Advanced Design Method of 3D-Printed Cutting Guides Development for Orthopedic Surgery

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Abstract

Computer Aided Design (CAD) and 3D printing are increasingly bringing innovation to orthopedic surgery by allowing customization of surgical procedures. This study proposes the design and 3D printing of patient-specific surgical cutting guides (PSCG) that can be implemented in orthopedic surgery. Cutting guides are surgical tools that allow surgeons to perform cutting operations more accurately, achieving the desired result with high accuracy. During an osteotomy, for example, the surgeon will be able to better determine the position of the cutting line and its direction. This study aims to propose an advanced method of designing cutting guides for an orthopedic surgery procedure. Proposed tools are obtained by an additive manufacturing process that starts with a 3D model of the patient's bone obtained from CT scan images and ends by designing the patient-specific cutting guide model in a CAD environment. Virtual surgical planning (VSP) allows for increasing the surgeon's awareness for developing an orthopedic surgical strategy and allows for the design of cutting guides designed around the patient's specific anatomy.

Keywords

Computer Aided Design, 3D printing, Additive Manufacturing, Patient-Specific Cutting guides, Virtual Surgical Planning.

1. Introduction

The use of patient-specific instruments in orthopedic surgery allows for improved effectiveness of corrective surgery in bone deformities. Cutting guides enhance the surgeon's operations to be better directed, minimizing error and achieving the corrective surgery in less time. Traditionally, the orthopedic surgeon evaluates the diagnosis and plans the procedure based on analysis of radiographic images and, in some cases, CT scans. In the traditional manner, a complete view of the patient's anatomy is not provided, and surgical operations depend on the surgeon's experience since CT scans are bidimensional images. The virtual representation of a three-dimensional model of the patient's anatomy offers real help to surgeons who can formulate a more detailed diagnosis for the patient. By obtaining a three-dimensional model of the patient's anatomy, patient-specific instruments can be designed to identify the correct placement and direction of the cut in a corrective osteotomy. This study aims to describe the design process of the cutting guides and the considerations taken to optimize their design.

1.1 Objectives

The objective of the study is to provide a guide for the design of patient-specific cutting guides by reprocessing a digital 3D model of the patient.

2. Literature Review

The applications of CAD and 3D printing in orthopedic surgery are increasing fast (Ejnisman et al., 2021; Wong, 2016). Three-dimensional reconstruction of a patient anatomy adds up to an augmented reality-based process development (De Amicis et al., 2018), next to modeling, and 3D printing of patient-specific instruments are practices that are revolutionizing orthopedic surgery. Studies reporting the use of patient-specific cutting guides have reported advantages over traditional procedures, including reduced time, reduced risk, and improved surgical accuracy (Ballard et al., 2020; Haglin et al., 2016). Cutting guides are tools that assist the surgeon during surgery, particularly in orthopedic surgery (Hafez, 2012). Traditionally, an osteotomy operation is done freehand. The use of a cutting guide helps to ensure better accuracy of the operation by avoiding alignment errors (Mattei et al., 2016; Schlatterer et al., 2015). The study by Chaouche et al. (2019) reported that the safety and accuracy of a patient-specific cutting guide for a high tibial osteotomy improved functional outcomes two years after surgery. The analysis by Jacquet et al., (2019) conducted on the comparison of two groups that underwent the same surgery, but with two different procedures, demonstrated a significant improvement in the accuracy of the correction achieved in the patient-specific tool group compared to the conventional group. Cutting guides in any case must be small in size in order to be as minimally invasive as possible (Caiti et al., 2021).

Fused Deposition Molding (FDM) is the most widely used molding system, and polylactic acid (PLA) is the most common material for 3D printing. The cutting guides are used during the operation, so they must undergo a sterilization process. Analyses of the effects of sterilization on 3D PLA printed objects have been studied and are still ongoing (Frizziero et al., 2021). PLA is not a high-performance material in terms of resistance to high temperatures (Maróti et al., 2020), but it still allows to obtain parts with good mechanical properties, if printed with the right set of parameters. In the medical field, thermoplastic polyurethane (TPU) is also used, which allows to obtain interesting results in 3D rapid prototyping thanks to its flexibility and anti-bacterial capabilities (Ferretti et al., 2021).

This research aims to illustrate the design of a cutting guide, geometry setup, and analysis of results after 3D printing. During CAD design and 3D printing, not only the size and shape but also the mechanical properties of the printed product should be considered. The cutting guides should not be too bulky for easy handling during surgery and guarantee less intrusion to the organ tissues. They must also provide good mechanical resistance to oscillations of the surgical saw blade.

3. Methods

The methodology for the design of the cutting guides follows the workflow in Figure 1.

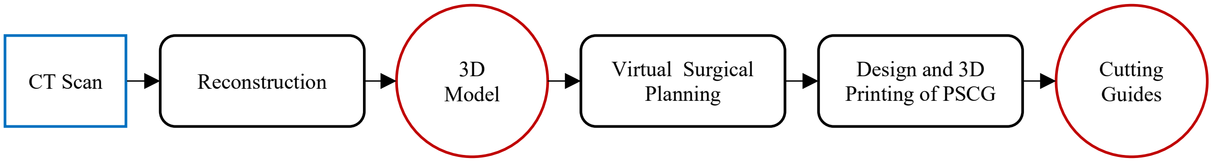


Figure 1: Workflow of the methodology.

3.1 Reconstruction of the 3D Digital Model from CT scan

The design of the cutting guides is a process that begins with the reconstruction of the 3D model of the patient's anatomy. This can be achieved through reprocessing and segmentation of CT images, through a digital image reconstruction process originated by camera 3D point reconstruction (Liverani et al., 2010). CT images show the body layer by layer in grayscale according to their density and are saved in DICOM format (Napolitano et al., 2021; Papaleo et al., 2021). There are several software programs for segmentation of human anatomy (Osti et al., 2019). In this study, CT images are imported into 3DSlicer (Fedorov et al., 2012), a medical scan reading and processing software that is widely used for medical, biomedical, and imaging research. In this environment, medical images are manipulated in order to select the relevant part by segmentation. The resulting 3D model is used for virtual planning and design of cutting guides.

3.2 Virtual Planning

To design the cutting guide, accurate procedure steps and guidelines have to be discussed and decided beforehand. In particular, it is important to know the cutting point and its direction, based on the patient's anatomy. To capture this information, virtual planning was performed on the 3D digital model by means of Blender, a mesh modeling and simulation software, is used. Through the simulation, the geometries useful for the design of the cutting guide are defined.

3.3 Design and 3D Printing of Patient-Specific Instruments

Once the cutting point and direction are known, the cutting guide was designed. A bone tissue surface is obtained from the 3D digital model of the patient's anatomy. This surface is the basis for designing the patient-specific cutting guide. In PTC Creo environment, the cutting guide traced the surface of the obtained bone tissue and the cutting plane identified by the virtual planning showed the entry hole of the orthopedic saw blade. In addition, there are holes for fixing it to the human bone during the operation by using Kirschner wires. However, the shape of the patient-specific instrument (PSI) must provide robustness while keeping the overall size small. The cutting guide model is exported in stereolithographic (STL) format to be read by Ultimaker Cura 3D printing software. The model was then printed on a FDM printer. The printer used is an AnyCubic and the material is FiloAlfa® PLA.

4. Data Collection

From the medical images acquired by the CT scan, a three-dimensional model of the case studied is reconstructed with 3D Slicer v4.11 (Figure 2). It is necessary to apply tools to clean and lighten the model exported in STL format.

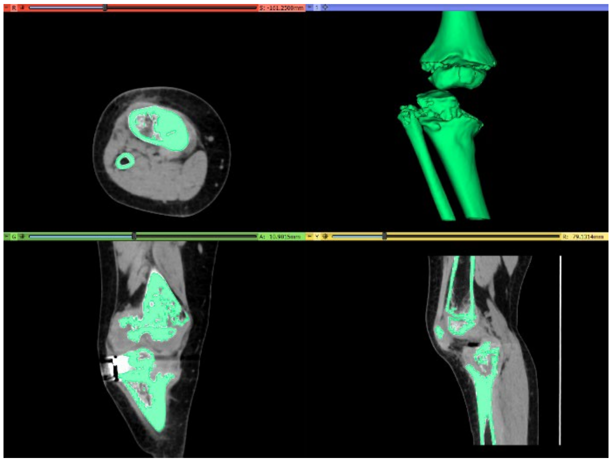


Figure 2: Segmentation on 3D Slicer.

The file obtained from the reconstruction was imported into Blender v2.93.4 for the virtual design and simulation phase. In this specific case, the pathology to assess was a proximal tibial osteotomy. Having defined the shear placement measurements and its direction, depicted in Figure 3, a tibial plateau correction of 25° is presumed.

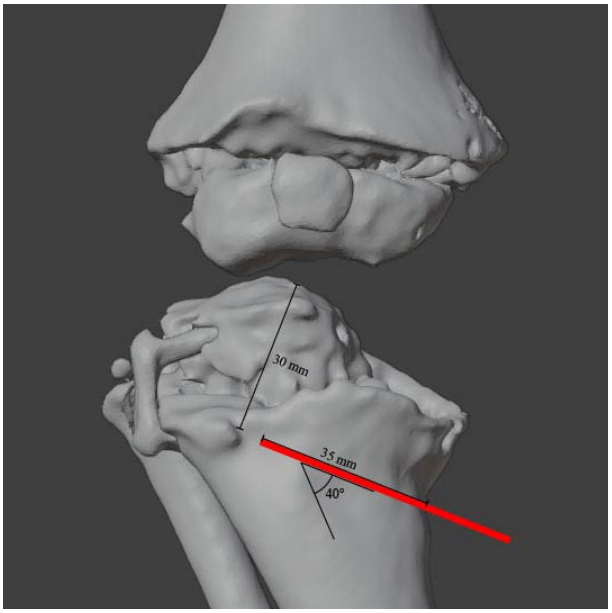


Figure 3: Definition of the positioning measures of the cut and its direction. The red line represents the blade.

Moreover, several models of cutting guides were made before reaching the optimal design. The design of the cutting guides was performed by using CAD software, PTC Creo v8. The idea was to design a cutting guide that traces the external geometry of the bone but is only supported on a few strategic points to stabilize the tool. It is deliberately avoided that the cutting guide rested directly on the inner surface of the bone because it is prone to inaccuracies due to reconstruction inaccuracies from CT and for digital surface cleaning. The surgical instruments used were taken as reference for the geometric constraints of the cutting guide. The Kirschner wires have a diameter of 1.8 mm and the blade has the following dimensions: width 19.5 mm, length 41 mm, thickness 0.38 mm.

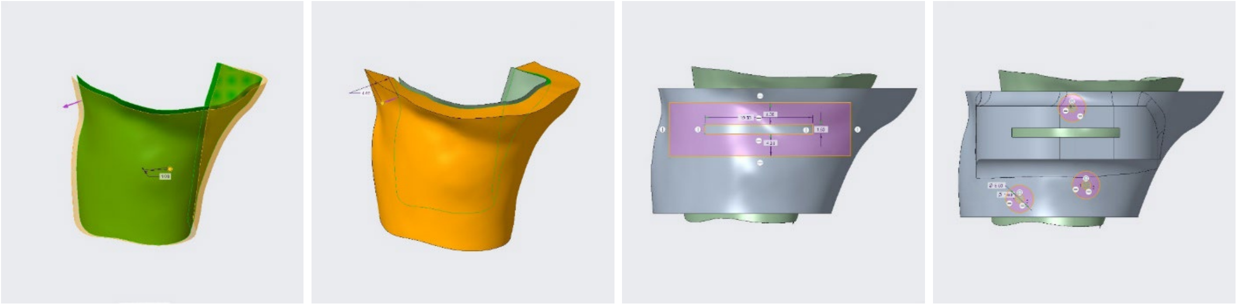
Afterwards, it is probable to address the emergent technology of additive manufacturing, that material-wise could be the right solution for elements at the prototyping stage (Frizziero et al., 2018) or even in real operation procedures. For the design of the cutting guide, it was necessary to consider the dimensional tolerances, due first to any dimensional alterations after 3D printing, and then to the oscillations of the blade during the operation. It was necessary to increase the values to avoid friction of the blade with the cutting guide. After the specifications were set, 3D printing is started and waited for completion (Table 1).

Table 1: Parameters set for 3D printing.

Parameters	Value
Printing (Nozzle) Temperature	200 °C
Heated Bed Temperature	60 °C
Nozzle Diameter	0.4 mm
Layer Thickness	0.2 mm
Printing Speed	60 mm/s
Infill Density	100 (%)
Flow	100 (%)
Max overhang angle	50°
Support	Yes
Material	FiloAlfa® PLA

5. Results

The results show both the main modeling steps and the 3D printed cutting guides. Modeling of the patient-specific cutting guides was conducted with reference to the geometric constrains of the surgical instruments used. Figure 4 shows the necessary modeling parameters on which the shape of the cutting guides must be designed.



a) b) c) d)

Figure 4: Required parameters for cutting guide modeling. As an example, the parameters of the first design cutting guide are reported. a) Offset from the bone's surface fixed at 1 mm; b) Main thickness of cutting guide fixed at 4 mm; c) Dimensions of the blade gap was set at 19.5x1.6 mm; d) Dimensions of holes was set at 1.6 mm.

After modeling the tool, it is 3D printed. The different 3D printed patient-specific cutting guides are shown in Figure 5. The results help to define a checklist for making patient-specific cutting guides. The first patient-specific cutting guide (Figure 5a) is considered as an initial test to understand the total footprint. A thickness of 4 mm was applied to the surface that traces the patient's bone; the blade gap was set at 19.5 mm in length and 1.6 mm in height; the holes were 1.6 mm in diameter. Three pins were also designed to allow the guide to rest on the patient's bone. This design was found to be too bulky and massive, and the gap so designed allows only frontal access of the blade. The thickness should be reduced, the measurements of the holes and the slot should be increased. Symmetry and regularity should also be given to arrange the fixation holes. The second cutting guide (Figure 5b) is modeled after the considerations made on the first cutting guide. The thickness is set to 3 mm; the gap measures 26 mm in width and 1.6 mm in height; the holes have a diameter of 3 mm. The three support pins remained. This design is much more streamlined and uncluttered, but it is fragile at the blade access point, which, due to oscillations, could lead to break. Afterwards it was necessary to strengthen the access area of the blade and ensure more stability by increasing the number of support pins. The third guide designed (Figure 5c) is intended to respect the considerations made previously. The changed parameters concern only the shape. The final design has strengthened the blade access area, but overall offers a cutting guide with many sharp edges. The ends should be chamfered for convenience. The fourth cutting guide (Figure 5d) included beveled ends and a more compact blade access area. The thickness was slightly increased to provide more strength to the workpiece. In making the cutting guide more compact, the size of the blade access slot was reduced. However, the result is a limiting cutting guide that was still too edgy. The last cutting guide (Figure 5e) is the result of an optimized design process. The overall size was minimized, the thickness was set to ensure mechanical strength during use, the gap and hole sizes have been set to ensure the insertion of surgical instruments, even after 3D printing, and the shape is blunted. The overall product is compact, thin and durable.

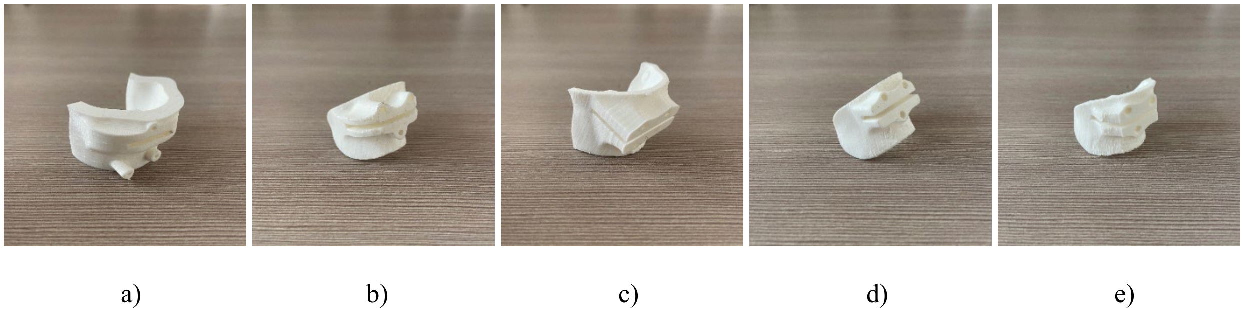

a) b) c) d) e)

Figure 5: The patient-specific cutting guide.

A summary of the features of the designed, modeled, and 3D printed cutting guide is provided in Table 2.

Table 2: Summary of cutting guides (CG) design.

	CG 1	**CG 2**	**CG 3**	**CG 4**	**CG 5**
Overall dimensions (mm)	37.7 x 48.0 x 22.7	25.7 x 40.3 x 24.6	26.1 x 41.7 x 24.7	22.4 x 43.0 x 23.7	22.5 x 43.0 x 24.0
Offset from the bone's surface (mm)	1	1	1	1	1
Thickness (mm)	4	3	3	4.5	4.5
Gap size (mm)	19.5 x 1.6	26.0 x 1.6	25.0 x 1.6	20.0 x 1.6	25.0 x 1.6
Hole diameter (mm)	1.6	3	3	3	3

Number of supporting pins	3	3	5	6	6
Cons	Intrusive design	Weak	Edgy design	Restrictive opening	-

5.2 Proposed Improvements

The cutting guides obtained for this study need to be improved to be effective in autoclaving processes, for more effectiveness in the operating room. The sterilization process implies the use of a material that supports high temperatures. PLA is not the most suitable material. The proposal is to search for a material that is resistant to high temperatures and set up the design and 3D printing described in this study.

6. Conclusion

The study provided a series of steps to consider when designing a patient-specific cutting guide. The workflow included a series of software that allowed to reprocess CT images to create a 3D digital model, which can also be printed. The result of this process allowed on the one hand to portray a complete virtual preoperative planning that granted a reduction in operating time and on the other hand the design of patient-specific cutting guides agreed to deliver a more effective surgical strategy. Nevertheless, the material used, PLA, allowed to provide a very versatile and low cost prototype.

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