CHALMERS
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Investigation of the potential of additive manufacturing in hand surgery

Master Thesis Report

MSc Product Development

DIMITRIOS ZARKADAS

Department of Industrial and Materials Science

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Cover: A parametric model of a fixation plate, fixating proximal and distal radius.

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Abstract

A broken wrist is a common injury after a fall. In most cases, wrist fractures heal uneventfully. However, in some patients, the forearm bones, radius and/or ulna, heal in the wrong position, resulting in deformations. These deformations can lead to a loss of range of motion (ROM) and pain in the wrist. In such cases, corrective surgery is necessary.
Precise cutting of the bone and insertion of the surgical plate that holds the bone together after surgery can be aided by custom surgical parts. This is where additive manufacturing (AM) for biomedical applications offers great potential for customized solutions according to the patient's needs. Surgical guides help place cuts and holes in the right places during surgery. Those guides can be developed during the planning phase and manufactured using polymer AM. For deformities, where the standard plate does not fit well enough to allow full mobility of the wrist after surgery, surgical plates that hold the bone sections in place can be tailored to the specific patient and fabricated with metal AM.
Through a case study, this Master's thesis explores and develops application strategies of AM solutions in reconstructive wrist surgery aiming to create a common link between surgeons and AM engineers. Current practices and the state of the art in wrist surgery are explored, in combination with potential AM solutions. An evaluation of the entire design and manufacturing chain is performed, including consideration for the unique aspects of biomedical applications such as biocompatibility and sterilization of the material. A parametric model of a metal surgical plate is designed and evaluated for use in the case study. Finally future developments required to fully implement the design and processing chain in the medical field are highlighted as well as the cases in which AM can be beneficial.

Keywords: additive manufacturing, reconstructive wrist surgery, surgery planning, AM biomedical applications, parametric modeling.

Acknowledgements

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Finally, I would also like to thank Anders Björkman for helping me become familiar with the medical terms and procedures of hand surgery.

This thesis has been performed in collaboration between CAM2 at Chalmers University of Technology and Sahlgrenska University Hospital.

Dimitrios Zarkadas, Gothenburg, June 2021

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1
Introduction

In this chapter, the background, the aims and the research questions as well as the limitations of the technology and the scope of the project will be presented.

1.1 Background

A broken wrist is a common injury after a fall. In most cases, these fractures heal uneventfully. However, in some patients, the forearm bones grow together incorrectly, resulting in deformed wrist bones. These deformities can lead to loss in range of motion (ROM) and pain in the wrist. In such cases, corrective surgery is necessary.

Precise cutting of the bone and insertion of a surgical plate that holds the bone sections together after surgery can be aided by custom surgical parts. Here, additive manufacturing (AM) for biomedical applications offers great potential for customized solutions according to the patient's needs. Surgical guides that help place cuts and holes in the right places during surgery can be developed in the planning phase and manufactured with polymer AM. For deformities that require more complicated adjustments to maintain full mobility of the wrist after surgery, surgical (metallic) plates which will be implanted to hold the cut bone sections in place can be tailored to the specific patient and fabricated with metal AM.

Preoperative planning is required to create custom-made surgical guides and implants. 2D planning uses X-ray images to prepare for the procedure. Today, there is also 3D planning, which uses 3D models generated from Computer Tomography (CT) to visualize the procedure and create patient-specific solutions. 3D planning is done in collaboration between surgeons and engineers. Both work closely together to design and manufacture patient-specific parts. This collaboration can often be a challenge because the two groups have different backgrounds and require common knowledge to solve the problems.

1.2 Aims and Research questions

This Master's thesis aims to investigate the potential of additive manufacturing in the field of reconstructive wrist surgery by means of a case study. The aim is to identify and break down the whole manufacturing chain into individual steps and

evaluate them with an open mind to identify weaknesses, limitations and opportunities. It also aims to propose a process chain that meets the needs of surgeons, engineers and leads to overall better solutions for the patients. Additionally, this work aims to identify the current constraints and the future steps needed for implementing AM in 3D planning and surgery.
This thesis aims to answer to the following questions regarding the potential of additive manufacturing in hand surgery:

1. What is the potential of AM for the patients, surgeons, and healthcare organizations (cost-quality of medical services)?
2. What is the possibility to create an in-house manufacturing chain for this application, which AM techniques are suitable and what is the potential of an AM custom made fixation plate?
3. In which cases can AM be beneficial?

1.3 Limitations

The duration of this master thesis was 20 weeks including the time for writing the planning report. This time frame limits the cases that can be evaluated and analyzed. In addition, there was no possibility to perform a study on patients operated with conventional or AM-based preoperative planning. The focus will be on a real case provided by the supervising surgeon, to serve as a case study. Due to biomedical regulations, the analysis of the possible component designs and the respective process chain will be limited to simulations.

1.4 Scope

In this thesis, several methods were used to investigate the topic. Firstly, a literature review is conducted to explore the current practice and state of the art in the field of reconstructive wrist surgery. At the same time, qualitative methods such as interviews and observations will be used to gain a better understanding of the whole process chain and the needs of the stakeholders. Afterwards, a case study will be investigated step by step to highlight the problems, challenges and potential of AM in the process.

2
Theoretical background

In the following sections, the necessary knowledge for this thesis is presented. First, an introduction to additive manufacturing and the major AM technologies used in biomedical field will be given, followed by an introduction regarding the wrist surgery and how preoperative planning and wrist surgery is done these days.

2.1 Additive Manufacturing

Additive manufacturing (AM), also known as three-dimensional (3D) printing, is the process of producing a three-dimensional object from a Computer Aided Design (CAD) file. While conventional manufacturing is typically referred to as subtractive manufacturing, where material is removed from a larger block until the final shape is achieved, AM involves adding material in a layer-by-layer process. In AM, material is applied, solidified, or bonded to create a three-dimensional object. The materials used in AM range from metals and polymers, to ceramics, composites and bio-based materials. [1].

AM offers a high degree of design freedom and (depending on the chosen method) excellent detail resolution, which makes it an interesting method for biomedical applications. The categories of biomedical applications are tissue scaffolds, cell printing, prosthetics and implants. Specifically for prosthetics and implants, AM processes of highest interest include material extrusion, often referred to as fused deposition modeling (FDM), laser based powder bed fusion (LB-PBF), electron beam powder bed fusion (EB-PBF), VAT photopolymerization, material jetting and binder jetting technology (BJT). Each AM process has different set of advantages and specific applications and is therefore suitable for specific biomedical applications. [1]

2.1.1 Fused Deposition Modelling

Fused Deposition Modelling (FDM), is the most widely used AM process. As shown in figure 2.1, during the process, material is extruded following a path that maps each layer of a 3D model. The material is extruded by forcing it through a hot nozzle. The first layer is placed on the build platform. The next layers are placed on top of the previous layer. In order to create certain geometries, support structures must be made at the same time as the main 3D model. These support structures ensure that the geometry of the 3D model can be created without any problems.

The support structures can be made with the same extruder/material as the main model, but there are also designs that use a different nozzle that is only used for printing support structures. If the same material is used for the support structures, the removal is done by breaking the structures. If a different material is used, it is possible to use support structures that can be dissolved in warm water or specific chemicals [2, 3].

Components can be created using this process with a variety of materials such as plastics, composites, biomaterials, and even metal by using filaments that are approximately 80% metal powder [2]. In this thesis the FDM process is used for the creation of prototypes of bones and guides that serve to visualise, control and justify the designs that are created.

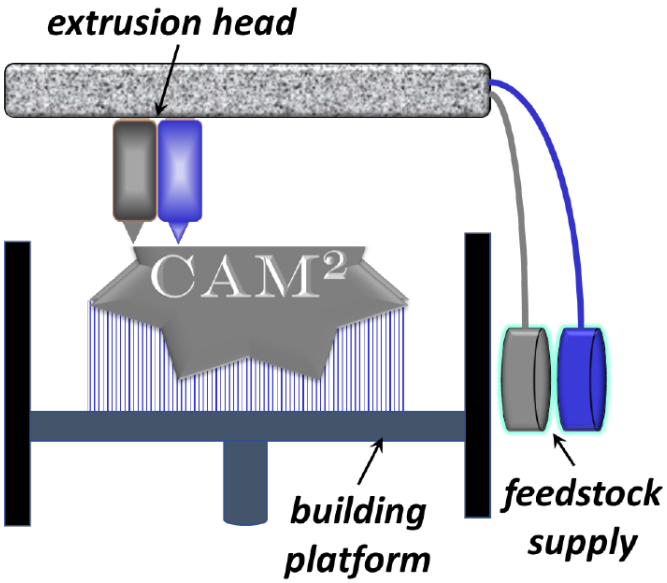

Figure 2.1: A representation of the FDM manufacturing process. Courtesy of E.Hryha, MTT120 lecture slides.

2.1.2 Powder Bed Fusion

Powder Bed Fusion includes Laser Based PBF (LB-PBF) and Electron Beam PBF (EB-PBF) [2]. These processes are based on the same principle that includes a build platform where a power source melts a thin layer of metal powder that is spread on it. These technologies have been developed to produce functional components in stainless or maraging steel, aluminium, titanium, and more. Nowadays, there is a significant focus on developing new materials that are compatible with existing machines to extend the method's capabilities.

2.1.3 Laser Based Powder Bed Fusion

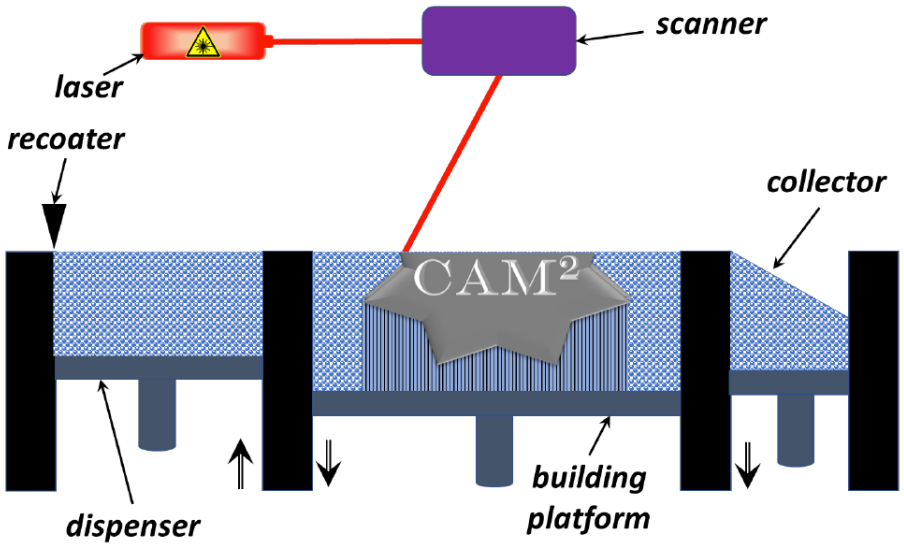

Figure 2.2: A representation of the LB-PBF manufacturing process. Courtesy of E.Hryha, MTT120 lecture slides.

As shown in figure 2.2, metal powder is spread over a build platform using a material spreading roller or recoater. Once covered, the laser beam or beams (depending on the machine's capabilities) selectively melt the powder, creating a solid layer. The build platform is then lowered a predefined distance, which represents the layer thickness, typically 0.02-0.08 mm. After each layer is formed, the recoater moves and creates another layer of metal powder. The excess powder is collected in a loose material chamber. For a build to be successful, there must be enough powder for each manufacturing process. Support structures are required to be able to build overhanging features, anchor the part to the build plate and also to ensure that the heat generated is conducted away from the part.

2.1.4 Electron Beam Powder Bed Fusion

Electron beam powder bed fusion (EB-PBF) uses an electron beam instead of a laser as the energy source, which requires the process to operate in a vacuum. Additionally, this process uses a high manufacturing temperature [2]. Since it is a hot process, the powder surrounding the solid part is partially sintered. This creates a so-called block of caked powder around the part. The schematics of an EB-PBF machine is shown in figure 2.3. After cooling, the build chamber is removed from the machine and transported to the next processing step, which involves removing the extra powder. Supports have a different function in EB-PBF; they are not needed to anchor the part, but are required to dissipate heat from the component. The layer thicknesses used in EB-PBF are greater compared to LB-PBF at 0.05-0.2 mm, which can result in a coarser surface finish.[3]. In some applications, such as hip implants, this rough surface is an advantage over other AM methods because it allows

bone ingrowth. If the part needs polishing, conventional mechanical or wet-chemical processes are used [2].

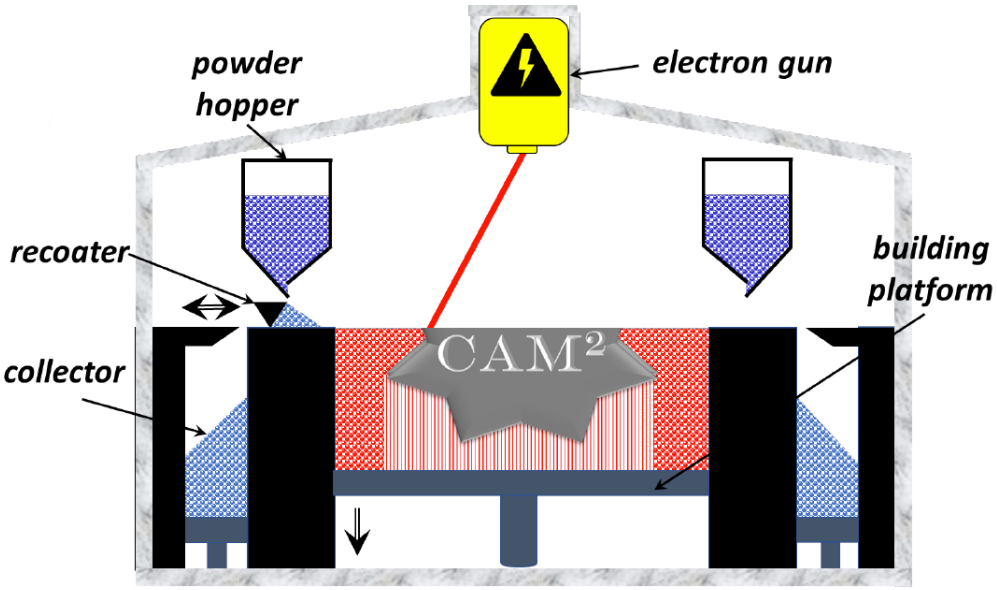

Figure 2.3: A representation of the EBM manufacturing process. Courtesy of E.Hryha, MTT120 lecture slides.

2.1.5 Binder Jetting Technology

Binder Jetting Technology (BJT) is a powder based AM technology that uses inject printer heads to depose a liquid binder to solidify the parts of the powder. As seen on figure 2.4, similar to FDM and PBF processes, the parts are created layer by layer, by lowering the build platform after each layer until the part is completed. The unique aspect of Binder Jetting is that the part that is removed after the print/build is not the final component. In metal BJT, the 'green' part is fragile and needs to be sintered to reach required mechanical properties. The advantage of this process is that it is relatively fast and several different materials can be used such as metals and polymers [2, 3, 4].

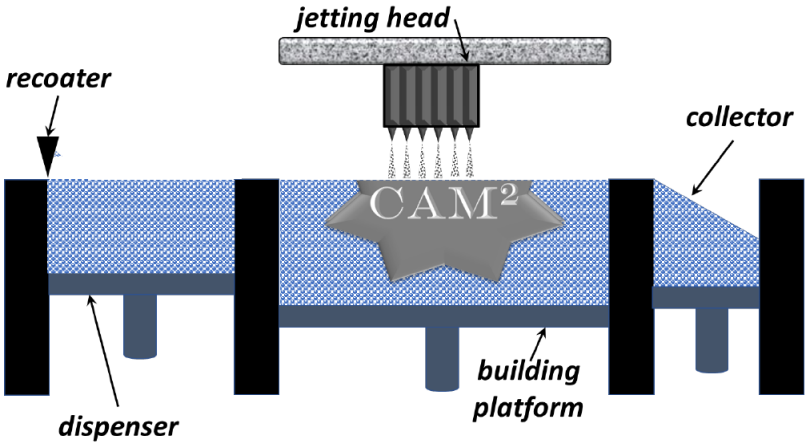

Figure 2.4: A representation of the Binder Jetting manufacturing process. Courtesy of E.Hryha, MTT120 lecture slides.

When metal powder is used, sintering is required to acquire the full properties. The post-processing first includes the excess powder removal, following by the removal of the binder material. After this, printed parts are sintered at the sintering temperatures (75-90% of the melting temperature of the main alloy) so that solid-state diffusion takes place. The sintering process leads to shrinkage (10-20%) [4] of the parts. Support structures for Binder Jetting are not required during the printing process, however, are sometimes used to assure geometry and tolerances of the component during the sintering step.

2.1.6 VAT Photopolymerization

VAT Photopolymerization creates parts using liquid resins that are cured by using UV light. The main technologies are stereolithography (SLA) and continuous Liquid Interface (CLIP) [2]. VAT Photopolymerization uses a UV laser or Digital Light Processing with a UV light source to cure (harden) a layer of resin. The layers are placed on top of each other, similar to other AM processes. The build plate is in a tank of resin, and after one layer is cured, it is moved slightly to allow the next resin layer to spread see figure 2.5. Depending on the machine, the build plate can move upwards or downwards during the process. Support structures are required for special geometries such as overhangs with a specific angle with respect to the build plate. This angle can differ from machine to machine and resin to resin.

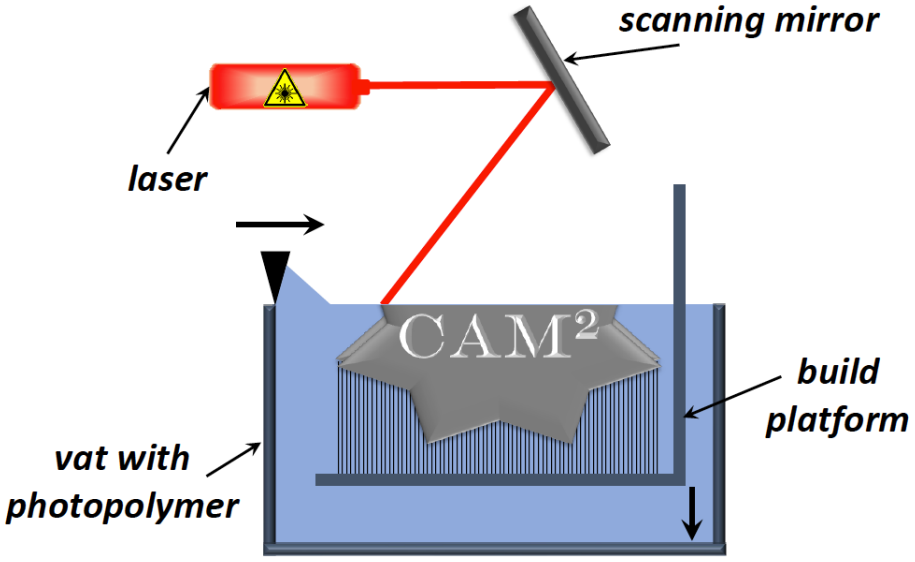

Figure 2.5: A representation of the VAT Photopolymerization manufacturing process. Courtesy of E.Hryha, MTT120 lecture slides.

After the build, the excess resin needs to be removed which is typically done using isopropyl alcohol (IPA). Additional UV light or natural light exposure can further enhance the properties of the component. Any support structures that were required during the build and were not incorporated into the component design need to be removed [5].

2.2 The wrist

The wrist can be described as the joint between the distal (further away from the body) aspect of the forearm and the proximal (closer to the body) aspect of the hand, and connects the hand to the forearm. The wrist contributes to the effectiveness of the upper extremity. The wrist joints allow the hands to be placed in an infinite number of positions with respect to the forearm while locking the hands with respect to the forearm to transmit the forces generated by the muscles. The bones of the wrist are presented in image 2.6. Loss of mechanical integrity of the wrist results in loss of function of the hand and consequently diminished the overall function of the upper extremity [6].

This thesis focuses on fractures of the distal radius. Generally, those types of fracture occur during a fall onto the outstretched hand. The forces required for a distal radius to fracture vary from 1050 N to 4400 N. The mechanism of fracture is not clear, but studies show that the radius can fracture due to stresses on its palmar surface. The mechanism of fracture can also vary depending on the age of the patient because bone may be osteoporotic [7].

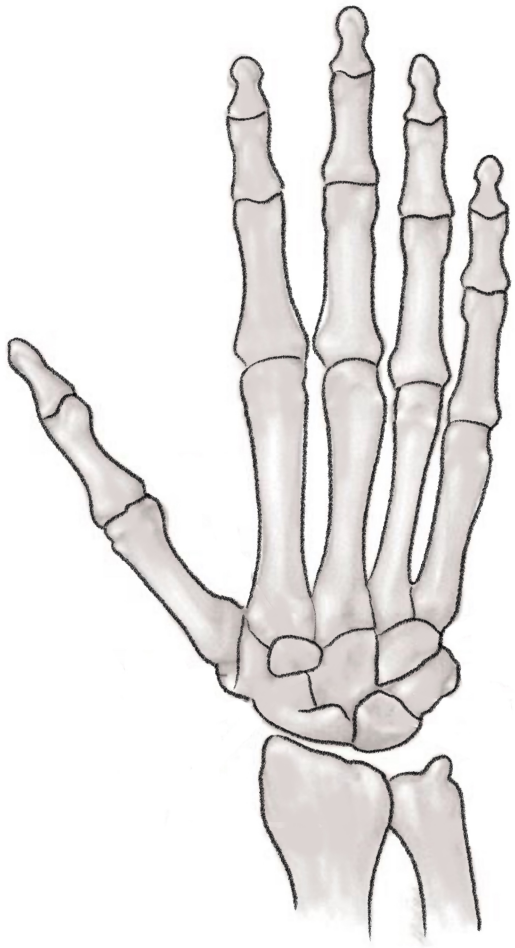

Figure 2.6: Skeletal hand and wrist, dorsal view. [6]

Depending on the type of distal radius fracture, there are several methods of treating the patient. If the fracture can be considered stable (no displacement between the two fractured bone fragments), a cast may be used to stabilize the wrist and help the fracture heal. If the fracture would be considered unstable, internal or external fixation is performed. As seen on figure 2.7, fixation is used to hold the two fragments of bone in an optimal position that will lead to healing after a period of time, usually six weeks. Internal fixation is done surgically by inserting plates, screws, or pins to hold the bone fragments in place. The above components are not usually removed after healing, unless irritation causes discomfort or pain for the patients. Compared to external fixations, internal plating may allow for earlier mobilization and the use of a less complicated cast. A disadvantage is the possibility of irritation of tendons near the components. The above risk can be reduced by thinner profile of

newly developed plates and could potentially be optimized through patient-specific solutions [8, 9].

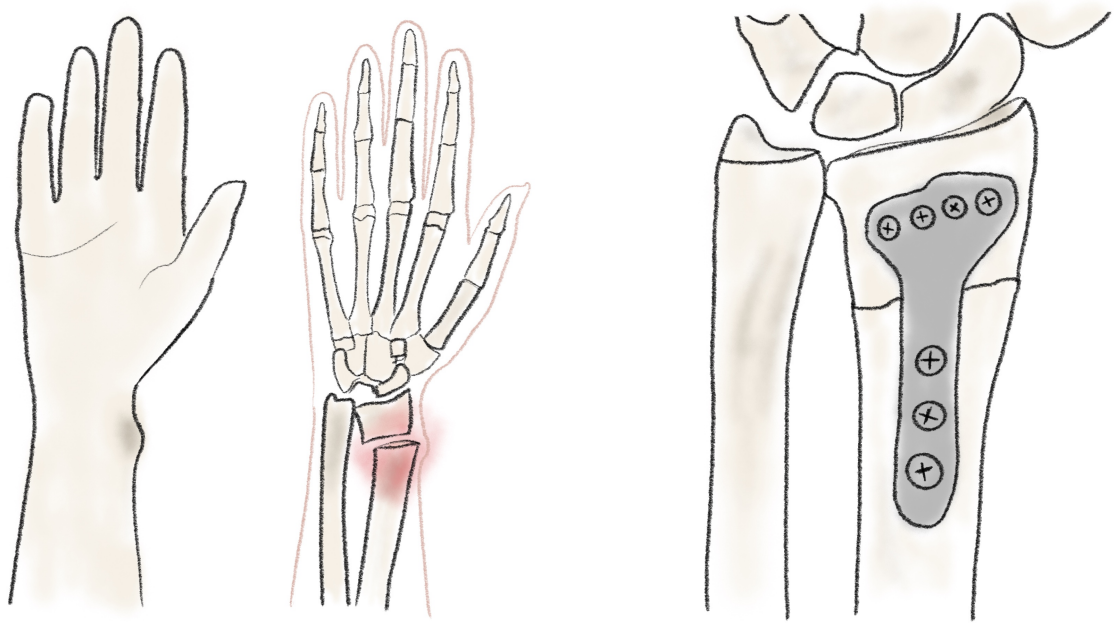

Figure 2.7: Left, cosmetic deformity of a broken wrist. Right, a metal plate that stabilizes the fracture. [7]

In cases where wrist fractures heal uneventfully resulting in deformity, surgery and correction of the deformity by internal fixation may relieve the symptoms such as decreased ROM, pain, instability and cosmetic deformity. Preoperative planning and patient specific surgical guides can be used to perform the surgery. Using 3D planning techniques has the potential to improve intraoperative accuracy, reduce surgery time, reduce stress during surgery, treat complex cases, reduce radiation absorbed by the human body during surgery (fluoroscopy), and ultimately allow complex corrections that may not otherwise be possible.

2.2.1 Pre-operative planning

Pre-operative planning is the process of visualizing the process of the surgery. At this stage, the geometry of the correction is determined, as well as the tools and implants to be used. In the following sections, both 2D and 3D planning techniques are presented.

2.2.1.1 2D planning

The process of preparing for a surgery using two dimensional images (X-rays) is called 2D planning. 2D planning is the traditional planning method as it offers a fast way to prepare and visualize the process that will take place in the surgery room. The process starts by printing the X-rays using ordinary office printers, and then use these prints to visualise the deformity and to design the process. Scans from two different angles are usually used to build a better understanding of each case. An example of this process can be seen in figure 2.8.

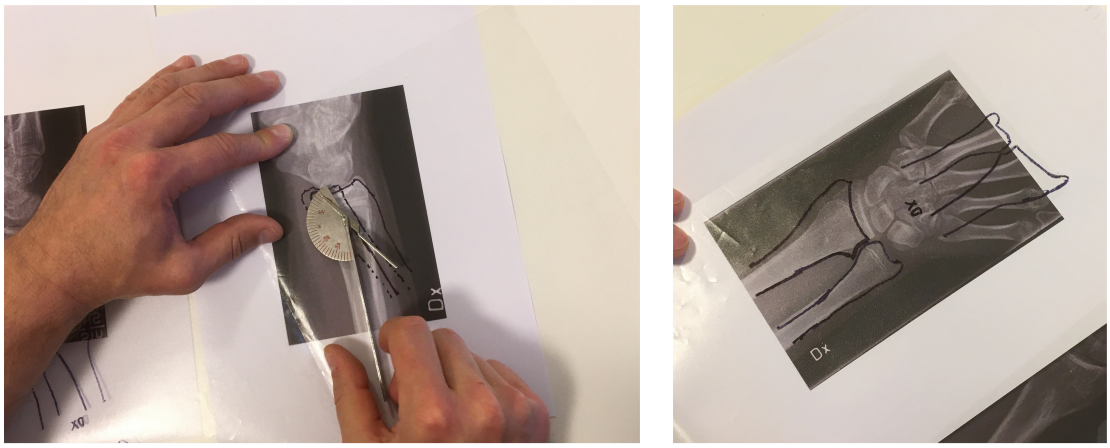

Figure 2.8: A surgeon performing a 2D planning. Photo taken by writer.

The images are used to make measurements on angles. These measurements are then used to compare the patient's anatomy to the normal anatomical model. If the patient has an uninjured side (healthy side), the scans of that side are used to compare how the injured side should be. In addition to measuring angles, a tracing paper or plastic film can be used to compare the two sides . Part of the 2D planning is also to plan the location of the cuts needed to perform the surgery.

Although the procedure is relatively simple and has a low cost (cost of printing paper, simple cheap tools), the accuracy is relatively low. Working with only two views leads to a loss of detail regarding the angle of correction and it is also impossible to visualise rotational deformities. To achieve high accuracy, the drills and cuts must be placed exactly as they were planned during 2D planning. This is almost impossible since no drill or saw guides are used during the surgery. The overall accuracy depends on the surgeon's experience and the way the fixation plate adapts to the geometry of the bone.

2.2.1.2 3D planning

Unlike 2D planning, 3D planning uses CT scans and special software to create 3D models of the wrist. The models of the wrist are further processed so that the surgeon can later proceed with a virtual correction. The 3D models are used in parallel

with CAD software to create specific corrections of the bone geometry. It is possible to create custom surgical guides, as well as custom surgical plates. In chapter 3 the complete 3D planning process is presented using a case study and the software Materialise Mimics and Materialise 3-matic.

Using 3D planning in parallel with CAD software allows the design and manufacture of patient-specific surgical guides and implants. Especially for distal radius fractures, customized surgical guides are already in use. Those surgical guides help to accurately position the drill holes for the screws that will later hold the plate in place and to cut the bone in the precise locations required to correct the wrist deformity. The 3D planning and the custom-made surgical guides help the surgeons to get an understanding of each case before performing the surgery. Using custom-made guides allows for translation of the preoperative planning to the actual operation, reduces stress and increases accuracy during the surgery. Although 3D planning has many advantages, there are issues that need to be addressed; the cost per surgery is relatively high, and the planning requires close collaboration between surgeons and engineers.

3

Case Study

The used case for this thesis is a young patient whose distal radius healed in a poor position after a fracture. The input for the case study is the patient's CT scan and the output are the custom designed and fabricated surgical saw and drill guides.

3.1 Pre-operative planning

Pre-operative planning includes all the processes that are required before the surgery is performed. There are different approaches to pre-operative planning depending on the case. As mentioned in the previous chapter, 3D planning involves the use of specialized software to visualize the anatomy, the correction as well as the tools that will be used during the surgery. The software used in this thesis is Materialise Mimics and 3-matic. These software packages are specifically designed for medical applications and comply with medical regulations. They are also used by the surgeons and engineers at Sahlgrenska University Hospital for 3D planning.

3.2 Conversion of CT scans into 3D models

CT scans need to be converted into 3D models. To do that, a dicom file which contains all CT data is converted into a 3D model of the arm. In reconstructive wrist surgery, the focus is on the radius and ulna. This conversion process takes place for both hands as they are needed for the next planning steps. An anonymization of the files can be performed through a feature built into the software Materialise Mimics.

3.2.1 Importing of CT into the software

The import process is quite simple; the dicom file is selected and imported into the software. Three different views as well as a 3D model of the bones are immediately displayed as shown in figure 3.1 and figure 3.2.

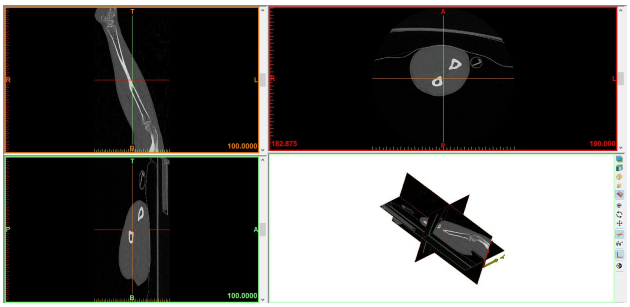

Figure 3.1: An overview of the basic screen of Materialise Mimics after importing the dicom file.

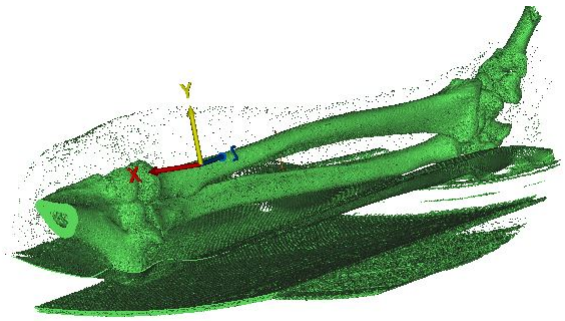

Figure 3.2: 3D view after importing the dicom file.

3.2.2 Segmentation of the 3D model

At this stage a segmentation step is necessary to keep the 3D models of the bones that are needed for the next steps. Different tissues absorb different amounts of radiation during the CT scan, resulting in images of different gray-scale. By adjusting the image threshold the bone structure can be isolated and generated as a 3D file. In most cases, voxels which fall into the same threshold window as the bone result in 'noise' surround the bones as a result of the 'noise' included in the dicom file. Using the feature 'region grow', the software identifies the continuity of the bone structure and the previous 'noise' is removed as can be seen in figure 3.3.

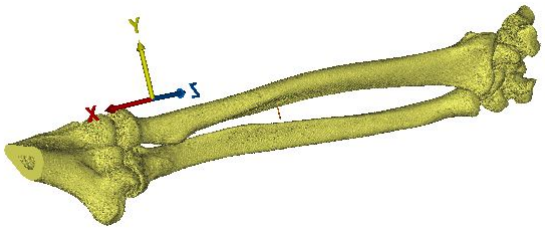

Figure 3.3: 3D view after using region grow command.

The next step is to separate the ulna and radius from the other bones. The "Split Mask" tool is used for this, see figure 3.4. Following this step, the 3D model is

compared with the images from the scan to identify problems with the conversion. Such problems can be areas where the 3D model has not been converted in the correct way, as the 3D model has less or more bone structure than it appears on the CT scan. Special tools can be used to correct these problems with the geometry.

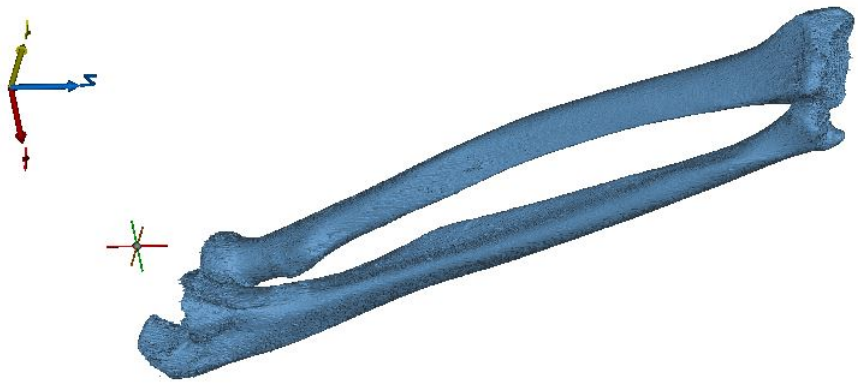

Figure 3.4: 3D view after using split mask command.

After ensuring that the 3D model matches the bone geometry, the next step is to rework the surface of the bones. This is done with the "Wrap" and "Smooth" tools. Figure 3.5 shows the rough surface of the bone and figure 3.6 shows the smoothed surface after using the wrap and smooth tool.

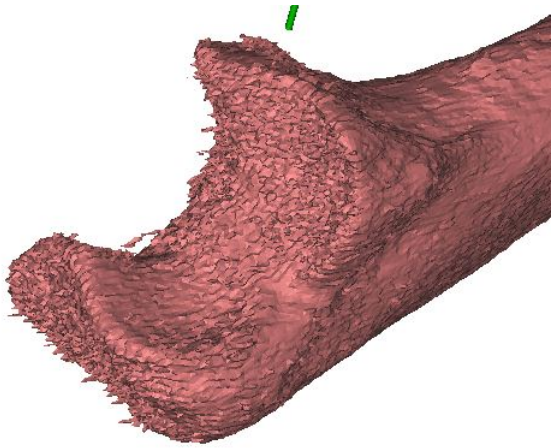

Figure 3.5: 3D view after segmentation. The surface is rather rough.

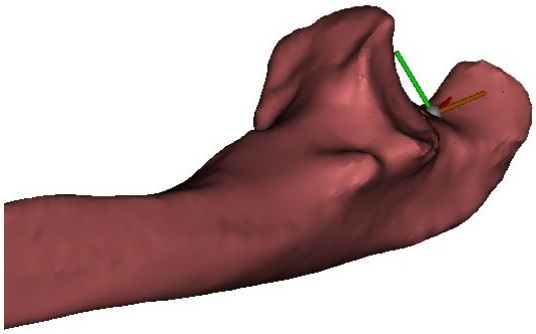

Figure 3.6: 3D view after using wrap and smooth commands.

Before moving on to identifying the injury, there is a final check to identify problems with the conversion of the dicom files to the 3D model. This can be done by checking the contour on the 2D images. If this step is successful, the 3D model is an accurate representation of the actual bones.

3.3 Identification of the injury

The injury is identified by comparing the injured bones with the healthy ones or, if both sides are injured, with a normal arm model. Materialise 3-matic is used for these comparisons. There are special tools in this software that make the comparison easy and at the same time, effective. For example, it offers the possibility to measure distances in the 3D models and also to register the 3D models on each other to compare them visually.

When a bone is injured, most of the times it is also shortened. At this point, it is important to mention that surgeons can identify the deformity by just looking at the bones. Without the surgeon's experience, an engineer needs specific metrics to identify the injury. Using only the lengths or geometry between both sides (left and right) to identify the injury can lead to incorrect conclusions.

Identifying of complex injuries only from the 3D model can be challenging for both surgeons and engineers. It is worth noting that the standard training for surgeons is based on measurements using 2D imaging such as X-rays. As mentioned in chapter 2, 2D planning is the technique with which surgeons are most familiar. The possibility of using 3D models has created the need to transfer the knowledge of 2D planning to that of 3D planning.

3.3.1 Comparison using the healthy side

To compare both sides (healthy and injured), the healthy side should be mirrored so that it matches the orientation of the injured side.The injured side should be kept in the same position throughout the process, to ensure the relative position of

radius and ulna. Materialise Mimics offers two different tools for superimposing two models. One tool is "N-point registration", which uses points on the surface of one 3D model to match with points on another 3D model. The final result is two models that are on top of each other. The other tool is "Global Registration", which can use a specific area as a reference or the entire model of the bone to automatically superimpose the two models. For better results, these two tools can be used one after the other, first the "N-point registration" and then the "Global registration".

In this case study, the left side is the injured side. This can be identified from measuring the length of ulna and radius and was confirmed by the input from the surgeons. In figure 3.8, the mirrored healthy and the injured radius have been placed on top of each other to allow visual comparison.

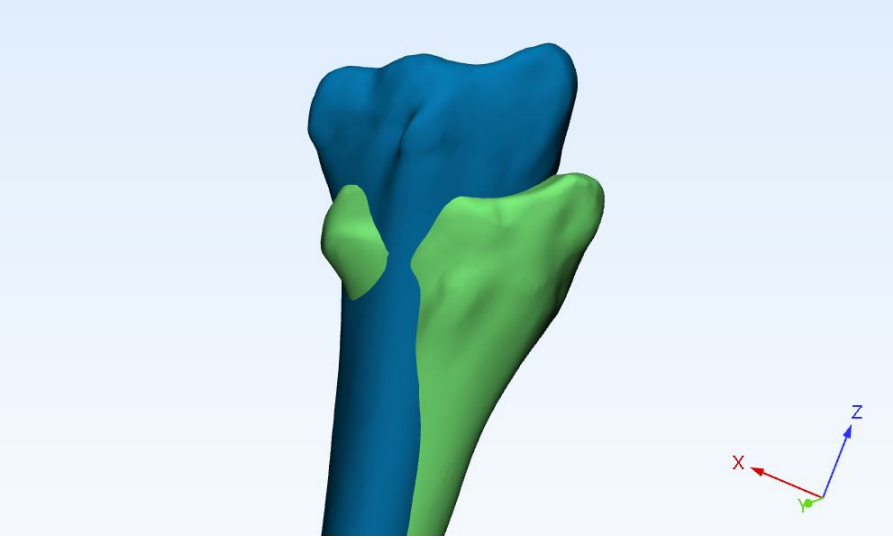

Figure 3.7: The two radius, injured and healthy, placed on top of each other to demonstrate the variation. The injured radius is the shortest and in green colour.

3.3.2 Comparison using the normal arm

If both arms are injured, the injured bones can be compared to a model of a normal arm. A normal arm or average model is a model of an arm that has the appropriate function. The normal arm can be scaled to match the anatomy of the injured arm. Due to human nature, the scaling can be uniform (uniform scaling refers to the same scaling in the 3 directions x,y,z). To achieve the best results, the optimal scaling factor must be defined. By scaling up or down the normal arm model and using global registration, the scaled model must be of similar size as the injured model. Another method is to use of statistical shape models in which an average shape is calculated from a large database of CT scans of "normal" arms.

3.4 Performing the correction

The implementation of the correction is the most complex step of the planning process, as it is strongly related to the following different factors.

At this stage, it is important that the healthy side or the scaled normal arm is already placed on top of the injured arm. The placement of the cut depends on various factors known to the surgeons. One factor is related to the geometry of the metal plate that will be used to fix the bone. The placement of the cut depends on various parameters such as the geometry of the metal plate that will be used to fix the bone. Depending on the plate geometry, preferably three or more fixation points on the proximal side and all distal screws should have sufficient hold in the bone as shown in figure 3.8.

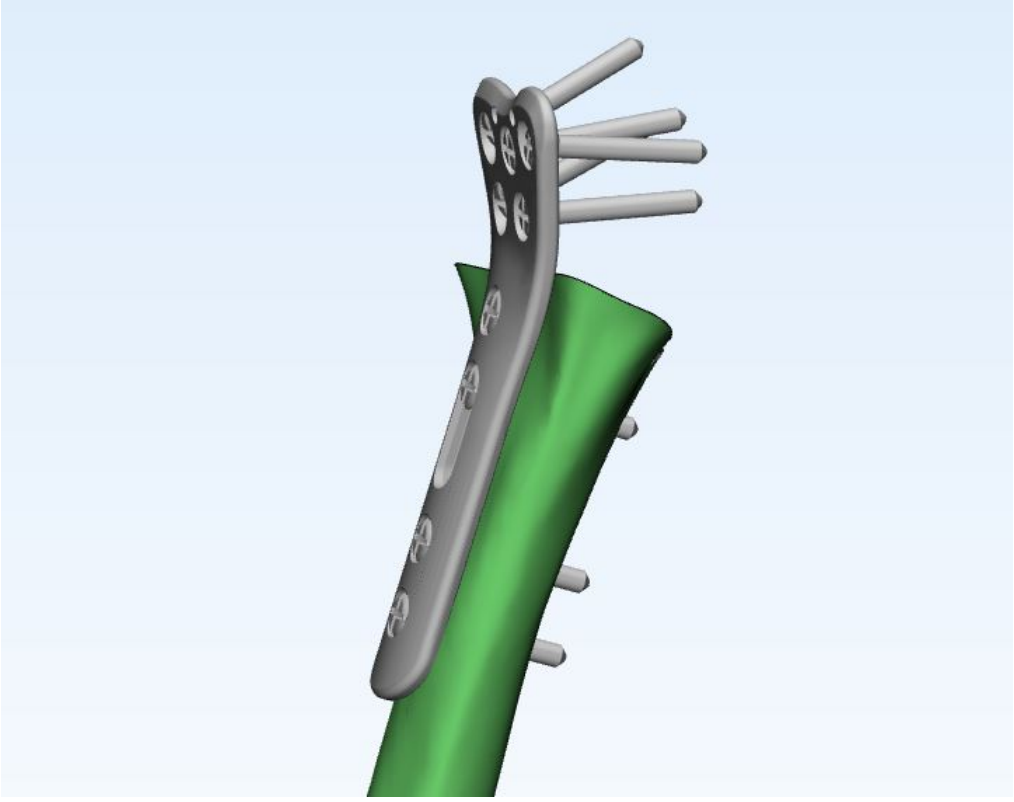

Figure 3.8: A plate that is fixated on the proximal side using 4 fixation screws.

After the cut has been made, the distal part of the radius must be placed in the optimal position. This position is related to the geometry of the mirrored healthy side or normal arm, but also to the relative position of the ulna. For this case study, the final position of the distal radius can be seen in figure 3.9.

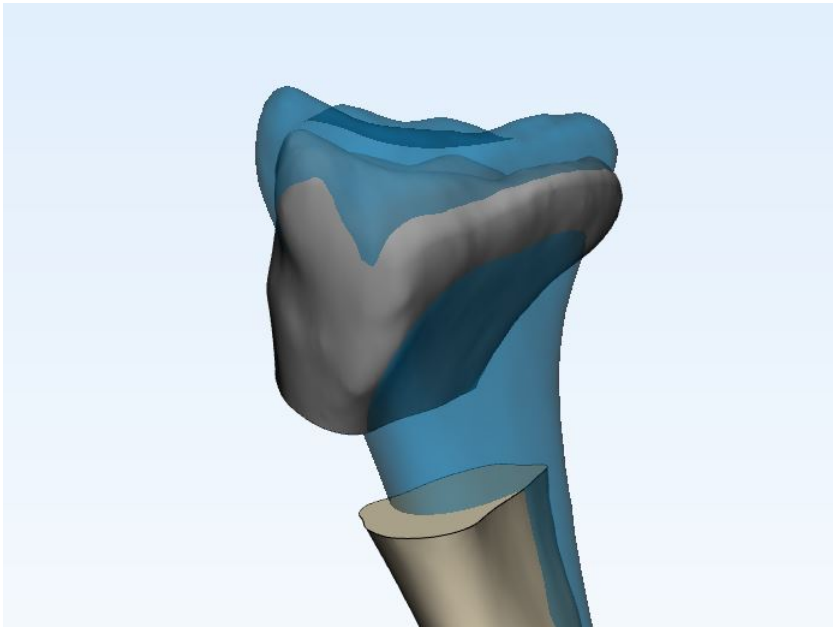

Figure 3.9: The final position of the distal radius.

Figure 3.9 shows that the distal radius has exactly the same orientation as the healthy side, but is placed slightly lower. This is due to the geometry of the ulna. As can be seen in figure 3.11, the ulna is slightly shorter. By lowering the radius, we ensure that the joint between the radius and ulna functions properly.

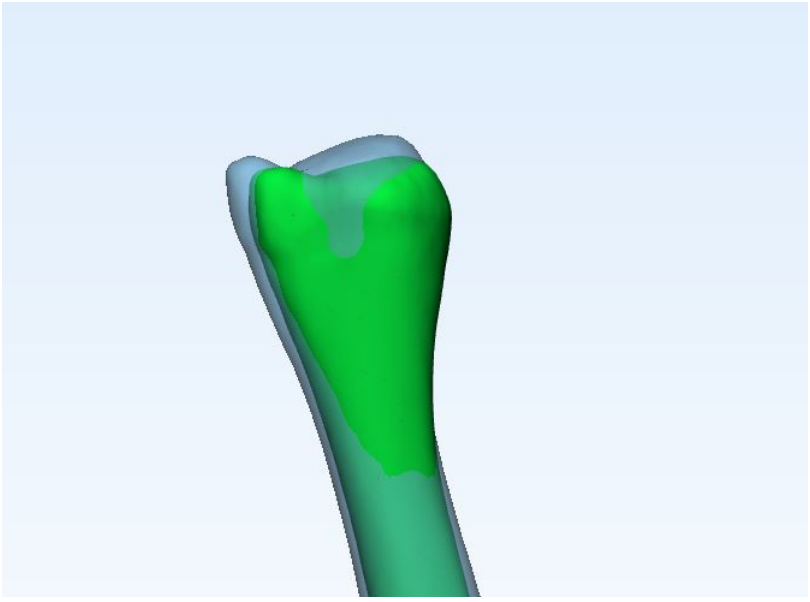

Figure 3.10: The two ulna's placed on top of each other. The injured is green one.

3.4.1 Relative geometry of the ulna and distal radio-ulnar joint

Planning must take into account the geometry of the distal radio-ulnar joint which is responsible for the rotation of the wrist.
The radius is often shortened and collapsed after a fracture. To correct it, the angle as well as the length must be corrected. If the required distraction is more than 12-15 mm, it is better to shorten the ulna simultaneously. In this way, the distraction of the radius can be limited. The main goal is that the distal radio-ulnar joint fits well. An important measurement is the ulnar variance. The surgeons are capable to decide on the desired variance. The ulnar variance can be seen in figure 3.11

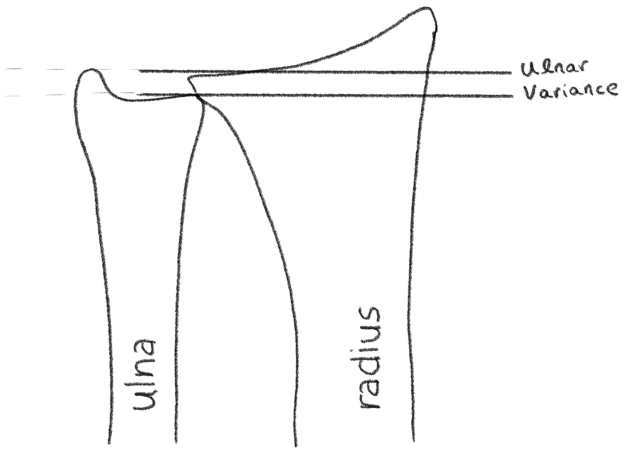

Figure 3.11: A sketch representing the ulnar variance.

3.5 Selection and placement of a standard plate

After deciding on the position of the distal radius, it is time to select a standard plate. The plate must fit and support the bones. Also, the placement of the plate should not interfere with the normal function of the wrist. When it comes to plates, there are many different variations. The variations refer to material, geometry, fixation points and screw mechanisms. The screws can be fixed-angled that are fixed to the plate or screws that are threaded into the bone. The screws on the distal part of the radius are placed in different directions from each other. This prevents the bone from sliding and provides support between the plate and the bone. Selecting and fitting a plate during 3D planning can be a time-consuming process. Every patient is different which means that there is no standard method for selecting a plate. At the same time, plate selection is critical to the planning process because it is strongly related to the geometry of the cut. In some cases, a certain plate can lead to a correction that is not the optimal for the patient. This problem is related to the plate design which is specific to fractures of the radius. In cases where the radius has healed undesirably, the bone may be so deformed that the standard plates do not fit its geometry. In the following figure 3.12, several plates are placed on the radius to examine the ability of supporting the distal and proximal part of the radius.

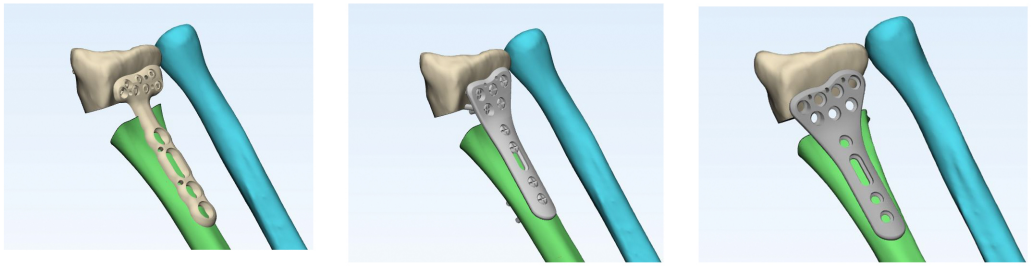

Figure 3.12: Trying to fit different plates to perform the correction.

3.5.1 Bending a plate

In cases where a standard plate does not fit, the selected plate can be bent to achieve the desired correction. Unfortunately, there is no specific tool in the Materialise 3-Matic software to perform accurate bending of a plate. To model this, FEM software should be used, however, this will increase the time of the planning process.

Bending a plate is common practice in wrist surgery. For specific types of corrections, there are plates that are designed to be bent. Additionally, there are special tools and specific bending steps that help to perform the optimal bending.
Bending a plate causes plastic deformation that can be critical to the strength of the plate. For this reason, surgeons and engineers prefer to spend time trying to find a plate that will fit the patient directly and support the bone without having to bend it.

3.6 Design of the custom surgical guides

Drill guides are used to position the holes and cut the bone, ensuring that the final correction matches the 3D planning. Depending on the selected plate and the geometry of the bone, two or more drill guides can be used. The guides can be designed using the Materialise 3-matic software. In the following subsections, the necessary steps for creating the guides are explained.

3.6.1 Creation of the axis of each screw

The creation of custom surgical guides is the final step in the 3D planning process. In order to perform this step, the selection and positioning of the plate must be completed. From this point onwards, even minor changes in the orientation or placement of the plate, bone, or cut will require the guides to be redesigned. The construction is done in reverse order of the surgery: the starting point is now the corrected geometry. The plate, and especially the screws, are used as a starting point for the construction. As can be seen in figure 3.13, a concentric axis is created for each screw. If the screws are not included in the model of the plate, creating each axis can be time consuming. If the screws are included in the model, the creation of the axis can be performed using the 'Fit Inertia Axis' tool in Materialise 3-matic.

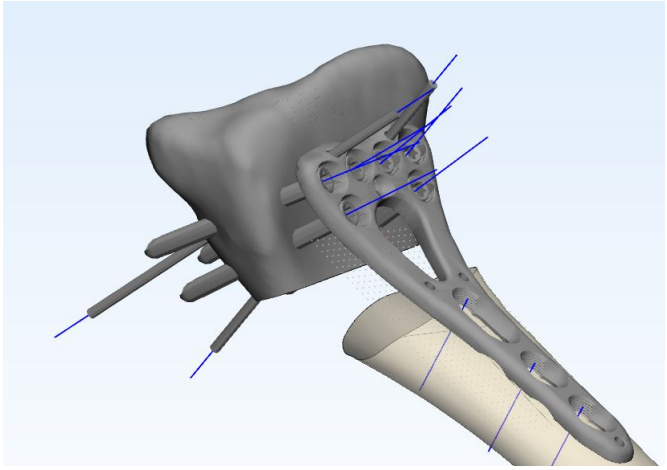

Figure 3.13: The final correction geometry. Each axis corresponds to one screw.

3.6.2 Placing the distal part to its pre-correction position

When all axes have been applied, the distal radius can be returned to its pre-corrected position as seen in figure 3.14. The distal radius should be brought into the pre-corrected position together with the axes of the screws.

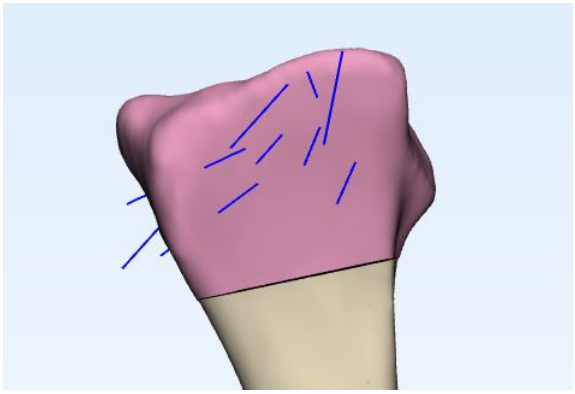

Figure 3.14: The distal radius with the screw axis, placed in the pre-corrected position.

3.6.3 Creation of the cylindrical drill guides

For each axis, two cylinders are created, one with a small diameter and one with a larger diameter. The diameter of the small cylinder refers to a tool (sleeve tool, see figure 3.15) used to guide the drill.

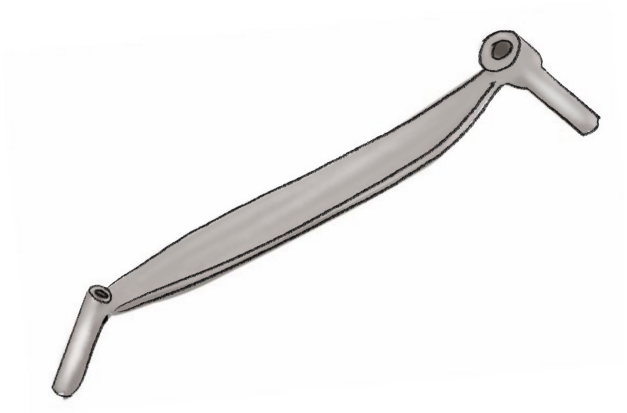

Figure 3.15: A sketch of a sleeve tool that is used to guide the drill bit.

The final cylinders are produced by subtracting the narrow diameter cylinders from the wider cylinders. Boolean operations are used to either merge or subtract the 3D models. In the end, the final result is shown in figure 3.16.

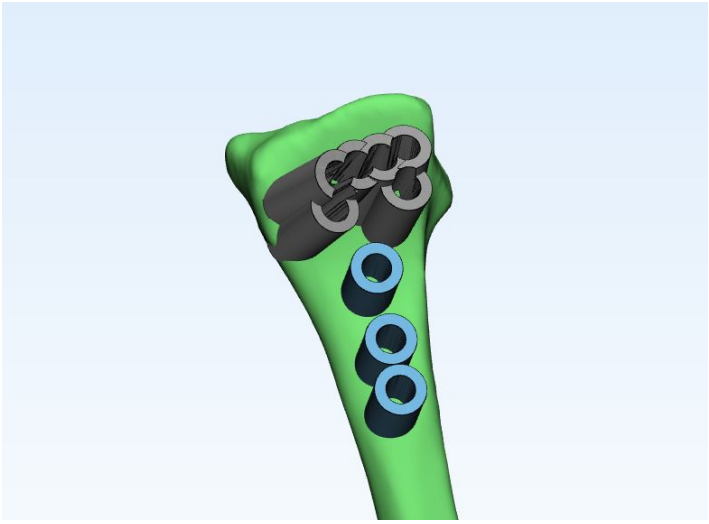

Figure 3.16: The final hollow cylinders.

3.6.4 Creation of the base of the surgical guides

The next step is to create a base that connects all cylinders together while matching the geometry of the bone. The base must be as small and at the same time as stable as possible, so that it has exactly the same position as it was designed in the 3D planning. To ensure this, the guide adapts to the geometry and "snaps" into place following the geometry of the bone. There are specific areas on the bone where the guide can be placed. The exact positioning of the base of the guide can be determined with the help of the surgeons. In figures 3.17 and 3.18 the selected area of guide base can be seen.

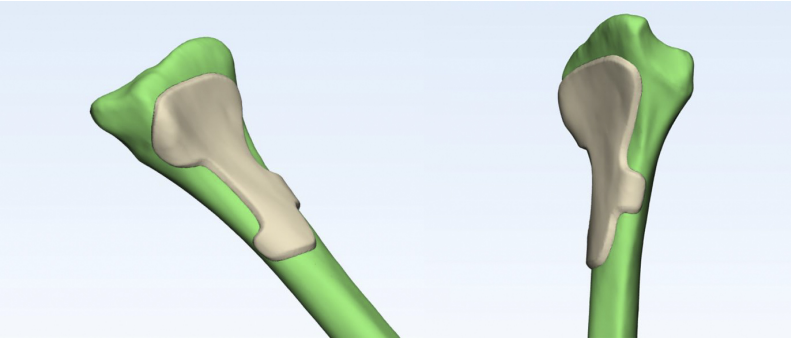

Figure 3.17: The selected area for the creation of the guide base.

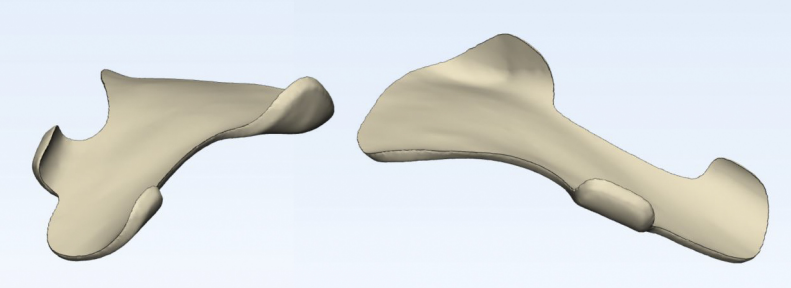

Figure 3.18: The 3D model of the guide base.

For this case study, the surgical guide is created as small as possible. Three additional cylinders are added to help securing the guide to the bone using metal pins. The guide must be rigid to allow placement of the sleeve tool and attach securely to the bone. The wings (parts that go on the side of the base) are designed to provide more stability to the guide. Unfortunately, there is no tool in Materialise 3-matic to judge how stable the fit of the surgical guide to the bone will be.

To create the final drill guide the cylinders and the guide base are merged into one 3D model as shown in figure 3.19.

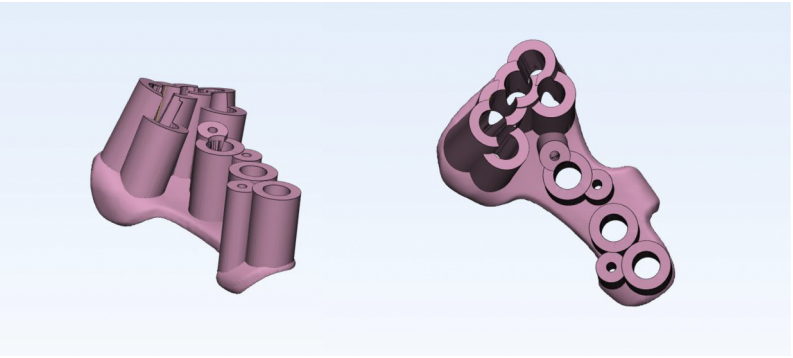

Figure 3.19: The final drilling guide.

The saw guide is made in a similar manner. It is used to guide the saw and cut the bone in exactly the same orientation as determined during the 3D planning. A box

is created with a gap designed for the saw blade. This box is then merged with the guide base and also the stabilizing pin cylinders. As demonstrated in figure 3.20, the width of the saw box is shorter than the width of the actual cut. This is because the guide must withstand the load during the surgery. After using the saw guide, surgeons need to continue cutting the bone using the already cut part as a reference.

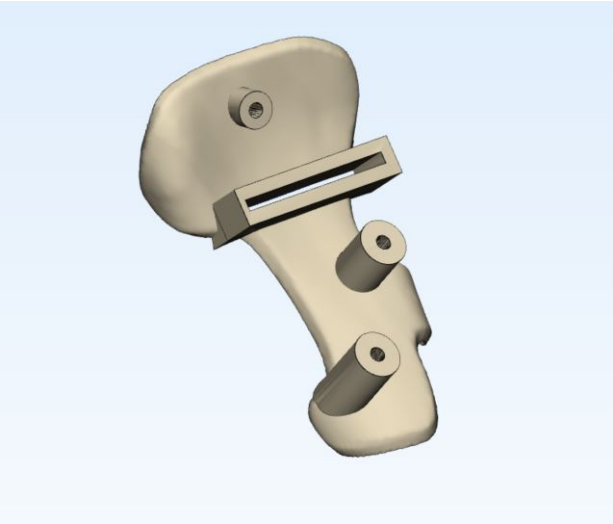

Figure 3.20: The final saw guide.

As can be seen in figure 3.19 and 3.20 the two guides have 2 cylinders in common. These cylinders are parallel to each other. During the surgery, when the first guide is placed, it is stabilized with at least 3 pins (2 parallel and 1 non parallel). When the drilling process finishes, the non-parallel pin is removed and the saw guide is pushed onto the other 2 stabilizing parallel pins. Then the saw guide is moved with the 2 parallel pins. This ensures that the relative position of all the surgical guides corresponds to the one during the 3D planning.

3.7 Prototyping the surgical guides

Prototypes of the surgical guides and bones can be made using a 3D printer.FDM technology is ideal to create prototypes and models at a low cost. For the purpose of this thesis an FDM printer was used with a nozzle of 0.4 mm and a layer thickness of 0.2 mm. For more detailed component, a smaller nozzle diameter could be used as well as a lower layer height. The prototypes of the custom made drill and saw guides as well as the radius before and after correction can be seen in the following figures 3.21 and 3.22.

Figure 3.21: A prototype of the radius before (left) and after (right) the correction.

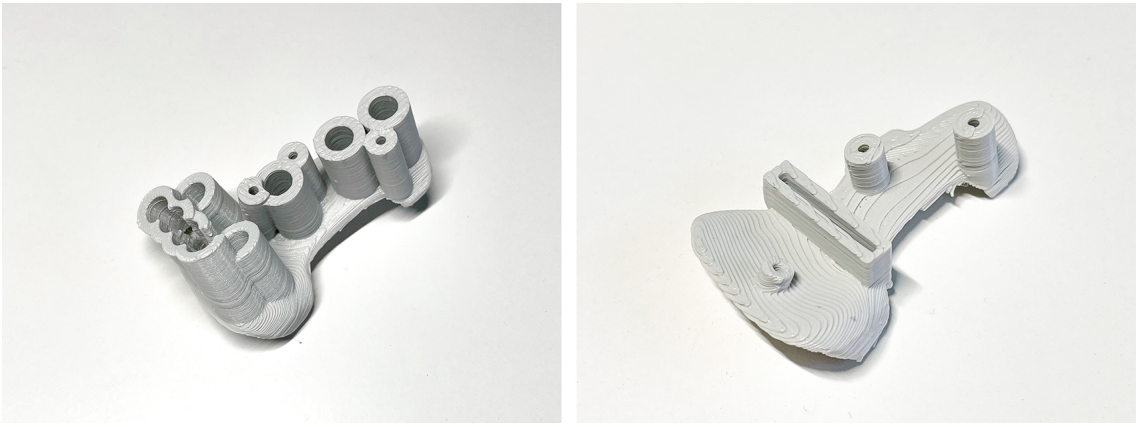

Figure 3.22: Left, the surgical drill guide prototype. Right, the surgical saw guide prototype.

3D printed prototypes are useful to visualize the surgical process. By fitting the guides, their contact and stability can be tested. At the same time, surgeons can visualize the different steps of the surgery and get an understanding of exactly how everything will be positioned. Another use of 3D model prototypes is to explain the procedure to the patient. Since they can be produced quickly and inexpensively, it is the easiest way for a patient to understand the procedure. It also serves as a kind of quality test. At this stage, errors during the design process can be identified.

For this case study, the prototypes were printed simultaneously and the time required was approximately 6 hours. All prototypes are shown in figure 3.23. 3.24.

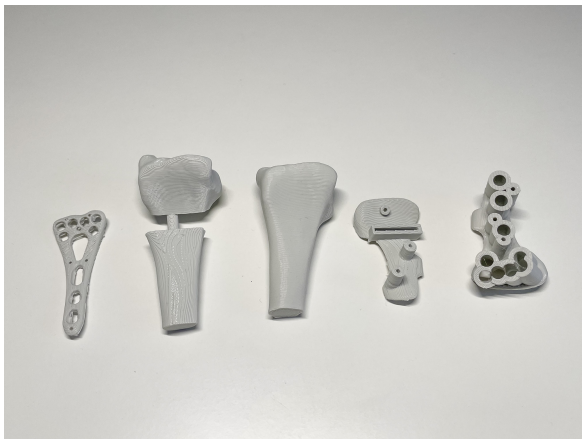

Figure 3.23: All the prototypes created. From left to right, the metal plate, the radius after the correction, the radius before the correction, the saw guide and last the drill guide.

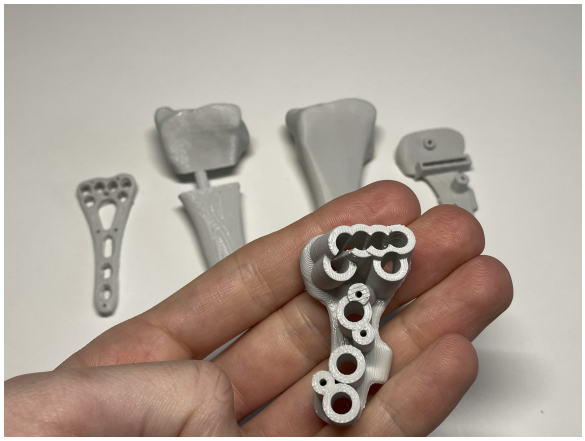

Figure 3.24: Holding the drill guide to show the size comparing to a hand.

3.8 Surgery leaflet

During the procedure, certain steps should be followed; Some steps are independent of 3D planning and some are directly related. For example, the sequence of drill guides to be used as well as sleeve tool dimensions or screw types and lengths vary from plate to plate and surgery to surgery. In order to provide all the necessary information, a surgical fold-out leaflet is prepared. It contains images to visualize drill guide placement, but may also contain measurements for screw lengths and angles.

The creation of a surgery leaflet can help to identify errors in the 3D planning, as it follows the surgery process step by step. It can also be used to inform the surgeons involved in a surgery about the exact procedure.

3.9 Sterilization

Sterilization is a necessary processing step for any implants and biomedical parts to ensure that all microorganisms on the surface of an item are destroyed. If a part is not sterilized, there is a high risk of transmission of pathogens [10].Before surgery, all tools and surgical guides and plates must be sterilized. A common method of sterilizing medical equipment is to use an autoclave which uses steam under pressure to deliver heat to the parts being sterilized. The temperature and pressure of the steam can vary depending on the application, but the most common is 121° at 15 psi pressure [11]. The parts should be able to withstand the heat of the autoclave. Depending on the size of the parts, the sterilization time varies.

3.10 Manufacturing of the surgical guides

If all of the above steps have been successfully completed, the drill and saw guides can be manufactured. The guides should be made of a material that is safe to use in the human body. At the same time, dimensional accuracy is of great importance as the surgical guides must conform to the bone surface to ensure that the holes and cut match the 3D planning.

3.10.1 AM processes for manufacturing of the surgical guides

Although AM guides can be fabricated using a variety of AM techniques, there are some material and geometry safety requirements that make some techniques more suitable than others. Surgical guides must be made with a material that is biocompatible according to ISO standard 10993 [12]. In terms of geometry, the surgical guides should have all the holes in the correct dimensions (fit of the sleeve tool) and also have a high quality of the surface that will be placed on the bone to ensure that the placement of the guides is consistent with the 3D planning.

3.10.2 Polymer LB-PBF

Polymer LB-PBF is an AM process that is already used in the biomedical field due to the strength of the parts, the availability of the machines, and the variety of materials. For the fabrication of surgical guides, Polymer LB -PBF allows fabrication without the use of supports. Due to the use of fine powder and a thin layer thickness, polymer LB-PBF is very precise. For example, the holes of the surgical guides, including the thin ones used for the locking pins, can be produced without the need of additional post-processing.

Polymer LB -PBF can create parts out of polymers that are biocompatible which can also be sterilized with an autoclave [13]. Nylon 12 is a material commonly used in polymer LB-PBF because of its mechanical properties, it is also biocompatible for use in the body and fulfils the requirement for sterilization. [14, 15].

3.10.3 VAT Photopolymerization

VAT Photopolymerization is an AM process that can produce parts in great detail. In terms of surgical guides, it is able to create the holes and the overall geometry in great detail. The process is used in the medical field and especially in dental applications. There is a wide range of materials that can be used to make surgical guides [5]. The resin for surgical guides can be sterilized by using an autoclave [16]. However, VAT photopolymerization parts require some support structures where there are overhanging elements. The design of the surgical guides can be modified to minimize these support structures. A simple way to modify the design to minimize the support structures is to make it flat on the side where the drill template holes are located (see figure 3.25).

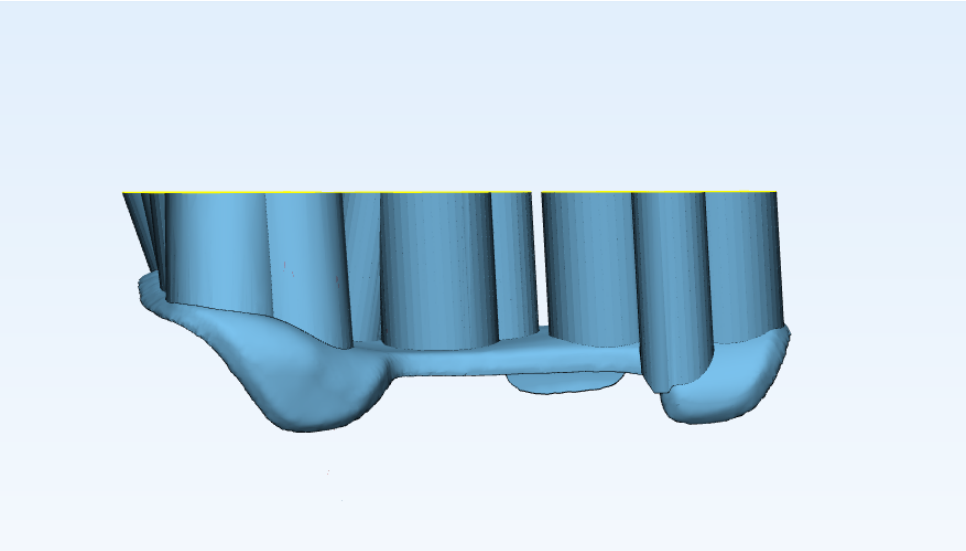

Figure 3.25: A design that creates a flat surface on the top of the drill guide to ensure minimum support structures during manufacturing.

For the case study, a prototype drill guide was created using this technique. As can be seen in figure 3.26, the material is transparent and smooth. Compared to the prototype created with FDM, it has a better surface finish, which can also be seen in the way it conforms to the bone geometry. A non-flat drill guide surface was used for the prototype, resulting in numerous support structures attached on the surface of the drill guide. A flat design, as suggested above, would result in minimization of support structures.

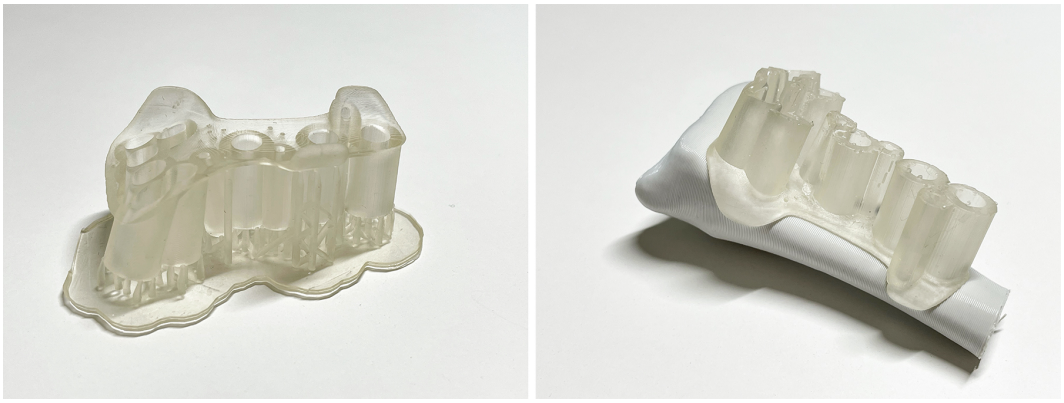

Figure 3.26: Left, a prototype of the surgical guides including the support structures. Right, the prototype fitted on the bone geometry.

As mentioned in the chapter 2, the part must be cured using UV light after manufacturing and then sterilized in an autoclave. The curing process depends on the polymer selected for this application.

3.10.4 FDM

FDM is the most accessible AM process that offers a wide range of materials. By using this process certain geometries must be supported by support structures. It is also not as accurate as polymer LB-PBF with higher layer thicknesses and large extruder dimensions. During the thesis, there was no filament on the market that was biocompatible to use it in the body. It seems that the only way to make such a filament is to use pellets of a material that is biocompatible. Not only the material, but also the process must be in accordance with the regulations. For example, a special nozzle should be used that will not corrode the material. The common brass nozzles cannot be used in biomedical applications because the nozzle wears out, allowing transfer of brass into the printed material. For all these reasons, FDM is not able to produce the surgical guides, but it can be used for prototyping and verifying the design in the 3D planning process.

3.10.5 Binder Jetting Technology

Binder Jetting Technology (BJT) is an AM process capable of producing parts with great detail. A wide range of materials can be used for this technology and many of them are biocompatible such as nylon 12. For the fabrication of surgical guides, BJT is able to replicate the exact geometry in detail and the final part has mechanical properties suitable for the current application. Although promising, there were no examples of BJT being used as a process for use inside the body. This may be due to the lack of a binder material that after curing offers good mechanical properties to the final part. Another aspect is the stiffness of the manufactured part. The guides should withstand the forces of the sleeve tool and saw, making BJT a process not capable to manufacture the guides. BJT is a new technology that is under development and therefore there is a high potential in using it in the future for the manufacturing of the surgical guides.

3.11 Surgery

The sterilized guides, screws, plate, and leaflet are created for each surgery. First, the patient is placed under anesthesia. Then the surgeons begin the surgery and use the guides once the bone is exposed and cleaned. If the guide does not fit, the bone is cleaned of soft tissue again. When the first guide (the drill guide) fits the bone, the stabilizing pins are inserted. When all the holes are created, the non-parallel stabilizing pin is removed and the drill guide is taken out. This step is summarized in figure 3.27. The next guide is placed with the help of the two remaining parallel pins and then stabilized by inserting the third pin. Once the saw guide is stable, the saw blade can be inserted and begin sawing the bone. The pins and guide are then removed and the saw continues to trim the bone until it is completely cut.

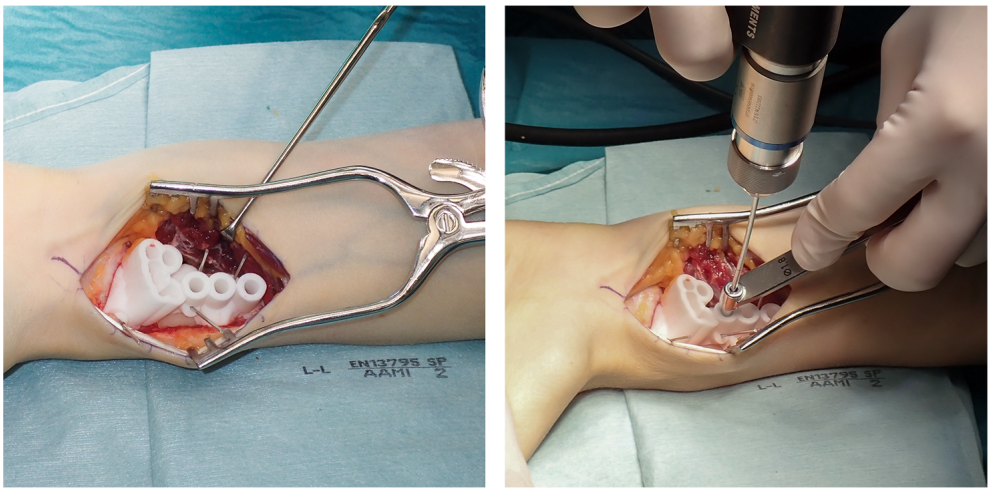

Figure 3.27: Left, the drill guide placed and secured with the metal pins. Right, drilling the bone using the sleeve tool, placed on the guide. Courtesy of Katleen Libberecht.

After the distal radius is separated from the proximal section, the metal plate needs to be placed on the bone sections to hold them in the predetermined position. When all screws on the distal part are in place, the distal radius must be placed appropriately so that the remaining holes in the proximal part line up with the holes in the metal plate. A screw is placed in the gliding hole of the plate and is used to pull the plate to the bone. Depending on the distraction between the distal and proximal part of the radius, the required force may be very large and two surgeons may be needed to apply the required force to align the plate with the holes. The first screw is usually placed to allow the plate to slide until all other screws are placed. The end result of the placement of the mettal plate can be seen in figure 3.28.

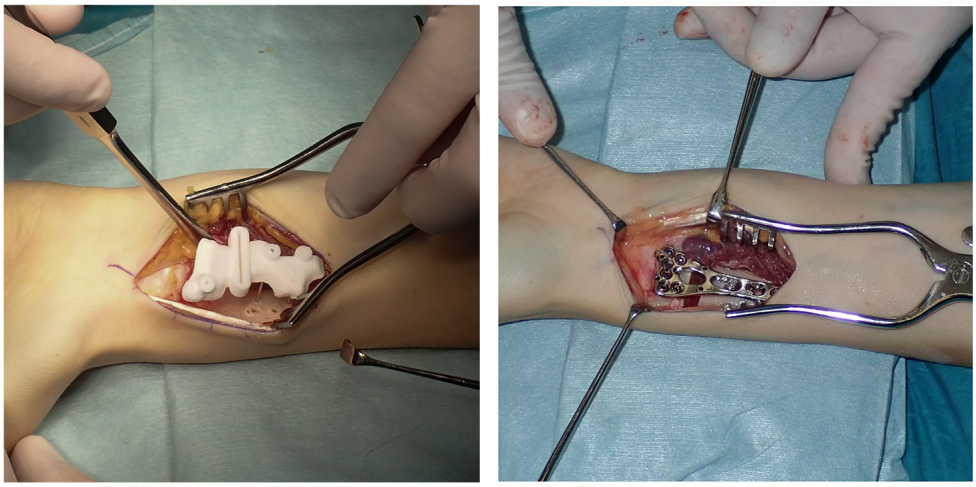

Figure 3.28: Left, the cutting guide is being placed on the bone using the mettal pins. Right, the metal plate is fixed using screws. Courtesy of Katleen Libberecht.

During the surgery, a fluoroscope is used to monitor the correction of the distal radius. With the help of these fluoroscopic images, the surgeons can ensure that the placement of the plate and screws matches the 3D planning. For example, if a screw is longer than expected, surgeons can see that on the fluoroscopic images.

4

Potential for additive manufacturing

4.1 Identification of challenges in 3D planning

Every step of the 3D planning process is critical to the end result. To minimize human error, all steps should be standardized. Tracking and breaking down the process into smaller parts allows identifying possible improvements that affect the quality, time and cost of the process.

Based on the process chain, it is clear that the geometry of the plate influences many parameters in the planning process. These parameters are the placement on the distal radius, the geometry of the cut and finally the creation of the custom guides. For patient cases which require significant correction of the distal radius, many different plates must be examined to find the best fit. As the plate design affects earlier stages of the process, a design loop is created. This loop adds to the overall process time. If the deformity of the bone is so severe that no standard plate fits accordingly, the plate has to be bent as mentioned in chapter 3. This creates design problems in modeling and also problems with the load that a bent plate can withstand.

In addition to the selection of the plate, the creation of the individual axes of the screws requires time. Depending on the 3D models, the engineer must create each axis from scratch. This process is time consuming and a potential cause of errors which could result in a misaligned axis, leading to an inaccurate positioning of the distal radius.

The 3D models of the plates are needed to create the custom guides. Unfortunately, these models are not always accessible; Some companies offer these models, but with restrictions on their use and distribution, other companies do not offer any 3D models. For 3D planning hand surgeries, however, surgeons would benefit from having as many plates available as possible to perform the best correction possible. Unlike the standard plates, the guides are not restricted in this way. Being custom designed, they can adapt to the geometry and be adjusted so that the selected plate can be installed as intended in the 3D planning.

All of the above problems are strongly related to the fact that the plates are designed

and manufactured for fractures and not for corrections as in the case study. Additive manufacturing can create custom plates, potentially reducing the time required for 3D planning while providing the best possible correction.

4.2 Implementation of custom surgical plates

Custom-made implants have been used for various types of surgeries. They can provide personalized solutions, tailored to the specific needs of the patient.

4.2.1 Surgical plate requirements

Surgical fixation plates have specific requirements that must be met in order to be used during surgery. These requirements are presented in the following subsections.

4.2.1.1 Material Requirements

Both fixation plates and screws must comply with regulations on what may be used inside the human body. Standard surgical plates and screws are made of stainless steel, titanium, or titanium alloys (such as Ti-6Al-7Nb) [17]. The plates that are made of stainless steel are the ones that can be bent. Titanium plates are brittle and are therefore not used in such cases.

4.2.1.2 Load Requirements

The fixation plate must withstand the stress of daily activity. Even though the in vivo loading conditions of the distal radius are not fully known, there is a study relating grip force to the force transmitted through the radius and ulna. This study showed that for every 10 N of grip force, 26.3 N are transmitted through the radius and 26.1 N through the ulna [18]. For every 10N of grip force, 26.4N are transmitted through the radius in the axial direction [19]. The existing fixation plates can be considered for calculating these load requirements. In one study, two different plates, a Synthes plate and a Stryker plate, were compared to determine the load each could withstand. The Synthes plate had a failure load of 834.1 N, while the Stryker plate withstood 492.2 N at a load applied with 0 degrees [20]. This highlights the big difference between different standard plates.

4.2.1.3 Geometry Requirements

The surgical plate must conform to the bone surface. At the same time, it should have a small volume (thin and narrow) for anatomical reasons. Another feature of the surgical plate and screws is that they should be removable. As described in the previous chapter, the plate and screws may need to be removed if, for example, there is another injury or the plate/screws are broken. Some materials may allow bone growth around the plate or screws, making the removal process difficult.

4.3 Design of a parametric model of a surgical plate

Additive manufacturing has the advantage of a high level of design freedom which allows tailoring specific designs. Combining AM with a parametric design model, allows parts to be produced with a great deal of differentiation without spending a lot of time in designing of each individual model. As seen in chapter 3, standard plates have disadvantages that may cause problems during 3D planning and the surgery.

A custom-made, patient-specific surgical plate, can minimize the disadvantages of standard plates and can provide the best possible fixation. There are many examples of custom plates being designed and manufactured using AM.In the case study for example, a custom plate would be optimal and would allow the optimal correction.

The manufacturing of an individual fixation plate for each patient would require a great deal of time. This time includes the design time, plus the time for manufacturing, testing, and obtaining all approvals for medical use. All of these steps would increase the cost per surgical plate. To overcome these obstacles, a parametric design of the surgical plate can be used. A parametric model allows numerous variations of a design to be created without the need for a new design cycle. It is also possible to verify the model so that it always conforms to given requirements. For example, all models that withstand a given load can be verified with Finite Element Method.

4.3.1 Parametric Plate Requirements

The parametric plate must provide enough design freedom to effectively support the distal radius and to adapt to different geometries. The existing designs of surgical plates can be used as references to initiate the design process and can provide the necessary design principles. These principles can later be tested with FEM and can also be modified to meet the requirements of the specific application.

4.3.2 Parametric Plate design

For this master thesis, a parametric model of a fixation plate was created using the CAD software Solidworks. The parametric plate has 5 different sections: A,B,C,D and E as shown in figure 4.1.

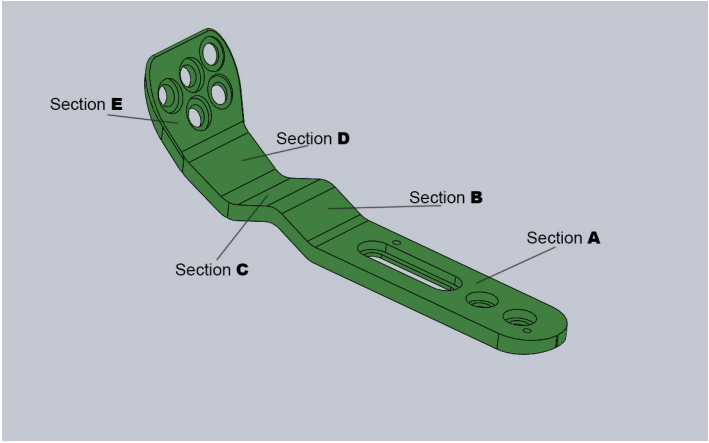

Figure 4.1: An image showing the different sections of the parametric plate.

Section A is responsible for fixation of the proximal radius with 3 screws. The distal screw can be placed in different positions. The design of the slot allows sliding of the plate and easier placement of the plate in the planned position. Section A has a curved surface on both sides so that it can follow the geometry of the radius. The edges are filleted to eliminate rough edges that could damage the tissue or bone and tissue around the plate. The plate can be adjusted in length, width and also thickness. These parameters can later be used as FEM parameters to ensure that the plate can withstand the loads.
Sections B, C and D are designed to bridge the gap between proximal and distal radius. The angles as well as the widths, lengths, and thicknesses can be adjusted. Finally, section E is designed to fix the plate to the distal radius using 5 screws. Similar to the standard plates, the screws are non-parallel to allow for better fixation. If more fixation points are needed, it is possible to introduce more than 5 screws in section E.
The sections of the plate can be adjusted in length, thickness, and also angle. In figure 4.2, three plates have been created using the parametric model. As can be seen, they all have different angles between the sections.

Figure 4.2: A image created by photo-realism software to demonstrate three different variations of the parametric fixation plate model.

4.4 Integration of the parametric model into 3D planning process

The parametric model can be used in 3D planning immediately after the cut is planned/applied, and when the distal radius is adjusted to the optimal position. Instead of trying to select a standard plate, the parametric model can be inserted into the software. Section A, which is intended to be fixed in the proximal part, is first placed on the proximal radius. Using the ruler tool, some measurements are taken to help determine the ideal length of section A. After this measurement, the length of section A is changed and the parametric model is inserted back into Materialise 3-matic. The next measurements are related to the gap between the proximal and distal radius. Similar to the previous step, the new measurements are added to the parametric model and the model is imported back into the 3-matic software. Finally, the cross-section is adjusted so that the plate adapts to the geometry of the distal radius in the best possible way.
As described above, the process of fitting and adjusting the parametric model requires the use of two software programs. This could be optimized by enabling plate adjustments within Materialize 3-matic software.

4.4.1 Using the parametric plate in the case study

The parametric plate model was used in the 3D planning of the case study. As described in the previous section, the model was introduced after making the cut and placing of the distal radius in its optimal position. This time, the parametric model was inserted into the 3-matic software as a step file. Section A was then fitted to the proximal radius and after this, the length of the gap between distal and proximal radius is measured. As can be seen in figure 4.3, the original model already seems to satisfy the bone geometry of the proximal radius without the need for further corrections.

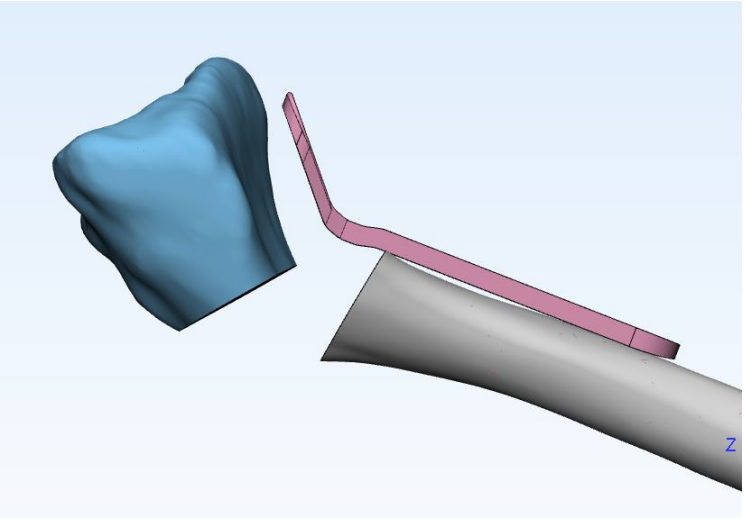

Figure 4.3: The initial model of the parametric plate.

The parametric model must, however, be adjusted to better fit the geometry of the distal radius. The distance of section E was minimized and lowered. After 3 iterations, the final plate geometry can be seen in figure 4.4. A representation of the fitting of the parametric plate on the distal and proximal radius can be seen in figure 4.5.

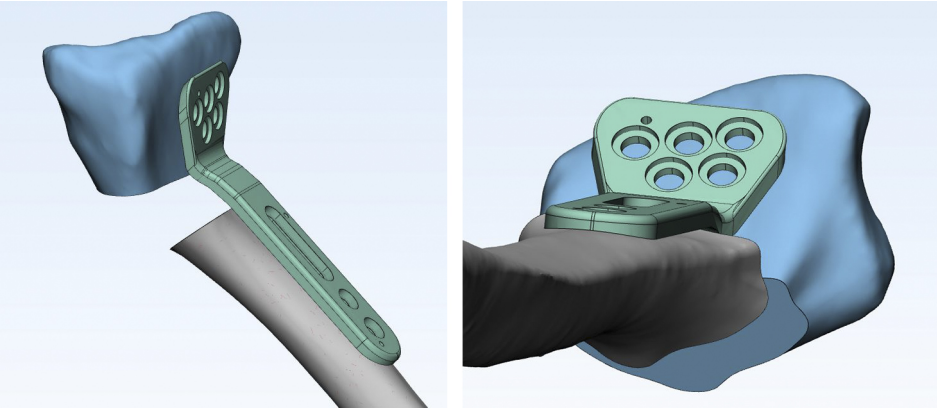

Figure 4.4: The final model of the parametric plate.

Once the plate design is complete, the next steps are the same as for 3D planning with a standard plate. The only difference is that the custom plate must first be manufactured.

Figure 4.5: An image created by photo-realism software to demonstrate the custom plate and the proximal and distal radius.

4.4.2 FEM analysis of the custom plate

Once the geometric parameters of the parametric model have been selected, the model must be verified for the loading requirements. This can be done using FEM software that can perform stress analysis while the parametric model is adjusted to withstand the loads. At this point, only the thickness parameters can be adjusted as the other parameters will result in a redesign of the 3D planning, increasing the total time needed.

4.5 AM process for manufacturing of the surgical plates

In order to produce a custom-made surgical plate, the AM process must be able to produce parts that are highly detailed, biocompatible, and have mechanical properties that must withstand the loading conditions. This section evaluates some of the metal AM processes for this particular application.

4.5.1 LB-PBF

LB-PBF is a process already used in the fabrication of custom surgical implants. Due to the low layer height and high precision, it provides parts of great quality. This process requires support structures to support or anchor and constrain the part on the build plate. However, custom surgical plates are relatively thin and grow in one direction, so their geometry could be ideal for this method as not many support structures may be needed. Additionally, this process cannot produce threads in small dimensions as used in this application. This means that the plate must be machined to create these threads, and some modifications must be made to be able to create the holes without support structures. Depending on the orientation on the build plate, circular geometries that are bellow 5 mm may need to be redesigned into a teardrop shape or be filled with support material that will be therefore removed during post-processing.

This process can produce parts in a variety of materials which meet the regulations for use inside the body [21] such as stainless steel, cobalt chrome, and titanium and its alloys. Plates made of these materials can also be sterilized in an autoclave.

The parts fabricated with LB-PBF have a rough surface. For the application of the surgical plates, the surface, especially the one on which the soft tissue will slide, must be smooth. To make the surface smooth, the plate must be further post-processed.

A study in which a custom-made surgical distal radius plate was fabricated using LB-PBF reported its mechanical properties. The custom-made plate was stronger compared to a standard plate [20]. This may be an indicator that fabricating custom plates with LB-PBF is not only possible, but that the plate may have better properties than the standard plates.

4.5.2 Binder Jetting Technology

Binder Jetting Technology (BJT) is a process that can offer parts with great detail and high surface finish. Using this process to create custom surgical plates has the advantage of being able to create the threads without any post-processing. One characteristic of the process is that the parts must be sintered in a furnace. Due to sintering because of the high temperatures in the furnace, the parts shrink changing geometry. Although this effect is more noticeable in larger parts, it will also be noticeable in the custom surgical plate with a minimum length of 50 mm. Therefore, the design must be modified, prior to fabrication to compensate for shrinkage and deformation during the necessary sintering step. As BJT is currently still in development, it may not be the ideal solution to create surgical plates for now. Additionally, sintering conditions for BJT printed plates as well as post-processing will have to be considered when evaluating the use of BJT for this application.

4.5.3 EB-PBF

As a hot process, EB-PBF is a process that can produce parts with great mechanical properties. Similar to LB-PBF, it is commonly used in the manufacture of implants, such as hip cups [22]. By using a greater layer height compared to BJT or LB-PBF, EB-PBF produces parts of lower detail. One drawback of the process is that the surface of the parts is rough. Similar to LB-PBF, post-processing is needed to polish the surface. Offering parts with great mechanical properties makes the EB-PBF a good option to manufacture custom surgical plates.

4.6 Manufacturing cost

The cost of manufacturing custom surgical plates varies depending on the process that is chosen. The total cost is made up of the cost of the feed stock material, fabricating the part and the cost of post-processing. Depending on the process, the cost for post-processing can make a difference in the total cost. For example, when using the BJT, the threads of the plate can be created at the manufacturing stage without the need for further post-processing. Creating threads on the plate requires additional tooling to ensure the alignment is correct. In this example, BJT may be cheaper than the other processes in terms of post-processing.

5

Future Steps

In previous chapters, the steps required to implement AM in the process of distal radius correction have been described. Although promising, there are specific steps required to fully implement AM into the planning and surgery process. Based on applications in other fields, we can definitely say that the implementation and use of AM is something realistic, at least for complex cases. The number of cases in which it can be implemented depends on many factors, which will be analysed in the following sections.

5.1 AM Technology

As seen in chapter 4, several AM technologies are suitable for the fabrication of the surgical guides and plates. In this case, the focus is mainly on the materials that each procedure can use. For example, BJT is a promising technology that could lead to a reduction in cost per part by offering parts that require minimal machining.

5.2 Finalise the design of the surgical plate parametric model

The parametric model designed for this thesis was intended to serve as a proof of concept. Although it allows for a wide range of variation, there may be further requirements in terms of its functionality. Attempting to use it for different cases, especially with detailed FEM, will result in a design capable to adapt to large variety of distal radius injuries. For example, there could be variations of the model that allow for the placement of more screws in the distal or proximal portion, or a design where the direction of each screw can be chosen to meet the needs of the particular patient.

Adding more degrees of freedom to the parametric model adds complexity. The models need to be tested and at the same time created in such a way that they can be easily adjusted by a surgeon or an engineer. This is a project that requires time for both design and testing to meet design, medical, and design for AM requirements.

5.3 Navigating Regulations

5.3.1 Patents

Since the design of individual surgical guides varies from patient to patient, it cannot be protected by patents. Similarly, most of the design of a custom surgical plate can be created without the use of already patented technologies. The only aspect of the design that can be protected by patents is the way the screws are placed in the plate. Some plates provide a locking mechanism for the screws that allows the screws to be placed at different angles. A patent analysis must be performed to determine, if the parametric plate design can be manufactured without infringing any existing design patents. In the event that the patent rights need to be acquired, the cost of a custom surgical plate can increase which may lead to a cost which is many times higher than the one of the standard surgical plates.

5.3.2 Patient data protection

The entire process must protect patient data. As seen in the first process step of 3D planning, the patient data was anonymized. As various software packages may be needed and different people may be involved in the planning process, the entire process must be designed to secure the patient data.

5.3.3 Certificates for medical use

The design and manufacturing process must be certified to a standard for the medical field. One such standard is ISO 13485:2016 [23]. This quality standard covers the design, development, production, storage, distribution and installation of medical devices and can also be applied to suppliers. In this process chain, the standard can be used for the suppliers of the material for the AM and also for the suppliers of the final parts such as the surgical plates and guides. The requirements of the standard are applicable regardless of the size of the organisation.

5.4 Special training for surgeons and engineers

The 3D design and additive manufacturing process for surgical guides and plates requires close collaboration between surgeons and engineers. Since these techniques are new to both groups, special training is required to facilitate communication and collaboration.

5.4.1 Special training for surgeons

From initial education to everyday work, surgeons are used to working with 2D imaging such as X-rays, CT scans, and MRIs. In this way, they can identify the injuries and also plan surgery, as described in chapter 2. New software, such as Materialise Mimics, offer the possibility of moving from two to three dimensions.

This transition is challenging because the literature is based on 2D imaging.

The ability to view a case using 3D models opens up new possibilities for surgeons. For example, in reconstructive wrist surgery, not only the compression and inclination of the bone can be considered, but also the rotation. Using advanced 3D tools requires training. On the positive side, software has become easier to understand and use over the years, including features that automate parts of the process. On the other side, there are specific steps that can greatly help the entire process chain. Through continuing education, surgeons could learn to use basic tools that allow them to do some parts of the planning. There are steps in the planning where their input is essential, and it would be very difficult for an engineer to achieve the same output. Training could allow surgeons to become familiar with the software so that they can better collaborate with engineers working in the same field.

5.4.2 Special training for engineers

The role of the engineer in this process is to provide the correction intended by the surgeon while meeting the requirements. Engineers need to be trained to perform the steps of the process that require their input. The training should relate to both the medical field and to AM. Engineers who will be included in the 3D planning need to understand medical terms in order to communicate with the surgeons without any problems. They also need to be familiar with the pre-operative planning and surgery, and learn its limitations as well as requirements. From my personal experience completing this project as an engineer, it takes time to fully understand the subject as it requires skills in specific software and at the same time skills to understand how the wrist and especially the surgery works. It is very important for engineers to completely understand the process of the surgery and, ideally, to observe one of them. As part of this thesis project, I was able to attend a surgery which allowed me to gain valuable insights into the medical procedure (the team and I took a picture before entering the surgery room 5.1).

Figure 5.1: A picture before joining an actual reconstruction wrist surgery.

Additionally, engineers should understand design for additive manufacturing. With regard to the technique to be chosen, the engineers needs this knowledge to ensure the manufacturability of the surgical guides and plates.

5.5 Identifying the needs

Different medical organisations have different needs. For example, smaller hospitals may not have the ability to support an engineering team that works closely with surgeons. A critical factor of creating a dedicated team of engineers could be the number of cases an organisation has per year. Having only few cases per year would lead to a increased cost per patient.

If the number of patients is not sufficient to justify the establishment of an engineering team within the organisation, there is the possibility of outsourcing engineering part of the 3d planning. For example, a specialized centre employing trained engineers could be used by a range of medical organisations such as small hospitals. An analogy is the services already offered by companies such as Materialise (Materialise offers 3D planning services including manufacturing of custom surgical guides). The disadvantage with such services is the high cost per surgery and sometimes the problematic collaboration between surgeons and engineers.

In large medical organisations such as big central hospitals, it can be beneficial to have a dedicated team of engineers and surgeons that will work with this applications and communicate on a regular basis. The number of patients that could be handled per year would increase, resulting in lower costs.

5.6 Software technology developments

For this master thesis, five different software programs were used to perform the 3D planning and the design of the custom surgical guides and plates. The Materialise software package Mimics and 3-matic was used for the 3D planning and guide design. Dassault Systèmes SOLIDWORKS were used to design the parametric model. To perform FEM analysis of the parametric plate, a special software such as Ansys is required. Finally, depending on the AM technology used, specialized software such as Materialise Magics is needed to design the support structures for manufacturing.

The problem with using different software programs is the way each software communicates with the others. Most of the process is based on STL files. If different software programs are used, the STL files may need to be converted to different formats. This conversion can result in files with geometry problems that take time to fix. Additionally, it takes time to learn how to use different programs, resulting in the need for more training.

In future, a platform that allows to perform all the above functions should be created. This way the communication between surgeons and engineers can be simplified. The

time taken from inserting CT scan files to exporting 3D models of the custom surgical guides and plates can be minimized.

5.7 Design and standardization of the process chain

Not all of the above future developments are required to integrate AM into wrist surgery, but they would offer a toolbox to help with the implementation. A standardised manufacturing chain is required to ensure high quality and efficiency. In each step, the role of the engineers and surgeons varies; some steps require close collaboration while others require approval, mainly from the surgeons. Depending on how the whole process chain is implemented, some steps may differ. For example, the way of communicating may differ depending on whether the engineers are part of the medical team and placed in the same location, or whether they work remotely while handling cases from other hospitals or places around the world. An example of a process chain is shown in the form of a decision tree in appendix. A.

The process may vary depending on the needs and resources of the organisation wishing to implement the 3D planning process. Each step should be well documented and standardised so that engineers, surgeons as well as manufacturers can work according to the process standards and provide quality services and products to patients.

6
Conclusions

3D planning of wrist surgery has significant advantages over 2D planning. It provides surgeons with a better understanding of each patient case and, when combined with AM, can allow the design of customised solutions. The entire process of 3D planning for the distal radius, including the design and manufacturing of custom surgical guides and plates, is quite complex. Close collaboration between surgeons and engineers is required for each step of the process. This collaboration is challenging as both groups need to be familiar with each other's frame of reference. AM is already used for medical applications and provides customised surgical tools and implants. One important advantage that has made AM popular in the biomedical field, is its ability to create personalised solutions for the patients. As applied today, the 3D planning process has some disadvantages like high cost, the time required for communication between surgeons and engineers, and in cases where the standard plates cannot perform the optimal correction the end result for the patient is less than optimal. Despite the current costs and increased time required for communication between surgeons and engineers, AM offers a great solution especially for complex distal radius deformities. In those cases, standard surgical plates cannot offer the required adjustments to correct the wrist in an optimal way. Especially with further development and increased knowledge and experience, AM could be fully implemented into the wrist surgery process. This could lead to a reduction in planning time, especially for complex patient cases.

To overcome the obstacle of increased complexity of the 3D planning process, the entire design and manufacturing chain must be standardised. Several AM processes are capable of creating the patient-specific surgical guides and plates. LB-PBF and VAT photopolymerization can be used to manufacture surgical guides, while LB-PBF, EB-PBF, and potentially BJT could be used to create patient-specific surgical plates. The selection of AM processes must be tailored to the needs of the particular medical organisation seeking to implement AM in its operations and requires further development and investigation of the manufacturing processes.

The following future steps are required to fully implement AM into the process.

- Identify the needs (patients/year)
- Finalize and verify the design of the surgical plate parametric model
- Navigate medical and organisational regulations
- Educate and train surgeons and engineers
- Develop software technology
- Design and standardise the 3D planning and manufacturing chain

Through interviews, literature study, and the design and prototyping activities conducted as part of this thesis, a better understanding of the process and the potential of implementing AM into the process emerges. Thus, the research questions can be answered:

What is the potential of AM for the patients, surgeons and healthcare organizations (cost-quality of medical services)?

Implementing AM into medical processes can have great potential for patients, surgeons as well as healthcare organizations. If implemented properly, AM can lead to providing patients with high quality services in cases that could otherwise not be treated. Surgeons would have more freedom during the planning phase and would be less stressed during the surgery itself. The healthcare organizations would benefit as higher quality services could be offered and the overall cost per surgery could potentially be minimized.

What is the possibility to create an in-house manufacturing chain for this application, what AM techniques are suitable, and what is the potential of an AM custom made fixation plate?

It is possible to create an in-house manufacturing chain for the surgical guides. If VAT photopolymerization is used for the surgical guides, manufacturing can be done within the healthcare facility, minimizing delivery, manufacturing as well as planning time. For the custom metal plates, it is preferred to outsource the manufacturing due to cost and also the complexity of using and maintaining a metal AM machine inside healthcare organization. Regarding the 3D planning, an in-house design team can help the process by allowing better communication between surgeons and engineers. In summary, the design and some of the manufacturing can be done in-house, while the manufacturing of the surgical metal plates should be done externally. The custom plates should only be used in complex patient cases where the standard plates do not provide the necessary/optimal adjustment.

In which cases can AM be beneficial?

AM is advantageous in complex cases where the precision of the procedure is important. AM is the manufacturing solution that can provide surgeons with customized surgical guides and plates suitable for unique cases. AM acts complementary to 3D planning and allows free design of the customized solutions. It can allow surgeons to rethink the way they approach a patient case, thereby creating new solutions that can increase the quality of medical services provided to patients. Whether or not it is used to create custom plates, AM can assist surgeons in creating models of bone geometry and also in creating custom surgical guides.

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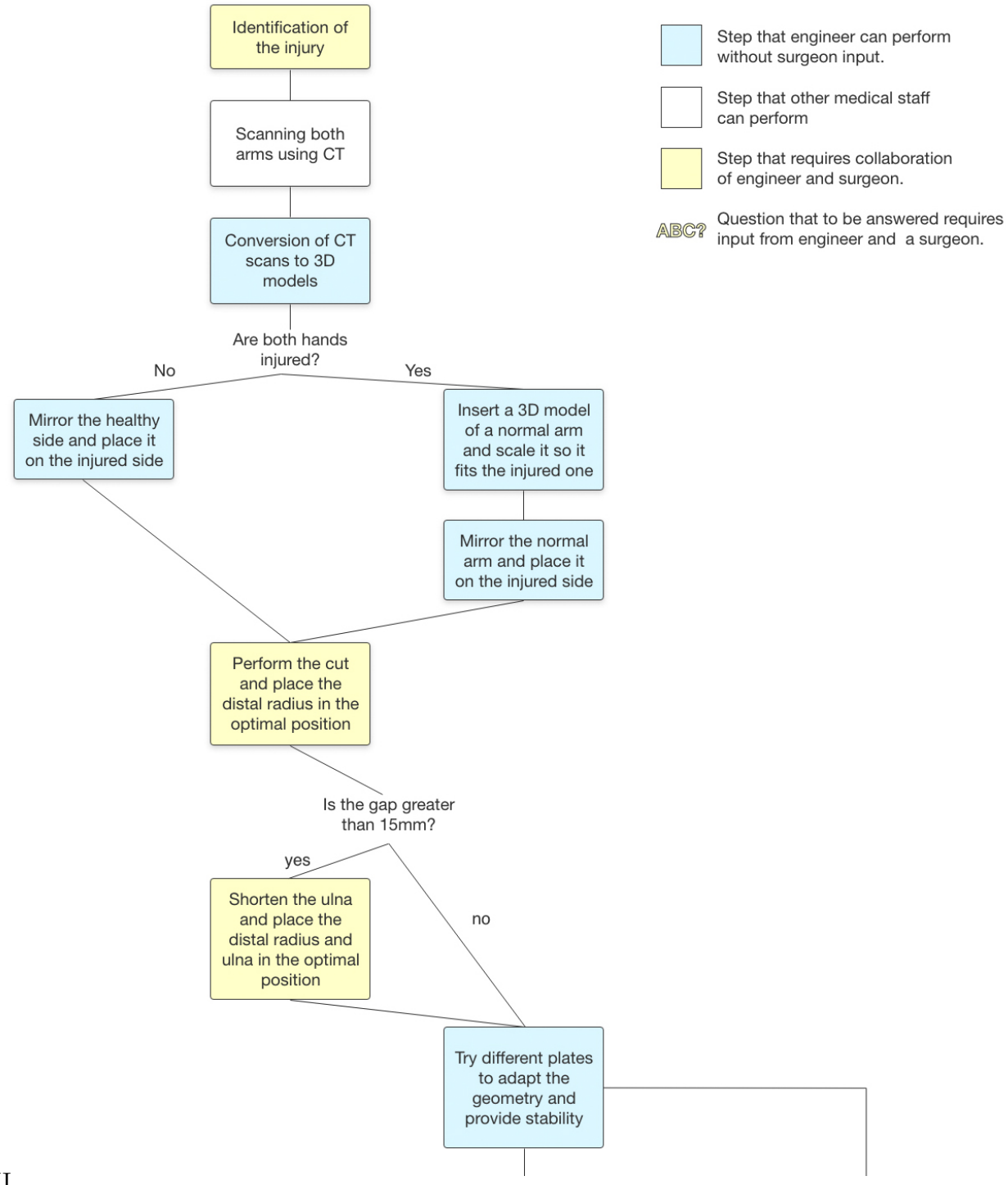
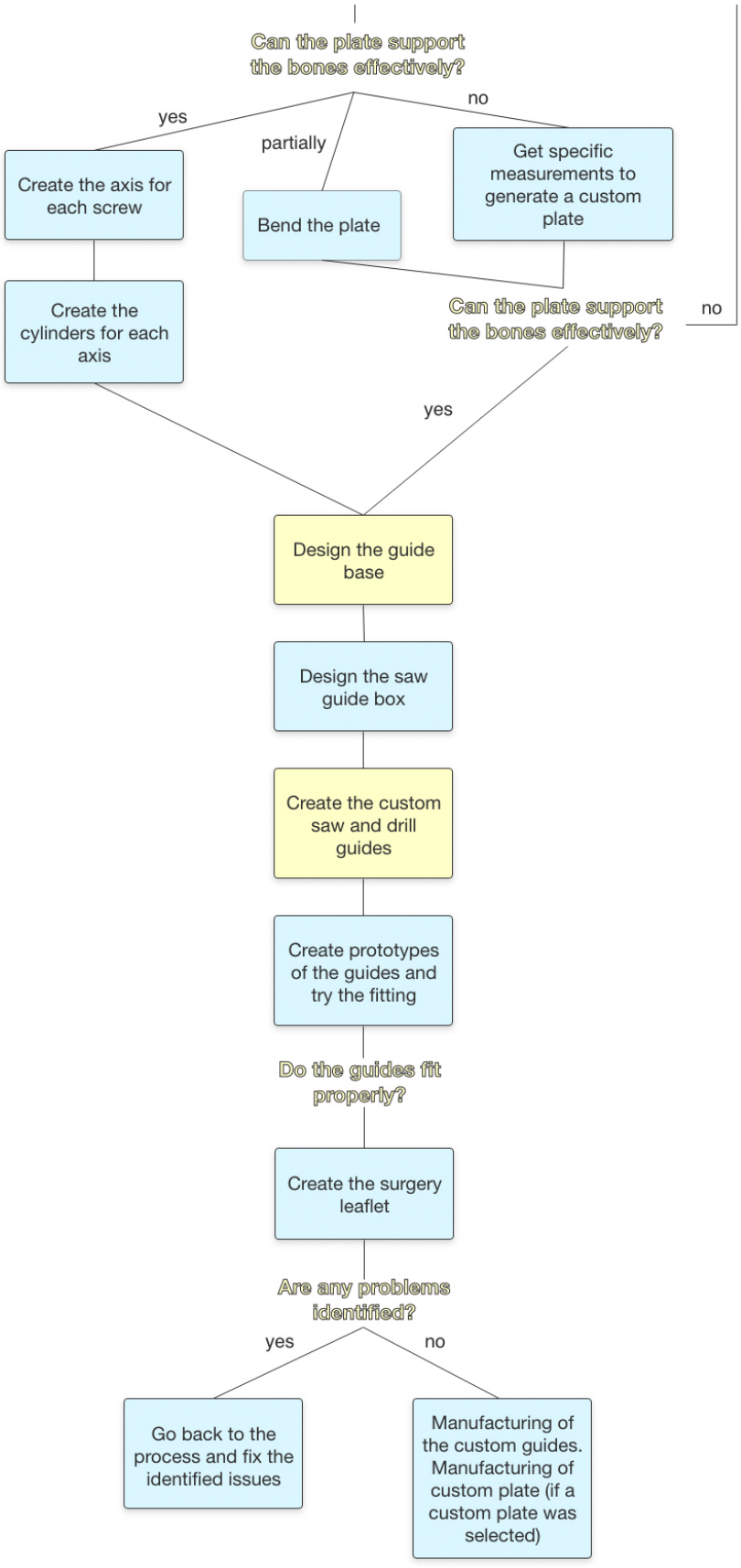
A
Appendix 1


Identification of the injury
Scanning both arms using CT
Conversion of CT scans to 3D models
Are both hands injured?
No
Yes
Mirror the healthy side and place it on the injured side
Insert a 3D model of a normal arm and scale it so it fits the injured one
Mirror the normal arm and place it on the injured side
Perform the cut and place the distal radius in the optimal position
Is the gap greater than 15mm?
yes
no
Shorten the ulna and place the distal radius and ulna in the optimal position
Try different plates to adapt the geometry and provide stability
Step that engineer can perform without surgeon input.
Step that other medical staff can perform
Step that requires collaboration of engineer and surgeon.
ABC?
Question that to be answered requires input from engineer and a surgeon.


Can the plate support the bones effectively?
yes
partially
no
Create the axis for each screw
Bend the plate
Get specific measurements to generate a custom plate
Create the cylinders for each axis
Can the plate support the bones effectively?
no
yes
Design the guide base
Design the saw guide box
Create the custom saw and drill guides
Create prototypes of the guides and try the fitting
Do the guides fit properly?
Create the surgery leaflet
Are any problems identified?
yes
no
Go back to the process and fix the identified issues
Manufacturing of the custom guides. Manufacturing of custom plate (if a custom plate was selected)

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