CAD Aided Pre-operative Planning and Prototyping of Cubitus Varus Cutting Guide

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Abstract

This work is the outcome of a partnership between the Department of Industrial Engineering of the University of Bologna and the Rizzoli Orthopedic Institute of Bologna.
The aim of this collaboration is using medical engineering tools during orthopedic surgeries.
This article focuses on the design and construction of a custom-made surgical guide for cubitus varus.
The guides are special aids that allow surgeons to perform operations smoothly, to achieve the planned result and to reduce the risk of inaccuracy.
They are obtained with an additive manufacturing process that starts from a 3D digital model of the patient's bone obtained from CT scans and allow designing patient-specific templates using specific software as the *Creo Parametric* CAD. For the proper functioning of the guide the internal shape must correspond to the external profile of the patient's bone. In this way, the tool obtained fits exactly to the bone and it is possible to direct the cutting during surgery in a very specific direction as identified in the preoperative planning phase.

Keywords
Cutting guides, 3D Printing, Pediatric Orthopedics, Surgery and Diagnostics

1. Introduction
The cubitus varus is a common elbow deformity among children. In most clinical cases it is caused by the malunion of supracondylar fractures of the humerus. This deformity causes both a poor aesthetic appearance and an impaired function of the elbow. In fact it affects the biomechanics of the elbow joint. Additionally, it might increase the risk of lateral condyle fractures and other secondary fractures (Jiang et al. 2019, Murase et al. 2014).
Three-dimensional corrective osteotomy is the common surgical procedure used for the treatment of cubitus varus deformity in children. In the sequel we'll describe in detail the preoperative planning and surgical technique for three-dimensional corrective osteotomy with the use of custom-made surgical guides for post-traumatic varus cubitus deformity.

1.1 Objectives
In traditional orthopedic procedures surgeons' preoperative evaluations are mentally developed. This preoperative planning however is very difficult when you have to work with a complex anatomy as in the case of the cubitus varus deformity. Errors often occur in the preoperative planning phases and they cause undesirable postoperative effects and therefor an unsatisfactory surgical result.

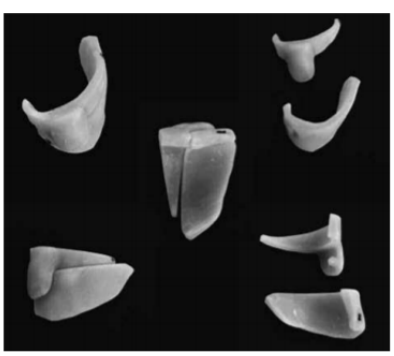
So planning is crucial in order to work for the cutting of a portion of a bone.
The first problem to solve is the identification of the right angle of intervention. In fact, controlling the correction angle during the operation is difficult and the degree of correction often has to be adjusted during surgery. A solution can be found using a cutting guide.
Using computing technology, it is possible to realize virtual models that faithfully correspond the patient's anatomy. This also provides concrete help to the surgeons who can preliminarily analyze a 3D model and formulate more detailed diagnosis on a patient-specific basis.

2. Literature Review

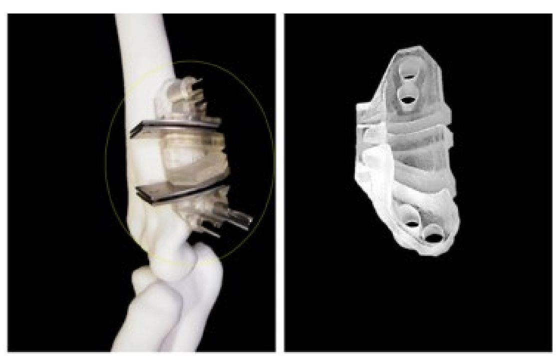
The first medical applications using computer-aided modeling and design and computer-aided manufacturing (CAD-CAM) began in the late 1970s. They mainly concern dentistry and the maxillofacial field.
With the evolution of technology, this methodology has also been applied to orthopedics.
The applications are manifold: from the printing of anatomical models using CT images to the most sophisticated preoperative planning to produce surgical guides. (Hafez and Moahmoud, 2012)
The cutting guides are tools that help the surgeon during surgery, especially during osteotomy cutting.
This is usually done freehand and causes several problems for surgeons who do not have a great view of the part to be cut. The cutting guides ensure greater effectiveness of the operation. Furthermore, there is a significant reduction in intervention times and, consequently, a reduction in the necessary costs (Ballard et al., 2019).
A study by Tricot et al. (2012) made an acrylic cutting mask for a patient with varus cubitus deformity (Figure 1a).
Instead, the model made by Yukari et al. (2013) with the use of commercially available software (Bone Viewer and Bone Simulator; Orthree, Osaka, Japan) was produced in medical grade resin. There are two metal slots and four metal sheaths on the model (Figure 1b). Resin models are made using stereolithography (SLA) as the printing technology. Other cutting guides made of resin with SLA technology were produced by Zhang et al. (2011) and Takeyasu et al. (2013).
The cutting guides made by Barbier et al. (2019) are printed in biocompatible polyamide material by selective laser sintering (Figure 1c). It consists in the production of parts using a laser to selectively sinter the individual layers of the powder material (Feng et al. 2019, Lindberg 2018, Zarringhalam 2006, Aguado-Maestro et al., 2020). Surgical guides made of nylon are very common (Nizam et al., 2018; Shi et al., 2019).
In any case, the most used molding system is FDM. Printers using this technology extrude a plastic wire depositing it layer by layer on the heated bed. This technology is used to print polylactic acid.
The cutting guides made by Hu et al. (2020) are printed in polylactic acid (PLA) (Figure 1d). This has a glass transition temperature of 55-65 °C which makes it deformable at high temperatures (Maroti et al., 2020).

2.1 Summary of the literature review

The first models of surgical guides were made in the dentistry and maxillofacial fields.
The use of surgical guides in orthopedics brings many advantages including a significant reduction in the intervention times which leads to a better resolution of the osteotomy.
The custom-made surgical guides made to date differ in design procedure, construction materials and printing technology.



(a)



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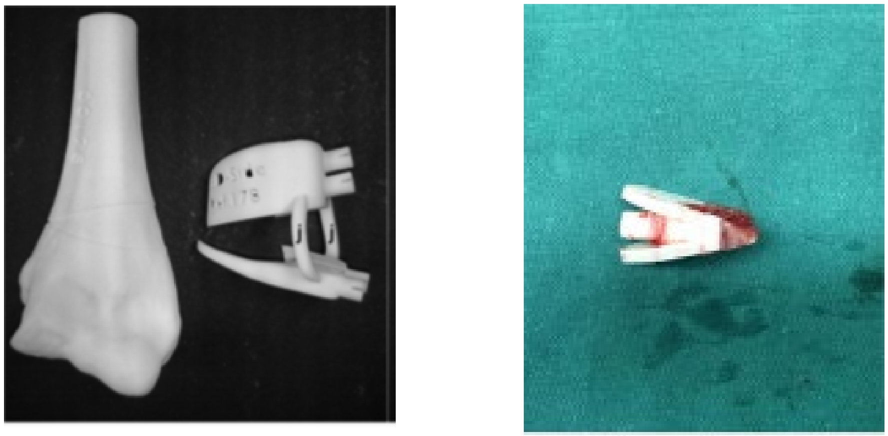


(c) (d)

Figure 1. Cutting guides printed in acrylic material (a), medical-grade resin (b), medical polylactic acid (PLA) material (c) and in polyamide biocompatible material (b)

3. Methods

3.1 From CT to 3D Digital Model

To convert a tomographic image into a three-dimensional model we use the Invesalius program, medical software that generates virtual reconstructions of human body structures (Osti et al. 2019, Frizziero et al. 2019, Napolitano et al. 2020, Papaleo et al. 2020). Once the file in DICOM format (Digital Imaging and Communications in Medicine) has been imported, the software allows you to view the biological structure of interest in the three main axes of the human being. From the right density range, the software highlights a specific region and creates its three-dimensional model, consequently eliminating all those parts not included in the range considered. The generated three-dimensional surfaces are called meshes and are exported in STL (Standard Triangulation Language) format.
MeshLab is a software that allows you to clean, remodel and remeshing the structure. Through MeshLab it is possible to eliminate the material inside the object. Many faces of the mesh are, in fact, hidden, not visible externally and therefore must be eliminated to obtain a 3D surface cavity.
Meshmixer is a 3D modeling software that allows you to eliminate additional mesh irregularities.
The optimized model can be exported in STL and OBJ format (Figure 2).

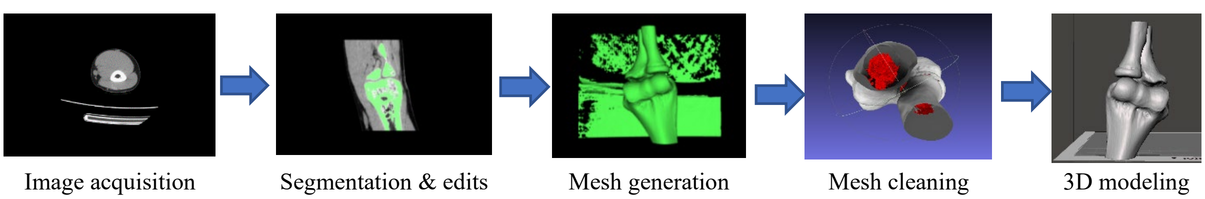
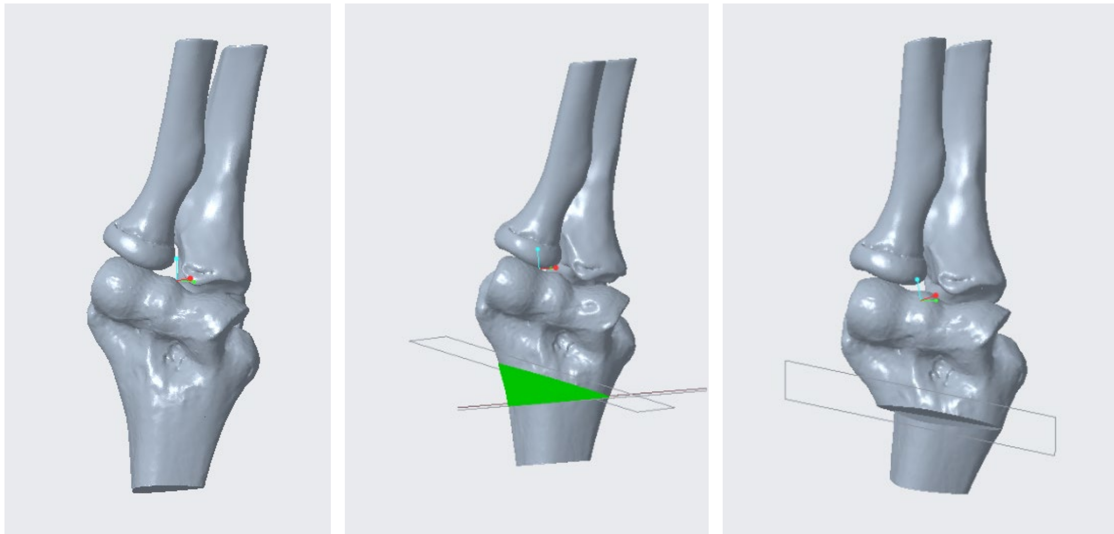


Figure 2. Steps to convert a 2D CT scan to the final 3D simulation.

3.2 Computer aided surgical simulation

The simulation is generated from the 3D digital model. The work consists in simulating the operation, choosing the level, shape and direction of the osteotomy (Frizziero et al. 2020, Donnici et al. 2019). In this work, the parametric software used to perform the simulation is PTC Creo Parametric (v6). Unlike the software previously illustrated, a parametric CAD is a design software that expresses each operation through parameters, i.e. numbers and mathematical formulas. A useful tool offered by parametric software is to modify the constraints imposed on the system even in the advanced stages of the process. Through the CAD simulation it is possible to trace the cutting planes to be used for the design of the customized osteotomy template (Figure 3).



(a) (b) (c)

Figure 3. Computer aided surgical simulation. (a) elbow before the operation (b) identification of the cutting planes and the dimensions of the bone wedge (c) elbow after the operation

3.3 Prototyping of the custom-made cutting guide

The bone model in PLA was printed with a Delta-type EZT3D printer.
The design of the cutting guide was chosen by the engineers together with the surgeons who communicated their ideas with small amounts of wax on the bone model.
The CAD software used for the design of the cutting guide is Creo Parametric (v6). The cutting guide adheres to the surface of the bone because its design faithfully follows the exact shape of the bone.
The cutting planes found in the preoperative simulation phase identify the position of the inserts that are made to facilitate the passage of the blades during surgery.
The designed cutting guide has two holes with a diameter of 3 mm which allow you to insert two Kirschner wires during the operation. The aim is to ensure the stability of the mask for the duration of the operation (Figure 4).

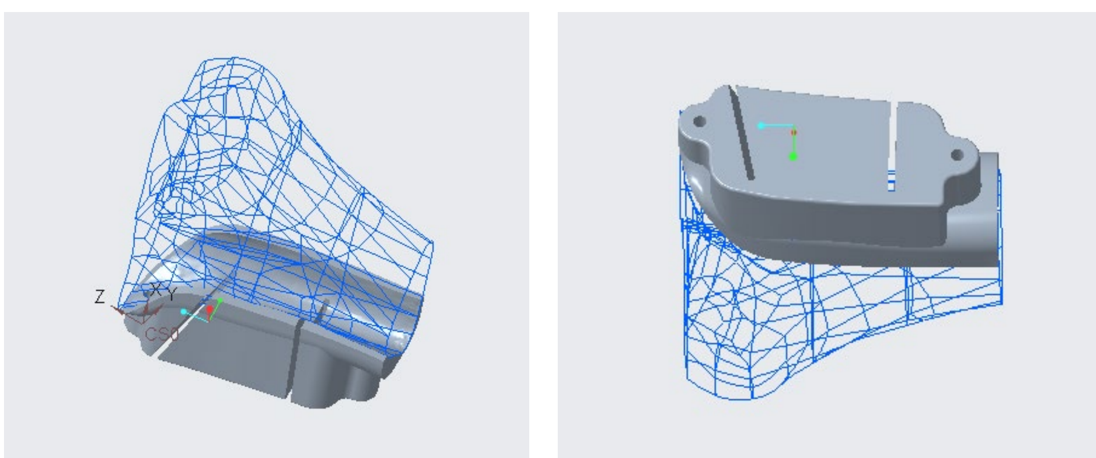


Figure 4. Design of the custom-made cutting guide performed on Creo Parametric.

The optimized template is ready for printing and we can use the Ultimaker Cura slicer to switch from the visualization of the three-dimensional model to 3D printing. The models that must be produced within the printing area are displayed in the 3D environment of the software once the type of printer to be used has been defined (Liverani et al. 2019, Francia et al. 2018, Frizziero et al. 2019). The printer used in this case case is an EZT3D of the

Delta type, a 3D wire printer that uses fused deposition modeling - FDM as a printing system. The material extruded from this printer model is in the form of filaments coiled to form a reel which is progressively unrolled during printing. The surgical guide was printed in HTPLA (Figure 5).

Figure 5. Cutting guide printed in HTPLA

4. Data Collection

4.1 Measuring model accuracy

The prototype was made for a boy who has a deformity in his left arm. The hospital ethics committee approved this study and the patient's legal guardians gave informed consent.
The lateral osteotomy plane was approximately 1.0 cm above the olecranon fossa, while the second plane was taken parallel to the CT cut plane. This resulted in an angle between the two cutting planes of approximately 18 degrees. The dimensions of the two holes were determined for the passage of two Kirschner wires with a diameter of 1.7 mm. The designed cutting guide has a thickness of 20 mm.

4.2 3D printing of the cutting guide

The cutting guide is printed in HTPLA, a material produced by the Proto-Pasta company and is obtained from heat-treated PLA. Like PLA, HTPLA is biocompatible, non-toxic and can be printed using the FDM technique.
Furthermore, HTPLA has better thermal and mechanical properties than PLA (Chen et al. 2020, Akhoundi et al. 2020). Table 1 shows the printing parameters used for HTPLA.

Table 1. HTPLA print parameters

PARAMETERS	VALUES
NOZZLE TEMPERATURE [ºC]	210
HEATED BED TEMPERATURE [ºC]	60
PRINT SPEED [mm / s]	25-45
EXTRUSION WIDTH [mm]	0.5 mm larger than the size of the nozzle
VOLUME FLOW [mm³ / s]	2-3

5. Results and Discussion

Table 2 shows a comparison between our procedure and the more common ones found in the literature.
The surgical mask design system described is innovative. In fact, new design programs and new molding materials were used.

Table 2. Procedures comparison

Ref.	INFORMATIC PROCEDURE	MATERIAL	3D PRINTING TECHNOLOGY
OUR PROCEDURE	Invesalius + MeshLab/Meshmixer + PTC Creo	HTPLA	FDM
Zhang et al., 2011	Mimics + Imageware	Medical-grade resin	SLA
Takeyasu et al., 2013	Bone Simulator (ORTHREE) + Magics	Resin	SLA/PoliJet
Murase et al., 2014	Bone Viewer (ORTHREE) + Bone Simulator (ORTHREE)	PLA	SLA/PoliJet
Pérez-Mananes et al., 2016	Orthoview + OsiriX + Meshmixer	ABS	FDM
Arnal-Burrò et al., 2016	Orthoview + Meshmixer	Acrylate resin	FDM
Shi et al., 2019	Mimics	Nylon	SLS
Nizam et al., 2018	//	Nylon	SLS
Gomez-Palomo et al., 2020	OsiriX + Netfabb + Fusion 360	PETG	FDM

5.1 Proposed Improvements

- Consider soft tissue for the design of the surgical guide
- Simulate real bone density

6. Conclusion

In this work we show a new custom-made surgical guide model created using CAD and 3D printing technology.
Free and open-source programs (except for Creo Parametric) and an entry level 3D printer were used to create the surgical guide.
The use of this guide allows a reduced surgical invasiveness for the patient, a reduction in the time required for surgery and an optimal cut of the bone wedge which leads to an optimization of the correction of the bone deformation.

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Biographies

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