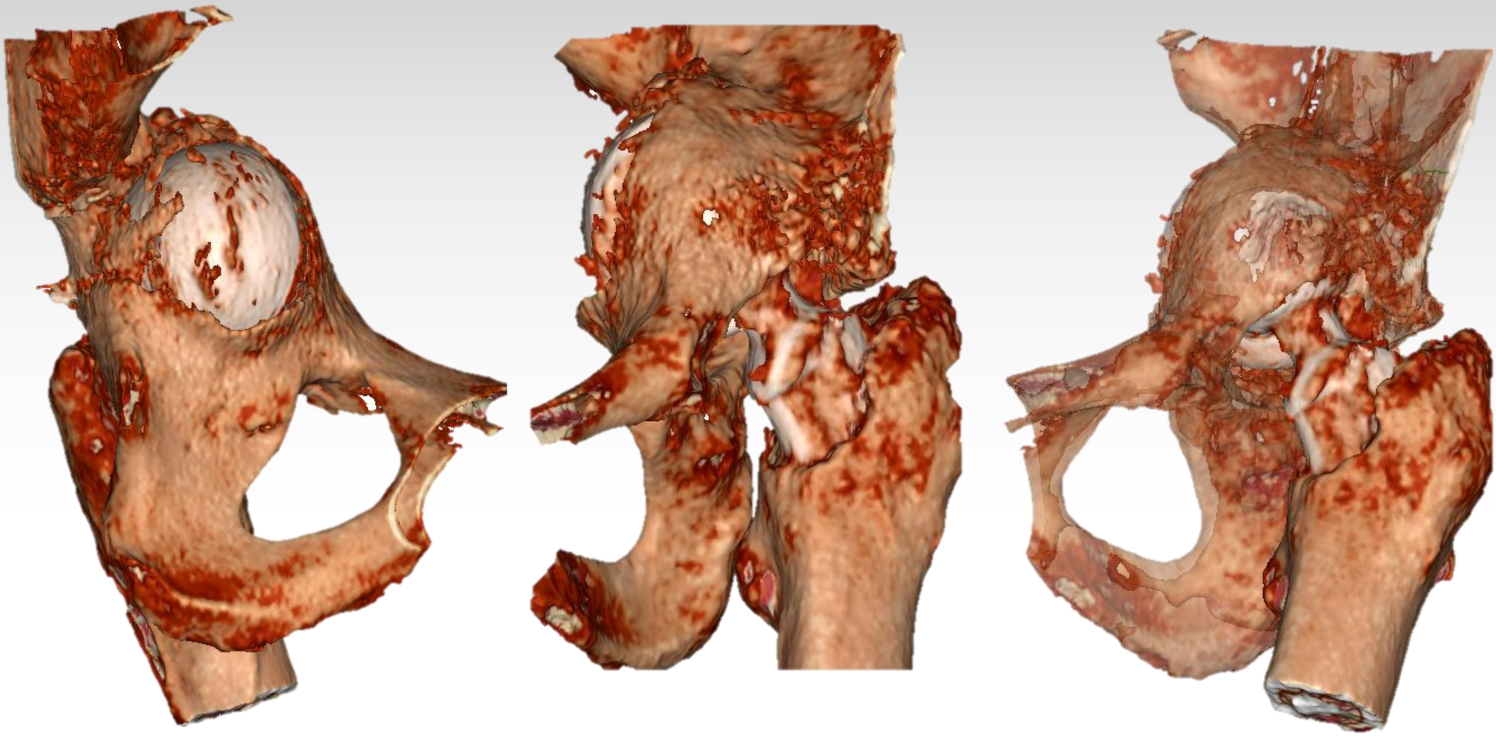
Added value of 3D printed anatomical models in a teaching hospital

A workflow proposal, survey study and business case to support the initiation of a 3D lab



Y. F. (Yaro) Roodenburg
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albert schweitzer

Added value of 3D printed orthopedic anatomical models in a teaching hospital

- A workflow proposal, survey study and business case to support the initiation of a 3D lab -

Roodenburg, Yaro

Student number : 4553322

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Supervisor(s):

Dr. ir. Bart L. Kaptein

Dr. ir. Jeroen Bosman

Dr. Joost C. Peerbooms

Thesis committee members:

Dr. ir. Bart L. Kaptein, LUMC (chair)

Dr. ir. Sjoerd Niehof, Maasstad hospital & TU Delft

Dr. ir. Jeroen Bosman, Albert Schweitzer hospital

Dr. Joost C. Peerbooms, Albert Schweitzer hospital

Preface and acknowledgements

This master’s thesis represents the end of my time as a student at the Technical University of Delft, the Erasmus Medical Center and the Leiden University Medical Center. During these six years as a Bachelor’s student in Clinical Technology and a Master’s student in Technical Medicine, I have learned so much about medical technology and its incredibly broad application, but also what it means for a patient to be hospitalized and to live far from optimal conditions. For me, enhancing a patient’s experience in a hospital or other healthcare facility through the use of innovative technologies, which sometimes requires to ‘think outside of the box’, was one of the most important reasons for both choosing this programme and to hopefully continue working in this field.

My final internship took place in the Albert Schweitzer hospital in Dordrecht, which is a familiar place for me as I did my first internship at this place as well. First of all, I would like to thank Sara Laros for the input she had in this project as my daily supervisor. It was really comfortable knowing that I could always discuss my work, questions and other practicalities regarding the project with you. Next, I would like to thank my two local supervisors, Jeroen Bosman and Joost Peerbooms, for providing objective feedback in both a technical and clinical perspective. The last person of the supervising team I would like to thank for his participation in the project is Bart Kaptein. As my external supervisor, your insights were very useful every time during the progression of this project. I would like to thank the complete supervising team for helping me with the third subject in this thesis, being the writing of a business case. I had never written a document like this, experienced quite some difficulties but still I am proud of what we achieved!

Lastly, I would also like to thank my parents, my sister, and my girlfriend for their inexhaustible support, motivational conversations and confidence during my entire graduation project.

Abstract

Introduction
Implementing a three-dimensional (3D) planning and printing lab in hospitals can offer multiple benefits for both healthcare professionals and patients. The aim of this master's thesis is to support the initiation of a 3D lab in the Albert Schweitzer hospital through three topics: a workflow proposal for development of anatomical models, a survey study investigating the added value of these models in collaboration with the department of orthopedics and a business case outlining three potential scenarios of implementation.

Methods
A hospital-specific workflow was established by incorporating existing literature and identifying the key stages, materials, hardware, software, roles and responsibilities for development and 3D printing of anatomical models. A survey study was conducted using a questionnaire containing Likert and categorical scales. Anatomical models for orthopedic cases were produced and utility of each model was evaluated with the participation of orthopedic surgeons. The business case included a cost-benefit analysis for the three scenarios: in-house 3D printing of anatomical models (scenario 1), 3D printing of orthopedic surgical guides for total knee arthroplasty (scenario 2) and 3D printing of orthognathic anatomical models and wafers (scenario 3).

Results
A 15-step workflow was created covering all stages from image acquisition to delivery of the anatomical model. 30 orthopedic cases were included for the survey study. A total of three orthopedic surgeons participated in the study and agreed that 3D printed models provide additional information during the process of preoperative planning (rated 3.4/5), might enhance surgical outcomes and efficiency (rated 3/5 and 3.2/5, respectively) and can reduce average operative time with several minutes. These advantages were particularly evident in hip revision and ankle/foot cases, whereas conventional hip cases benefited the least. Cost-benefit analyses in the business case demonstrated cost-savings in scenarios 2 and 3 for in-house planning and printing over outsourcing of these tasks, considering a 5-year period.

Conclusion
This work presents a clear and implementable workflow for the development of 3D printed anatomical models. These models can function as a valuable tool in the process of preoperative planning of orthopedic surgery and hold potential for other applications. To optimize financial benefits, it is recommended to initiate a 3D lab with the in-house production of orthopedic surgical knee guides. Future work should explore the demand for 3D printing in other departments to further optimize the usefulness of a 3D lab in this hospital.

Contents

1

Introduction

The healthcare industry is constantly evolving, with the primary objectives of enhancing healthcare accessibility, improving the effectiveness, and enhancing patient outcomes (1). To achieve these goals, new technologies are increasingly being implemented in hospitals, including three-dimensional (3D) printing. 3D printing is a process in which a digital three-dimensional model is transformed into a physical object of any shape, typically by depositing a material layer by layer (2). The increasing use of 3D printing technology in healthcare is driven by decreasing costs of 3D printers and materials, as well as through the wider availability of medical computer-aided design (CAD) software (1).
According to the literature, the use of 3D printing technology in hospitals can offer benefits for both patients and physicians. 3D printing has a great potential to revolutionize healthcare through development of patient-specific anatomical models, aiding in preoperative planning, and for education and training purposes (3). Other parts that can be produced through 3D printing are intraoperative cutting guides, which ensure optimal alignment of cutting planes, and implants that are customized to fit a patient's anatomy (4, 5).
One of the potential advantages of using 3D printed devices in medicine is a reduction in operative time, which can lead to a decreased risk of intraoperative infections (6, 7). Furthermore, 3D printing technology has the potential to minimize the risk of intraoperative complications, optimizing overall patient recovery (8).

While multiple 3D labs have emerged in recent years in the Netherlands, most of these labs are located in larger, academic hospitals. Smaller hospitals are now increasingly exploring financial resources, often through grants or funds, to establish their own 3D lab and embrace the potential benefits of 3D printing technology. To maximize the value of 3D printing for a specific hospital, it should be investigated how 3D printing can offer advantages, which mainly depends on the interest in 3D printing in this hospital. In the Albert Schweitzer hospital, initial interest in the potential of 3D printing was observed within the departments of orthopedics and oral and maxillofacial surgery, particularly in orthognathic surgery. A collaboration between the department of medical physics and these departments was established to explore the potential of 3D printing technology in this hospital.

Potential of 3D printing in orthopedics

In the field of orthopedics, preoperative planning is a crucial step in ensuring the success of a surgical intervention and optimizing postoperative outcomes. In current practice, preoperative planning primarily relies on X-rays, while in more complex cases computed tomography (CT) or magnetic resonance imaging (MRI) can be used additionally. For the majority of surgeries performed at the department of orthopedics in the Albert Schweitzer hospital, using these scans as a preoperative planning tool is sufficient for a successful procedure. However, for more complex cases that are not encountered regularly, these

modalities often fall short in providing orthopedic surgeons with a comprehensive understanding of spatial orientation of the anatomical structures within the region of interest (ROI) (9).
To optimize the preoperative planning process in these cases, 3D printing of anatomical structures within the surgical target area can be performed. Through this technology, improvements might be achieved in terms of more efficient preoperative planning and surgery execution, reduction in operative time and optimized postoperative outcomes (10).
In addition to anatomical models, 3D printed surgical guides can be valuable tools for this department, particularly in total knee arthroplasty (TKA). These guides can be designed to match a patient's anatomy, with strategically positioned drilling holes and cutting slits. The application of intraoperative cutting or saw guides during surgery could lead to a reduction of operative time, a less invasive procedure for the patient and improved alignment of the prosthesis (11, 12).

Figure 1. 3D printed anatomical model of a fractured humerus shaft.

Potential of 3D printing in orthognathic surgery

In the business case (chapter 4 of this thesis), financial effects of the implementation of 3D printing in orthognathic surgery are evaluated. 3D technology in orthognathic surgery is used for virtual surgery planning (VSP) and 3D printing of anatomical models and wafers. With VSP, the operating surgeon can determine the cutting planes and the optimal position of the mandibula and maxilla relative to each other (13). For the latter, a 3D printed interocclusal wafer can be used. This is a device that serves as a guide for repositioning of the mandibula relative to the maxilla and vice versa. Additionally, orthognathic anatomical models can be used for insights in anatomy both before and during the surgery (14).

Figure 2. 3D printed orthognathic interocclusal wafer. Image from Seres et al.

Goals & objectives

A literature review on 3D printing of anatomical models was conducted prior to the work in this thesis, and can be found in Appendix A. The main objective of the thesis is to provide an overview of the initial steps in the implementation process of a 3D lab in the Albert Schweitzer hospital. Subgoals are defined as follows:

1) creating a hospital-specific workflow for development of 3D printed anatomical models (chapter 2);
2) conducting a survey study in collaboration with the department of orthopedics to determine potential benefits of 3D printed anatomical models in this hospital (chapter 3);
3) developing a business case to determine financial consequences of implementing a 3D lab in this hospital (chapter 4).

By addressing these subgoals, this thesis aims to contribute to the implementation of a 3D lab in the Albert Schweizer hospital, with the ultimate goal of optimizing patient care in alignment with the hospital's positive attitude towards innovation.

2

Workflow for in-house development and printing of anatomical models

1. Introduction

This chapter aims to provide a comprehensive overview of a workflow for 3D printing of anatomical models in the Albert Schweitzer hospital, that was specifically designed to fit the in-house standard. Throughout this chapter, each stage of the workflow is explored, ranging from data acquisition to delivery of the model to the physician. The goal of an extensive description of each step is to provide future anatomical model designers with a detailed outline of actions to be taken when the workflow is implemented in practice.
A successful implementation of this workflow requires collaboration among the departments of radiology (image acquisition), medical physics (model development and printing) and the requesting department (model request and intended use). The workflow is generalized to allow for hospital-wide application and is not limited to use in orthopedics or orthognathic surgery.
Appendix B contains a description of the roles and their responsibilities in each step of the process.

2. Graphical representation of the 3D printing workflow

The graphical representation of the workflow as described in the previous section is illustrated in Figure 1. Each of the 15 key steps is visually represented by a purple box, input for each step is presented in an orange box positioned above the purple box, and output of each step is displayed in a blue box below the purple box. Go/no-go moments are indicated by a red and green box between two steps of the workflow. Additionally, for steps where an estimation of the duration could be made, a time indication is provided.

3. Description of stages in the workflow

3.1 Image acquisition
The initial input for model development is an imaging dataset of the region of interest (ROI) specified by the surgeon. In the implementation phase of this workflow, it can be determined for which patient groups a 3D printed anatomical model is considered standard of care. For these patient groups, it is important to include a note in the imaging request to ensure that the radiology staff can acquire reconstructions that are optimized for model development.
The most commonly used imaging modalities for the development of a 3D printed anatomical model are computed tomography (CT) and magnetic resonance imaging (MRI). The choice of which modality best represents the part(s) to be printed depends on the specific case and region of interest (ROI), and should be selected based on the desired model.

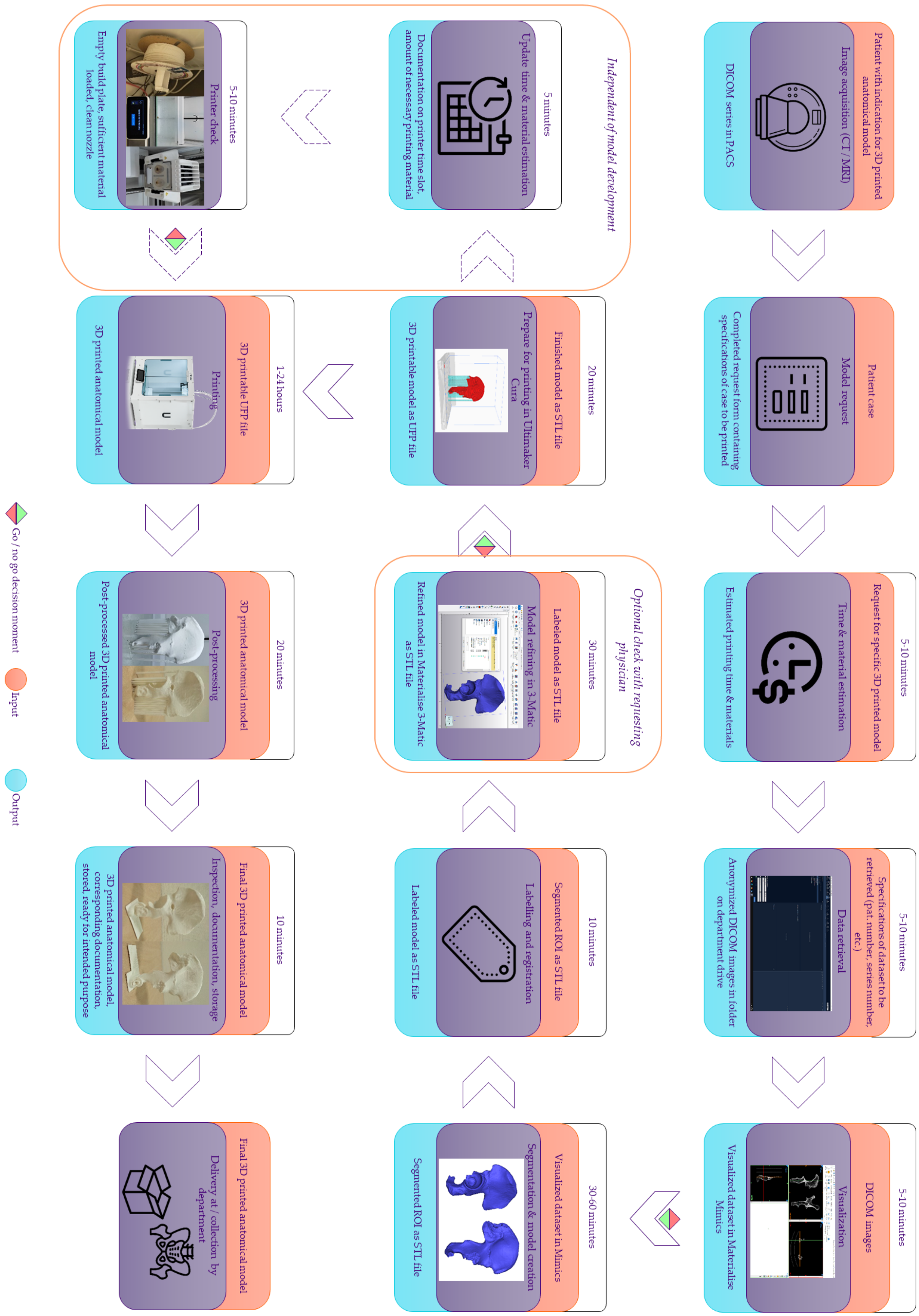


Figure 1. Graphical representation of the in-house workflow for development and 3D printing of anatomical models.

For models that need to accurately depict a complex bone defect, CT is generally the preferred modality as the contrast between bone and surrounding tissue is relatively large, allowing for more accurate bone segmentation compared to MRI. As an example, a CT scan of a complex trimalleolar fracture (Figure 2) is the best choice for the development of a 3D anatomical model that can be used during preoperative planning (15).

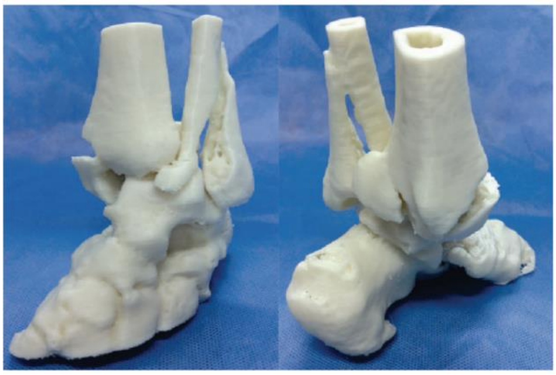


Figure 2. 3D printed anatomical model of the ankle joint demonstrating a trimalleolar fracture.

For the development of models with a focus on soft tissue abnormalities, MRI is the modality of choice as it allows for more accurate distinguishment of soft tissues. Disadvantages of MRI compared to CT is the relatively longer scanning time, resulting in more patient discomfort during acquisition, and a more time-intensive segmentation of the ROI.
A selection of other important factors that need to be considered before image acquisition with either CT or MRI is:

- *optimal axial slice thickness:* to develop an anatomical model that accurately resembles the ROI, it is important to determine what slice thickness is required prior to image acquisition. Usually, the optimal axial slice thickness is around 1 to 2 millimetres, and the optimal value is dependent on the amount of detail the surgeon requires for a specific case. Slice thickness might be larger than 2 millimetres, but it should be realized that a significant part of anatomical information will be lost by using a relatively large value for the slice thickness (16, 17).

- *use of contrast agent:* to obtain a better contrast between the ROI and surrounding tissue, the use of a contrast agent might be considered. A contrast agent should only be used when it will have a significant influence on the segmentation process, as it entails additional costs for the hospital and risks to patients (for example, hypersensitivity reaction, contrast-induced nephropathy and thyroid dysfunction (18)).

- *metallic artifact reduction:* in orthopedics, metallic implants are used on a regular base, for example in shoulder, hip or knee prostheses. These implants entail a risk of loosening or wear, resulting in the need for revision surgery. When these patients receive a new scan for preoperative planning of the revision surgery, the active implant can cause metallic artifacts on the images. To avoid these artifacts, most modern imaging systems are equipped with metallic artifact reduction techniques (Figure 3). It must be ensured that these techniques are used in the imaging of this patient population, as accurate segmentation might otherwise be impeded (19, 20). It must be mentioned that even with artifact reduction techniques, accurate segmentation can be a difficult and time-intensive task.

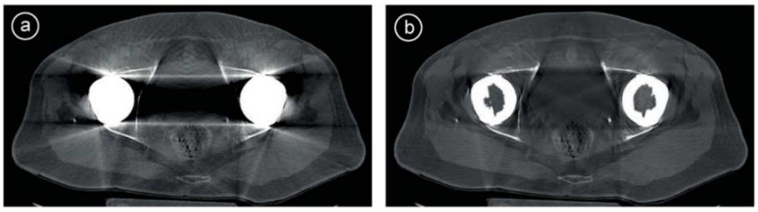


Figure 3. Bilateral metal-on-metal total hip arthroplasties without (a) and with (b) the use of an orthopedic metallic artifact reduction (O-MAR) technique in a CT scan.

3.2 Model request

A standardized process for surgeons to request a 3D printed anatomical model requires a standardized formal request that clearly outlines the details of the parts to be printed. The request can be submitted through three different methods, depending on the frequency of requests in this hospital. When dealing with a larger number of requests, it becomes essential to implement a more organized approach for documenting and processing the requests, as there exists an increased risk of data loss or confusion.

Method 1 involves submitting an e-mail in which details about the requested model are specified. Method 2 adopts a more structured approach of model requests through a request form. Method 3 describes the model request through a form in the electronic health record system.

3.2.1 Method 1: model request through e-mail

In the first method, models are requested through an e-mail addressed to the 3D printing team, in which the requesting surgeon provides details on the specific case. To ensure safe patient data handling in this phase, correspondence can only take place through secured e-mails and by using the in-house e-mail service. Information that must be provided consists of the patient number, a short description of the anatomy to be printed, whether the healthy/mirrored side should be included, model scale and, in case image acquisition has yet been performed, the scanning date.

3.2.2 Method 2: model request through a request form

When the number of requests increases, a more structured and documented approach of requesting an anatomical model should be used. In order to achieve this, a request form can be utilized (see Appendix C for the request form that was created for future use in the Albert Schweitzer hospital). This request form can be filled out digitally and subsequently submitted to the 3D printing team. Using this method will ensure proper storage of case-related information without the chance of leaking sensitive information to persons or instances outside the hospital. The request form is developed in consultation with orthopedic surgeons, taking into consideration their role as end users. They should be provided with a straightforward concept that allows for a simple model request and minimizes the time to complete the form.

3.2.3 Method 3: model request through the electronic health record system

The third method of model request involves integrating the request form into the electronic health record system. This integration ensures that the request of an anatomical model is linked to the patient's medical record, resulting in an even more structured and secure way of data storage. Additional benefits to this approach are the ability for surgeons to easily track the progress of their model request for a specific case, and the ability for the 3D printing team to include details about the development of the model within the same folder.

3.3 Time and material estimation

When the model request is submitted to the department of medical physics, a first estimation on the expected printing time and amount of required filament to complete the printing of the anatomical model can be made. The estimations are based on the expertise of the 3D printing specialist of the department and are documented in an Excel spreadsheet that holds info on the printing schedule.

3.4 Data retrieval

When image acquisition is completed, the images are automatically stored in the Picture Archiving and Communication System (PACS). From here, imaging datasets for the

development of 3D anatomical models can be searched and downloaded using a patient number. Responsibility for the selection of the appropriate series for model development is carried by the 3D specialist.
An encrypted key file will be kept that specifies the patient numbers for which a 3D model was requested. This key file is stored in 3D printing folder on the departmental drive and can only be accessed by individuals that are in possession of the password of this key file. The dataset is stored in a folder specified by this patient number in the general format of 'Patientnumber_ROI_slicethickness', providing information on the patient number, ROI and slice thickness of the images for convenient retrieval of the data.

3.5 Visualization in software
Before the actual model can be developed, the dataset is loaded into and visualized in Materialise Mimics (Materialise, Leuven, Belgium). This allows for an inspection of the dataset, ensuring that no mistakes were made during the image acquisition and data retrieval phases. It is essential to verify whether the images accurately represent the anatomy and any potential anatomical defects as stated in the request correctly. If any errors are identified in the data, the requesting surgeon or a radiologist should be consulted to determine the need for additional image acquisition.

3.6 Segmentation and model creation
If the dataset is inspected and approved for development of the model, the ROI can be segmented using tools in the Materialise Mimics environment. This section provides a concise description of operations that can be performed in order to segment the ROI, but the exact order of steps to be taken is dependent on the desired model.

- *global threshold:* for CT scans, a global threshold can be used to select a range of Hounsfield Unit (HU) values that is segmented, resulting in a first rough segmentation of the ROI. Depending on the HU value of the tissue to be segmented, it might be necessary to adjust this range of values so that the correct tissue is obtained.

- *3D LiveWire:* for MRI and low contrast scans, a more interactive method of initial segmentation is required. The 3D LiveWire tool in the Mimics environment enables the user to indicate a number of points at the boundaries of the ROI in a specific slice. This process can be performed in the axial, sagittal and coronal plane, which results in an accurate segmentation of the ROI.

- *mask operations:* with this first rough segmentation of the ROI, which is indicated by the term 'mask' from here, an estimation of the final version of the anatomical model can be made visually. To achieve this final version, several operations on the mask can be performed, of which region growing, hole filling and cropping and splitting of the mask are examples. A combination of these mask operations, which will differ slightly per case, will eventually result in the desired anatomical model.

- *part calculation and wrapping:* when mask operations have been performed, the tools 'calculate part' and 'wrap' can be used to create a version of the model that is labelled as one part (or multiple parts when multiple different structures in one model are segmented) and to create an outside shell and remove internal hollowing.

3.7 Labelling
The created model requires labelling with the corresponding patient number. This step can be performed in either Materialise Mimics (mask labelling) or Materialise 3-Matic (part labelling) and depends on user preference.

3.8 Model refining

Once the model satisfies the design requirements, it can be imported into Materialise 3-Matic. This software environment is used for refinement of the model that was created in Materialise Mimics. It can be used for refinement of the mesh (the surface) of the model, with operations such as surface smoothing and the removal of spikes on the surface, and it contains a built-in 'fix wizard', which evaluates the model on topics such as overlapping triangles and remaining holes in the model. This fix wizard consequently suggests actions that should be taken to fix the encountered issues, which the software can perform automatically.

If necessary, multiple parts (for example, the radius and ulna bones) can be merged together into a single model at this point, ensuring that the correct anatomical relationship is maintained while exporting the standard tessellation language (STL) file.

The file is now ready for exportation as an STL file and should be stored in the folder that holds all relevant documentation of the specific case (e.g., the imaging dataset or request form). From here, the created model can be imported into the printing software.

3.9 Preparation for printing in Ultimaker Cura

The STL file is now ready for importation into Ultimaker Cura, which is the printer-specific software package that accompanies the Ultimaker S5 3D printer. Within this software environment, the model is prepared for printing by the addition of lattice supports to avoid possible instabilities during the printing process. With lattice supports, structures that allow printing parts of the model that would collapse without these structures are indicated. Additionally, a number of properties can be adjusted according to the desired model, of which at least the following ones should be evaluated in each case:

- *infill percentage:* the infill percentage indicates the amount of internal volume that is filled with building material. The usual value that is used in-house is between 10 and 20 percent, however the value may vary depending on the desired model strength.

- *layer thickness:* the layer thickness indicates the distance between each layer of building material in the model. Usually, a value of 0.2 to 0.3 millimetres is used, but it might be required to adapt this value depending on required model accuracy.

- *scale:* depending on the request, there may be a need for upscaling or downscaling of the anatomical model relative to its true anatomical size. The scale can easily be adapted in the software environment.

If required, the model can be rotated along the x-, y- and z-axis and scaled within the software. Once the desired result is achieved, the model can be sliced. The term 'slicing' indicates the calculation of the estimated printing time and the amount of material that will be used for printing the model (with eventual lattice supports included). As a final step, the model is exported as an Ultimaker format package (UFP) file, which is the Ultimaker-specific file format. The file can be transferred to the 3D printer through a physical medium like a USB drive, or through a digital method.

3.10 Update of time and material estimation

Before initiating the printing process for the anatomical model, it is essential to check if there are any other scheduled prints. This will be tracked using the Excel spreadsheet that was mentioned in step 3, which can be accessed on the shared drive of the department. Multiple users can access this document to reserve printing time The amount of printing material required for a single print (which is calculated in the slicing process in the Ultimaker Cura environment) and the total amount of printing material present at the department should be documented as well. The use of this spreadsheet ensures that there is no overlap between scheduled prints, and documentation of the remaining printing material enables timely reordering of materials. The material used for printing of the anatomical models is polylactic acid (PLA), which is a biodegradable, thermoplastic polymer.

3.11 Check printer

Final checks before initiation of the printing process include whether the build plate is empty, whether sufficient material is loaded into the printer and whether the nozzle is free of any cured printing material. Furthermore, a stock check is performed and if necessary, new printing material will be reordered.

3.12 Printing

Once all necessary checks are carried out and no obstacles are identified, the printing process can be started. The model can be selected from the menu displayed on the touch screen. During the printing process, the screen will show an estimation of the remaining printing time for the corresponding model.

If any issues are encountered during printing of the model, the process can be interrupted at any time by pressing either the 'Pause' or 'Abort' buttons on the side menu of the touch screen, depending on the severity of the problem. If the problem can be solved without affecting the printed part, the pause button may be used to temporarily halt the printing, but if an error occurred in the printed part it might be necessary to abort the printing process and restart. For example, when the nozzle of the printer is clogged with cured filament, the pause button may be used after which the filament can be removed and the printing process can resume. However, if for some specific reason the printed part is shifted inside the printer, the remaining part will be printed on top of the shifted part, resulting in a discontinuity of the model. The process should then be aborted and restarted to obtain an accurate model.

3.13 Post-processing

When model printing is completed, it might be necessary to apply post-processing. Steps in post-processing include:

- removal of the printed model from the build plate;
- removal of any support structures.

In case there is a large interval between completion of the printing process and removal of the model from the build plate, the bottom layer of the model might adhere to the build plate. The printed model or parts of the model might break when applying excessive force. Therefore, it is important to remove the model carefully from the build plate, eventually by using a putty knife. If difficulties persist, it can be helpful to seek for assistance during the removal process.

Supporting structures should be removed manually or with the use of small tools. If a water-soluble material is used for the supporting structures, the model can be soaked in water to facilitate the removal of these structures.

3.14 Model inspection, documentation and storage

After obtaining the final model, it is important to conduct a thorough inspection to detect any errors that might have occurred during the printing process. A form that reports on the completeness of the model must be filled in, and when the model corresponds to the STL file, the requesting surgeon can be informed about the completion of the manufacturing process by e-mail.

Any further documentation might be required depending on the request and the specific case, and must be handled in this phase so that all documentation is complete. Examples of these documents include a completion form that provides a brief description of the manufacturing process along with a signature of the responsible developer of the model, and a quality control form (which are considered beyond the scope of this thesis).
Once all documents are complete, the model can be securely stored until agreements have been made regarding the delivery of the model to the requesting surgeon or department.

3.15 Delivery or collection of model
The process is completed with the delivery of the model to the requesting surgeon at the department. In case of high demand, it might be more convenient to set up a collection point at the department of medical physics, at which departments that requested a 3D printed model can pick up their print when they received an e-mail informing on the completion of the process. Implementing a collection point would avoid excessive delivery moments by the 3D printing team.

4. Roles and responsibilities

In Appendix B, the roles and responsibilities in each step of the workflow are documented. It must be mentioned that some of the roles can be fulfilled by individuals of multiple disciplines, depending on the departmental preferences.

5. Discussion

This chapter outlined the description of a workflow for in-house 3D printing of anatomical models in the Albert Schweitzer hospital. The success of this workflow depends on multiple factors. First, it is of crucial importance that all disciplines involved in the production of 3D printed anatomical models (being radiologists, surgeons, 3D specialists, administrative assistants and medical technicians) work closely together for optimal quality of the anatomical model. Furthermore, each model should be evaluated on quality. This can be done with the use of a quality control form as mentioned in section 3.14. If errors in a model are detected in this step of the workflow, good communication between the requesting physician and the 3D printing team is required to discuss the actions to be taken in this situation. Last, a Quality Management System (QMS) should be set up before this workflow can be used in practice. This QMS, which includes a Prospective Risk Inventory (PRI), ensures that all processes involved in the workflow are carried out in line with international standards and guidelines. Setting up a PRI for this workflow was considered to not be in the scope of this work, as for now the workflow is not yet implemented in clinical routine. Results from the survey study in chapter 3 might support the implementation of this workflow. When implementation is considered, a PRI must be carried out prior to deployment of the workflow.

By carefully addressing these considerations, quality of the anatomical models developed through this workflow is optimized, while risks are minimized. This can in turn result in a higher quality of preoperative planning and eventually in better patient outcomes.

3

Utility of 3D printed anatomical models for preoperative orthopedic planning: a survey study

1. Introduction

At the department of orthopedics in the Albert Schweitzer hospital, seven orthopedic surgeons perform surgery on the knee (6/7 surgeons), hip (4/7 surgeons), shoulder (3/7 surgeons) and ankle or foot (2/7 surgeons). The surgeries that are most frequently performed are hip arthroplasty and knee arthroplasty, with approximately 400 procedures annually. Shoulder and ankle/foot surgeries are less frequently performed in this hospital, with a procedure count of approximately 100 to 200 annually for both subspecialties.
This study aims to explore the utility of 3D printed anatomical models for preoperative planning of these surgeries. By analysing the potential benefits of these models, it can be determined whether 3D printing can be useful in this setting and for this department. Topics that are reviewed in this study include the impact of 3D printed anatomical models on preoperative decision-making, confidence of the surgeon and operative time, as well as the complexity of the included models. Additionally, the surgeons' attitude towards future use of these preoperative models is evaluated.
It is hypothesized that for complex orthopedic cases, 3D printed anatomical models can provide additional insights that could result in a better understanding of spatial orientation, improved confidence in the preoperative plan and an improved surgical outcome.

2. Methods

2.1 Study characterisation
Ethical approval (study number: 2022.095) by the institutional review board was obtained before initiation of this study. This is a retrospective study on the added value of 3D printed anatomical models among different subspecialties within orthopedics: shoulder surgery, hip surgery, knee surgery and ankle/foot surgery. From these subspecialties, six subgroups were created, being shoulder revision surgery following a complication (subgroup 1), primary shoulder fracture surgery (subgroup 2), revision hip surgery following a complication (subgroup 3), primary hip fracture surgery (subgroup 4), knee surgery (subgroup 5) and ankle or foot surgery (subgroup 6). For the knee and ankle/foot subgroups, included cases could either involve primary fractures or complications after joint repairing surgery (JRS). Typical examples of included indications for each subgroup are displayed in Table 1.

Subgroup	Typical indication
Primary hip fracture	Femoral neck fracture (medial or lateral)
Hip revision	Loosening of acetabular cup, protrusion
Primary shoulder fracture	Proximal humerus fracture
Shoulder revision	Fracture following prosthesis placement, infection following prosthesis placement
Knee	Fracture following prosthesis placement, infection following prosthesis placement
Ankle/foot	Weber fracture, tarsal bone fracture

Table 1. Typical indications for each of the six subgroups included in this study.

2.2 Data collection

For this study, only CT scans are included. The CT scans and the age of the included subjects was retrieved from the hospital's Picture Archiving and Communications System (PACS), along with the radiological report of the scans. Medical history and measurements carried out prior to the actual surgery (length, weight and body mass index (BMI)) of the subjects were retrieved through the hospital's electronic health record, as well as the operative time. These data are presented as 'mean +- standard deviation'. All data used during this study was anonymized to avoid recognition of a specific case by a treating surgeon.

2.3 Inclusion and exclusion criteria

Going back in time from March 5th, 2023, cases were evaluated until for each subgroup 5 cases were included, resulting in a total number of 30 included cases. Figure 1 provides a schematic overview of the created subgroups.

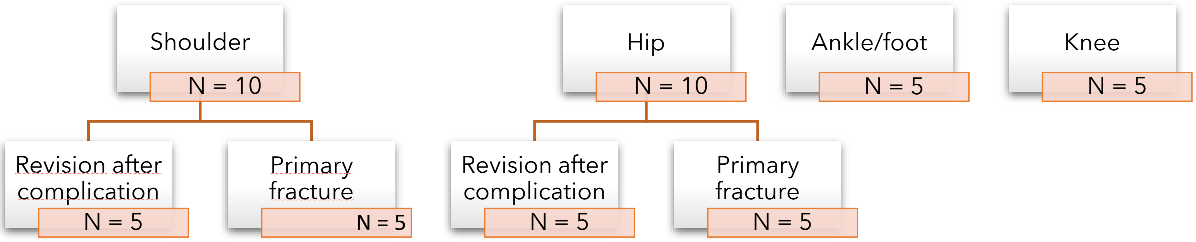


Figure 1. Schematic overview of included subgroups and number of patients in each subgroup.

Inclusion criteria for groups were:

- The case involves a primary fracture of the hip, shoulder, knee or ankle/foot.

OR

- The case involves a complication after joint replacement surgery of the hip, shoulder or knee (e.g., prosthesis loosening/fracture, (sub)luxation of the joint, infection).

AND

- A preoperative CT scan with a slice thickness of at least 1.5 millimetres is available in the PACS.
- Surgery was performed for the case.

Exclusion criteria were:

- The patient is younger than 16 years or older than 90 years.
- The patients' CT scan shows excessive scatter in the region of interest caused by metallic implants.
- The patient actively objected against use of his or her data for scientific research.

2.4 Model development
For each case, a 3D printed anatomical model was developed following the 'in-house workflow for 3D printing of anatomical models', which was developed for in-house printing of anatomical models (see chapter 2 for details).

2.5 Evaluation of anatomical models
To assess the added value of an anatomical model in the preoperative planning process of each case, a survey containing 11 statements was developed based on utility questionnaires found in literature (15, 21-23). Topics were categorized as 'usefulness and efficiency in planning', 'time expectation', 'effect on surgical outcome', 'alteration of preoperative plan', 'complexity' and 'attitude towards future use' (see Appendix D for the full survey). Complexity of the included cases were rated by the orthopedic surgeons. Topics were scored using 5-point Likert scales, 7-point Likert scales and categorical scales. For all cases, the orthopedic surgeons were asked to plan their surgical strategy using the anonymized X-ray scan, CT scan (including the radiological report and the digital 3D reconstruction that can be created in the PACS) and a summary on patient characteristics extracted from the electronic health record. Subsequently, the 3D printed model was presented and the surgeons were asked to complete the survey based on that model.
In total, 3 orthopedic surgeons participated in this study, each representing different subspecialties. The surgeon with a subspecialty in shoulder surgery reviewed cases in subgroup 1 and 2, the surgeon with a subspecialty in hip surgery reviewed subgroups 3 and 4 and the surgeon with a subspecialty in ankle and foot surgery reviewed subgroups 5 and 6. Responses were recorded on printed questionnaires, which were collected immediately after reviewing a case.

2.6 Analysis
Results on statements with a 5-point Likert scale are visualised in Likert scale charts for all subgroups. Results on statements regarding the effect of the 3D printed anatomical models on preoperative planning time and operative time, and model complexity are visualised in tables. Results on statement 4 ('*I would alter my preoperative plan for this case after reviewing the printed model*') are visualised through a pie chart with options being either 'Yes' or 'No'.

3. Results

Included cases were dated in between 25-10-2018 and 03-03-2023 (Table 2 presents the baseline characteristics per subgroup). In total, 30 anatomical models were reviewed by 3 different orthopedic surgeons, with each surgeon reviewing 10 models. Responses on the questionnaires are discussed in the subsequent sections, categorized by topic.

	Shoulder revision	*Shoulder*	*Hip revision*	*Hip*	*Knee*	*Ankle/foot*
Age	52 ± 22	60 ± 22	75 ± 8	83 ± 4	72 ± 10	44 ± 23
Length (cm)	180 ± 9	171 ± 4	167 ± 11	167 ± 3	175 ± 13	170 ± 10
Weight (kg)	101 ± 24	81 ± 12	75 ± 25	68 ± 8	91 ± 23	77 ± 12
Body Mass Index (BMI)	31 ± 6	27 ± 3	26 ± 5	25 ± 3	30 ± 6	27 ± 5
Gender						
Male (%)	80	20	20	40	40	40
Female (%)	20	80	80	60	60	60
Operative time (minutes)	162 ± 58	127 ± 17	229 ± 55	113 ± 35	211 ± 66	101 ± 31

Table 2. Baseline characteristics of patients included in each subgroup.

3.1 Usefulness and efficiency in planning
Figures 2a-2d display the Likert scale charts depicting the results on statements 1a-1d from the survey. Results are discussed per statement.

1a. The model provides additional information in preoperative planning
Among 4 subgroups, the surgeons (strongly) agreed that the anatomical model provided additional information in the preoperative planning process for at least 60% of the models. The hip subgroup showed the highest disagreement with this statement (60%). Total level of agreement with this statement was 53%, neutral opinion was 27% and disagreement was 20%.

1b. Improvement in understanding of spatial orientation
Improvement in understanding of the spatial orientation of the anatomy was observed in 5 subgroups: shoulder revision and shoulder (100%), hip revision and ankle/foot (80%) and in the hip and knee subgroups (20%). The highest percentage of disagreement was observed in the hip subgroup (80%). Total level of agreement with this statement was 80%, levels of neutral opinion and disagreement were both 10%.

1c. Improvement of confidence in the preoperative plan
Improvement of confidence in the preoperative plan was highest in the hip revision and ankle/foot subgroups (80% and 60%, respectively), while 3 other subgroups (shoulder revision, shoulder, knee) showed a neutral opinion on this statement in the majority of the cases. Total level of agreement with this statement was 43%, level of neutral opinion was 43% and disagreement was 14%.

1d. Confusion caused by the model
A high level of disagreement with this statement was observed in all subgroups (60-80%), except for the hip subgroup (20%). The total level of agreement was 13%, level of neutral opinion was 23% and level of disagreement was 64%.

Considering the hip revision and the ankle/foot subgroups, results are positive for at least 80% and 60% of the cases for each substatement in this section. A high level of agreement with statements 1a-c was observed, while disagreement with statement 1d was seen. There was a high level of disagreement with the statement whether the anatomical model causes confusion during the process of preoperative planning in all subgroups except for the hip subgroup, where agreement with this statement was observed for 40% of the cases.

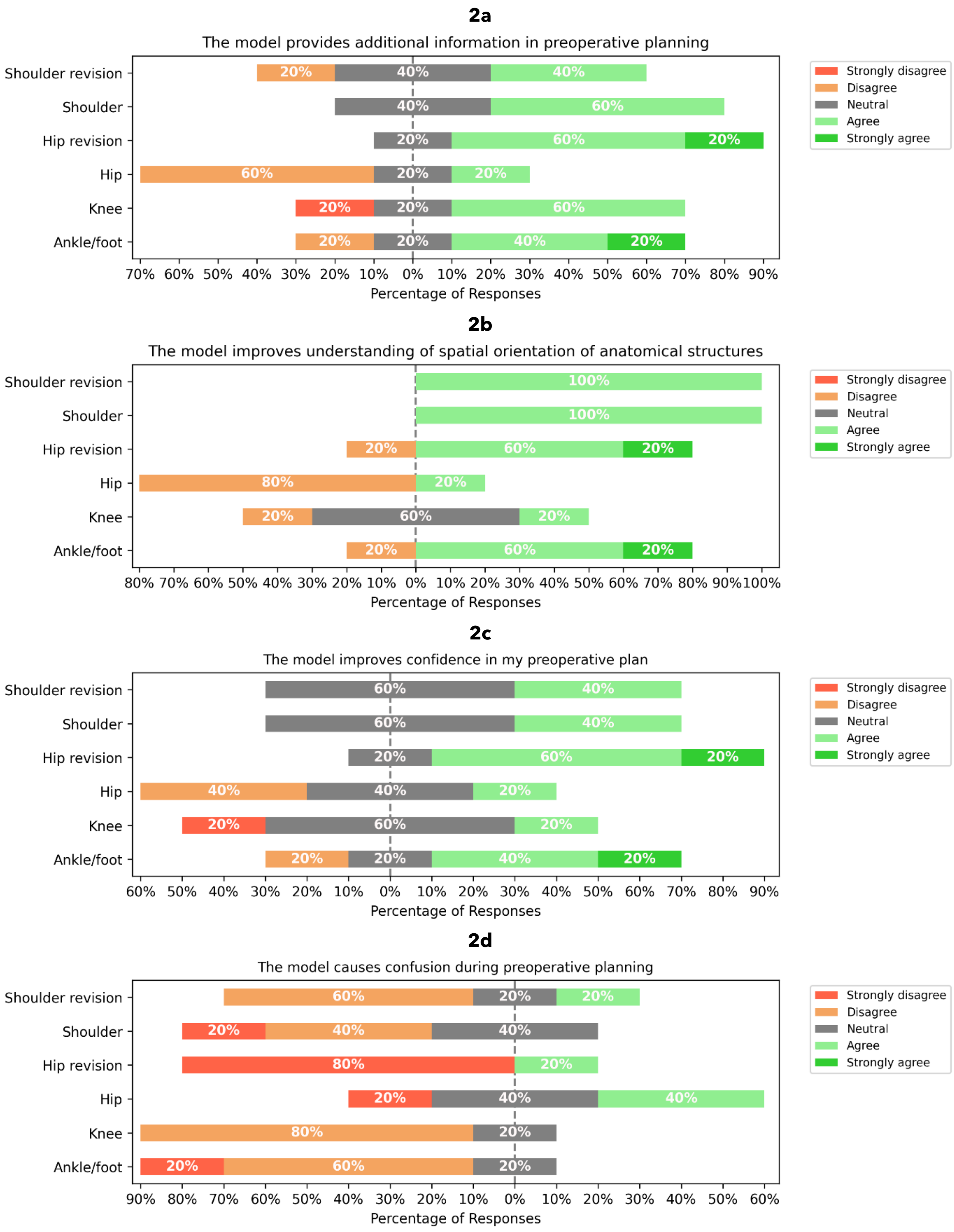


Figure 2. Likert scale chart for the statements '*The printed model in combination with conventional data (X-ray, CT scan, etc.) is more useful in preoperative planning for this case compared to reviewing the conventional data alone*' (**2a**), '*The printed model improves understanding of spatial orientation of anatomical structures relative to each other*' (**2b**), '*Using the printed model, I feel more confident about my preoperative plan*' (**2c**), '*The model causes confusion during preoperative planning of this case*' (**2d**). Red indicates 'strongly disagree' with this statement, gray indicates a neutral opinion and green indicates 'strongly agree' with this statement.

3.2 Time expectation

In section 2, the potential effect of anatomical models on 1) preoperative planning time and 2) operative time was evaluated. Tables 3a and 3b show the results on statements 2a and 2b.

In 5 subgroups, estimated increase in preoperative planning time was no more than 5 minutes. The ankle/foot subgroup was the only subgroup for which additional time was rated as 10 minutes in 40% of the cases.

For the hip revision subgroup, an expected reduction of 15 minutes in operative time was observed in 40% of the cases, while in the ankle/foot subgroup a maximum reduction of 10 minutes was observed for 40% of the cases. The average operative times in these two subgroups were 229 ± 55 and 101 ± 31 minutes, respectively (see Table 2). The average reduction of operative time in these subgroups is 6 minutes, corresponding to an average reduction in operative time of 3% and 6%, respectively when considering these actual operative times. Only in the hip subgroup, an expected decrease in operative time was not observed.

	0 minutes (%)	*5 minutes (%)*	*10 minutes (%)*	*15 minutes (%)*	*20 minutes (%)*	*25 minutes (%)*	*30 minutes (%)*	***Average increase (minutes)***
Shoulder revision	40	60	0	0	0	0	0	3
Shoulder	20	80	0	0	0	0	0	4
Hip revision	40	60	0	0	0	0	0	3
Hip	80	20	0	0	0	0	0	1
Knee	40	60	0	0	0	0	0	3
Ankle/foot	20	40	40	0	0	0	0	6

Table 3a. Expected increase in preoperative planning time for all included subgroups. A maximum increase of 10 minutes of preoperative planning time was observed in the ankle/foot subgroup.

	0 minutes (%)	*5 minutes (%)*	*10 minutes (%)*	*15 minutes (%)*	*20 minutes (%)*	*25 minutes (%)*	*30 minutes (%)*	***Average decrease (minutes)***
Shoulder revision	80	20	0	0	0	0	0	1
Shoulder	80	20	0	0	0	0	0	1
Hip revision	60	0	0	40	0	0	0	6
Hip	100	0	0	0	0	0	0	0
Knee	40	60	0	0	0	0	0	3
Ankle/foot	20	40	40	0	0	0	0	6

Table 3b. Expected decrease in operative time for all included subgroups. A maximum expected decrease of 15 minutes of operative time was observed in the hip revision subgroup. No expected decrease in operative time was observed in the hip subgroup.

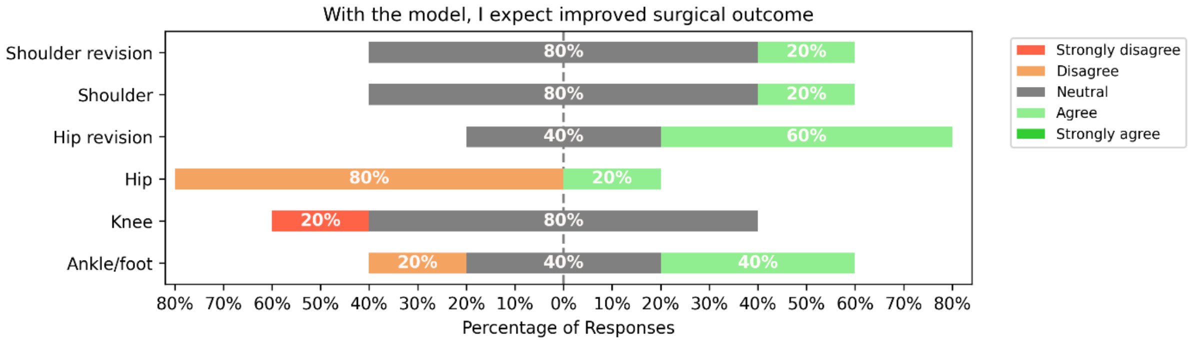
3.3 Effect on surgical outcome

In section 3 of the survey, the impact of 3D printed anatomical models on 1) the surgical outcome, and 2) the surgical efficiency, was evaluated. Corresponding figures 3a and 3b display the Likert scale charts for the results on statements 3a and 3b.

Agreement with the statement whether the models will contribute to an improved surgical outcome for the majority of the models was solely observed in the hip revision subgroup. High level of disagreement with this statement was observed in the hip subgroup. The remaining subgroups mainly showed a neutral opinion on this statement. Total level of agreement with this statement was 27%, the level of neutral opinion was 53% and the level of disagreement was 20%.

Expected increased surgical efficiency in at least 60% of the cases was observed in the shoulder (60%), hip revision and ankle/foot subgroups (both 80%), and was minimal in both the hip and knee subgroups (20%). Total level of agreement with this statement was 50%, the level of neutral opinion was 27% and the level of disagreement was 23%.

3a



3b

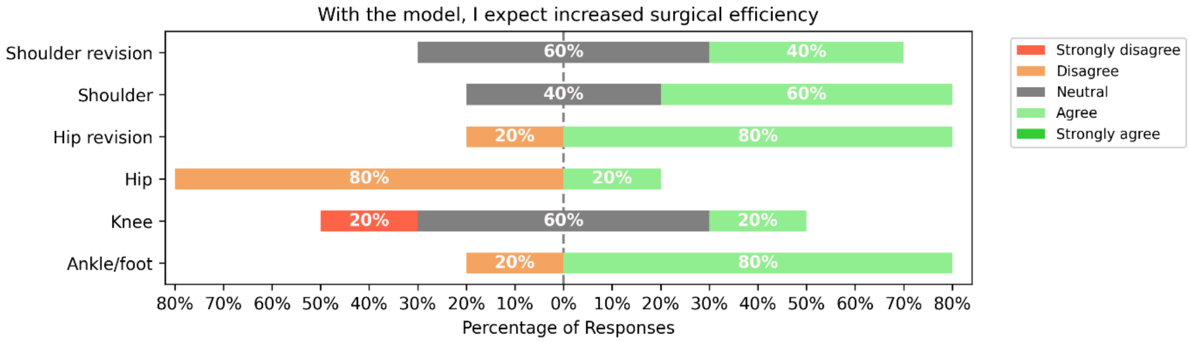


Figure 3. Likert scale chart for the statement '*With this printed model, I expect the surgical outcome to improve*' (3a) and '*Using this printed model, I expect increased efficiency during surgery*' (3b). Red indicates 'strongly disagree' with this statement, gray indicates a neutral opinion and green indicates 'strongly agree' with this statement.

3.4 Alteration of preoperative plan

The effect of the anatomical models on a potential change in the preoperative plan for a case was evaluated in the fourth section of the survey. Figure 4 shows a pie chart of the results of this section. In 13.3% of all included cases, the preoperative plan would have been altered after reviewing the corresponding anatomical model, compared to 87.7% of the preoperative plans that would not have been altered.

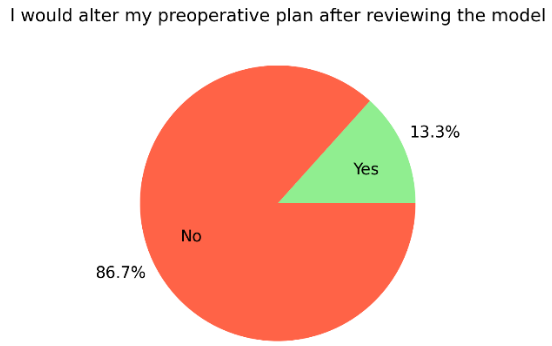


Figure 4. Pie chart for the statement '*I would alter my preoperative plan for this case after reviewing the printed model*'.

3.5 Model complexity
Through section 5 of the survey, the complexity ratings of the included cases and corresponding anatomical models were evaluated. Models were rated extremely complex only in the shoulder revision and hip revision subgroups (40% of the cases), and complex model ratings were mostly observed in the shoulder subgroup (80% of the cases). In the hip subgroup, cases were mostly rated as simple (80% of the cases). Not a single included case was rated extremely simple. Table 4 displays the model complexity per subgroup.

	Extremely simple (%)	*Simple (%)*	*Normal (%)*	*Complex (%)*	*Extremely complex (%)*
Shoulder revision	0	0	20	40	40
Shoulder	0	0	20	80	0
Hip revision	0	0	20	40	40
Hip	0	80	20	0	0
Knee	0	20	60	20	0
Ankle/foot	0	40	20	40	0

Table 4. Model complexity for all included subgroups.

3.6 Attitude towards future use
Results regarding the statement whether an anatomical model would be requested for a similar future case varied among the subgroups (see Figure 5 for the corresponding chart). The highest level of agreement was observed in the hip revision and ankle/foot subgroups, with a (strong) agreement level of 80% and 60%, respectively. For the shoulder revision and shoulder subgroups, there was no strong desire to request an anatomical model again (neutral opinion in 60% and 80% of the cases), while the hip subgroup showed substantial disagreement with the statement (80%).

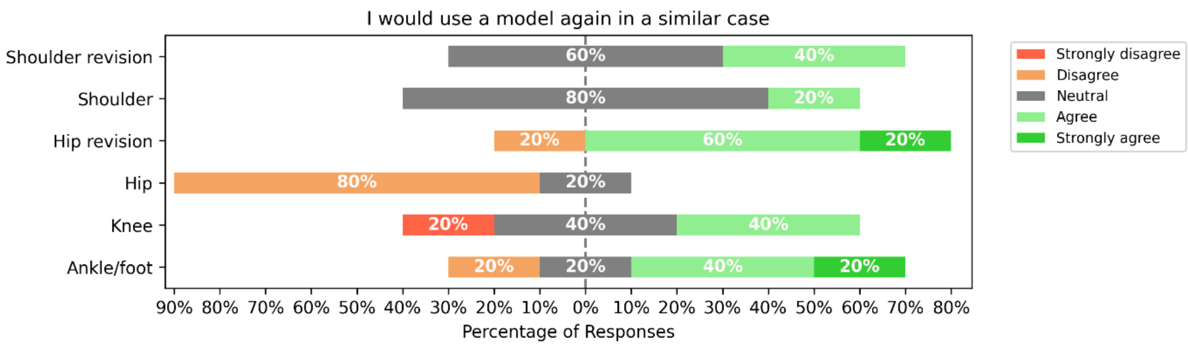


Figure 5. Likert scale chart for the statement '*I would use a 3D printed anatomical model again for a similar case.*'. Red indicates 'strongly disagree' with this statement, gray indicates a neutral opinion and green indicates 'strongly agree' with this statement.

4. Discussion

The goal of this study was to investigate the added value of 3D printed anatomical models in orthopedic preoperative planning through a survey containing 11 statements. The study aimed to incorporate all subspecialties in the field of orthopedics, providing useful insights for future application of 3D printed anatomical models in preoperative planning for this department.
The results of this study only partially correspond to the hypothesis that for complex cases, the 3D printed models are useful. The majority of cases in the shoulder revision and shoulder subgroups were rated as complex, and provided additional insights in preoperative planning. However, only in 40% and 20% of these cases, a model would be used again in a similar case. This could be explained by the fact that the surgeon that

evaluated these models has a positive attitude towards 3D printing, but relies on his/her own qualities with respect to preoperative planning and performing surgery.
Meanwhile, the hip and hip revision subgroups support the hypothesis. Included cases in the hip subgroup were mainly rated as simple, and a 3D model would not be used in a similar case in the future. The opposite was true for the hip revision subgroup: these cases were mainly rated as complex or extremely complex, resulting in the desire to use a 3D printed model again in a similar case.

Among all statements, there are two subgroups that stood out with consistently positive results: the hip revision subgroup and the ankle/foot subgroup. In each statement, a positive impact of the anatomical models on the preoperative planning process and the surgical outcomes was observed in these groups.
For both subgroups, the 3D printed models provided additional information in preoperative planning, improved understanding of the spatial orientation of the ROI and improved the surgeon's confidence in the preoperative plan. The majority of the hip revision cases included in this study involved loosening of the acetabular cup or protrusion through the pelvis and were rated as complex cases. Surgeons explained that having a physical 3D model that can be studied in detail in their own hands is an addition to a patient's 2-dimensional CT scan, as the amount of acetabular cup loosening or protrusion can be estimated with more certainty.
Similar explanations were observed for cases included in the ankle/foot subgroup. As ankle or foot fractures often involve small bone fragments, having a 3D printed model that is focused on the spatial orientation of this fragment increases understanding of the fracture and provides useful insights during preoperative planning. This could explain why both the surgical outcome and the surgical efficiency are expected improve in the majority of the cases included in these subgroups.
Utility of anatomical models was the lowest in the hip subgroup. Usefulness in preoperative planning was minimal, and 3D printed anatomical models would generally not be useful for future procedures. Included cases in this subgroup mainly involved femoral neck fractures. The surgeon reviewing these cases explained that operative treatment of this type of hip fractures is generally straightforward. Having a 3D printed model in the process of preoperative planning is considered to not improve the understanding of spatial orientation or confidence in the preoperative plan. This explains why both an improved surgical outcome and an improved surgical efficiency are not expected in these cases.
For the remaining subgroups (shoulder revision, shoulder, knee), surgeons explained that 3D printed models could be useful in specific cases, depending on the complexity of a case and the potential of providing additional insights regarding the surgical site. This might explain why observations in these subgroups were variable.

No studies were found in the literature that evaluated the added value of 3D printed anatomical models in orthopedics for multiple subgroups. When comparing the results of the hip revision subgroup with a similar study by Maryada et al. (21), results are in line with conclusions from this study. The average result on a statement in the study of Maryada et al., *'Models give better understanding and more information about abnormal pelvic anatomy than 3D images'*, was 4.8/5, whereas the average score in this study for hip revision cases on a similar statement, *'The model provides additional information in preoperative planning of this case'*, was found to be 3.8/5. It must be mentioned that overall usefulness of the models in the study of Maryada et al. was rated 4.86/5, which raises the question whether these surgeons could have been biased towards a positive outcome of their study.

There is a number of limitations in this survey study. First, the sample size of each subgroup was relatively low (n=5) caused by a limited number of cases that met the inclusion criteria. This resulted in the inability to perform statistical tests on the data to compare the included subgroups.
Second, complete anonymization of the included cases was difficult, as in some cases, the orthopedic surgeons recognized a case by its CT scan. However, the effect of surgeons recognizing their own patients on the outcomes of this study is considered small, as knowing personal details about a case is assumed to not alter the surgeon's interpretation significantly.
Third, each 3D printed anatomical model was evaluated by only one orthopedic surgeon, which might have led to subjective assessment of the patients in a subgroup. Furthermore, an orthopedic surgeon could have had a prejudice about patients in a subgroup based on personal experiences or knowledge. These factors could both have led to introduction of bias in the results, limiting the generalizability of conclusions in this study. For future research, it is therefore recommended to increase the sample size and to involve multiple physicians in the evaluation of patient cases to minimize the impact of bias on study results and to improve generalizability.

In conclusion, this study suggests that for hip revision and ankle/foot cases in orthopedic surgery in this hospital, 3D printed anatomical models are valuable in preoperative planning. The models provide additional insights during planning and can improve surgical outcome and surgical efficiency. For preoperative planning in shoulder or shoulder revision cases, the added value of the models is variable, while for conventional hip cases, the value of 3D printed anatomical models is minimal.

4

Business case highlighting three scenarios for implementation of 3D printing

1. Introduction

To support the initiation of a 3D lab in the Albert Schweitzer hospital, this business case aims to provide insights in the financial consequences of implementing an in-house 3D printing service. The case includes a cost-benefit analysis of 3D printing of orthopedic anatomical models, along with a comparative analysis between in-house 3D printing and outsourced 3D printing services for production of orthopedic surgical guides and orthognathic anatomical models and interocclusal wafers. Factors such as annual demand for 3D printed parts and availability of resources have an influence on the outcomes of this business case.

This business case describes three possible scenarios of implementation of a 3D lab in the Albert Schweitzer hospital:

1. in-house 3D printing of orthopedic anatomical models in the preoperative planning process;
2. in-house 3D printing versus outsourcing of orthopedic surgical knee guides for prosthesis alignment;
3. in-house planning and 3D printing versus outsourcing of orthognathic surgical cases.

The inclusion of these scenarios demonstrate diverse applications of 3D printing within this hospital. By outlining three different scenarios, it is explored what method of initiating a 3D lab in this hospital has the most favourable financial effects.
All calculated monetary values in this business case have been rounded to the nearest ten units for ease of calculation.

2. Scenario 1: orthopedic anatomical models

In this scenario, benefits and costs for in-house development and printing of orthopedic anatomical models are outlined. It is assumed that for the department of orthopedics approximately 15 models will be requested annually. This number was estimated by determining the average annual demand for 3D printed anatomical models per subgroup included in the survey study (chapter 3), based on the inclusion period of the cases.

2.1 Benefits

The use of 3D printed anatomical models in orthopedic preoperative planning offers multiple benefits. Results from the survey study conducted in this hospital (see chapter 3) demonstrate that anatomical models can provide additional insights in spatial orientation during the process of preoperative planning and can improve the surgeon’s confidence in his/her preoperative plan. Additionally, a reduction of 5-15 minutes of operative time could be achieved in certain cases, as well as an improved surgical outcome and surgical efficiency. Findings from studies conducted in other hospitals are in line with the results of the study that was conducted in this hospital (24-26).

2.2 Costs

This section outlines the costs related to the 3D printer, software, salaries and materials.

3D printer

The department of medical physics in the Albert Schweitzer hospital currently owns an Ultimaker S5 3D printer. The initial costs for acquiring this printer are €5300, resulting in annual depreciation expenses of €1060, over a 5-year period. Furthermore, maintenance costs associated with the 3D printer, such as replacing the air filter, print core and feeder, are taken into account. These costs are estimated to be €300 per year (27-29).

Software

For this scenario, the software from Materialise has been chosen due to its compliance with the Medical Device Regulations (MDR). This software has been acquired with a CE marking, ensuring righteous processing of medical imaging data. To develop anatomical models, the Base license of Materialise Mimics Medical is required, with an annual cost of €5480.

Salaries

For this scenario, one of the medical technicians with an interest in 3D printing can produce the anatomical models. Activities consist of model development (approximately 3 hours per model) and office time consisting of meetings, e-mails, and printer and material maintenance (approximately 0.5 hours per week). A demand of 15 models per year results in an approximate required amount of 50 hours annually (or 0.03 Full-Time Equivalent, FTE), corresponding to costs of €1030 per year.

Materials

For production of anatomical models, polylactic acid (PLA) is the material of choice. Included cases in the survey study (chapter 3) had an average weight of 137 grams. This corresponds to material costs of €5 per model, resulting in total annual material costs of €75 for this scenario.

Total costs

Table 1 provides a schematic overview of all 3D printing-related costs for scenario 1. For detailed costs and hour calculations, see Table 1 and Table 2 in Appendix E1. Total annual costs for scenario 1 are €8100, resulting in costs per model of €540. Figure 1 shows the cumulative costs for this scenario over a 5-year period.

	*Total annual costs (**€**)*
3D printer	
Ultimaker S5 3D printer	1060
Ultimaker S5 Air Manager	150
Maintenance	300
Software	
Materialise Mimics Medical Base license	5480
Salaries	1030
Materials	75
Total (n=15 models)	*8100*
Total per model	*540*

Table 1. Overview of costs in scenario 1 for the production of 15 anatomical models per year.

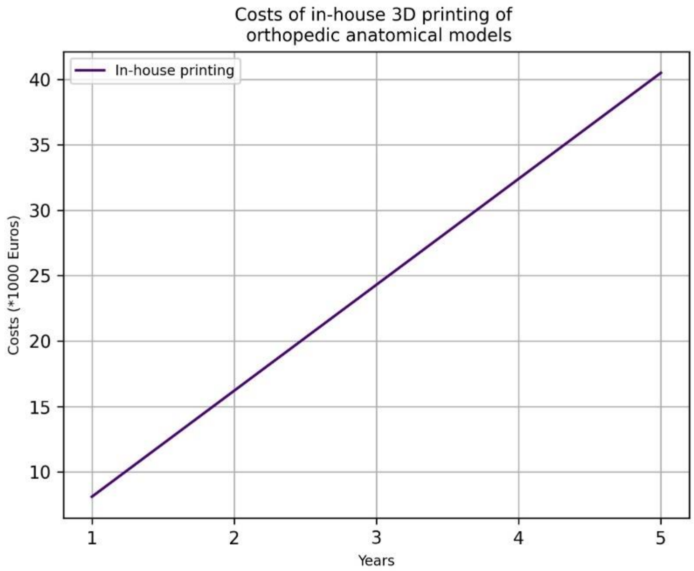


Figure 1. Cumulative costs in scenario 1.

3. Scenario 2: orthopedic surgical guides for total knee arthroplasty (TKA)

In this scenario, benefits and costs for development and printing of orthopedic surgical guides for total knee arthroplasty (TKA) are outlined. According to conversations with orthopedic surgeons in this hospital, the attitude towards these guides is increasingly positive and the future goal would be to apply surgical guides in all TKA surgeries, of which approximately 450 procedures are performed annually. However, a realistic scenario must be outlined in order to present a realistic cost expectation for the hospital. Therefore, calculations were performed for the following situations: application of surgical knee guides in 1) 25% of the cases (n = 113); 2) 50% of the cases (n = 225); 3) 75% of the cases (n = 338) and 4) 100% of the cases (n = 450).
In consultation with orthopedic surgeons, we decided that the application of surgical guides in 50% of the cases is most likely for the upcoming years.

3.1 Benefits

Scenario 2 includes the in-house printing of orthopedic surgical guides for total knee arthroplasty (TKA), which allows accurate, patient-specific alignment of the drill holes and cutting planes to be applied for optimal prosthesis placement (11, 12). The use of 3D printed patient-specific surgical guides tends to reduce operating room time and operative time, is less invasive and easier to use, and minimizes the risk of error in the alignment of the prosthesis (12, 30, 31). According to literature, a reduction in operative time of 7-9 minutes and a reduction in operating room time between 9-30 minutes could be achieved by using patient-specific instruments for TKA (30, 31). This is advantageous for the hospital, as more surgeries can be planned when a reduction in operating room time is achieved for multiple surgeries. For patients, a reduction in operative time and a less invasive procedure both contribute to reduced risk of infection intraoperatively and less pain postoperatively (32, 33). Additionally, the use of patient-matched instruments has a higher tendency for correct femoral component rotation and might result in an improved mechanical axis postoperatively (34, 35).

3.2 Costs

In this scenario, costs for in-house printing of orthopedic surgical knee guides are compared to costs of outsourcing this task.

3.2.1 In-house printing

First, costs for in-house printing of the knee guides are outlined. Similar to scenario 1, costs can be divided among printer costs, software costs, salary costs and material costs. Table 2 displays the total annual costs for in-house printing in this scenario.

3D printer

To enable the production of these surgical guides, investing in a 3D printer that can produce high-quality, sterilisable parts is necessary. For this scenario, the Formlabs Form 3B+ 3D printer would meet the demand for printing such parts. The build volume of this printer is 145 x 145 x 185 millimetres, which allows for printing of multiple surgical guides in a printing cycle. Costs of acquiring this printer are €7000, and additional post-processing machines for washing and curing the printed parts are €700 and €600, respectively. Depreciation costs over a 5-year period would be €1400, €140 and €120. Maintenance costs are estimated to be €300 annually.

Software

Regarding software licenses, an additional software module is required to develop surgical guides based on a patient's anatomy. The Materialise Medical Design module is one of the software packages that are suitable for development of surgical instruments. This annual costs for this module are €6080. Assuming that both the Materialise Mimics Medical Base (€5480) and Design modules are required in this scenario, software license expenses result in a total of €11560 per year. Additionally, a 2-day on-site training for the Design module is approximately €4310 (based on quotes from Materialise), which is considered to be a one-time expense in the first year, and is not displayed in the annual costs overview.

Salaries

Another important difference with respect to scenario 1 is the need to hire a technical physician. As it is of crucial importance that the surgical guides match a patient's anatomy with the highest possible accuracy, a decent level of anatomical knowledge is required. A technical physician that is trained to develop surgical guides is the appropriate individual for the execution of this task. It is estimated that the development of a guide takes 2 hours and post-processing takes 15 minutes. Similar to scenario 1, 0.5 hours per week for meetings and other activities are accounted for, resulting in a total annual amount of 776 hours. Costs for post-processing of the printed parts are again based on the average salary costs for a medical technician as this step requires no anatomical knowledge. All other salary costs are calculated based on an average monthly salary of €4000 for a technical physician. Total costs for acquisition of the CT scan and sterilization of the printed parts (for both in-house printing and outsourcing) are not included in these calculations. Total FTE for this scenario, based on a production of 225 surgical guides, is 0.42. Full details on FTE calculations can be found in Appendix E2.

Materials

Materials for surgical guides must meet two important requirements: 1) the material must be biocompatible for at least the duration of the surgery, and 2) the material must be sterilizable. One of the potential materials is Formlabs Biomed Resin White, which is a strong, hard and biocompatible resin that is compatible with steam and autoclave sterilization. Approximate costs per unit of 1 litre are €440 and it is assumed that production of 1 surgical knee guide requires 50 millilitres of resin, resulting in costs of €22 per guide (36). For washing of the printed guides, isopropyl alcohol is required. Costs of €27,50 per 5 litres of isopropyl alcohol are assumed, and a total amount of 30 litres is approximately required in this scenario, resulting in total costs of €165.

	Total annual costs, n=113 (€)	*Total annual costs, n=225 (€)*	*Total annual costs, n=338 (€)*	*Total annual costs, n=450 (€)*
3D printer				
Formlabs Form 3B+ 3D printer	1400	**1400**	1400	1400
Formlabs Form Wash	120	**120**	120	120
Formlabs Form Cure	140	**140**	140	140
Maintenance	300	**300**	300	300
Software				
Materialise Mimics Base License	5480	**5480**	5480	5480
Materialise Mimics Design License	6080	**6080**	6080	6080
Salaries	11800	**19550**	27320	35060
Materials				
Formlabs Biomed Resin White	2490	**4950**	7440	9900
Isopropyl alcohol 5L	82,50	**165**	247,50	330
Total	*27900*	***38190***	*48530*	*58810*
Total per model	*247*	***170***	*144*	*131*

Table 2. Overview of costs in scenario 2. Application of a surgical guide in 50% of the total amount of annual cases (n = 225) is highlighted, as this is considered the most realistic scenario in the coming years.

3.2.2 Outsourcing

Costs for outsourcing the guides are calculated to be €516 per guide, according to contracts with manufacturers, and incorporate design, printing, post-processing and delivery of the guide. Costs for transfer of the CT scans to the external instance have been neglected in these calculations. Annual costs in the four different scenarios are outlined in Table 3.

	Total annual costs, n=113 (€)	Total annual costs, n=225 (€)	Total annual costs, n=338 (€)	Total annual costs, n=450 (€)
Total	*58308*	***116100***	*174408*	*232200*
Total per model	*516*	***516***	*516*	*516*

Table 3. Overview of outsourced costs in scenario 2, based on 4 possible scenarios. Application of a surgical guide in 50% of the total amount of annual cases (n = 225) is highlighted, as this is considered the most realistic scenario in the coming years.

3.2.3 Total costs of in-house printing versus outsourcing

Figure 2 displays the cumulative costs of in-house printing of the knee guides versus outsourcing for these four situations. Based on a number of 225 surgical guides produced annually, total costs of in-house printing are €38190, compared to €116100 for outsourcing. Per surgical guide, costs for in-house printing are €170, compared to €516 when outsourced. This results in a saving of €344 per surgical guide produced, or €77400 per year.

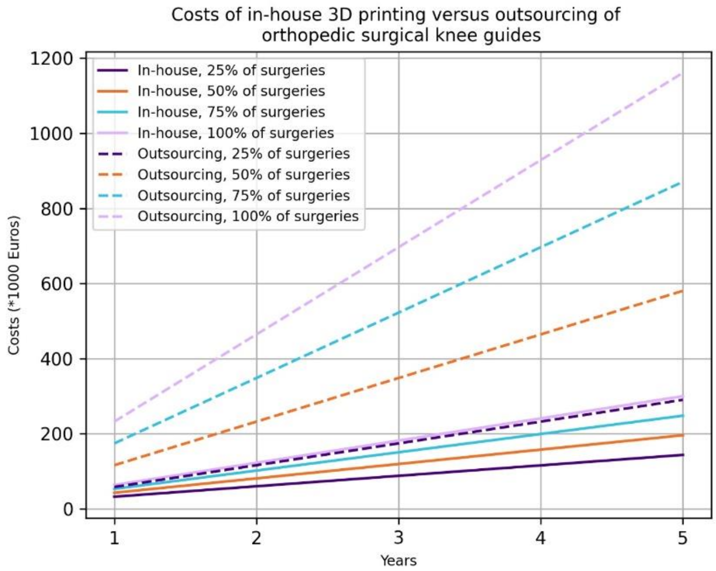


Figure 2. Cumulative costs for in-house 3D printing of surgical knee guides versus outsourcing over a 5-year period. Solid lines represent in-house production, dashed lines represent outsourced production.

3.2.4 Break-even analysis

To consider in-house printing with respect to outsourcing of the production process, a break-even analysis is performed to determine the potential cost reduction of in-house printing. Furthermore, this analysis can be used to determine the required number of surgical guides that should be produced in-house in order to be financially advantageous compared to outsourced production. To explain this, Figure 3 displays the break-even analysis in a graphical format. Based on these calculations, once the number of produced surgical guides reaches 42, in-house printing will be financially more beneficial than outsourcing the printing process.

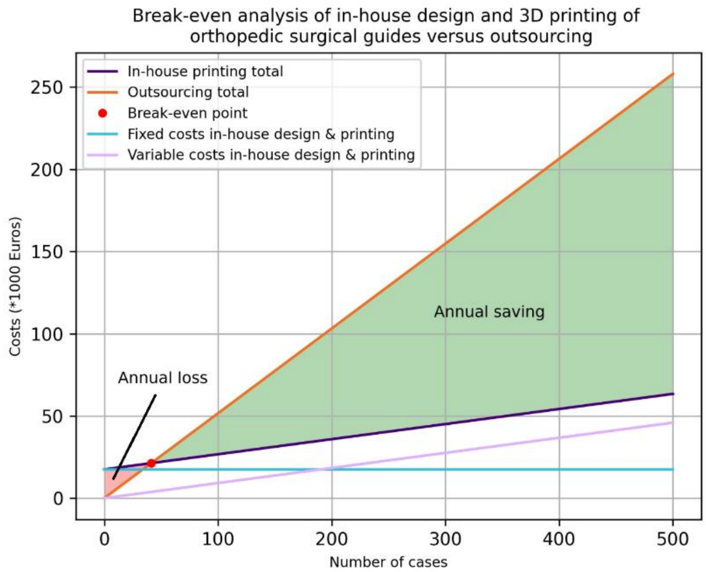


Figure 3. Break-even analysis for in-house 3D printing of surgical knee guides versus outsourcing. The red area represents a potential loss in costs, the green area represents a potential saving in costs. In-house costs were divided among fixed costs (independent of the amount of surgical guides produced) and variable costs (dependent on the amount of surgical guides produced). The break-even point is defined as the intersection between the lines of 'In-house printing total' and 'Outsourcing total' and is situated at n = 42 surgical guides.

4. Scenario 3 (orthognathic planning, anatomical models and wafers)

In scenario 3, in-house versus outsourced costs for virtual surgery plannings (VSP) with design and printing of anatomical models and orthognathic surgical wafers is outlined. These wafers are used as an intraoperative reference tool during surgery to re-establish maxillomandibular symmetry, translating the 3D computer-assisted virtual planning to a desired outcome of the actual surgery. Previously, wafers were constructed by making a plaster cast of the mandibula preoperatively.

4.1 Benefits

In the past, wafers were constructed by making a plaster cast of the mandibula preoperatively, resulting in an increased procedure time. Additionally, the orientation of these plaster casts does not replicate the orientation of the patient's dental anatomy, introducing a systematic error during preoperative planning (37). Using 3D technology, wafers can be designed preoperatively with optimal accuracy, based on preoperative imaging, after which the wafer can be printed using a medical 3D printer. Moreover, VSP results in increased efficiency and accuracy in orthognathic surgery (38). Recently, declaration codes for virtual surgery planning and the production of 3D printed surgical guides, wafers and implants for orthognathic surgery were published by the Dutch Health Authority (see Table 3 in Appendix E3 for declarable costs) (39). According to these codes, a total amount of €31240 could be declared annually. Currently, these declaration codes only apply to the discipline of craniomaxillofacial (CMF) surgery, of which orthognathic surgery is a subspecialty.

4.2 Costs

Through conversations with the CMF surgeon, it is estimated that approximately 100 patients per year require a surgical wafer, with 50 patients requiring a double wafer (bimaxillary osteotomy) and 50 patients requiring a single wafer (Le Fort 1 osteotomy or bilateral sagittal split osteotomy). This results in a total number of 150 surgical wafers. Additionally, an anatomical model is printed for better visualization and spatial orientation of the anatomy. Costs in this scenario are calculated per patient case, including costs for 1) a virtual surgery planning and design of a wafer, 2) design and printing of an anatomical model and 3) printing of a single or double wafer. Material costs for the anatomical model and wafer (which is either single or double) are averaged to determine an average material cost per patient case.

4.2.1 In-house planning and printing

This section outlines the costs related to the 3D printer, software, employment, and materials of in-house planning and printing in the third scenario (see Table 4 for details).

Hardware

At the department of oral surgery, a Cone-Beam CT (CBCT) scanner has been purchased and will be commissioned later this year. This investment is not included in the costs of this scenario. Furthermore, an intraoral scanner is necessary to obtain detailed scans of the teeth. The 3Shape TRIOS 3 Intraoral scanner is a widely used scanner and meets the demand in this scenario (40). Costs for this intraoral scanner are approximately €23500, resulting in depreciation costs of €2350 based on a 10-year depreciation period.

3D printers
A Formlabs Form 3B+ 3D printer (wafers) and an Ultimaker S5 3D printer (anatomical models) would meet the demand of this scenario. The wafers should be sterilized before clinical use and therefore, they cannot be printed using the Ultimaker S5.

Software
Materialise has a software package named 'ProPlan CMF', which is a module that covers all preoperative planning steps, including determination of the cutting planes, repositioning and wafer design. Additionally, anatomical models can be developed in the same software. Annual costs for this software package is €9890, based on quotes from Materialise. A 2-day training programme to get familiar with the software incorporates additional costs of €4310 and is considered a as a one-time expense in the first year.

Salaries
Similar to scenario 2, a decent level of anatomical knowledge is required for surgery planning and wafer design, requiring a technical physician. Costs for post-processing of the wafers and anatomical models are again based on average salary costs for a medical technician, as this step requires no anatomical knowledge. All other salary costs are calculated based on an average monthly salary of €4000 for a technical physician. Costs for sterilization of the printed parts are not included in the calculations. A total amount of 4.75 hours is estimated per orthognathic case (2 hours for VSP, 1.5 hour for development of the wafer(s), 1 hour for development of the anatomical model 15 minutes of post-processing). Total FTE for this scenario, based on a production of 150 wafers and 100 anatomical models, is 0.42 (see Appendix E3 for details).

Materials
Materials for wafer production must be biocompatible and sterilizable. Formlabs Biomed Resin White, a strong, hard and biocompatible resin that is compatible with steam sterilization, meets these requirements. For the anatomical models, PLA filament is the appropriate material to use, as the anatomical models are only used for visualisation of the anatomy and do not require sterilization. Similar to the orthopedic surgical guides, it is assumed that an average amount of 50 millilitres of resin is required for printing an orthognathic wafer, which corresponds to €22 for a wafer and €3300 for 150 wafers. Material costs for the anatomical models are similar to those in scenario 1 (approximately €5 per model and €500 for a total of 100 anatomical models).

	*Total annual costs (**€**)*
3D printer	
Ultimaker S5 3D printer	1060
Ultimaker Air Manager	150
Formlabs Form 3B+ 3D printer	1400
Formlabs Form Wash	120
Formlabs Form Cure	140
Maintenance	600
TRIOS 3Shape intraoral scanner	2350
Software	
Materialise ProPlan CMF license	9890
Salaries	20120
Materials	
PLA White	500
Formlabs Biomed Resin White	3300
Isopropyl alcohol 5L	110
Total (n=100)	***39740***
Total per case	***398***

Table 4. Costs of in-house planning, design and printing for patients requiring orthognathic surgery.

4.2.2 Outsourcing

Costs for outsourcing are determined in conversations with the CMF surgeon. These costs involve virtual surgery planning (VSP) with wafer design included of €300, outsourced printing of an anatomical model of €30 and printing of a single or double orthognathic wafer of €60, resulting in a total of €390 per orthognathic case. Furthermore, depreciation costs of €2350 for the intraoral scanner are taken into account as these cans need to be acquired in-house. Assuming an annual number of 100 cases, total annual outsourced costs are €41350 (see Table 5).

	*Total annual costs (**€**)*
Design & printing (n=100)	*39000*
TRIOS 3Shape intra-oral scanner	2350
Total (n=100 cases)	41350
Total per model	*420*

Table 5. Total annual costs for outsourcing the VSP, and design and printing of the anatomical models and wafers for patients requiring orthognathic surgery.

4.2.3 *Total costs of in-house planning and printing versus outsourcing*

Figure 4 displays the cumulative costs of in-house printing of the models and wafers versus outsourcing the process. After 2.7 years, in-house 3D printing will be financially more beneficial than outsourcing. Before this point, total in-house costs are higher than outsourcing due to the costs for the training programme at the start of in-house design and printing. However, when considering a 5-year period, in-house planning and printing will be more beneficial after 2.7 years (as illustrated in Figure 4). Annual in-house versus outsourced costs are €39740 (€398 per case) versus €41350 (€420 per case), resulting in a beneficial situation for in-house printing over outsourcing.

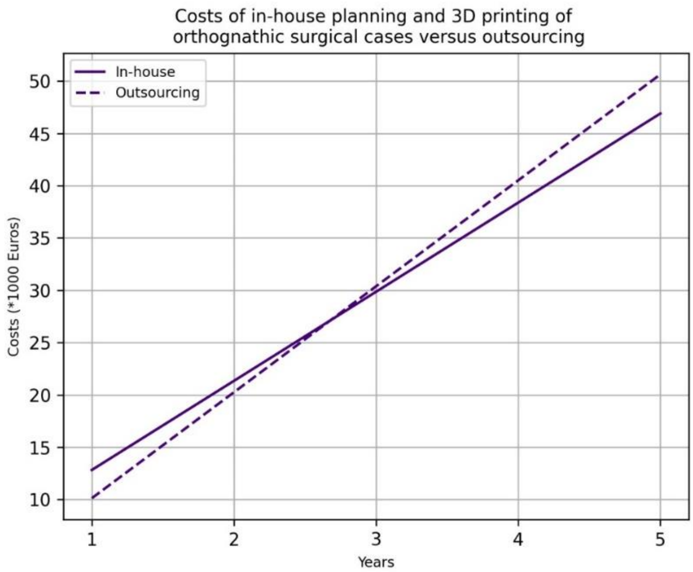


Figure 4. Cumulative costs of in-house 3D planning and 3D printing of orthognathic surgical cases versus outsourcing after subtraction of declarable costs. After 2.7 years, in-house planning and printing would be financially more beneficial than outsourcing.

4.2.4 Break-even analysis

Figure 5 shows the break-even analysis of scenario 3. The red dot marks the point of break-even, which is defined at n = 115 cases. This means that from 115 cases or more, in-house planning and printing of these cases will always be more beneficial than outsourcing.

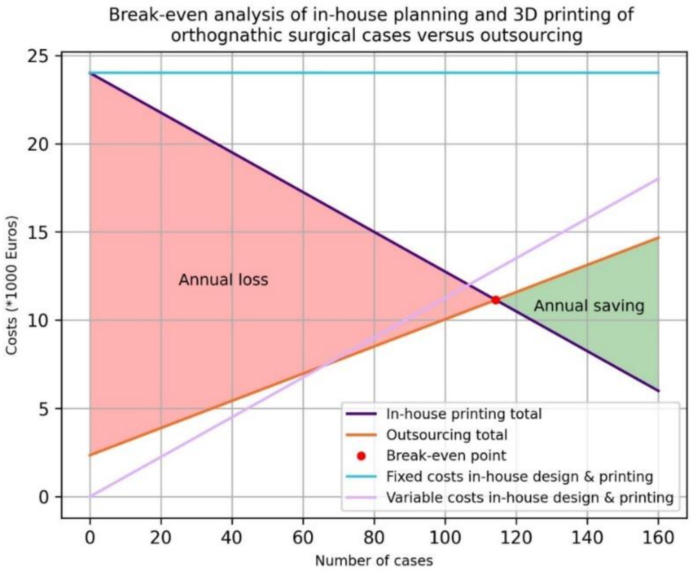


Figure 5. Break-even analysis for in-house 3D printing of orthognathic virtual surgery plannings (VSPs), anatomical models and wafers versus outsourcing. The red area represents a loss in costs, the green area represents a saving in costs. The line representing costs for in-house planning and printing has a negative slope after subtraction of declarable costs, meaning that a higher number of included cases would result in lower costs. The break-even point is defined as the intersection between the lines of 'In-house printing total' and 'Outsourcing total' and is situated at n = 115 surgical cases.

5. Discussion

This business case outlines three possible scenarios of implementation of a 3D printing service in the Albert Schweitzer hospital. In scenario 2 and 3, a comparative analysis of initiating an in-house 3D printing service and outsourcing of all parts was performed. In both scenarios, based on a 5-year period, in-house printing of the parts would be more beneficial than outsourcing the 3D printing process. According to these calculations, after 5 years, total savings of €385390 (scenario 2) and €3740 (scenario 3) can be achieved.

5.1 Scenario 1

In scenario 1, in-house 3D printing of anatomical models was outlined, with total annual costs of €8100 for all models and €540 per anatomical model. It could be argued that the cost per model is relatively high, considering the material costs of €5 per model. The high costs are mainly the result of the license costs of €5480, which is roughly two-thirds of the total costs in this scenario. It should therefore be determined whether the benefits of starting a 3D lab through implementation of this scenario outweigh the costs. Implementation of this service could be considered after implementation of scenario 2. In this situation, the license costs for scenario 1 would be reduced as only 1 Mimics Medical Base license is required for development of both anatomical models and surgical knee guides.

5.2 Scenario 2

This scenario outlines a comparison of in-house printing versus outsourcing of orthopedic surgical guides for TKA. As can be concluded from the cost comparison and the cumulative difference chart (Figure 2), in-house printing would be more beneficial over a 5-year period compared to outsourcing of the printing process. After 5 years, the total savings in the most realistic scenario (n = 225 surgical guides) would be approximately €385000. Break-even analysis shows a break-even point at the annual production of 42 surgical guides (Figure 3), which is largely exceeded assuming this scenario.

While both clinical and financial benefits seem to be robustly substantiated, actual benefits depend on multiple factors.
To start, the use of surgical guides for TKA is mainly steered by the orthopedic surgeons in a hospital. Where the surgeons in an academic center might be very positive about the use of these guides and its accompanying scientifically proven benefits, surgeons with a similar work experience in a smaller hospital might not directly acknowledge these benefits. Especially experienced surgeons might prefer to rely on their own skills rather than being introduced to a new tool which might minimally improve prosthesis alignment and reduce operative time with only a limited amount of minutes. On the other hand, surgical residents and starting orthopedic surgeons are increasingly gaining interest in 3D printing of patient-specific instruments and might be the correct target group for optimal use of these guides.
A second issue is related to the financial aspect of 3D printing of surgical guides for TKA. As mentioned in the first part of this chapter, studies have shown the benefits of these guides. However, this hospital should consider carefully whether these benefits outweigh the additional costs of 3D printed surgical guides, which include costs for design and printing of the guides, acquisition of a CT scan and costs for meetings between involved parties such as the orthopedic surgeon and the guide designer. Currently for this application, there are no declaration codes in the Netherlands for a hospital to declare their additional service of 3D printing in orthopedics, making it less attractive to apply guides in every orthopedic surgery. This consideration is hospital-specific and is related to departmental budgets.
Eventually, the decision whether a surgical guide will substantially contribute to the postoperative outcome and so outweigh the costs should be made on a case-by-case basis in consultation with the treating orthopedic surgeon.

5.3 Scenario 3

Opposed to the point made in scenario 2 of this business case, the need for 3D printed orthognathic models and wafers is not negotiable, as they are instruments which determine the success of a surgery. These 3D printed parts are already extensively being used in other hospitals, validating the importance of this service. The consideration whether this service is provided through an in-house 3D lab or through outsourcing depends mainly on future perspectives. For now, a number of 100 cases is set to determine the possible benefits of in-house 3D printing versus outsourcing. Looking at the break-even analysis in this case, in-house printing would outweigh outsourcing with a break-even point of 115 cases annually. Additionally, costs for a 2-day training programme of €4310 are taken into account in the first year when choosing for in-house printing. Considering the cumulative difference between in-house printing and outsourcing, the former would become more beneficial 2.7 years after the implementation of in-house printing. Concluding, in-house planning and printing of orthognathic cases would be more beneficial when a multi-year plan is considered.
One method to achieve break-even earlier would be to increase the number of annual cases for which 3D printing is applied. In this way, costs of in-house printing would be less compared to outsourcing more rapidly. Another potential method of achieving break-even in an earlier stage would be to evaluate the financial aspect of combining all scenarios outlined. This could result in a cost decrease per 3D printed model or case for which 3D printing is applied in all scenarios. This combination is beyond the scope of this business case and are not described in detail for now, however in future work it could be interesting to look into the financial benefits of combining scenarios.

5.4 Limitations

While the benefits in this business case seem substantial, the three scenarios are a simplified version of the actual situation.

First, to comply with international standards, a new 3D lab should set up a Quality Management System (QMS) which is in line with ISO13485. Setting up a QMS will certainly increase the amount of FTE required for in-house 3D printing. This increase in FTE was not accounted for in this business case, however when a 3D lab is initiated, these additional costs must be added to the costs as calculated in the scenarios. Implementation costs for a QMS are approximately between €7000 and €15000, and might even be higher when ISO14385 certification is desired (41).

A second consideration is the continuity of the production process. As the possibility exists that in the future, 450 surgical guides are required annually, it is of vital importance that the 3D lab may not come to a standstill. To anticipate on this situation, the hospital should consider recruiting more than one individual to take care of the production process, as employees responsible for production of the guides also have their holidays similar to other hospital staff.

5.5 Conclusion

Concluding, in-house 3D printing in scenario 2 and 3 can offer financial benefits when compared to an outsourced 3D printing service, and can be considered for this hospital. The cost comparison in scenario 2 showed a substantial saving for in-house printing relative to outsourcing, while in scenario 3, only a minimal difference in costs is observed. Implementation of scenario 1 would be financially unfavourable, unless it follows the implementation of either scenario 2 or 3. It is important to note that in all scenarios discussed, clinical benefits are substantial. Therefore, it is recommended to start a 3D lab in this hospital with in-house printing of orthopedic surgical guides, and to expand the lab with additional services for printing of anatomical models and orthognathic wafers. Future work should focus on the implementation of 3D printing for other departments in this hospital.

5

General discussion

This master's thesis highlights three important topics with regard to the implementation of a 3D lab in the Albert Schweitzer hospital. These topics include: 1) a 3D printing workflow for development of 3D printed anatomical models, 2) a survey study investigating the added value of these models and 3) a business case outlining three possible scenarios for starting a 3D lab in this hospital.
To support implementation of a 3D printing service, a workflow proposal was presented in chapter 2, outlining all steps and considerations to develop a 3D printed anatomical model from a patient's CT or MRI scan. The workflow includes an overview of roles and responsibilities and takes into account available resources and expertise in this hospital, ensuring the completeness of the workflow.
In chapter 3, results of the survey study showed that a 3D printed anatomical model can be a valuable tool in preoperative planning, providing anatomical and planning related insights which could have been missed by using conventional planning methods. Furthermore, anatomical models might improve a surgeon's confidence in a preoperative plan and may reduce operative time in certain orthopedic surgical cases. These benefits were mainly observed in orthopedic surgery for hip revision and surgery of the ankle or foot.
The business case presented in chapter 4 explored the opportunities of starting a 3D lab in a more financial aspect. Three scenarios were outlined: 1) 3D printing of anatomical models, 2) 3D printing of orthopedic surgical guides for TKA and 3) 3D planning and printing of orthognathic surgical cases. Among these scenarios, scenario 2 turned out to have the greatest financial benefit. Therefore, it was recommended to initiate a 3D lab with a focus on orthopedic surgical guides, as a break-even point with regard to outsourcing is reached more rapidly compared to scenario 3, and yielded significantly higher cost savings.

This thesis marks the initial steps towards establishment of a 3D lab in the Albert Schweitzer hospital. The success of this lab relies on 3 crucial aspects.
The attitude of medical specialists towards 3D planning and printing within the hospital will have a significant impact on the success of a 3D lab. The level of interest in 3D-related facilities by various departments will determine the importance of a 3D lab and its sustainability in the future. The more departments want to leverage 3D technologies, the greater the importance of this lab will be.
The success of a 3D lab also depends on the available resources for the 3D lab. Adequate staffing, budgets and available infrastructure are key factors that should be considered. Skilled staff with an expertise in 3D planning and printing is required to operate the lab. Additionally, sufficient financial resources will determine the amount of cases the lab can process. Lastly, working spaces where printers can be located and that feature adequate air ventilation are required for appropriate functioning of the lab.
To successfully operate a 3D lab, all requirements regarding quality management of the 3D printed parts must be met. Furthermore, regulatory compliance is an important factor

when printing parts that will have direct contact with the human body. By having an appropriate quality management system in place that follows international guidelines, patient safety is optimized and errors are minimized.

A clear and implementable workflow for the development of 3D printed anatomical models was presented. These models can function as a valuable tool in the process of preoperative planning of orthopedic surgery and hold potential for other applications. To optimize financial benefits, it is recommended to initiate the 3D lab with the in-house production of orthopedic surgical knee guides. Future work should explore the demand for 3D printing in other departments to further optimize the usefulness of the 3D lab in the Albert Schweitzer hospital.

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Three-dimensional printing of anatomical models: an overview of techniques, workflows, quality assurance and applications

Y. F. (Yaro) Roodenburg[a,b]

[a] Technical Medicine student, Delft University of Technology, Erasmus Medical Center Rotterdam and Leiden University Medical Center, The Netherlands

[b] Intern, department of Clinical Physics and Medical Technology, Albert Schweitzer hospital, Dordrecht, The Netherlands

Abstract

Introduction: Medical three-dimensional printing (3DP) is rapidly evolving, with an increasing number of available printer types, materials and software packages that can be used to create patient-specific anatomical models, implants, drill and saw guides. 3D printed anatomical models are printed representations of patient-specific anatomy based on imaging data such as computed tomography (CT) or magnetic resonance imaging (MRI) scans. These models have shown to be useful during preoperative planning, for use as intraoperative guidance, for professional and student education of complex anatomy and for patient understanding.

Aim: This review aims to provide an overview of 3DP methods, workflow, quality assurance (QA) and known applications of 3D printed anatomical models in orthopedics, traumatology, cardiology and plastic and reconstructive surgery.

Main findings: To gain knowledge in 3DP, multiple books are available that describe all known medical and non-medical 3DP methods, and the five most commonly used methods are mentioned in this review. There are several conducted studies that propose a workflow for the development of 3D printed anatomical models, which can be used as a guideline for an institution's own 3DP service. The steps that are mostly mentioned are image acquisition, segmentation, model refinement, model printing and post-processing.

A number of studies also report methods to measure model accuracy by comparing the printed model with the digital model, the original scan data or cadaveric specimens. To develop a solid framework for 3DP of anatomical models, it is important to incorporate a quality assurance (QA) program to continually monitor the models that are created.

Examples of applications of 3D printed anatomical models include preoperative planning of complex orthopedic and traumatological cases, education of healthcare professionals, medical students and patients of congenital heart diseases in cardiology and guiding assistance during dissection of abdominally-based free flaps for breast reconstructions.

The field of medical 3DP will continue to grow, as new printing technologies and materials will become available, and future research should evaluate extensively the cost-benefit ratio of the anatomical models in order to further implement this technology in clinical practice.

Keywords: three-dimensional printing, 3D printing, anatomical model, three-dimensional printed model, 3D printed anatomical model.

Introduction

Three-dimensional printing in a clinical setting

Three-dimensional printing (3D printing, 3DP), a process sometimes also referred to as additive manufacturing or rapid prototyping, is a technology that is rapidly gaining ground in all kinds of fields, including the medical world. The increasing use of 3DP is being driven by decreasing costs of three-dimensional (3D) printers and 3D printing materials, and the fact that there is an increasing number of low-cost or open-source software packages available to create three-dimensional objects. 3DP has shown to be useful in preprocedural planning, scenario simulation and clinical education (1-3). Additionally, it can be used for the creation of patient-specific cutting and drill guides and personalized implants, as well as the shaping of medical devices such as fixation plates and screws (4-6). Medical 3DP can be the base of a greener healthcare environment, as parts can be on demand and patient-specific, possibly resulting in reduced waste production (7). An overview of applications of 3DP in a medical perspective can be seen in Figure 1.

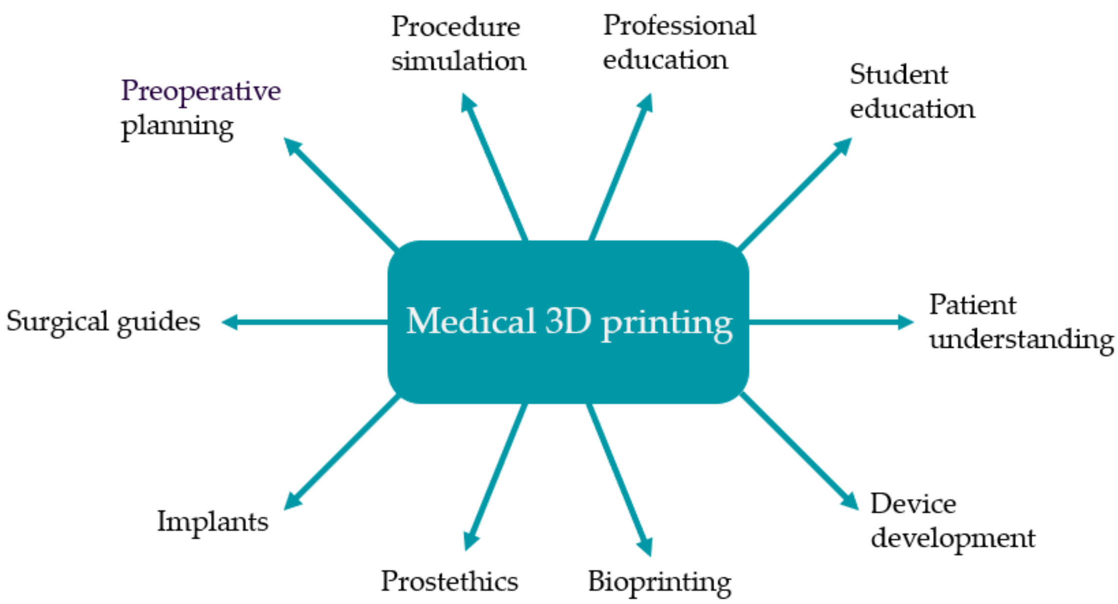

Figure 1. Most common applications of medical 3D printing found in literature (8).

Main purposes of 3D printed anatomical models

The term '3D printed anatomical model' indicates a printed representation of patient-specific anatomy based on imaging data such as computed tomography (CT) or magnetic resonance imaging (MRI) scans. Figure 2 presents an example of a 3D printed anatomical heart model diagnosed with tetralogy of Fallot (TOF) and atrial septal defect (ASD).

Numerous studies report the use of 3D printed anatomical models in the preoperative planning process (9-13). It allows the surgeons to obtain a real hands-on feeling of what the anatomic orientation of a specific patient is like. The models can also be taken into the operating room as a navigational guide for the actual surgery. Results show that the vast majority of surgeons surveyed acknowledge that the 3D-printed anatomical models are a valuable addition in the preoperative planning process, next to the conventional planning tools such as 2-dimensional (2D) scans (14). However, the most important drawbacks mentioned by surgeons are the preparation time and costs of the models (15).

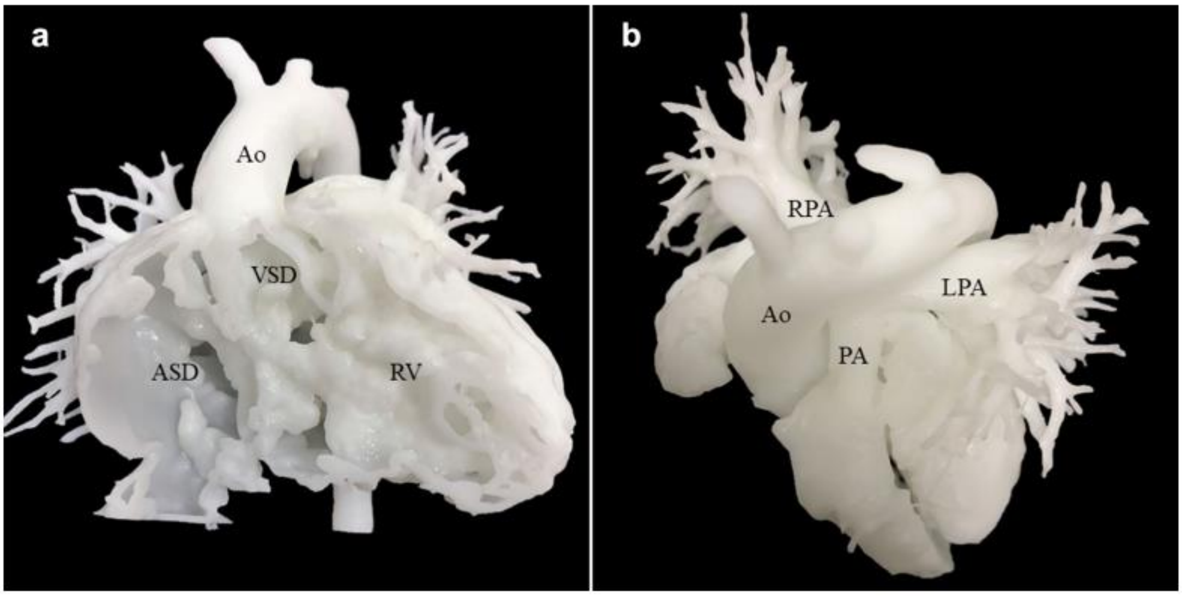

Figure 2. Example of a 3D printed anatomical model: a heart diagnosed with tetralogy of Fallot (TOF) and atrial septal defect (ASD) used in the preoperative planning process. Ao = aorta overriding, ASD = atrial septal defect, VSD = ventricular septal defect, RV = right ventricle, PA = pulmonary artery, RPA = right pulmonary artery, LPA = left pulmonary artery. Image from Xu et al. (16)

3D printed anatomical models can also be used for educating doctors that are new in the field. There are a number of studies that mention the beneficial effect that 3D printed models have on the understanding of complex anatomy by students or starting surgeons (1, 2, 17-19).

A third purpose the 3D printed anatomical models could serve is as a tool during the communication between the physician and the patient. Studies have been conducted in which the accordance between the physician and patient have been evaluated and there are examples in which patient comprehension of a complex procedure and the long-term consequences are poor (20). 3D printed models of a patient's own anatomy can help one to understand the reasons for planning a specific surgery, and to consent in the physician's decisions (21).

Other 3DP applications

Another application of 3DP in a medical scope is the creation of patient-specific surgical drill and saw guides. There are a lot of studies that report the added value of these personalized instruments, and advantages are for example seen in outcomes after orthopedic and oral and maxillofacial surgery. For example, studies show less displacement after reconstructing scaphoid fractures using patient-specific guides relative to conventional instruments, and in-house produced cutting guides for mandibular reconstruction after cancer show promising results when the preoperative model of the reconstructed mandibula was compared with the volume rendering of a postoperative CT scan (22). Additionally, Xie et al. show an application of a cutting guide in anterior mandibular body ostectomy (5).

3DP can also be used in creating personalized implants. This way, implants that match a patient's complex anatomy can be developed, resulting in optimal alignment between the unique anatomy and the implant. Applications of personalized implants are seen in lower extremity reconstructions, such as the use of 3D printed cages for tibiotalocalcaneal (TTC) arthrodesis or ballistic navicular fractures (23). Personalized implants are also used in reconstructions after bone tumor resections, where 3D printed implants as replacement for (a part of) the pelvis, femur or humerus can be created (24, 25).

Starting a 3D printing service

Besides the applications that are mentioned in the previous sections, medical 3DP is used in numerous other departments and this trend is evolving rapidly with the increase of starting in-hospital 3D printing labs (26, 27). It has, however, not yet been fully determined whether the in-hospital use of 3DP is advantageous in terms of clinical utility and costs. Various studies have been conducted that show advantages in terms of reduction of operating room time and intraoperative blood loss using 3D printed anatomical models (12, 28-30). Additionally, there are studies reporting the added value of 3D printed surgical guides, plates and implants compared to conventional instrumentation (6, 31, 32).

In this paper, the focus is on 3D printed anatomical models and its corresponding processes and applications in orthopedics, traumatology, cardiology and plastic and reconstructive surgery. Creating an overview of processes and applications in these disciplines will form a theoretical base for setting up a 3D printing service in this hospital, as these departments have an increasing interest in 3D printing. The desire of the department is to start a small-scale 3D printing service for the development of anatomical models, with the possibility to extend this service to the printing of surgical guides and other patient-specific instruments. This paper provides an overview of 3DP methods, workflows, quality assurance (QA) and known applications of 3D printed anatomical models in orthopedics, traumatology, cardiology and plastic and reconstructive surgery.

3D printing methods

The principle of 3-dimensional printing (33)

3-dimensional printing is a process in which a specific kind of material is used to build up a three-dimensional object layer by layer, following certain boundaries that are defined within a standard tessellation language (STL) file. These boundaries are physically manufactured by depositing or fusing the building material at the locations of each layer as specified in the STL file at a certain layer thickness. The layer thickness usually ranges from 0.1 mm to approximately 0.4 mm, depending on the 3D printing technology that is used. Currently there are seven different groups of 3DP technologies, which are vat photopolymerization, material jetting, binder jetting, material extrusion, powder bed fusion, sheet lamination and directed energy deposition. The first five technologies in the ones mentioned above are the ones that are mostly seen in clinical settings, and details on each of these five technologies will be shortly discussed (34). Table 1 presents an overview of the technologies.

Vat photopolymerization / stereolithography

This technology, also referred to as stereolithography (SLA) or digital light processing (DLP), consists of a high-intensity light source that selectively cures consequent layers of an epoxy- or acrylic-based photo-curable resin inside a vat or tray by inducing a chemical reaction in the resin. This reaction causes the resin to solidify at the desired locations. After printing, excess resin and lattice supports are removed, after which the model is cured in an ultraviolet (UV) chamber to complete the polymerization. With lattice supports, structures that allow printing parts of the model that would collapse without these structures are meant (Figure 3). These parts are printed alongside the desired object and can be removed after the printing process is completed.

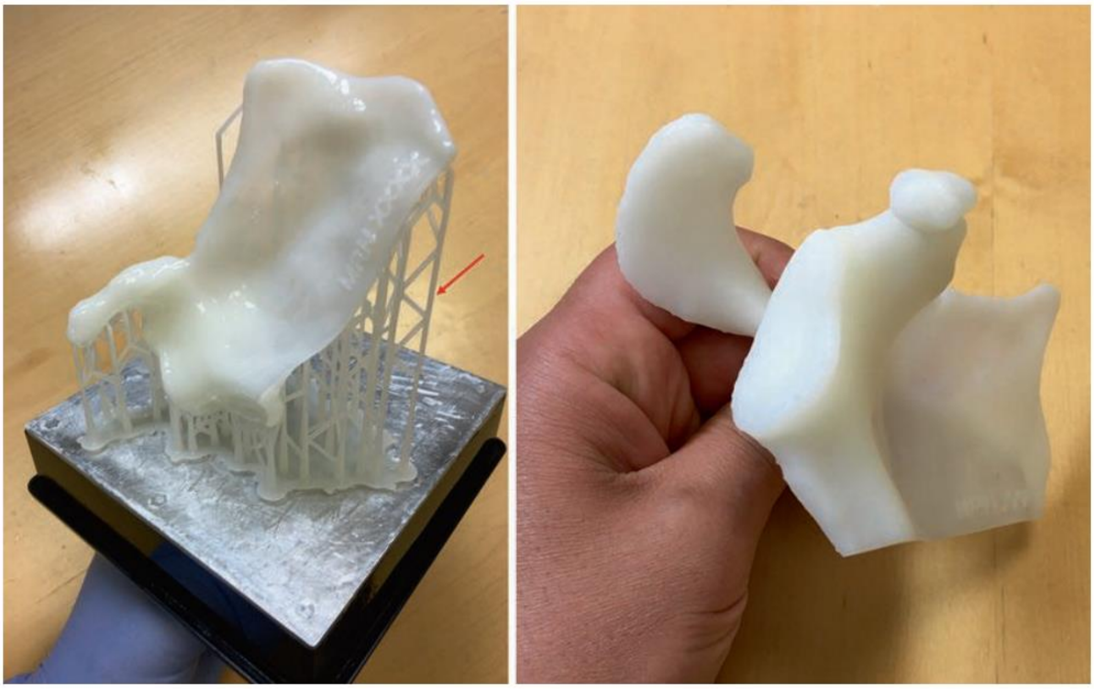

Figure 3. Example of a 3D printed scapula model using vat photopolymerization. In the left image, the red arrow indicates lattice support structures, which are to be removed, resulting in the model in the right image. Image from Rybicki et al. (34)

Materials for SLA printing cost around $60-200/kg and are available in multiple colors. The materials can be both rigid and flexible, and even biocompatible and sterilizable resins are now emerging. The drawback of this technology is the fact that these printers can only print with one material at once, forcing the user to print separate model parts in different printing sessions.

Material jetting

Material jetting is based on the same chemical principle as vat photopolymerization; however, the resin is not stored in a vat but is jetted in consecutive layers through a head onto a build tray on the positions defined by the user after which it is polymerized with UV light. The printer switches layers by either moving the jetting head upward or moving the build tray downward. Generally, the printer consists of two heads, one containing the building material and one containing wax-like support material. An advantage of material jetting with respect to vat photopolymerization is that post-processing of the model is reduced, as the material does not need to be cured after printing. The printer can also have multiple print heads, allowing the use of multiple materials in one printing session and the creation of complex models with different material compositions. Material costs are around $300/kg and have the same properties as those for vat photopolymerization.

Binder jetting

Binder jetting is the technology of building a model from a bed of fine powder by jetting a liquid binding agent through a print head, and so bonding the powder together. Once all binding agent for one single layer has been jetted onto the powder, the build plate will be lowered after which a roller will spread out a new powder layer and the process is repeated, until the model is completed. Binding agents can be of all sorts of colors, and combinations of colors can be created during printing. Post-processing consists of vacuuming of the residual powder and infiltration of the model with a wax or resin. Models built with this technology are not biocompatible, as the powders and resins used are not favorable for use in vivo. Support materials are not needed as the model is always surrounded with powder. Material costs are around $150/kg, which is less expensive than vat photopolymerization and material jetting.

Material extrusion

Material extrusion, also known as fused deposition modeling (FDM), is the most frequently used 3DP technology for both medical and non-medical applications and uses an extrusion print head that is heated upon use. The material used for printing is a thermoplastic filament. This filament is led through the heated print head and is deposited layer-by-layer onto the build plate, after which it cools down and hardens. A broad scope of materials can be used in material extrusion, including polylactic acid (PLA) plastics, biocompatible polyether ether ketone (PEEK) and metals, depending on the application. Commercial printers often include two print heads, one for the build material and one for support material, which can be soluble in water. The support material can also be of the same material as the model, and can be removed easily. The technology is favored by starting 3DP labs because of its economical and easy-to-use properties. Material costs are often less than $100/kg, and currently PLA plastics can already be bought for around $40/kg.

Powder bed fusion

This technology is a collective name for multiple 3D printing methods, and generally consists of a high-power laser or electron beam that is used to melt together small particles in powder form in a tray. These particles can be of plastic, metal, ceramic or glass. The laser or electron beam is selectively applied on predefined locations to form a layer, after which the build plate is lowered and a new powder layer is deposited by a roller. The technology is often used for the printing of medical devices such as implants, fixations, surgical tools and guides. Biocompatible or bioresorbable metals are mostly used in this technology, and material costs range from $200/kg to $400/kg for some metals. A challenge in using this technology is the powder that remains in cavities inside printed models, which may affect biocompatibility.

Technology	Also known as…	Materials used	Relative accuracy	Cost	Advantages	Disadvantages
Vat photopolymerization	Stereolithography (SLA), Digital Light Processing (DLP)	Epoxy- or acrylic-based polymers	+++	$60-200/kg	Accuracy, biocompatibility, can print small details	Moderate strength, single material, limited colors, UV curing necessary
Material jetting	MultiJet Printing (MJP)	Acrylic-based polymers	+++	$300/kg	Accuracy, multi-material, biocompatibility	Moderate strength
Material extrusion	Fused Deposition Modeling (FDM)	PLA, composites, metals	+	$150/kg	Low cost, strong materials	Lower accuracy, layers are visible
Binder jetting		Gypsum, sand, metals	+	$40-100/kg	Build speed, wide material range, no supports	Low strength, infiltration necessary
Powder bed fusion	Selective laser sintering (SLS), electron beam melting (EBM)	Plastics, synthetic polymers, metals	++	$200-400/kg	Mechanical properties, wide material range, biocompatibility	Finish dependent on machine, single material

Table 1. Overview of most commonly used 3D printing technologies.

The 3D printing technologies mentioned above are all applicable in a medical setting, depending on the institution's desires, budget and phase of development of a 3DP lab. The requirements of the medical setting depend on the purpose of the object to be 3D printed. For example, a cutting guide that is to be used intraoperatively should be sterilizable, whereas this property does not necessarily apply to an anatomical model. From here, this review will focus on the process of 3DP using FDM of anatomical models and structures and its applications in orthopedics, traumatology, cardiology and plastic and reconstructive surgery.

Workflow for three-dimensional printing of anatomical models and structures

The process of 3DP of anatomical models consists of multiple steps, starting with the scanning of the anatomy of interest and concluding with the desired 3D printed model (35-42). In this section, the steps in the workflow of 3DP of anatomical models are explained.

Image acquisition

Technically seen, any set of volumetric data can be 3D printed. However, in the case of medical 3DP, it is essential to obtain a set of images, normally stored in Digital Imaging and Communications in Medicine (DICOM) files, that together represent an anatomical region of interest (ROI) that one wants to print. CT and MRI are the most commonly used imaging modalities for acquisition of sets of medical images; however, ultrasound (US) images are also regularly used (43). CT allows for a high spatial resolution, high level of contrast and low signal-to-noise ratio, and datasets can be reconstructed with very thin slices (around 0.5 mm) after the actual scanning. In MRI, high spatial resolutions can also be achieved, but it must be noted that a smaller slice thickness can require a longer scanning time in MRI. When using a greater slice thickness, a greater volume is reflected onto the 2D plane, possibly causing the ROI to be blurred. It is therefore important that the desired slice thickness is determined before MR imaging is performed (44), however, research shows that the effect of slice thickness on the measured volume of an ROI using MRI is little (45).

Segmentation

When creating an anatomical model, one or more specific structures are often of interest. So when the dataset has been acquired, the next step is to segment the ROI. This starts with importing the DICOM files into the segmentation software. The segmentation is usually performed by isolating a group of voxels (the 3D version of a pixel) with corresponding intensity, which in most software packages is done using a combination of automatic and manual (semi-automatic) processes. Often, automatic segmentation is performed based on thresholding, selecting all voxels above (or below) a specific intensity value, and manual finetuning is performed afterwards to obtain a realistic representation of the anatomical structure. There is a broad range of software packages available for medical image segmentation, such as 3D Slicer (46) (open-source software) or Materialise Mimics Innovation Suite (Materialise, Leuven, Belgium). Most software packages can convert the segmented model to a new file format: the Standard Tessellation Language (STL), which is a file format that is widely used in 3DP. It describes the surface geometry of a certain object through simple triangles, called the triangular mesh, which allows for the actual printing of the object. Figure 4 shows a model of the talus with visible triangular mesh and a color map of the principal curvatures.

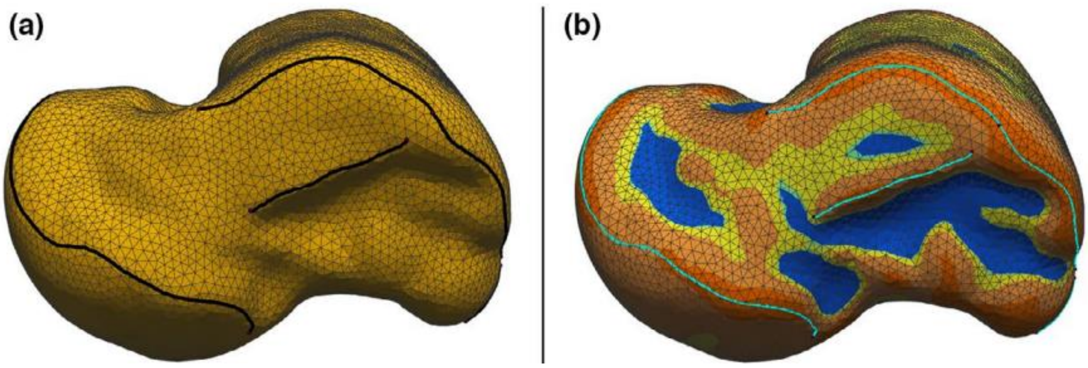

Figure 4. 3D model of the talus showing a) the triangular mesh and b) a color map of the principal curvatures. Image by Vafaeian et al. (47)

Model refinement

After segmentation of the ROI, the created model can be refined so that it is converted into a printable model. The term 'refining' covers a broad range of operations that can be performed on the model using computer-aided design (CAD) methods. The ones most commonly used for anatomical models are repairing (fixing errors and removing discontinuities and holes in the model), surface smoothing and appending (unifying the model and removing unneeded parts). One can refine the model as much as desired and there is no limit in performing these refinement actions on the model. How far a model should be refined depends on model requirements and user goals.

Printing

After the model has been refined, it can be imported into printer-specific software. Most 3D printers have an accessory software package, which provides a digital representation of the 3D printer and its build plate. In the software, the model can be imported and different configurations of the model on the build plate can be visualized. Depending on the configuration and the shape of the object, support material might be necessary. In some software packages, for example Ultimaker Cura (Ultimaker BV, Utrecht, The Netherlands) that comes with the Ultimaker 3D printers, it is possible to automatically generate the supporting structure that is needed for a model to be printed. A wide spectrum of other parameters can be tuned according to the user's requirements, such as the infill percentage (how much of the model is filled with material), layer thickness and printing speed (48). When the model is configured and the parameters are tuned, it can be exported to a printer-specific file format. The printing process can then be started. The printing time depends on the parameters mentioned above, as well as the model size and printer type and is usually in the range of hours (for small models) to days (for large models).

Post-processing

Depending on the printer used, additional post-processing of the printed model might be needed. This topic covers actions depending on the 3D printing method used, such as removal of support material, removal of excess resin, curing of the model with UV light, cleaning the model from unbonded powder particles and infiltration of the model with a material. If the anatomical model will be in contact with sterile environments like operating rooms, one should consider the options for (and apply) sterilization of that specific model. Figure 5 depicts an example of a workflow for 3DP of a heart model.

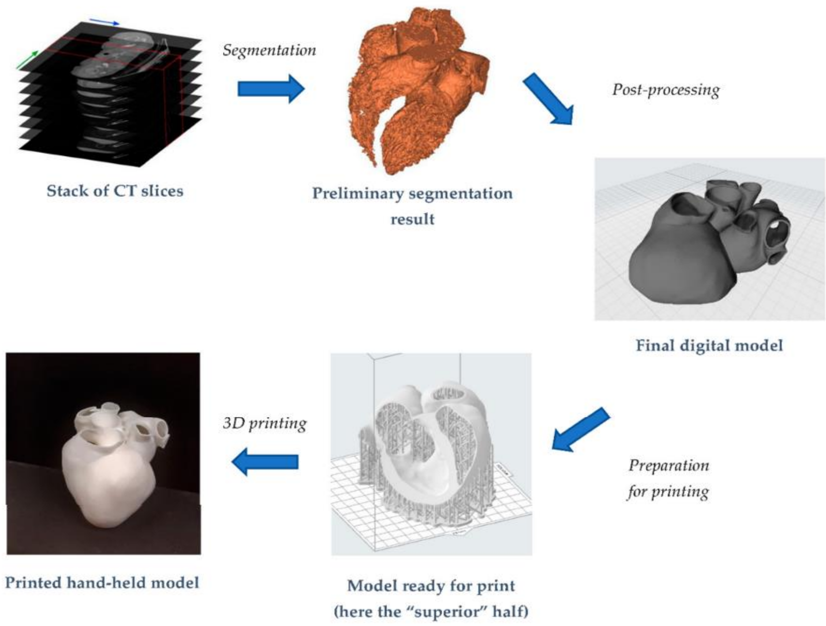

Figure 5. Key steps to obtain a hand-held heart model. Image by Bertolini et al. (18)

Quality assurance (QA)

While 3D printed anatomical models are now emerging rapidly, there is no standardized methodology for the development of such models, which could cause one to question their reliability and accuracy. 3D models can be generated from datasets with a slice thickness ranging from 0.6 mm to 5 mm, which has a drastic influence on the accuracy of the model. In order to achieve the highest quality, datasets with the smallest possible slice thickness should be used. However, it is possible to generate models from datasets with a larger slice thickness, and the decision should be based on 1) the goal of the model and 2) the available data.

Despite the fact that 3D printers can create models that deviate no more than 1 mm from their corresponding STL files, it is important to have a quality control system in place before the models are actually used in the daily workflow (49). There are several methods described in the literature to evaluate the quality of the model, and the three most frequently mentioned are discussed.

- *printed model vs. digital model*
  The most frequently used method to assess the accuracy of the printed model is by comparing it to the digital model. This can be done by scanning the 3D printed model, which can be achieved by high-resolution CT scanning or 3D scanning (50, 51). Consequently, a new segmentation can be performed on these images, generating a new STL file from this segmentation and then comparing it with the original STL file. The models can then be compared by either performing an overlay of both models and visualizing the differences, or by measuring predefined distances in both models and comparing the results (50).

- *printed model vs. imaging data*
  The accuracy of the model can also be determined by comparing the images from the original patient data with those of the 3D printed model (52). This can be done by performing a CT scan of the printed model, and overlay this dataset on that of the patient. In order to determine differences between the model and the patient data, measurements can be performed similar to the ones mentioned in the previous section.

  Another method of comparing the 3D printed model with the radiological images is by measuring predefined distances in the printed model using a caliper, measuring the corresponding distances on the digital images and comparing the results (49). It is mentioned that differences are usually in the acceptable range of 1 mm (53).

- *printed model vs. cadaveric specimen*
  A third method of assessing the accuracy of the printed model is by comparing the 3D printed model to a cadaveric specimen (53). There are examples in literature reporting the use of this method on assessing accuracy of 3D printed skulls, mandibles, vertebral bodies and a pelvis (9, 54, 55). By using this method, one must always keep in mind that perfectly prepared cadaveric material is not influenced by adjacent anatomical structures anymore, while this does apply during the segmentation process for the 3D printed model. In the study of Van den Broeck et al. (56), it is mentioned that an STL model created from CT data results in

an overestimation of a cleaned tibial specimen, whereas using MRI data results in an underestimation of the bone. However, differences are relatively small and it is concluded that both CT and MRI data are accurate for the creation of 3D anatomical models within 0.5 mm of the ground truth. Overall, CT data is preferred over MRI data for the segmentation of bones, as it generally allows for more precise model generation (57), but the choice of modality depends on the level of required accuracy per individual case and should be considered before model creation.

The methods for model verification described above indicate that there are multiple ways to assess the accuracy of a 3D printed model. There is no golden standard as it comes to quality assurance, and the options are not limited to the ones mentioned above. Surface scanning (a non-invasive scanning method to capture the shape, texture and volume information of a 3D object) and photogrammetry (the method of obtaining information about 3D objects by recording and measuring photographic images) are two other methods that could be used in the assessment of a model's accuracy (51). It is of importance that an institution that desires to develop its own 3D printing service considers the options for validation of the printed models before they are actively used in practice. It is also important to determine the required accuracy of the model before the development, which is dependent on the application of the model.

Most studies report accuracy deviations that are no greater than 1 mm, and it has been found that most errors are introduced during the image segmentation stage (58). Different observers can make different measurements due to differences in background and training methods, thus making it important to evaluate the inter-operator variability as a part of the quality assurance process for a 3DP service.

Applications

3DP of anatomical models is used in almost every medical discipline, with the use being more intensive in one department than in the other, depending on factors such as budget, resources and applicability. Three disciplines that are frequently mentioned in literature having applications of 3D printed anatomical models are orthopedics, traumatology and cardiology. Applications in plastic & reconstructive surgery are also considered in this section regarding the institution's interest in this discipline. Per discipline, applications known to date will be discussed, and Appendix A provides an schematic overview of the applications.

Orthopedics / traumatology

Osteotomy planning

3D printed anatomical models have shown to be of great use in osteotomy planning. Applications are seen in the planning of corrective surgery of distal radial vicious consolidations (59), and a study on the effect of wedge size and osteotomy angle on deformity correction using 3D printed models of the foot was performed (60). Significant differences were found in the choice of wedge size on the degree of heel varus correction and the choice of sagittal angle on resulting change in calcaneal length using these models, compared to cases in which no model was used. Kim et al. studied the use of 3D printed anatomical models in preoperative simulation of an open-wedge high tibial osteotomy (61) and found that satisfactory correction could be established without affecting the posterior tibial slope (PTS) angle.

Hip arthroplasty

The anatomical models can also be used for determining the acetabular cup size preoperatively for total hip arthroplasty (THA). Studies researched a new method to restore hip rotation center with the assistance of 3DP (62, 63), and found strong agreement on acetabular cup size between simulated operations on 3D printed models and the actual operations. High agreement between simulated and actual bone defects was also reported, acetabular cup size determination was accurate in 92.6% of the cases, and the surgeons rated the anatomical models as very useful, with an overall usefulness of 4.86/5 (64).

A study showed that 92.7% of the surveyed orthopedic surgeons have great confidence in the added value of 3D printed bone models of the hip in diagnosis, treatment, education and simulation of a surgery, and demonstrated that 3D printed models could alter a planned osteoplasty significantly for femoroacetabular impingement (FAI) surgery in specific angles (10). It was also demonstrated that physical models yielded more accurate visual judgments than using an on-screen model in hip dysplasia (65). Additionally, Zeng et al. showed the added value of 3D printed anatomical models for the pre-bending of fixation plates for acetabular fracture reduction and concluded that these plates had an anatomical shape specifically fit to the individual pelvis without further necessary bending of the plates at the time of surgery, and fracture reductions were significantly improved (66). The maximum displacement after fracture reduction using the pre-bended plates shaped through the 3D models was between 1-2 mm. Figure 6 shows two examples of the use of 3D printed pelvis models for determination of acetabular cup size and for pre-bending of fixation plates for hip reduction surgery.

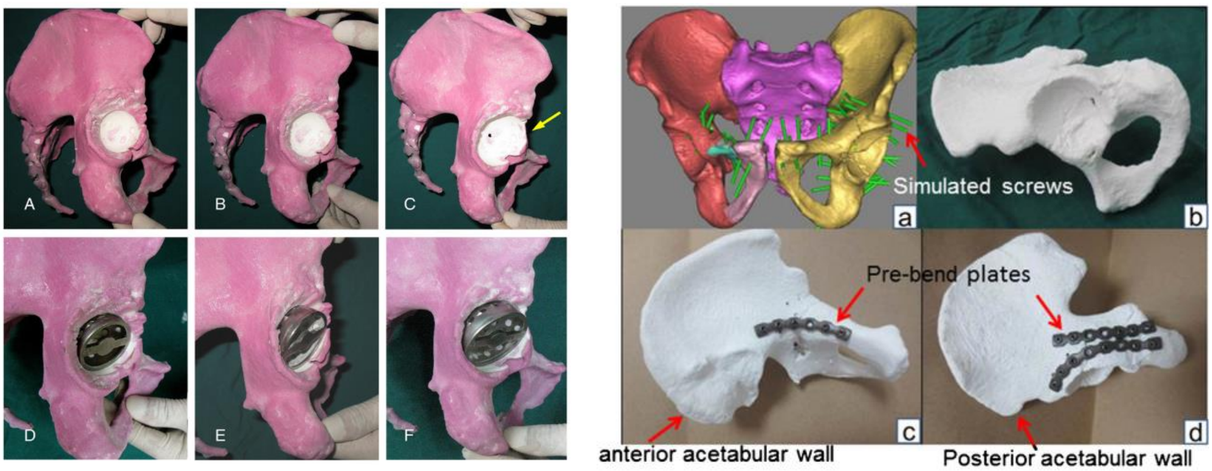

Figure 6. Examples of 3D printed pelvis models. (left) For determination of the acetabular

cup size in developmental dysplasia of the hip (DDH). Image from Xu et al. (67). (right) Pre-bending of fixation plates using the model and reduction simulation. Image from Zeng et al. (66).

Knee joint surgery

3DP can also be used for the creation of knee joint models. Ruiz et al. describes a method for the 3DP of soft-tissue knee joint models that can be used for medical training, preoperative planning, research and educational purposes (68). The models were mechanically tested and could withstand high stresses, mimicking the soft tissue as realistic as possible.

Fritz et al. investigated the diagnostic accuracy of 3D printed models of the knee for detection of patellofemoral dysplasia and found similar results for these models in comparison to CT images (69). Another study reports the advantages of 3D printed models of the knee in high-energy tibial plateau fractures and found that they were useful in surgical planning and optimizing surgery in terms of reduced operation time, blood loss and use of intraoperative fluoroscopy (70).

Foot surgery

3D printed anatomical models are also useful in foot surgery. In a research on the effect of these models in displaced intra-articular calcaneal fractures, significantly reduced operation time, blood loss, fluoroscopy usage and instrumentation time were seen in the 3D model-assisted group (28). Additionally, determination of screw size and plate resizing could also be performed preoperatively, while for the conventional group it was necessary to do this intraoperatively.

Foo et al. looked into the usefulness of 3D printed models for preoperative planning of tibial plafond fractures, and found through surveys that most surgeons believe that 3D models and CT scans combined provide more information than CT scans alone (11).

Radius fractures

The study of Langerhuizen et al. could not determine the added value of 3D printed models in the characterization of intra-articular distal radius fractures (71). However, another study mentions the efficacy of 3D printed radius models and found that they reduce operative time, blood loss and fluoroscopy time, help the doctors in preoperative planning and communication with patients (30).

Other orthopedic and traumatological applications

There are numerous other applications in the field of orthopedics and traumatology for which 3D printed anatomical models could be useful. One study showed that these models are useful in the pre- and intraoperative planning of complex oncological cases by for example decreasing the incision length and selecting the appropriate acetabular supporting ring (72). The study shows that CT-based, MRI-based or a combination of both modalities can result in reliable 3D models showing bone, soft tissue and vascularization. A study by Kanagasuntheram et al. shows that 3D printed models of the midcarpal joint can be effective educational tools and possibly can replace cadaveric specimens (73). Corona et al. created 3D printed models of the full tibia, which allowed detailed preoperative planning and to pre-construct the frames used for treatment of acute fractures (12). Effectiveness was also seen in 3D printing for the treatment of Pilon fractures (74) (distal part of the tibia), and the same was demonstrated for elbow fractures (75). Patients with die-punch fractures, a fracture of the distal radius, also benefit from 3D printed models, which reduce operation time, blood loss and fluoroscopy time (76).

Proximal humerus fractures and (tri)malleolar fractures are other groups for which the 3D printed models can be advantageous, as the models clearly display the complex fracture, and allow the surgeon to plan the fixation preoperatively (77-79).

Cardiology

Ventricular septal defect repair

The first application of 3D printed anatomical models in cardiology are in ventricular septal defect repair. Deng et al. mention the use of a 3D printed cardiac model for preoperative consent and understanding of the procedure to be performed (13). Significant improvements in understanding of anatomy and potential complications by guardians were found. Other studies report that 3D printed models for ventricular septal defect repair are found effective in the education of healthcare professionals (17, 80). As an example, the reduction of risk to patients is mentioned as a great advantage of the models.

Atrial septal defect repair

Similar to ventricular septal defects, 3D printed models can also aid in the repair of atrial septal defects. The appropriate occluder size is difficult to estimate from conventional scans, however with the use of a patient-specific 3D printed model, the procedure can be simulated and the right occluder size can be chosen, leading to a lower frequency of occluder replacement and eventually to lower costs (81, 82).

Left atrial appendage

It is important to treat left atrial appendage to reduce the risk of stroke, and it is proved that 3D printed models can also improve the outcomes after left atrial appendage (LAA) closure by demonstrating that these models may reduce LAA leak by enabling the physician to select the appropriate closure device size, as well as reduce the operation, anesthesia and fluoroscopy time (83-85).

Congenital heart disease education

3D printed models are efficient learning tools for medical students, as has been shown in several studies. Students share that they feel more confident in congenital heart disease (CHD) anatomy by using the 3D models in their curriculum (1, 18, 19, 86) , but it is not limited to this specific group: also healthcare professionals benefit from these cardiac models. This group of users can also apply the models in preoperative planning of CHD surgery, and trends for reduced operation time are observed (16, 87) . Further advantages of 3D printed cardiac models in CHD consist of creating a simulation environment for complex procedures and improving the communication between parents and the physician (88-90). One study by Hopfner et al. even described the possibilities of creating several different CHD models from one single patient scan, demonstrating the ease at which these models can be made.

Other cardiological applications

Other applications of 3D printed models of the heart mentioned in the literature are surgical training of the arterial switch procedure, preoperative planning for the debulking of pediatric cardiac tumors and preoperative planning for complex univentricular hearts with abnormal systemic or pulmonary venous drainage (29, 91, 92).

Plastic & reconstructive surgery

Literature on the use of 3D printed anatomical models in plastic and reconstructive surgery is scarce. However, there are some studies mentioning the added value of the models in this field. One example is the use of 3D printed models for use as a guide during the intramuscular dissection in abdominally-based breast reconstructions. In a study by Jablonka et al., the models represent the deep inferior epigastric subfascial vascular tree, which can assist in the execution of the intramuscular dissection of an abdominally-based free flap that can be used for breast reconstructions (93). Another study by Lobb et al. showed that 3D printed models of the craniofacial anatomy were useful and an addition to resident training for preoperative planning, resulting in decreased planning time (2). Guest et al. demonstrated that 3D printed models for preoperative maxillofacial surgery are useful tools for both surgeons (improved planning) and patients (improved comprehension of the procedure) (94). Nicot et al. presented a 3D printed haptic anatomical model for cleft lip/palate which enables better surgical planning and parent understanding (95).

These applications demonstrate that 3D printed anatomical models can also be of important added value in plastic and reconstructive surgery.

Discussion

The use of 3D printed anatomical models has increased drastically over the past years with applications in preoperative planning, student and healthcare professional education and patient understanding, and this growth will undoubtedly continue in the future. In-hospital 3D printing and visualization labs are slowly becoming a concept and the advantages are innumerable. Studies in this review demonstrated that 3DP can have broadly ranging applications, ranging from educational models to implantable, patient-specific devices. In order to produce these models, a 3D printing system should be selected that covers the needs of a specific institution, and the most used 3D printing methods were presented, with various materials, costs, printing time and accuracy. If an institution wants to generalize the use of 3DP, it is of importance that a workflow is developed that can be optimized from image acquisition to intended use of the model, with all intermediate steps described in detail. When the goals are set, printer choices are made and a workflow has been designed, the institution is ready to print its first model. In order to gain an insight into how accurate this model is, a QA program should be incorporated. Accuracy of the printed models can be determined via several methods (see section 'Quality Assurance').

For a medical institution to establish such a 3DP service it is essential to consider both the advantages and disadvantages of medical 3D printing, as well as to evaluate the cost-benefit ratio 3DP will have for that specific institution.

According to the literature, usefulness of the 3D anatomical models can be scored in different ways. To assess the usefulness according to surgeons and other medical specialists, one could use the Likert scale, which requires the respondent to provide a numerical answer between two extremes, for example with 'totally agree' representing a score of 10 and 'totally disagree' representing a score of 0 (18). A disadvantage of using this scale is that it is focused on the added value of a 3D printed model in addition to the conventional method, and that it does not allow for two (or more) groups to be compared.

Another method for scoring usefulness is by looking at objective measures, such as the operation time, amount of blood loss or fluoroscopy time. These measures allow for easy analysis of the influence of the 3D printed anatomical models in the workflow because two (3D printed versus conventional) groups can be compared on multiple outcome measures.

In the article of Ozturk et al., the Friedman test was used to compare the physicians' perception of the 3D printed model relative to radiographs and CT scans (14). Langerhuizen et al. presented a statistical analysis using the Fleiss Kappa as a measure to determine the inter-surgeon agreement on the added value of 3D printed models (71). In the study of Zhuang et al., patient understanding and satisfaction is measured through self-developed questionnaires (3).

3DP offers innumerable possibilities, but there are limitations regarding the 3DP of anatomical models, of which size is the most important one. 3D printers have predefined dimensions, and only models of a size fitting the 3D printer dimensions can be created (33, 34). Another factor that limits the printing process is the build speed. Printing anatomical models can take up to several hours to days depending on the size of the model, but the speed could be increased by adjusting the layer thickness, infill percentage and other printer settings. However, making these adjustments could cause a decrease in model accuracy.

In order to achieve an effective in-hospital 3DP service, it is of great importance to set the goals the 3DP service should fulfill in advance, and to enthuse the departments that are initially involved in the process, which could be accomplished by presenting work from other institutions and showing the added value 3DP can have for a department. It is also important that the proposed workflow is evaluated according to the predefined goals once in practice, as well as to refine the workflow where needed.

Future perspectives

The future of medical 3DP looks promising, as the number of applications continually increases. It is of importance however, that a 3DP department keeps evaluating its products and is eager to improve itself whenever and wherever possible. Future research should focus on identifying methods to assess the cost-effectiveness of 3D printed anatomical models in specific clinical scenarios. Only then can the 3DP service be implemented and used efficiently, and eventual expansion of the service be realized. It is also of importance that more generalizable protocols for starting a 3DP service are developed, which provides a handle for implementing medical 3DP and can form the basis for the development of reporting guidelines for the implementation processes of medical 3DP. These guidelines should carefully describe the role of each actor in the workflow, varying from the patient to a 3D lab technician or specialist.

The range of commercially available materials for 3DP is broad and newly developed materials are continually being marketed, currently allowing for very accurate tissue mimicking. 3D printed anatomical models with various colors, flexibility or elasticity can be created nowadays, representing the actual anatomy as closely as possible. The development of new materials with all sorts of properties will continue and 3D printed models will become more and more representative of reality.

With medical 3DP expanding rapidly, ethical and legal considerations related to quality assurance, safety and accountability should be made. May it be small, there is always a risk of making mistakes in the treatment of a patient due to errors in the 3D printed anatomical model, and in this case it should be clear who carries responsibility. Future work should focus on documenting each actor's responsibilities regarding the development of a 3DP service. Additionally, it should be documented when a 3D printed object is considered a medical device and thus when it should meet applicable legislation.

In conclusion, 3DP of anatomical models is a quickly evolving topic and applications are found in the domains of preoperative planning, simulation of complex surgery, student and healthcare professional education and patient understanding. Benefits are mainly based on the unique principle of rapidly creating a model that is tailored to the individual, and healthcare professionals are only too happy to embrace this feature. However, before 3DP of anatomical models can be used in practice, it is important to create standardized protocols

with in-detail explanation of each step involved to maximize accuracy and efficiency and minimize the chance of errors.

List of abbreviations

In order of appearance: 3DP = three-dimensional printing, 3D = three-dimensional, CT = computed tomography, MRI = magnetic resonance imaging, 2D = two-dimensional, TOF = tetralogy of Fallot, ASD = atrial septal defect, TTC = tibiotalocalcaneal, STL = Standard Tessellation Language, SLA = stereolithography, DLP = digital light processing, UV = ultraviolet, FDM = fused deposition modeling, PLA = polylactic acid, PEEK = polyether ether ketone, DICOM = Digital Imaging and Communications in Medicine, ROI = region of interest, CAD = computer-aided design, QA = quality assurance, PTS = posterior tibial slope, THA = total hip arthroplasty, FAI = femoroacetabular impingement, LAA = left atrial appendage, CHD = congenital heart disease.

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Appendix A. Overview of applications mentioned

Discipline	Application in…	3D printed model used for/as…	Key findings	Reference
Orthopedics / traumatology	Osteotomy planning	Planning of corrective surgery of distal radial vicious consolidations	Better understanding of the deformity in a realistic surgical approach	Belloti et al. (59)
	Osteotomy planning	Effect of wedge size + osteotomy angle on deformity correction of the foot	More accurate determination of wedge size and sagittal angle	Weinheimer et al. (60)
	Osteotomy planning	Preoperative simulation of open-wedge high tibial osteotomy	Satisfactory correction was established without affecting PTS angle	Kim et al. (61)
	Hip arthroplasty simulation	Preoperative simulation of hip rotation center surgery	Strong agreement on acetabular cup size between simulated and actual procedure	Zhang et al. (62) Choi et al. (63)
	Hip arthroplasty simulation	Preoperative simulation of hip rotation center surgery	High agreement on simulated and actual bone defects, accurate acetabular cup size determination	Maryada et al. (64)
	Hip arthroplasty planning	Preoperative planning of femoroacetabular impingement (FAI) surgery	Models could cause alteration preoperative planning significantly	Wong et al. (10)
	Hip arthroplasty planning	Preoperative planning of hip dysplasia surgery	Physical model yields more accurate visual judgments than on-screen model	Zheng et al. (65)
	Knee joint surgery	Medical training, preoperative planning, research, educational purposes	Accurate soft-tissue models which could withstand high stresses	Ruiz et al. (68)
	Knee joint surgery	Detection of patellofemoral dysplasia	3D printed models equally accurate as CT images	Fritz et al. (69)
	Knee joint surgery planning	Surgical planning and optimization in high-energy tibial plateau fractures	Models are useful during planning and result in reduced operating time, blood loss, fluoroscopy	Ozturk et al. (70)
	Foot surgery planning	Screw size determination and plate resizing in surgery of displaced intra-articular calcaneal fractures	Reduced operating time, blood loss, fluoroscopy, instrumentation time	Ozturk et al. (28)
	Foot surgery	Preoperative planning of tibial plafond fracture surgery	3D printed models provide additional information	Foo et al. (11)

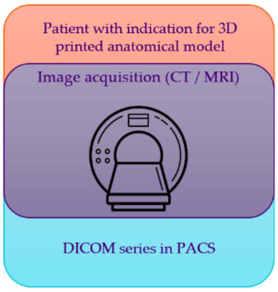
	Radius surgery planning	Preoperative planning of radius fracture surgery	Reduced operating time, blood loss, fluoroscopy, better communication with patient	Chen et al. (30)
	Oncological surgery planning	Pre- and intraoperative planning of oncological cases	Decreased incision length, selection of appropriate acetabular supporting ring	Punyaratabandhu et al. (72)
	Midcarpal joint education	Anatomy education	3D printed model might replace cadaveric specimens	Kanagasuntheram et al. (73)
	Tibial surgery	Preoperative planning and pre-construction of frames for surgery	3D printed models are an effective tool for preoperative planning and frame construction for tibial surgery	Corona et al. (12)
	Pilon fracture surgery	Pre- and intraoperative tool	Reduced operating time, blood loss, fluoroscopy time and higher excellent outcome	Zheng et al. (74)
	Elbow fracture surgery	Preoperative planning, physician-patient communication tool	Reduced operating time, blood loss, higher elbow function, model is effective communication tool	Yang et al. (75)
	Die-punch fracture surgery planning	Preoperative planning of surgery	Reduced operating time, blood loss and fluoroscopy time	Chen et al. (76)
	Proximal humerus fracture surgery	Planning of fixation method preoperatively	3D printed model clearly displays complex fracture, useful tool for preoperative planning	You et al. (77)
	(Tri)malleolar fracture surgery	Planning of fixation method preoperatively	3D printed model is an accurate representation of actual fracture, useful for preoperative planning	Chung et al. (78) Yang et al. (79)
Cardiology	Ventricular septal defect repair surgery	Preoperative consent and procedure understanding	Significant improvement of anatomy and potential complications by guardians	Deng et al. (13)
	Ventricular septal defect repair surgery	Education of healthcare professionals	Risk reduction for patients	Hadeed et al. (17) Valverde et al. (80)
	Atrial septal defect repair	Preoperative simulation of surgery, occluder size determination	Appropriate occluder selection leading to less occluder replacement intraoperatively and lower costs	Li et al. (81) Yan et al. (82)

	Left atrial appendage surgery	Preoperative selection of closure device size	Correct selection of closure device size leads to reduced operating time, blood loss and fluoroscopy time	Conti et al. (83) Hachulla et al. (84) Obasare et al. (85)
	Congenital heart disease education	Learning tool for students, healthcare professionals, communication tool between physician and parents	Students feel more confident in CHD anatomy, physicians use the models in preoperative planning and as simulation environment, improved communication between physician and parents	Smerling et al. (1) Su et al. (18) Loke et al. (19) Yi et al. (86) Xu et al. (16) Ryan et al. (87) Hoashi et al. (88) Yoo et al. (89) Biglino et al. (90)
	Arterial switch surgery	Surgical training of procedure	Objective improvement in time and technical performance of the procedure	Hussein et al. (29)
	Pediatric cardiac tumor debulking surgery	Preoperative planning of debulking surgery	3D printed models helped to define a safe surgical strategy	Riggs et al. (91)
	Univentricular heart surgery	Preoperative planning of complex univentricular hearts with abnormal venous drainage	3D printed models could assist the decision whether or not to proceed with surgery	McGovern et al. (92)
Plastic & reconstructive surgery	Abdominally-based breast reconstruction surgery	Guide for intramuscular dissection of flaps; representation of subfascial vascular tree	3D printed models can assist in execution of the intramuscular dissection	Jablonka et al. (93)
	Craniofacial surgery	Preoperative planning and as training tool	Decreased preoperative planning time, improved resident training	Lobb et al. (2)
	Maxillofacial surgery	Preoperative planning and as communication tool	Improved preoperative planning, improved comprehension of the procedure by patients	Guest et al. (94)
	Cleft lip/palate surgery	Preoperative planning and as communication tool	Improved preoperative planning, improved comprehension of the procedure by patients	Nicot et al. (95)

Appendix B. Roles and responsibilities in the proposed workflow

This document provides an overview of all steps of the workflow for 3D printing of anatomical models that can be used in preoperative planning, including details on the division of responsibilities.

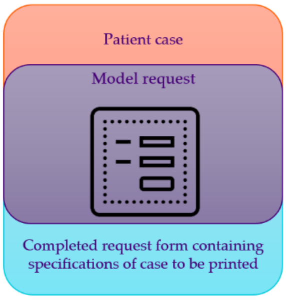
1. Image acquisition



The requesting surgeon should request a scan at the radiology department for a patient with an indication for a 3D printed anatomical model through the electronic health record. Scanning should be performed by the radiological lab technicians and the DICOM series is then uploaded into the PACS. A radiologist will review the scan and submit a report into the PACS.

Task	**Responsible**
Scan request	Requesting surgeon
Scanning	Radiological lab technician
Data transfer to PACS	Radiological lab technician

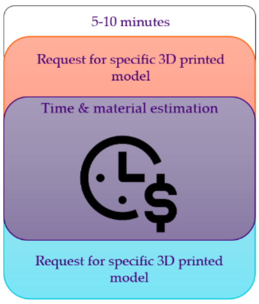
2. Model request



The request of the model is performed by a surgeon or its administrative assistant, who should fill in the form and submit it to the department of medical physics. The request should be processed (storage of the request form in the correct folder and addition of the case to a work list) by a medical technician[1] or an administrative assistant at the department of Medical Physics. The request form should be stored in a folder named 'Patientnumber_ROI', which can be found in 'S:\Klinisch fysici\3D\3D printer'.

Task	**Responsible**
Model request	Requesting surgeon
Processing of request	Medical technician / administrative assistant

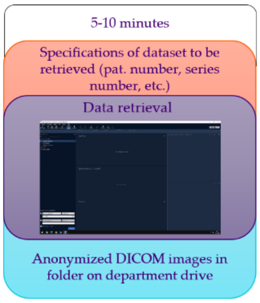
3. Time and material estimation



The request form is the basis for a first estimation of the required production time and amount of material. This estimation should be performed by a technical physician[2] or medical technician. According to this estimation, the printing time can be scheduled in the Excel file named 'Time_materials' that can be found in 'S:\Klinisch fysici\3D\3D printer'.

Task	**Responsible**
Estimation of required printing time and material	Technical physician / medical technician

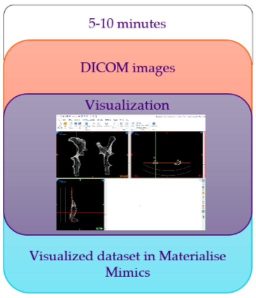
4. Data retrieval



Retrieval of the dataset from the PACS can be performed by a medical technician or an administrative assistant. The dataset must be stored in 'S:\Klinisch fysici\3D\3D printer', in a folder named 'Image data' in the earlier mentioned folder 'Patientnumber_ROI'.

Task	Responsible
Retrieval of dataset	Technical physician / medical technician
Anonymization	Technical physician / medical technician
Storage of dataset	Technical physician / medical technician

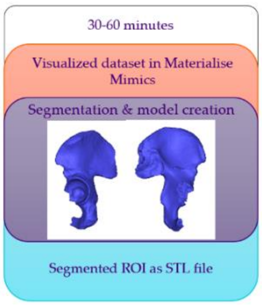
5. Visualization



As the dataset must be interpreted and anatomical knowledge is required, a technical physician or medical technician is the person responsible for the correct visualization of the dataset. The dataset should be checked for any possible errors.

Task	Responsible
Visualization of dataset	Technical physician / medical technician
Check for errors	Technical physician / medical technician

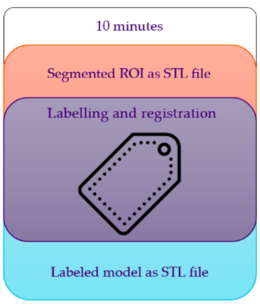
6. Segmentation and model creation



As already mentioned in the previous step it is important to have knowledge on anatomy for the correct segmentation of the region of interest. Deploying a trained technical physician to carry out this step will result in an time-efficient and accurate segmentation of the ROI, consisting of an initial segmentation and further refinement of the segmentation through mask operations.

Task	Responsible
Initial segmentation of the ROI	Technical physician / medical technician
Operations on segmentation	Technical physician / medical technician

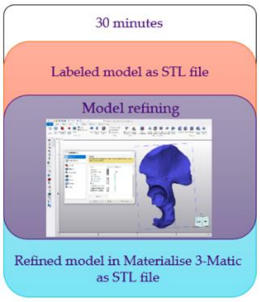
7. Labelling and registration



When the segmentation process is finished the model must be labelled with the case identifier that was assigned to the case in step 4 of the workflow. As the labelling is executed in the same software package as the segmentation process, a technical physician will carry out this task. The segmentation file must be stored in 'S:\Klinisch fysici\3D\3D printer' in the folder that corresponds to the correct case identifier.

Task	Responsible
Labelling of the model	Technical physician / medical technician
Check if correct label is assigned to model	Technical physician / medical technician

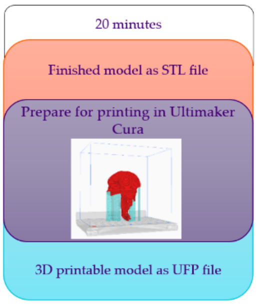
8. Model refinement



The model is now ready for further refinement in 3-Matic. Depending on the complexity of the model, this step can be performed by either a technical physician with anatomical knowledge or a medical technician. The model can be prepared for printing by using the 'Fix wizard', which ensures the removal of bad edges and overlapping triangles. The resulting model can be checked by the requesting physician. The model file, named as 'Patientnumber_ROI.stl' and must be stored in 'S:\Klinisch fysici\3D\3D printer' in the folder that corresponds to the correct patient number.

Task	Responsible
Model refinement	Technical physician / medical technician
Model fixing	Technical physician / medical technician
Check of model	Requesting surgeon

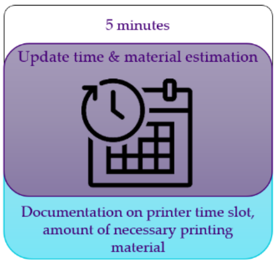
9. Preparation for printing



The final model must be loaded into Ultimaker Cura for configuring the printing process. This step does not require anatomical knowledge and can be executed by a technical physician or a medical technician. Depending on the shape of the model, supporting structures are added. The printable file must be stored in 'S:\Klinisch fysici\3D\3D printer' in the folder that corresponds to the correct case identifier or patient number.

Task	Responsible
Configuration of printing process	Technical physician / medical technician
Addition of support structures	Technical physician / medical technician
Exportation of final model to USB drive	Technical physician / medical technician

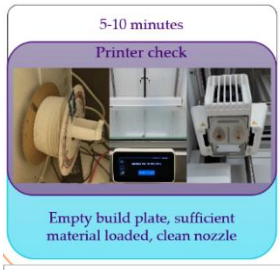
10. Update time & material estimation



Ultimaker Cura outputs the printing time and amount of material needed. An update of the printing time that was scheduled in the Excel file in step 3 must be performed by the person responsible for managing this file which can be either a technical physician or a medical technician.

Task	Responsible
Update of required printing time & material	Technical physician / medical technician

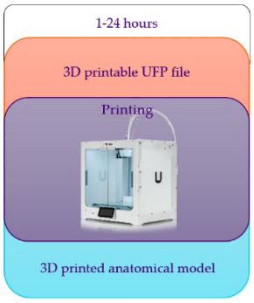
11. Printer check



Before the printing process is started, the following should be checked: whether the build plate is clean and empty, whether sufficient printing material is loaded into the printer and whether the nozzle is free of any material cured to the printer head. These checks can be performed by either a technical physician or a medical technician.

Task	Responsible
Check build plate	Technical physician / medical technician
Check printing material	Technical physician / medical technician
Check nozzle / printer head	Technical physician / medical technician

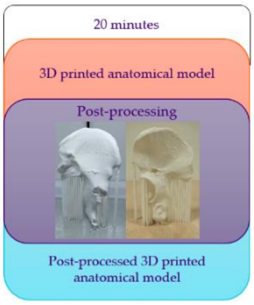
12. Printing



The printing process can be started at this point. The part to be printed is selected from the USB drive after which the printing will initiate. Starting the printing process can be performed by either a technical physician or a medical technician.

Task	Responsible
Select part from USB drive	Technical physician / medical technician
Start printing process	Technical physician / medical technician

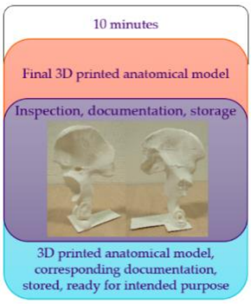
13. Post-processing



Post-processing tasks consist of removal of the printed part from the 3D printer and the removal of support structures. These tasks can be performed by either a technical physician or a medical technician, depending on the complexity of the printed anatomy (more complex anatomy possibly requires a deeper knowledge on how to remove all supports).

Task	Responsible
Remove printed part from 3D printer	Technical physician / medical technician
Remove support structures	Technical physician / medical technician

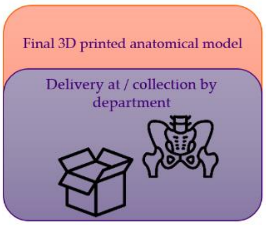
14. Inspection, documentation and storage



After support removal, the model must be inspected for possible significant deviations with respect to the original planned part. If this is the case, it should be documented in the case folder. When the model is ready it can be stored awaiting the delivery or collection by the requesting department. These tasks are assigned to a technical physician (except the storage task), as it covers evaluation of anatomy.

Task	Responsible
Inspection of the model	Technical physician / medical technician
Documentation on findings	Technical physician / medical technician
Storage of the model	Technical physician / medical technician

15. Delivery at / collection by department



The final step consists of the delivery or the collection of the part at the requesting department. This task can be regulated by a medical technician. Alternatively, the model can be collected by the an individual of the specific

Task	Responsible
Delivery of model to the department	Medical technician
Collection of model	Requesting surgeon / administrative assistant of department

1: With medical technician, an individual performing repair work of medical devices is indicated.
2: With technical physician, an individual with a Master's Degree in Technical Medicine (TM) is indicated.

Request form for 3D printed anatomical model

Name:		Phone number:		Date of request:		Patient ID:	

1. Imaging data

a. Acquisition date

b. Modality

CT	MRI
☐	☐

c. Body part

d. Side

Left	Right	Bilateral
☐	☐	☐

2. Surgery details

a. Intended surgery

3. Model preferences

a. Visualisation

Bone(s)	Soft tissue	Other…
☐	☐	☐

b. Which part of the anatomy are you specifically interested in?

c. Spatial relationship of anatomical structures relative to each other must be preserved (if applicable)

Yes	No
☐	☐

d. Printing on scale:

Yes	No
☐	☐

4. Logistics

a. Production before:

b. Model transfer:

Delivery at department	Pick-up	Other…
☐	☐	☐

Appendix D. Utility survey 3D printed anatomical models

Utility evaluation survey for 3D printed anatomical models in preoperative planning

Developed by: Y.F. Roodenburg, student of master's programme Technical Medicine and intern at Medical Physics dept., Albert Schweitzer hospital, Dordrecht, The Netherlands

Name:		Date:		Case ID:	

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
1. Usefulness and efficiency in planning					
a. The printed model in combination with conventional data (X-ray, CT scan, etc.) is more useful in preoperative planning for this case compared to reviewing the conventional data alone.	☐	☐	☐	☐	☐
b. The printed model improves understanding of spatial orientation of anatomical structures relative to each other.	☐	☐	☐	☐	☐
c. Using the printed model, I feel more confident about my preoperative plan.	☐	☐	☐	☐	☐
d. The model causes confusion during preoperative planning of this case.	☐	☐	☐	☐	☐

	0 minutes	5 minutes	10 minutes	15 minutes	20 minutes	25 minutes	30 minutes
2. Time expectation							
a. Usage of the printed model results in an increased preoperative planning time of:	☐	☐	☐	☐	☐	☐	☐
b. Using this printed model, I expect the surgery time to decrease by:	☐	☐	☐	☐	☐	☐	☐

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
3. Effect on surgical outcome					
a. With this printed model, I expect the surgical outcome to improve.	☐	☐	☐	☐	☐
b. Using this printed model, I expect increased efficiency during surgery.	☐	☐	☐	☐	☐

	Yes	No	Uncertain
4. Alteration of preoperative plan			
a. I would alter my preoperative plan for this case after reviewing the printed model.	☐	☐	☐

b. Please motivate your answer on question 4a briefly.

	Extremely complex	Complex	Normal	Simple	Extremely simple
5. Alteration of preoperative plan					
a. I would rate the complexity of this printed model / patient case as:	☐	☐	☐	☐	☐

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
6. Attitude towards future use					
a. I would use a 3D printed anatomical model again for a similar case.	☐	☐	☐	☐	☐

Appendix E. Tables corresponding to the business case

Appendix E1. Details on scenario 1 of the business case

	Amount	Unit price (€)	Annual depreciation (€)	Costs (€)
Facilities, services & parts				
Working station (PC)	0	2820	0	0
Ultimaker S5 3D printer	0	5300	1060	0
Ultimaker Air Manager	0	750	150	0
Total costs (€)				0

Table 1. Overview of fixed costs in scenario 1.

	Amount per year	Unit price (€)	Amount of hours per model	Amount of hours per week	Amount of hours per year	Amount of FTE	Total annual costs (€)
3D printer							
Ultimaker S5	1	1060	-	-	-	-	1060
Ultimaker S5 Air Manager	1	150	-	-	-	-	150
Software							
Materialise Mimics Base	1	5480	-	-	-	-	5480
Salaries							
Model development	15	-	2,83	0,82	42,5	0,023	870
Meetings, checkups with surgeon	15	-	0,5	0,15	7,5	0,004	160
Materials							
Orthopedic anatomical model	15	5	-	-	-	-	80
Maintenance							
Air filter replacement	3	44	-	-	-	-	150
Maintenance	1	150	-	-	-	-	150
Total						0,027	8100

Table 2. Overview of variable costs in scenario 1. Costs related to salaries are based on the average gross salary in scale 45.

	Amount	Unit price (€)	Annual depreciation (€)	Total costs (€)
Facilities, services & parts				
Working station (PC)	0	2820	0	0
Formlabs Form 3B+ 3D Printer	1	7000	1400	7000
Formlabs Form Wash	1	600	120	600
Formlabs Form Cure	1	700	140	700
Maintenance	1	300	300	300
2-day training in Materialise Innovation Suite	1	4310	-	4310
Total costs (€)			**1960**	**12910**

Table 1. Overview of fixed costs in scenario 2. The 2-day training is not incorporated in the annual depreciation under the assumption that these costs are only made once and are not recurrent.

	Amount per year	Unit price (€)	Amount of hours per model	Amount of hours per year	Amount of FTE	Total costs per year (€)
113 guides						
Licenses						
Materialise Mimics Base	1	5480	-	-	-	5480
Materialise Mimics Design	1	6080	-	-	-	6080
Salaries						
Model development	113	-	2	226	0,120	5780
Post-processing	113	-	0,25	28,25	0,015	580
Meetings, check-ups with surgeon	113	-	0,5	56,5	0,030	1450
Other departmental activities	-	-	-	156	0,083	3990
Materials						
Orthopedic surgical guide	113	22	-	-	-	2490
Isopropyl alcohol 5L (Form Wash)	3	27,50	-	-	-	82,5
Total (113 guides)					**0,248**	**25940**
225 guides						
Licenses						
Materialise Mimics Base	1	5480	-	-	-	5480
Materialise Mimics Design	1	6080	-	-	-	6080
Salaries						
Model development	225	-	2	450	0,240	11510
Post-processing	225	-	0,25	56,25	0,030	1150
Meetings, check-ups with surgeon	225	-	0,5	113	0,060	2890
Other departmental activities	-	-	-	156	0,083	3990
Materials						
Orthopedic surgical guide	225	22	-	-	-	4950

Isopropyl alcohol 5L (Form Wash)	6	27,50	-	-	-	165
Total (225 guides)					**0,413**	**36220**
338 guides						
Licenses						
Materialise Mimics Base	1	5480	-	-	-	5480
Materialise Mimics Design	1	6080	-	-	-	6080
Salaries						
Model development	338	-	2	676	0,360	17280
Post-processing	338	-	0,25	84,5	0,045	1730
Meetings, check-ups with surgeon	338	-	0,5	169	0,090	4320
Other departmental activities	-	-	-	156	0,083	3990
Materials						
Orthopedic surgical guide	338	22	-	-	-	7440
Isopropyl alcohol 5L (Form Wash)	9	27,50	-	-	-	247,5
Total (338 guides)					**0,578**	**46570**
450 guides						
Licenses						
Materialise Mimics Base	1	5480	-	-	-	5480
Materialise Mimics Design	1	6080	-	-	-	6080
Salaries						
Model development	450	-	2	900	0,479	23010
Post-processing	450	-	0,25	112,5	0,060	2300
Meetings, check-ups with surgeon	450	-	0,5	225	0,120	5760
Other departmental activities	-	-	-	156	0,083	3990
Materials						
Orthopedic surgical guide	450	22	-	-	-	9900
Isopropyl alcohol 5L (Form Wash)	12	27,50	-	-	-	330
Total (450 guides)					**0,742**	**56850**

Table 2. Overview of variable costs in scenario 2. Four scenarios are outlined: application of a surgical guide in 1) 25% of the surgeries, 2) 50% of the surgeries, 3) 75% of the surgeries and 4) 100% of the surgeries, corresponding to 113, 225, 338 and 450 surgical guides produced.

	Amount	Unit price (€)	Annual depreciation (€)	Total costs (€)
Facilities, services & parts				
Working station (PC)	0	2820	0	0
Ultimaker S5 3D printer	0	5300	1060	0
Ultimaker Air Manager	0	750	150	0
Formlabs Form 3B+ 3D Printer	1	7000	1400	7000
Formlabs Form Wash	1	600	120	600
Formlabs Form Cure	1	700	140	700
TRIOS 3Shape Intraoral scanner	1	23500	2350	23500
Maintenance	1	600	600	600
2-day Materialise/ProPlan CMF training on-site	1	4310	-	4310
Total costs			**5820**	**36710**

Table 1. Overview of fixed costs in scenario 3. The 2-day training is not incorporated in the annual depreciation under the assumption that these costs are only made once and are not recurrent.

	Amount per year	Unit price (€)	Amount of hours per case	Amount of hours per year	Amount of FTE	Total costs per year (€)
Licenses						
Materialise ProPlan CMF	1	10000	-	-	-	9890
Employment						
Virtual surgery planning (VSP)	100	-	2	200	0,106	5120
Anatomical model development	100	-	1	100	0,053	2560
Wafer development	150	-	1,5	225	0,120	5760
Post-processing	150	-	0,25	37,5	0,020	770
Meetings, check-ups with surgeon	150	-	0,5	75	0,040	1920
Other departmental activities	-	-	-	156	0,083	3990
Materials						
Anatomical model	100	5	-	-	-	500
Surgical wafer	150	22	-	-		3300
Maintenance						
Isopropyl alcohol 5L (Form Wash)	4	27,50	-	-	-	110
Total					0,422	**33920**

Table 2. Overview of annual costs for in-house printing of orthognathic wafers in scenario 3.

Declaration code	Service / part	Amount	Unit price (€)	Total annual declaration, n=100 (€)
Q0203	Virtual surgery planning (VSP)	100	182,47	18250
Q8001	Scanning for the purpose of CAD	100	32,76	3280
Q8013	Design CAD splint	150	43,54	6540
Q9801	Materials for the purpose of CAD	150	21,12	3170
Declarable annual costs				31240

Table 3. Declaration codes issued by the Dutch Health Authority for declaration of Computer-Aided Design (CAD)-related services or parts in orthognathic surgery.