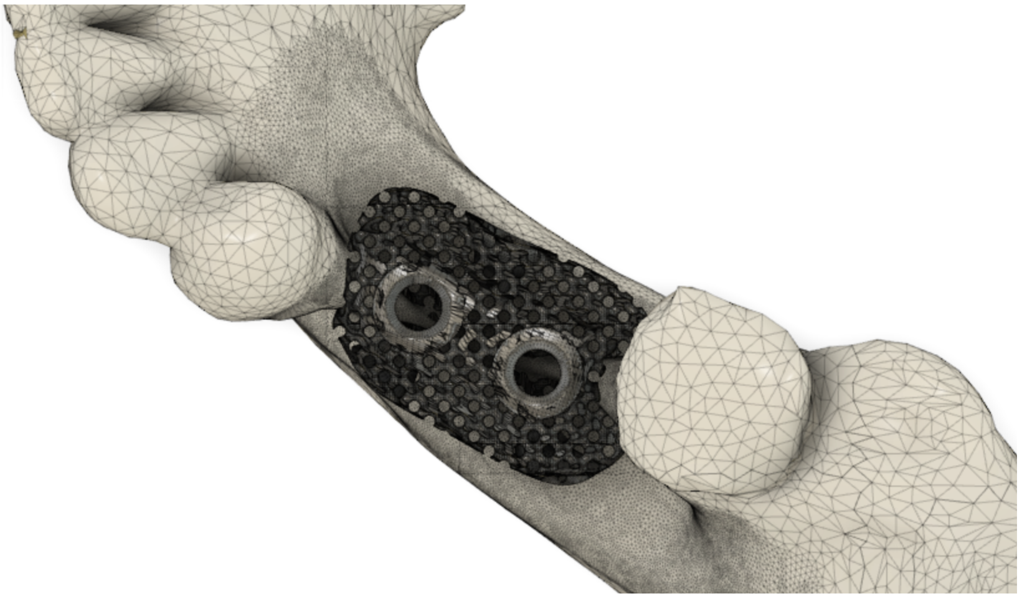

Figure 4.41: DESIGN LINE 3

It is clearly a custom made case, because each crest in each patient will be different. Each case can demand different requirements but mostly, the piece will have 3 attachment entries, a porous structure as the main matrix and two upper "female" tapers cones. The morse tapers will accommodate a multiple teeth restoration. The custom made porous structure will allow bone to grow through. The pin attachments are there to achieve a primary stability using pins and/or needles. As seen in Figure 4.42.

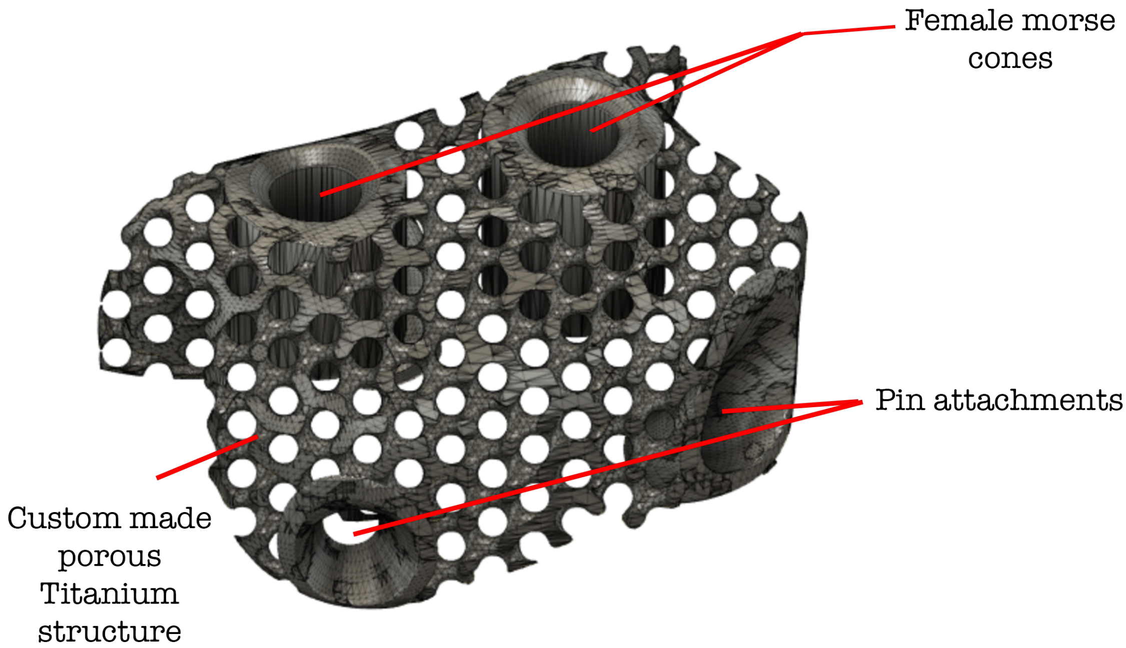

Figure 4.42: Technique's Diagram

An FDM 3d printed jaw model is shown in Figures 4.41, 4.42 and 4.43 with an EBM Titanium "Porous Chair" prototype sitting on top. The main drawback, as shown in the SWOT analysis in Figure 4.46, is that, even though Titanium is a bioinductor material, there is a limit for bone growth induction. This piece defies nature in terms of bone growth, it is not reallistic to think that bone will grow through the entire piece ad cover it completely (more than 5 mm). Personally, I decided to left this case as a design exercise and to admit that its limitation were to big to be solved.

Figure 4.43: DESIGN LINE 3, Titanium EBM printed prototype

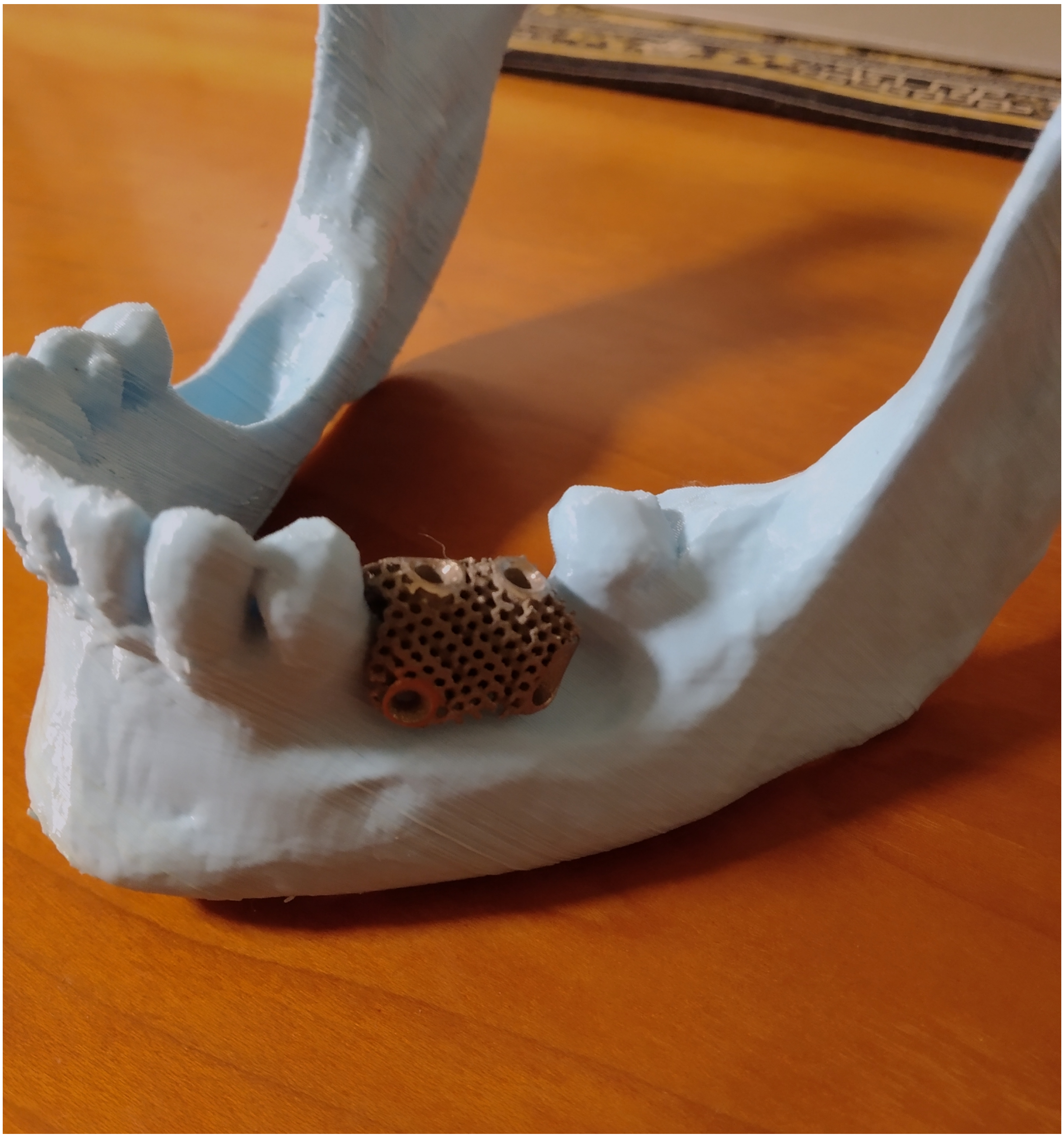

Figure 4.44: DESIGN LINE 3, Titanium EBM printed prototype

Figure 4.45: DESIGN LINE 3, Titanium EBM printed prototype

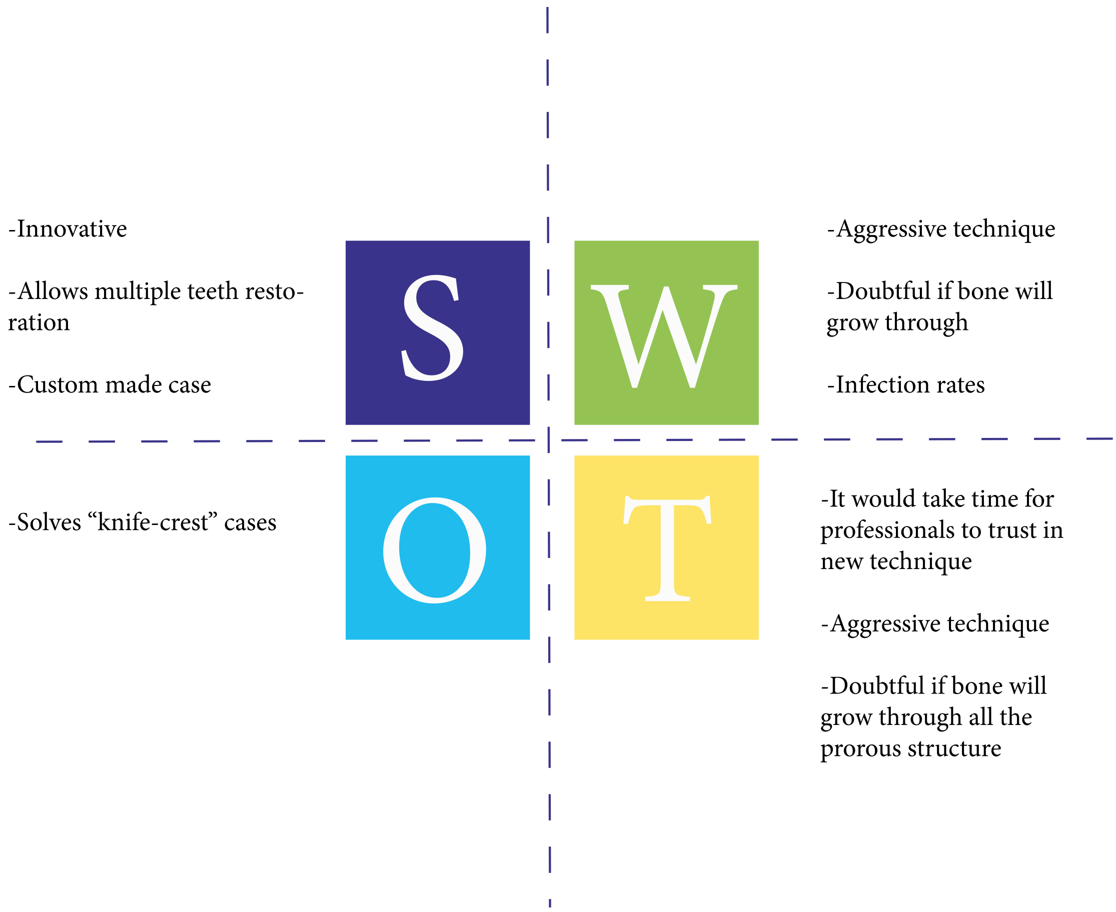

Figure 4.46: SWOT analysis

4.4 Case study 4. Dental Implant line

Being a company that has a broad knowledge of Titanium and it's manufacturing processes, it was hard not to think about a standard dental implant production line. Modern dental implantology has more than 50 years [23] of evolution and dedicated studies. According to the American Dental Association, around 5 milion dental implants are placed yearly, only in the United States [24], and a value market of 1.1 billion dollar in 2019 only in the United States, and expected to rise up to 1.5 billion dollars by 2025 [25]). When my supervisor told me that the CNC Lathe that was waiting, still in its original box, was a Multispindle CNC Lathe (HANWHA XE20H), I realised that that particular type of machine is used for dental implant manufacture. I proposed him to develop a Dental implant line (few designs with different spirals and self-tapping cuts shown in Figure 4.47).

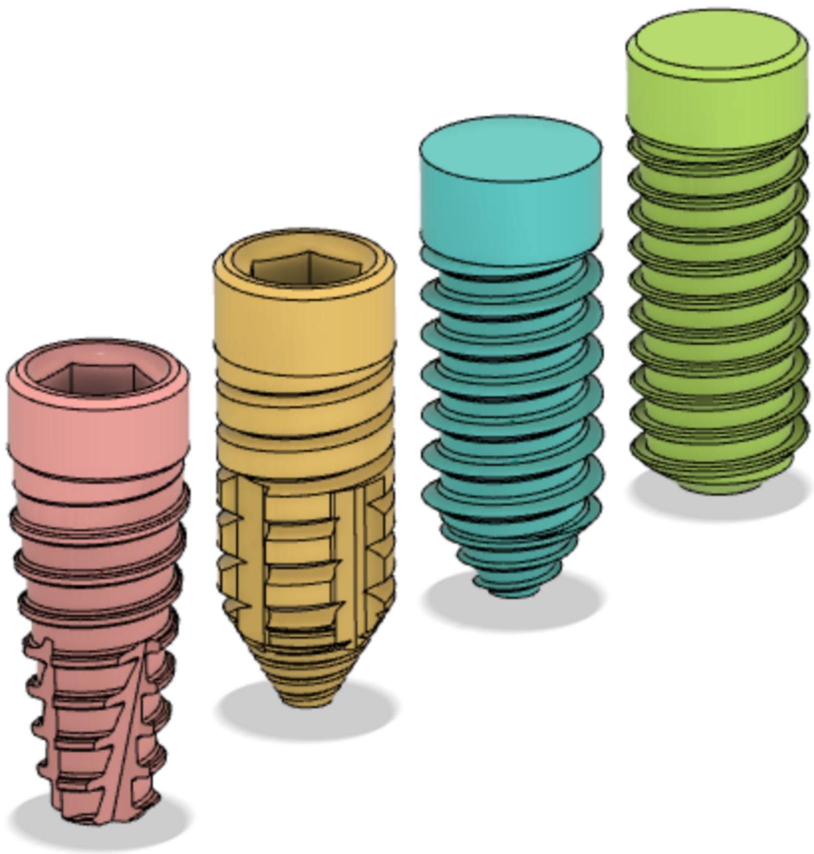

Figure 4.47: Dental Implant macrodesign

In order to test the viability of the product I decided to produce a prototype. The CNC Lathe that we currently have has plenty of limitations in this field. Self-tapping cuts can't be done in it for example. Timewise, the actual CNC Lathe is very slow for a full production line, while the Multispindle works with two pieces at the same time, machining first one side, then the other, speeding up the production line considerably. Even with this limitations I moved ahead

and pursued a prototype.
As it can be seen in the SWOT analysis (Figure 4.48), in the weaknesses category, we, as a company can not manufacture standard product according to the European certification regulation. That point left this project in a legal limbo, which made it impossible to occur. Even so, it was very interesting observing how the dental implant market operates and how a single unit was produced. So, I advanced and produced a few prototypes (seen in Figures 4.48 and 4.49).

Figure 4.48: 3d generated surface

Figure 4.49: 3d generated surface

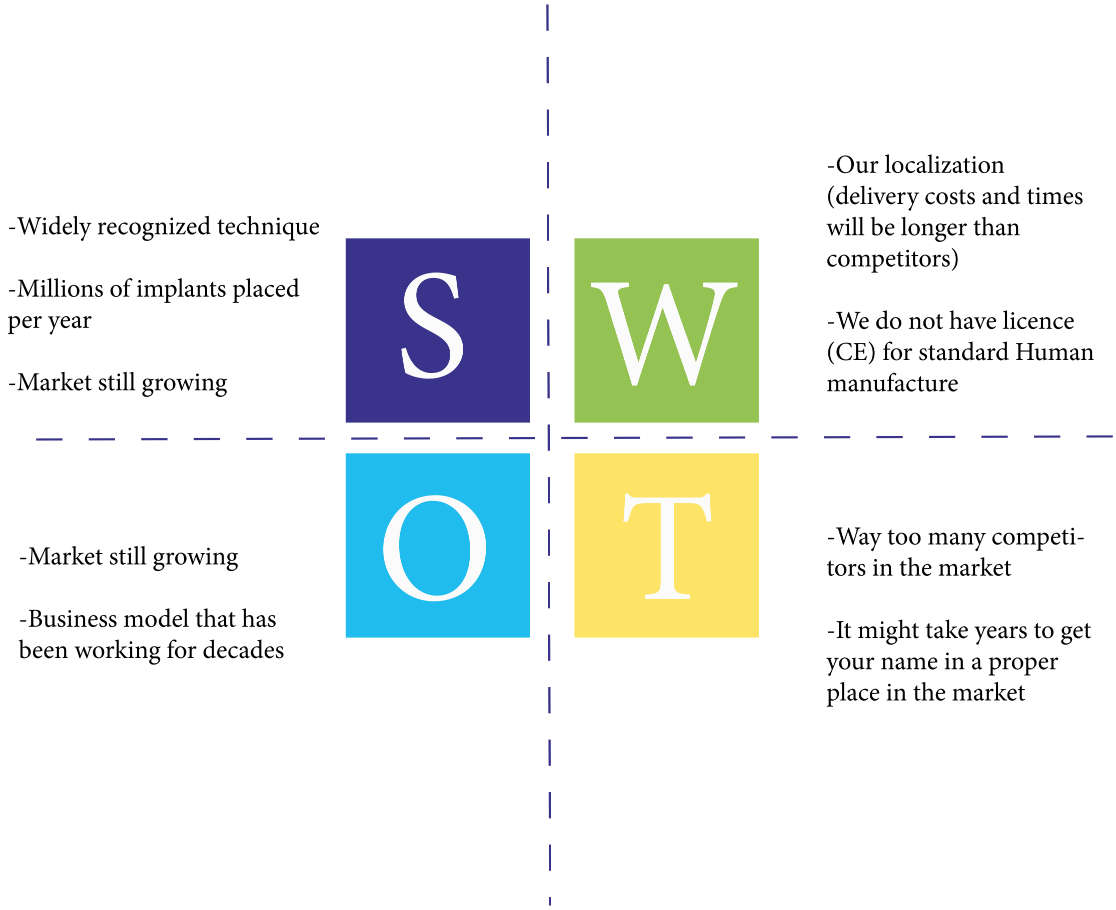

Figure 4.50: Dental Implant macrodesign

5 Our COVID-19 interpretation

The 14th of March, State of alarm was declared allover the Spanish territory. Due to COVID-19, we were forced to remain at home until the 1st day of June. As it happened all over Europe, people whose jobs allowed it, were forced into remote work. My supervisor forced me to remain doing the internship remote. It is interesting that this happened during my internship. I think the paradigm of works, offices, worksites in general has already been modified for good. Jobs that allow computer based work will no longer be held at the worksite for 40 hours/week again. And even though it is such a negative situation that we face nowadays, I think it is an interesting situation that I learnt still as a "student".
As a company, we had to admit that during a worldwide pandemic, the demand for custom made prosthesis for humans would peak down. And so it happened, we barely had 2 cases along the second trimester. Human surgeries stopped suddenly. Doctors and healthcare systems were worried about the new situation, and they were readjusting their forces towards the Coronavirus situation. And this was a huge learning of how a small industry makes its living, and how one of your economic pillars collapsed in a matter of days. This is a learning beyond the academical and beyond the technical/design competences that I have gained along this year. Diversification is really important for small industries. We saved our trimester thanks to the veterinarian market. Our prosthesis for the animal market are standard, not custom made. And suddenly the worldwide demand for these prosthesis increased considerably.
The entire team was working remote, except for the Machinery Manager and one technician who were trying to fix the upcoming problem. It is said that "misfortunes never come alone". The EBM got broken 1 week after the state of alarm occurred. Somehow it was a good moment for the EBM to collapse, because custom made prosthesis manufacture was on zero demand, and we had plenty of stock for the animal market. But at the same time, technicians from ARCAM (headquarters in Sweden) could not fly over to repair the machine. They tried guiding our Machinery Manager in order to repair the EBM, but they didn't succeed. Still nowadays, the EBM is not working. They were suspicious of an error at the vacuum seal. The machine was not creating the airtight environment needed. They tried seal substitution, front glass substitution, and many other small pieces replacement. They couldn't find what was creating the malfunction. Finally, ARCAM claimed that the machine was too old, (bought in 2008) and that they couldn't ensure proper function after all these years, the lifespan of the machine was over.

Along these 2 months I helped in stock duties, developed a few design cases and started cooperating with an organization printing face protective shield.

5.1 Carafe

My supervisor tends to propose alternative projects that can enter the market either locally, nationally or internationally. Amid this Coronavirus (COVID-19) crisis, Spain and most countries in Europe faced a shortage in the health or biological barrier protection elements (masks and protection shields). Pharmacies, specialized stores, medical suppliers and supermarkets ran out of mask supplies the first week of the COVID-19 crisis. He proposed me to design a 5 or 8 litre plastic bottle, a regular big bottle, which companies manufacture thousands per day. He wanted me to include a mask and a face shield protector within the shape that the plastic bottle would have.

Figure 5.1: 8L bottle design

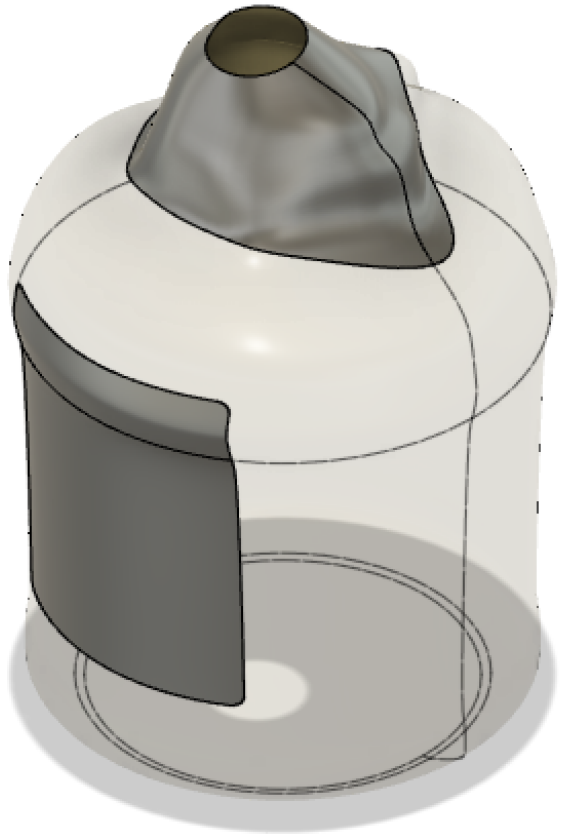

Figure 5.2: Parts to cut from the bottle

Out of my design you would cut (through guided gutters) 2 elements to protect a single individual in an biological emergency situation (as seen in figures 5.1, 5.2, 5.3, 5.4 and 5.5) to keep himself or herself protected until supplies reach the stores. The smart thing about this design is that it does not imply a higher waste of material, bottles are produced by thousands per day as said before. During a crisis period people will see the bottle as masks and shield protectors while during normal times, it would be seen as a simple water bottle.

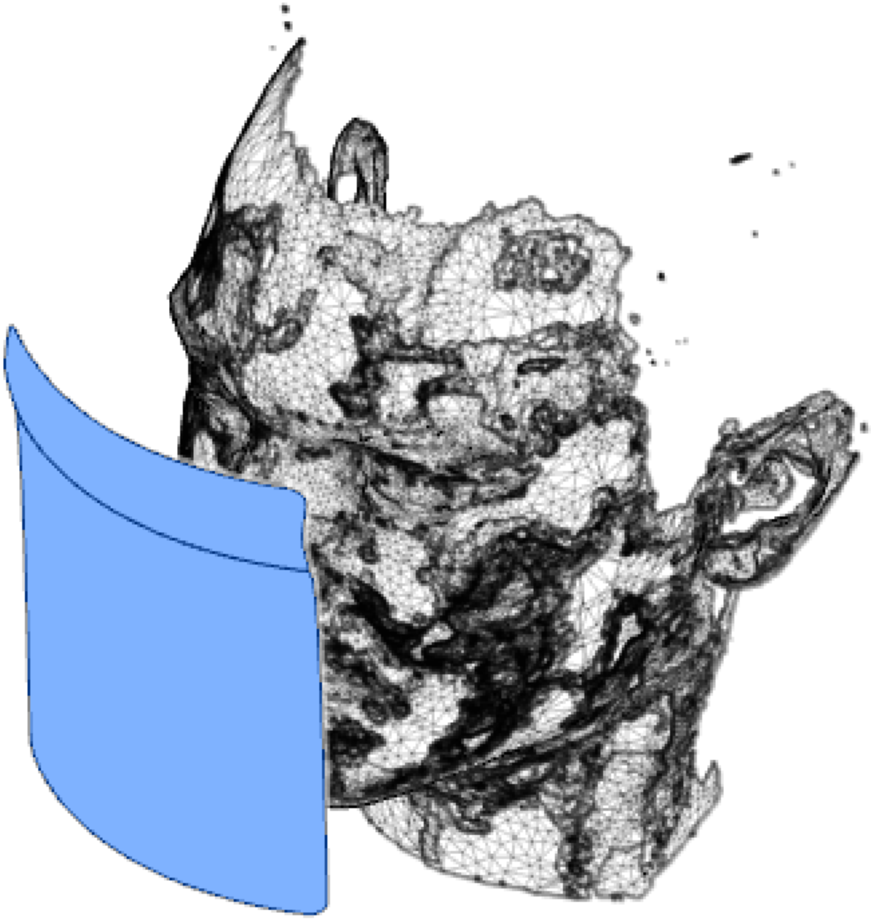

Figure 5.3: Face shield protector

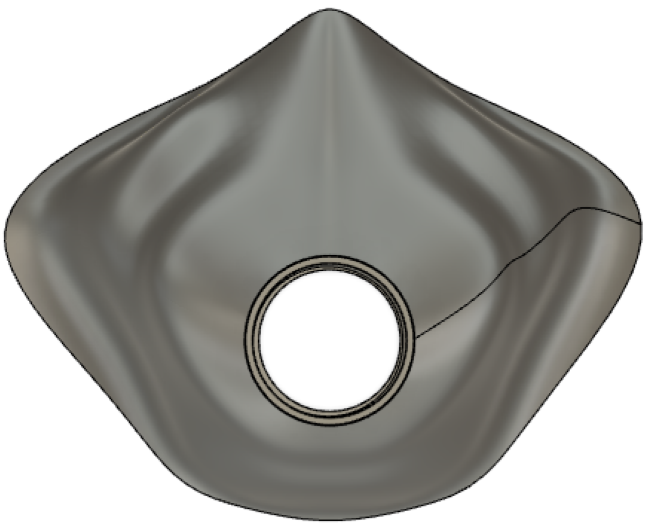

Figure 5.4: mask

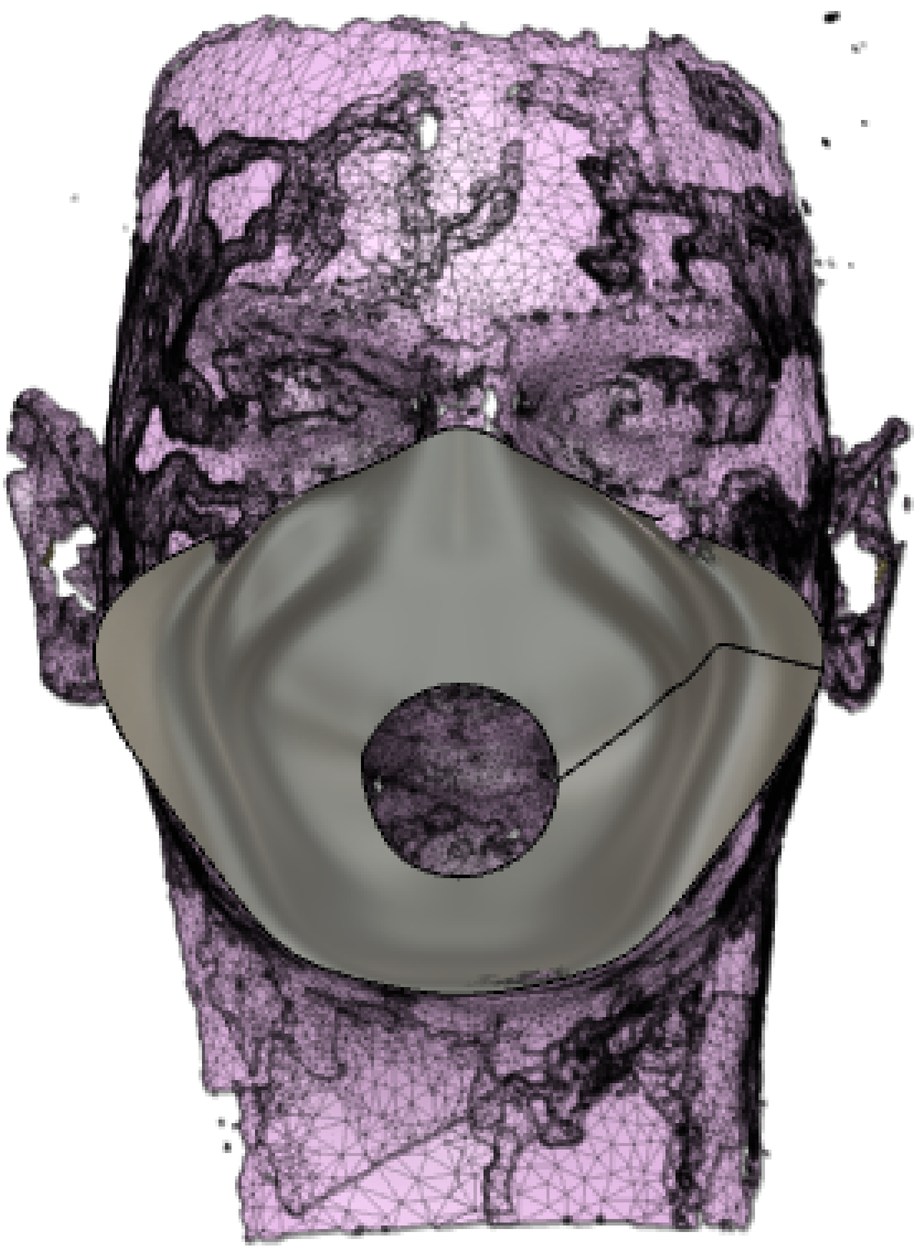

Figure 5.5: Mask adaptation to a real 3d(.DICOM)

The individual would cut the lid, keeping only the threaded surface. The lid of the bottle, now hollow frontally would be use to trap cotton, foam, gauze or similar fabric to allow air to flow through. A rubber band will be placed in both sides of the mask to allow it to self sustain around the head.

5.2 Face Protection

I started cooperating with a non-profit association that contacted people with FDM 3d printers in order to produce as many face shield protectors as possible in order to handle them over to people that were still working facing public , and for regular people, so they could be protected when leaving home. About 100 hundred units left my FDM (as seen in Figures 5.6 and 5.7). This was clearly not part of the internship, but my supervisor was aware of it and agreed for me to spend some time of my working hours collaborating.

Figure 5.6: FDM printed Face shield structure

Figure 5.7: FDM printed Face shield structure

6 Conclusions

A thesis might look for a final result, numeric, an observation or a verification. A project might look for a final (physical or digital) product. After an internship, the greatest conclusion that one can get is how much that person has learnt.

Regarding where I have spent this past 10 months, I could not have found a better company in the Canary Islands to develop this second year of the Masters Degree. It has been stimulating to have freedom of design and to debate any design line proposed by me, my supervisor or any peer in an atmosphere accustomed to do so. As stated in the introduction, my goal is to drift away from the clinical exercise and apply to the dental product manufacturers. I think that this internship is a first step in that direction.
Other goals were to improve design skills and software knowledge, which I honestly reckon I have achieved. Also, to develop a few products, prototype them and if possible, test them. Most of those goals have been achieved and depicted on this paper.
I have learnt the importance of methodologies when talking about design and product development. I have also learnt that when you build your own company and compete in the market with others, it is really important to take care of your products. The finer you finish and detail every single unit that leaves the building it your best advertisement. It is important, then, to understand materials, processes and how to treat them. That is why I value even more what we studied last year.
In order to summarise and conclude each case that has been presented and how far I reached:
1.The pectus excavatum moved forward reaching the doctors hands. Sadly, due to COVID-19, non essential surgeries stopped on most of our clients. Case might continue in some time if things get better, hopefully.
2.The crumble is a product that, as shown here, has already been prototyped. In order to move forward, it should be implanted in animals (more than one) in order to evaluate, in short-term and long-term its osseointegration, infection rates, drilling resistance and more parameters.
3.The porous chair was a design exercise. My supervisor had the idea and insisted on me developing it. I insisted that the bone growth was a big handicap as a technique. Still, it was interesting to design it and prototype it.
4.Dental implants. Our CE certifications and the multispindle lathe still unboxed were a big obstacle, but a good design exercise and prototyping exercise.
5.The carafe was a marvelous idea, and an excellent design exercise, but machining a mold is a big expensive task, that the company couldn't afford and had no previous experience.

Thereby, I conclude that my knowledge in Additive Manufacturing (EBM, FDM and SLS), Titanium as raw material and its properties, several other materials, design skills and CAD/CAM softwares, problem solving, design methodologies, team-work, brainstorming sessions, file formats, file preparation for additive manufacturing, post-processing, stock logistics have increased considerably along 2020. And so I consider this internship optimal for my growth.

Bibliography

[1] *osteobionix - osteobionix*. URL: http://www.osteobionix.com/#whyosteobionix.

[2] *biosurgex. Veterinary Implants*. URL: http://www.biosurgex.com/.

[3] Matthew J. Donachie. *Titanium : a technical guide*. ASM International, 2000, p. 381. ISBN: 9781615030620. URL: https://books.google.es/books?hl=es&lr=&id=HgzukknbNGAC&oi=fnd&pg=PR7&dq=titanium&ots=K1_Xke6A0L&sig=hskFWsTpozPXHTiTPRMfY-xhm8o#v=onepage&q=titanium&f=false.

[4] *ISO 14644-15:2017(en), Cleanrooms and associated controlled environments — Part 15: Assessment of suitability for use of equipment and materials by airborne chemical concentration*. URL: https://www.iso.org/obp/ui/#iso:std:iso:14644:-15:ed-1:v1:en.

[5] Eelco van den Berg, Willem F. Bronsvoort, and Joris S.M. Vergeest. "Freeform feature modelling: concepts and prospects". In: *Computers in Industry* 49.2 (Oct. 2002), pp. 217–233. ISSN: 01663615. DOI: 10.1016/S0166-3615(02)00080-5. URL: https://linkinghub.elsevier.com/retrieve/pii/S0166361502000805.

[6] *DICOM*. URL: https://www.dicomstandard.org/.

[7] Ana Robustillo Rodela. "Comorbilidad y factores de riesgo asociados a la infección de localización quirúrgica en artroplastia de rodilla". In: *undefined* (2016). URL: https://www.semanticscholar.org/paper/Comorbilidad-y-factores-de-riesgo-asociados-a-la-de-Rodela/82c9f15f3f1e4ca8567491bdae12b10840b9cbc9.

[8] Jukka T. Tuomi et al. "In vitro cytotoxicity and surface topography evaluation of additive manufacturing titanium implant materials". In: *Journal of Materials Science: Materials in Medicine* 28.3 (Mar. 2017), p. 53. ISSN: 0957-4530. DOI: 10.1007/s10856-017-5863-1. URL: http://link.springer.com/10.1007/s10856-017-5863-1.

[9] Carlos Nelson. "Factors Affecting the Success of Dental Implants". In: *Implant Dentistry - A Rapidly Evolving Practice*. InTech, Aug. 2011. DOI: 10.5772/18746. URL: http://www.intechopen.com/books/implant-dentistry-a-rapidly-evolving-practice/factors-affecting-the-success-of-dental-implants.

[10] S. Parsons et al. "Green chemistry for stainless steel corrosion resistance: life cycle assessment of citric acid versus nitric acid passivation". In: *Materials Today Sustainability* 3-4 (Mar. 2019), p. 100005. ISSN: 2589-2347. DOI: 10.1016/J.MTSUST.2019.01.001. URL: https://www.sciencedirect.com/science/article/abs/pii/S2589234718300149.

[11] Christoph Brochhausen et al. “Pectus excavatum: history, hypotheses and treatment options.” In: *Interactive cardiovascular and thoracic surgery* 14.6 (June 2012), pp. 801–6. ISSN: 1569-9285. DOI: 10.1093/icvts/ivs045. URL: http://www.ncbi.nlm.nih.gov/pubmed/22394989%20http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=PMC3352718.

[12] “Method of jawbone abutment implant for dental prostheses and implant device”. In: (Mar. 1982). URL: https://patents.google.com/patent/US4439152A/en.

[13] D. Buser, H.-P. Weber, and N. P. Lang. “Tissue integration of non-submerged implants. l-year results of a prospective study with 100 ITI hollow-cylinder and hollow-screw implants.” In: *Clinical Oral Implants Research* 1.1 (Dec. 1990), pp. 33–40. ISSN: 09057161. DOI: 10.1034/j.1600-0501.1990.010105.x. URL: http://doi.wiley.com/10.1034/j.1600-0501.1990.010105.x.

[14] *Tigran TM PTG [Porous Titanium Granules] for Bone Regeneration and Implant Osseointegration*. Tech. rep. URL: http://www.cmsdental.dk/gfx/pdf/Tigran%20PTG%20for%20bone%20regeneration%20and%20implant%20osseointegration%202010.pdf.

[15] Heidi Andersen, Anne Merete Aass, and Johan Caspar Wohlfahrt. “Porous titanium granules in the treatment of peri-implant osseous defects-a 7-year follow-up study.” In: *International journal of implant dentistry* 3.1 (Dec. 2017), p. 50. ISSN: 2198-4034. DOI: 10.1186/s40729-017-0106-2. URL: http://www.ncbi.nlm.nih.gov/pubmed/29199392%20http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=PMC5712508.

[16] MSc* Sherif H. Tehemar BDS. *Factors Affecting Heat Generation During Implant site preparation.* Tech. rep. 2000, p. 10. URL: http://coimplante.odo.br/Biblioteca/Geracao%20de%20calor%20na%20perfuracao/Factors%20Affecting%20Heat%20Generation%20During%20Implant%20-%20Sherif%20Tehemar.pdf.

[17] Kathleen Ceonzo et al. “Polyglycolic acid induced inflammation: Role of hydrolysis and resulting complement activation”. In: *Tissue engineering* 12.2 (2006), p. 301. DOI: 10.1089/TEN.2006.12.301. URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1769522/.

[18] *Polylactic Acid - an overview | ScienceDirect Topics*. URL: https://www.sciencedirect.com/topics/medicine-and-dentistry/polylactic-acid.

[19] Zachary Seeley, Amit Bandyopadhyay, and Susmita Bose. “Tricalcium phosphate based resorbable ceramics: Influence of NaF and CaO addition”. In: *Materials Science and Engineering: C* 28.1 (Jan. 2008), pp. 11–17. ISSN: 0928-4931. DOI: 10.1016/J.MSEC.2006.12.010. URL: https://www.sciencedirect.com/science/article/abs/pii/S0928493106003985.

[20] J.I. Gonzalez, D. M. Escobar, and C.P.O. Ossa. “Manufacturing and characterization of hydroxyapatite foams produced by gel-casting technique”. In: *2013 Pan American Health Care Exchanges (PAHCE)*. IEEE, Apr. 2013, pp. 1–6. ISBN: 978-1-4673-6257-3. DOI: 10.1109/PAHCE.2013.6568289. URL: http://ieeexplore.ieee.org/document/6568289/.

[21] *Does B-Tricalcium Phosphate Work as a Bone Regenerative Material?* Tech. rep. 2017. URL: http://www.remedypublications.com/open-access/does-b-tricalcium-phosphate-work-as-a-bone-regenerativenbspmaterial-4762.pdf.

[22] “65-Article Text-120-1-10-20170608”. In: ().

[23] Celeste M Abraham. “A brief historical perspective on dental implants, their surface coatings and treatments.” In: *The open dentistry journal* 8 (2014), pp. 50–5. ISSN: 1874-2106. DOI: 10.2174/1874210601408010050. URL: http://www.ncbi.nlm.nih.gov/pubmed/24894638%20http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=PMC4040928.

[24] Jordan Johnson and Johnson Dental Associates. *Dental Implants*. Tech. rep. 2014. URL: http://www.beta.mydentalhub.com/ada/test/.

[25] IData Research. *Dental Implants Market Analysis, Size, Trends | United States | 2019-2025 - iData Research*. URL: https://idataresearch.com/product/dental-implants-market-united-states/.