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An Innovative and Cost-Advantage CAD Solution for Cubitus Varus Surgical Planning in Children

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Abstract: The study of CAD (computer aided design) modeling, design and manufacturing techniques has undergone a rapid growth over the past decades. In medicine, this development mainly concerned the dental and maxillofacial sectors. Significant progress has also been made in orthopedics with pre-operative CAD simulations, printing of bone models and production of patient-specific instruments. However, the traditional procedure that formulates the surgical plan based exclusively on two-dimensional images and interventions performed without the aid of specific instruments for the patient and is currently the most used surgical technique. The production of custom-made tools for the patient, in fact, is often expensive and its use is limited to a few hospitals. The purpose of this study is to show an innovative and cost-effective procedure aimed at prototyping a custom-made surgical guide for address the cubitus varus deformity on a pediatric patient. The cutting guides were obtained through an additive manufacturing process that starts from the 3D digital model of the patient's bone and allows to design specific models using Creo Parametric. The result is a tool that adheres perfectly to the patient's bone and guides the surgeon during the osteotomy procedure. The low cost of the methodology described makes it worth noticing by any health institution.

Keywords: cutting guides; preoperative simulation; CAD Modeling; 3D Printing; pediatric orthopedics; surgery and diagnostics

1. Introduction

In the last few decades, the development of techniques and materials has allowed great advances in various fields of technology; medicine, in particular orthopedics, is among the sectors that have benefited most from it. The term computer assisted orthopedic surgery (CAOS) synthetically denotes a large group of applications in the orthopedic field that use computers in order to make surgical procedures less invasive, more effective, safe and reliable [1–3].

The custom-made surgical guides are cutting tools made to measure for the patient. In the orthopedic field, they help the surgeon by facilitating osteotomy bone cutting in highly complex surgical interventions. To date, most surgical operations are performed freehand and their success is strongly correlated to the skill and experience of the surgeon. The use of surgical guides allows you to cut the bone in a very specific direction. In this way, the operation is completely constrained and therefore can be carried out easily even by less experienced surgeons. In addition, research conducted by Ballard et al. has shown that the use of surgical guides in orthopedics allows a reduction in intervention times and,

consequently, a reduction in the necessary costs [4]. This research considers 21 orthopedic cases (Table 1, Figure 1, Reproduced with permission from Ballard, D. et al., Copyright publisher, 2020).

Table 1. Reduction of time in the operating room following the use of cutting guides. The negative values in the "Operative minutes saved" column denote minutes saved while positive values denote added time with the 3D printed construct.

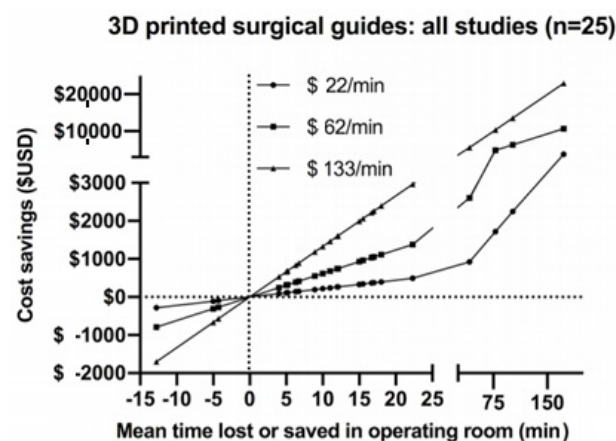|	Study	Operative Minutes Saved in Experimental Groups Compared to Control Group	Patients in Experimental Group	Patients in Control Group
1	Zhang et al. [5]	78	11	11
2	Hsu et al. [6]	−12	42	29
3	Chareancholvanich et al. [7]	−5.1	40	40
4	Abane et al. [8]	−6.3	59	67
5	Barrack et al. [9]	−11	100	100
6	Barrett et al. [10]	−5.2	66	86
7	Boonen et al. [11]	−10	39	40
8	Boonen et al. [12]	−5	90	90
9	Ferrara et al. [13]	−22.3	15	15
10	Gan et al. [14]	−15	35	35
11	Hamilton et al. [15]	4.3	26	26
12	Kassab and Pietrzak, [16]	−16.7	270	595
13	Kerens et al. [17]	5	30	30
14	Nankivell et al. [18]	−4	40	45
15	Noble et al. [19]	−6.7	19	15
16	Nunley et al. [20]	−12.1	57	57
17	Pfitzner et al. [21]	−15.5	60	30
18	Pietsch et al. [22]	−12	40	40
19	Rathod et al. [23]	−18	15	14
20	Renson et al. [24]	−8.9	71	60
21	Roh et al. [25]	12.8	50	50
	Mean (median)	**−12 (−10)**	56 (40)	70 (40)

Figure 1. Cost-savings from operative room time. The study included 21 orthopedic cases and 4 maxillofacial cases (n = 25).

The innovative methodology with the use of surgical guides provides for preoperative CAD planning aimed at identifying the cutting plans and, consequently, at verifying the positioning of the guide. Finally, the 3D printed bone model allowed to simulate the positioning of the guide before the actual surgery is performed.

1.1. Cubitus Varus Syndrome

Cubit varus is a deformation of the elbow caused by a deviation of the forearm inwards. This deformation can have a congenital or acquired origin. Among the main causes of acquired cubitus varus is the supracondylar fracture of the humerus. Cubitus varus following supracondylar humerus fracture in children consists of varus deformity, hyperextension and internal rotation of the distal humerus bone fragment [26–29].

The slight forms of cubit do not alter the functionality of the elbow and are mainly a problem of an aesthetic nature. Conversely, severe forms of cubitus varus can cause functional elbow disorders (Figure 2).
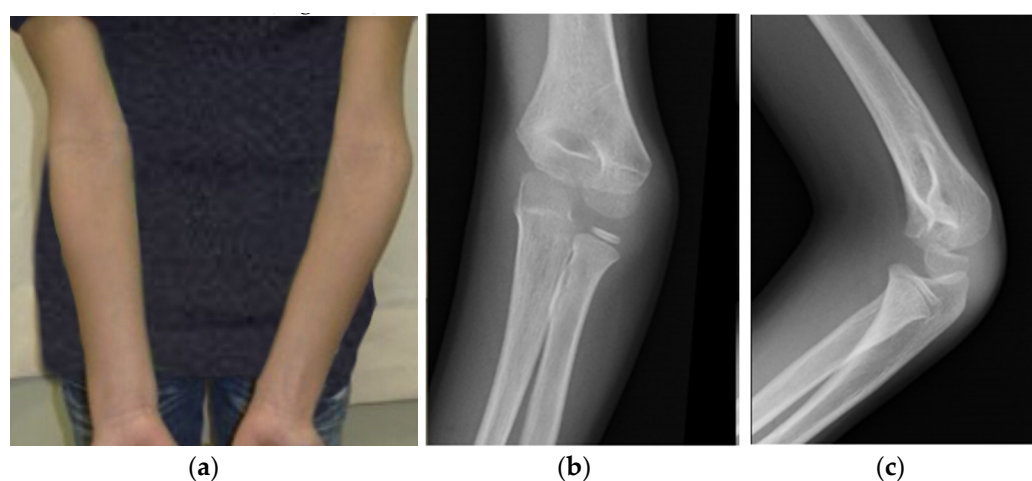

(**a**)　　　　　　(**b**)　　　　　　(**c**)

Figure 2. Deformity of the varus cubitus in the left elbow (**a**). The inclination angle is 15 varus (**b**) and 25 (**c**) respectively.

1.2. Cutting Guides for Surgery

Below are some representative examples of custom-made orthopedic surgical guides taken from the literature, analyzing their peculiar characteristics. All the surgical guides analyzed were made for pediatric patients suffering from cubitus varus deformity.

A study conducted by Tricot et al. [30] led to the fabrication of a real acrylic model of an osteotomy template [30]. A model of the patient's humerus was created by rapid prototyping using a 3D-plaster printing based on the CT scanner data. The guides were created by the contact of the prototypes with one unique possible position. The surgical guide made by Zhang et al. [31] was also made in acrylate resin and printed with the stereolithography rapid prototyping technique (SLA) (Figure 3a) [31]. Invented in the 1980s, it was the first 3D printing technology in the world and is still one of the most popular technologies on a professional level. Stereolithography uses a laser to polymerize the liquid resin into hardened plastic.

The template made by Murase et al. [28] was designed based on a preoperative three-dimensional computer simulation with use of commercially available software (Bone Viewer and Bone Simulator; Orthree, Osaka, Japan) and was produced as a plastic model with use of rapid prototyping technology and medical-grade resin. Two metal osteotomy slits and four metal sleeves are mounted on the template (Figure 3b) [28].
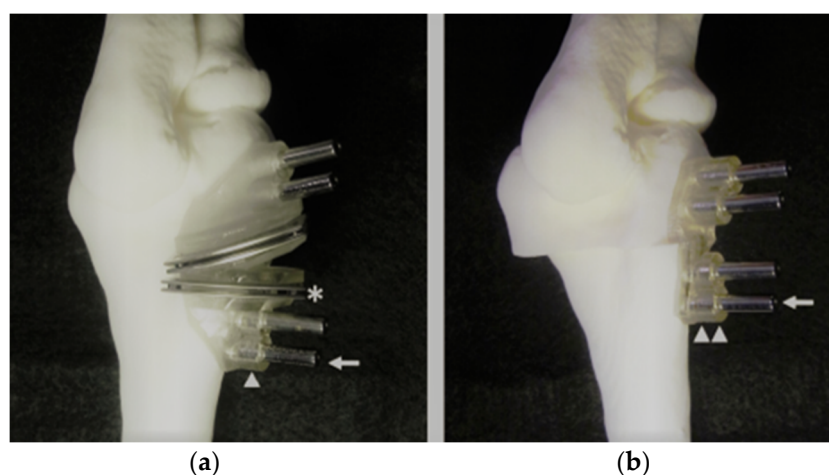
Figure 3. The osteotomy template made by Murase et al. [28] (2014): (**a**) two metal osteotomy slits and (**b**) four metal sleeves are mounted.

The surgical guides made by Hu et al. were printed using polylactic acid (PLA) (Figure 4a) [32,33]. The PLA guides are printed using thermoplastic material deposition technology (FDM-Fused Deposition Modelling or FFF-Fused filament fabrication), which is the most used method as it is economical, reproducible and versatile. FDM printers basically consist of a nozzle that heats up to 200 °C–250 °C depending on the material and extrudes a plastic filament depositing it layer by layer on a heated bed. This material has printing temperatures between 200 and 220° and it is not toxic. However, its glass transition temperature of 55–65 °C makes it deformable at high temperatures [33]. In fact, once the print is finished, the piece must undergo a sterilization process in order to be used in the operating room. There are several sterilization methods available in hospitals. The most common are sterilization in an autoclave, gas plasma and ethylene oxide (EtO). The sterilization in an autoclave is the most common method of sterilization because it is inexpensive and non-toxic. It involves temperatures between 121 and 134 °C under pressure. The higher temperatures used in the process could theoretically affect the structure of prints, especially those made from PLA with lower glass transition temperatures. Ethylene oxide is a gas frequently used for low temperature sterilization (54 °C), but due to its high toxicity it requires cycles of up to 14 h mainly for washing with air. The gas plasma uses hydrogen peroxide and temperatures of 37–44 °C. It represents one of the most advanced techniques for sterilization: it consists in the application of hydrogen peroxide in the gaseous state in the presence of a strong electric field. This brings the peroxide to the plasma state by stripping electrons and generating free radicals. The radicals have a high germicidal capacity and considerably damage cell membranes. However, bacterial growth was observed on cylinders printed in PLA using a 3D printer with a filling density of 12% and sterilized with hydrogen peroxide. Therefore, the use of plasma gas for the sterilization of PLA surgical guides is not recommended. Otherwise, in order to avoid the risk of contamination during the sterilization process, a filling density of 100% should be used when molding the surgical guides [34]. It follows that the use of PLA as a printing material for surgical guides is not particularly convenient.

The surgical guides made by Barbier et al. [35] were printed in biocompatible polyamide material by selective laser sintering (Figure 4b) [36]. PA12 (Poliammide 12, Nylon 12) is a polyamide synthetic fiber commonly used for 3D printing in the medical field. It is characterized by high thermal and mechanical resistance; therefore, it is suitable for producing functional prototypes. Selective Laser Sintering (SLS) is preferred as a material printing technique. It is an additive manufacturing technology that uses a high-powered laser to sinter small particles of polymer powder and transform them into a solid structure based on a 3D model [36–38]. Nylon can withstand high temperatures. The sterilization of the prototypes in an autoclave is therefore allowed.
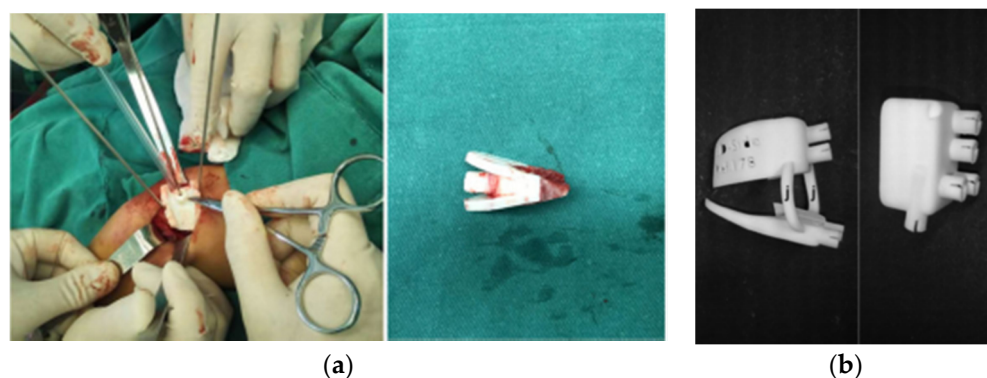
(**a**)   (**b**)

Figure 4. (**a**) Cutting guides printed in medical polylactic acid (PLA) material and (**b**) in polyamide biocompatible material.

Ultimately, the custom-made surgical guides made to date differ in design procedure, construction materials, printing technology and sterilization method. The most used programs for 3D simulation and mask design are not available for free use (Materialize Mimics, Bone Viewer and Bone Simulator). In recent years, the materials mainly used for printing the cutting guides are PLA and Nylon. PLA is widely used for its low cost and extreme printing simplicity. However, it is not suitable for use at high temperatures. An alternative is Nylon PA12, which shows the best thermal characteristics, but its production is complex because it is made with SLS technology.

The goal of this research is to design an innovative custom-made cutting guide that can gather the advantages that emerged from the study of the surgical guides made to date. The central focus of the entire work carried out is represented by the precious collaboration between the Department of Industrial Engineering (DIN) of the University of Bologna and the Rizzoli Orthopedic Institute (IOR) of Bologna, aimed at identifying useful engineering tools to be applied to medical field.

2. Materials and Methods

2.1. Study Design and Clinical Case

The case of a unilateral post-traumatic cubitus varus deformity is examined below. The pediatric patient in question has clinical varus in the left forearm of about 15–18°.

The therapy to be followed is exclusively surgical and consists of a corrective osteotomy with the removal of a bone wedge, followed by a period of physiotherapy.

In traditional orthopedic procedures, during the surgical operation it can be difficult to accurately check the angle of correction due to the reduced visibility of the intervention area. For this reason, the degree of correction often has to be adjusted several times during surgery and this can cause a prolongation of the operative phases with related complications and a high risk of incurring unsatisfactory clinical results. Accurate preoperative planning using the CAOS system, Software Systems for Structural Optimization, Springer, and the creation of patient-specific instruments (PSI) such as surgical guides are therefore necessary in order to achieve an accurate anatomical correction for cubitus varus deformity.

2.2. Computer Aided Surgical Simulation

The starting point is the generation of the 3D Digital Model of the bone from the tomographic images (CT). The software used were Invesalius (v. 3.1), MeshLab (v. 2016.12) and Meshmixer (v. 2017). Invesalius is an open-source software for reconstruction of computed tomography and magnetic resonance images. MeshLab and Meshmixer are graphic software used to correct any mesh irregularities [39–44]. The process from CT to 3D digital model is illustrated in Figure 5.

The surgery is planned using the 3D generated model. In this work, the parametric software used to perform the simulation is Creo Parametric (v.6), made by PTC, 121 Seaport

Boulevard, Boston, MA, 02210. Parametric software is the ideal choice if you plan to make quick changes to the project, even during construction, as in the case of simulations.
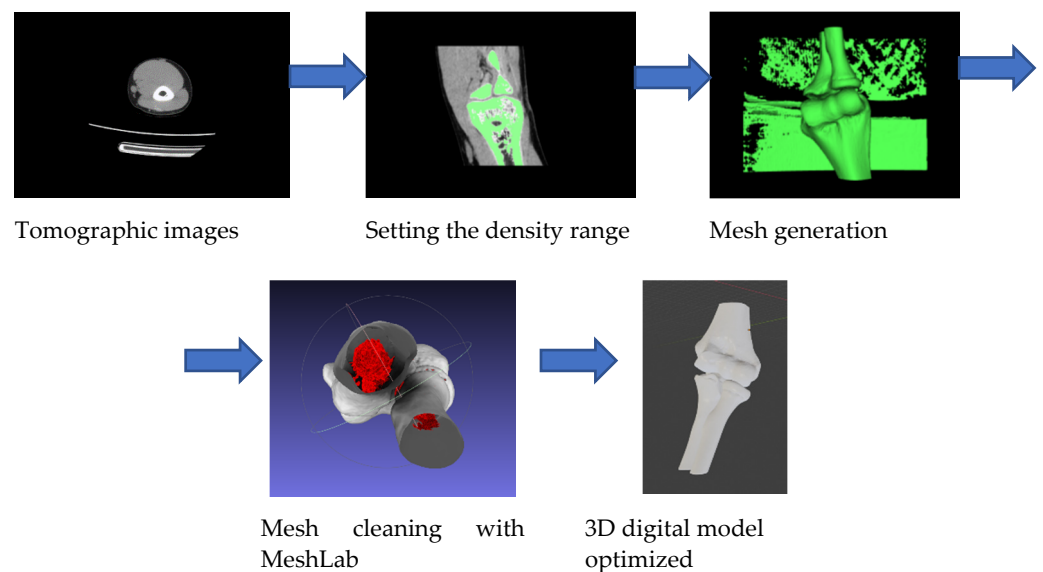

Tomographic images   Setting the density range   Mesh generation

Mesh cleaning with MeshLab   3D digital model optimized

Figure 5. From CT to 3D Digital Model.

Based on the theoretical guidelines provided by the doctors, the engineers simulated the interventions and the results that can be achieved during the operation. If these results do not meet the surgeons' expectations, it is possible to regenerate the model and proceed with the identification of the best solution to be achieved. Ultimately, the preview knowledge of the result of the operation gives rise to a relevant tool that favors the identification of the most suitable surgical strategy in relation to the case analyzed (Figure 6).

The simulation of corrective osteotomy also has the purpose of identifying the cutting planes to be used for the sizing of the surgical guide. In the case analyzed, it is considered that:

✓ The plane of the distal osteotomy, approximately parallel to the distal articular surface, is placed approximately 10 mm above the olecranon fossa;
✓ The proximal osteotomy plane forms an angle of 22° with the distal osteotomy plane.

2.3. Surgical Guide Planning

Before proceeding with the CAD design of the cutting guide, it is necessary a comparison between engineers and surgeons in order to outline the guidelines to be followed for a correct configuration of the mask.

To this end, it was useful to print the 3D model of the bone on which the cut is to be made. This model can be printed in PLA since the print is not intended for use in the operating room and sterilization is not required.

Using small quantities of wax or plasticine it is possible to make a preliminary reproduction of the surgical guide. In this way, surgeons can communicate their ideas, highlighting the crucial points that need to pay particular attention when designing the cutting template (Figure 7).

During this phase, the choice of blades to be inserted in the surgical motor and of the pins to be used for fixing the guide is also made. In the case in question, blades were chosen with a cutting thickness of 1.04 mm and with an edge size of 17.2 mm. The chosen pins have a diameter of 1.80 mm.

The choice of the blades and pins to be used and the verification of the oscillatory motion performed by the blade when the drill is in operation, are fundamental for the choice of the dimensions and tolerances to be used in the design of the notches, necessary for the passage of the blades and holes, necessary for the passage of the pins.

SIMULATION PROCESS

Figure 6. Computer Aided Surgical Simulation with Creo Parametric.

(**a**)	(**b**)

Figure 7. Surgical Guide Planning: (**a**) Preliminary reproduction of the surgical guide made with wax; (**b**) Choice of blades to be used during the operation and sizing of the notches.

2.4. CAD Design of the Surgical Guide
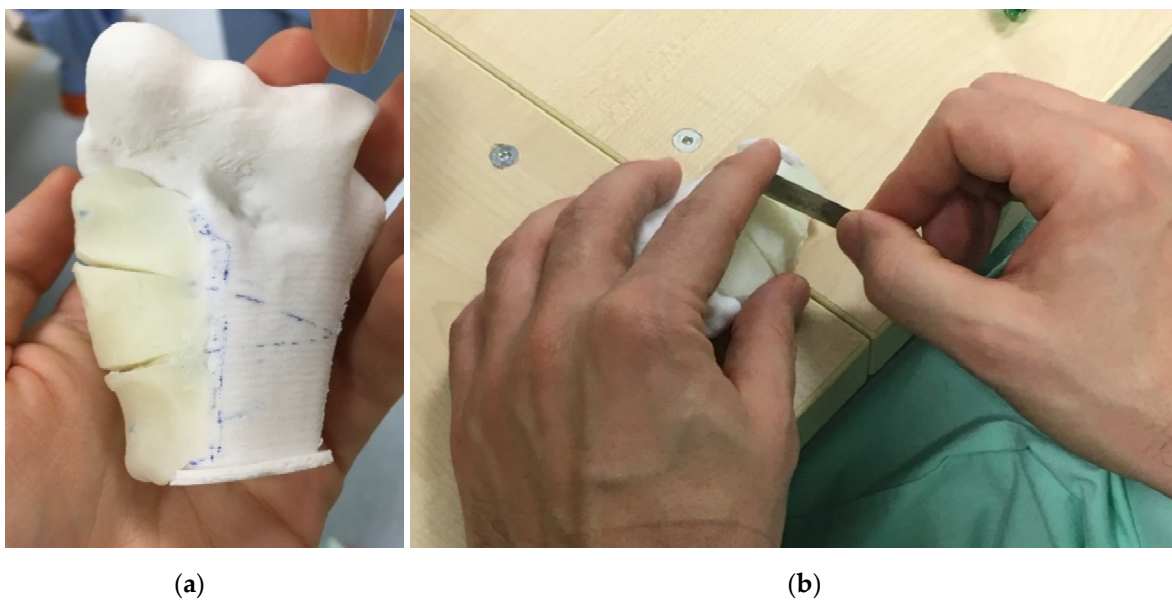
The next step is to design the cut guide outlined, using the Creo Parametric CAD software (v6), made by PTC, 121 Seaport Boulevard, Boston, MA, 02210. The cutting guide must adhere perfectly to the surface of the bone. For this reason, its design traced the exact shape of the bone faithfully.

On the surgical guide, it is possible to generate the holes for the passage of the pins. A diameter of 2.10 mm was chosen for the holes. This measure was identified after several prints aimed at choosing the right tolerance margin.

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 blades chosen during the design phase have a thickness of 1.04 mm; therefore, considering a tolerance margin, notches are made with a thickness of 1.08 mm (Figure 8).
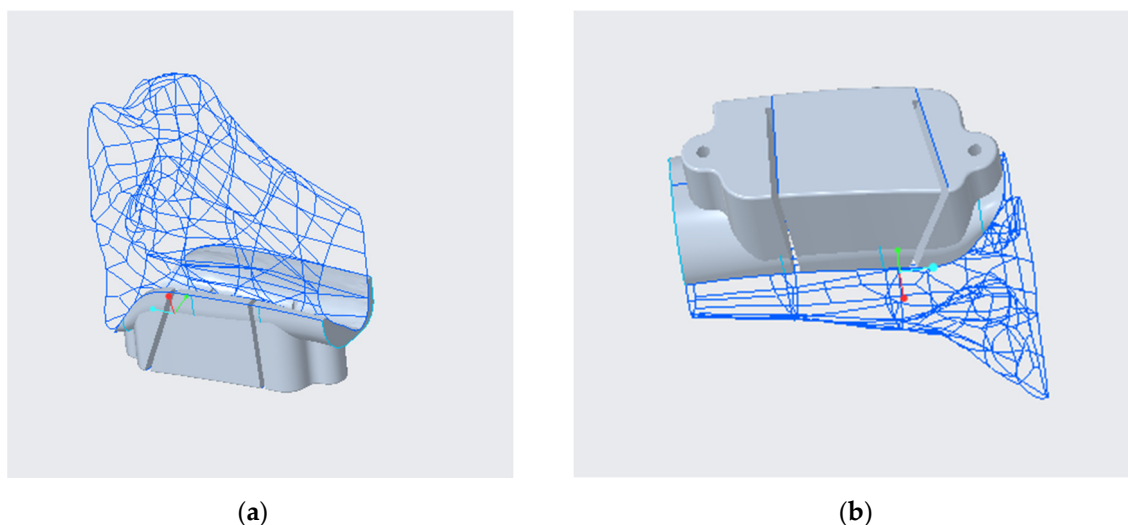

(**a**)　　　　　　　　　　　　　　　　　　　(**b**)

Figure 8. Design of the custom-made cutting guide performed on Creo Parametric: (**a**) from above; (**b**) from below.

2.5. 3D Printing of the Surgical Guide

The generated surgical guide template can be saved in Stl format. The Ultimaker Cura 4.8.0 slicer, made by Ultimaker B.V., Stationsplein 32, 3511 ED Utrecht, was used for printing the surgical guide. Cura is an open-source program developed by Ultimaker that converts a 3D model into instructions that the printer uses to produce the object. The printer chosen is the Delta-type EZT3D, a 3D printer that uses fused deposition modeling (FDM) technology as a printing system. Since the surgical guide is intended for use in the operating room, it must be sterilized before being used. An autoclavable material called HTPLA (High-Temperature PLA) was therefore chosen as the printing material (Figure 9). Table 2 indicates the printing parameters to be used for the HTPLA surgical guide.

Table 2. HTPLA Print Parameters.

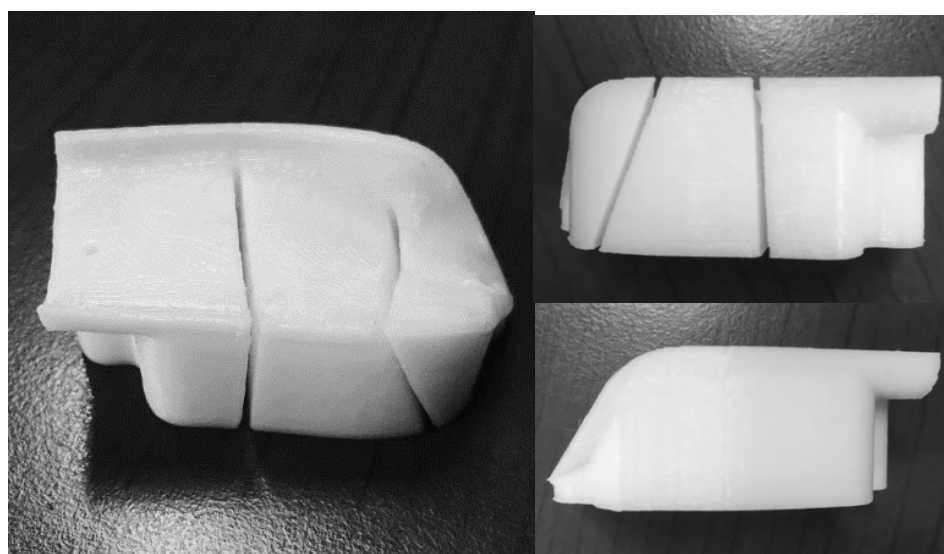| PARAMETERS	VALUES
Nozzle Temperature [°C]	210
Heated Bed Temperature [°C]	60
Print Speed [mm/s]	25–45
Extrusion Width [mm]	0.5 mm larger than the size of the nozzle
Volume Flow [mm³/s]	2–3

Figure 9. Printing the surgical guide in HTPLA from different angles.

3. Results and Discussion

The methodology described has led to the creation of a surgical guide that adapts perfectly to the patient's bone model. This favors its positioning in the operative phase and guarantees a precise cut of the bone that takes place exactly along the predetermined planes during the simulation (Figure 10).
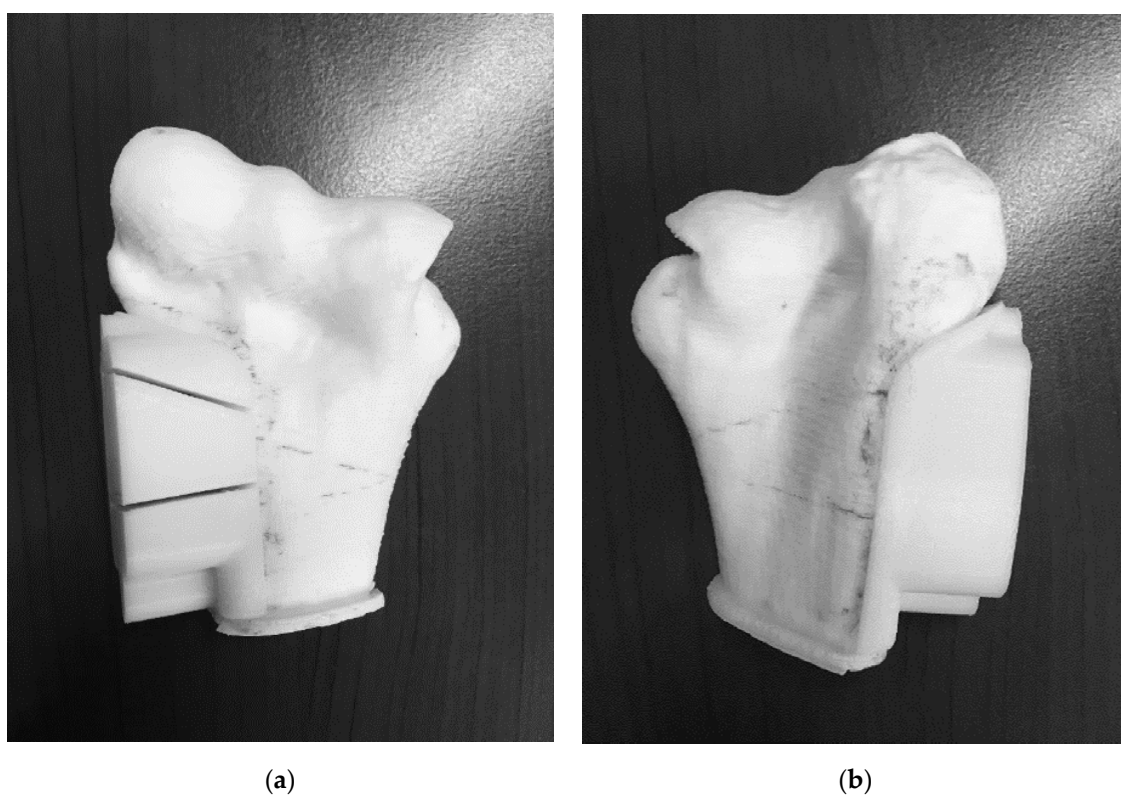

(**a**)   (**b**)

Figure 10. Perfect adhesion between the surgical guide and the bone model: (**a**) this favors its positioning in the operative phase and guarantees a precise cut of the bone that (**b**) takes place exactly along the predetermined planes during the simulation.

The analysis of the direct costs incurred to produce the surgical guide concerned:

- the cost of materials;
- the purchase of the 3D printer;
- the cost of the software used;
- the cost of qualified personnel.

A crucial point of the whole study was to find a material for printing that was biocompatible and non-toxic, with high mechanical properties, printable with FDM technology and sterilizable in an autoclave.

The choice fell on HTPLA. It is 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.

In addition, HTPLA has a higher strength and tensile modulus due to its semi-crystalline structure. The percentage of crystallinity in HTPLA can be improved by heat treatment to improve its mechanical properties.

Figure 11 compares the thermal and mechanical properties of PLA with those of HTPLA. In particular, the maximum tensile strength and modulus for the PLA samples are respectively 65.75 MPa and 4.9 GPa at 250 °C. For the HTPLA samples, the maximum tensile strength and modulus were acquired respectively 67.4 MPa and 5.65 GPa at 250 °C. This increase in tensile strength and modulus is due to the heat treatment and recrystallization of the samples, which improved the mechanical properties [45,46].
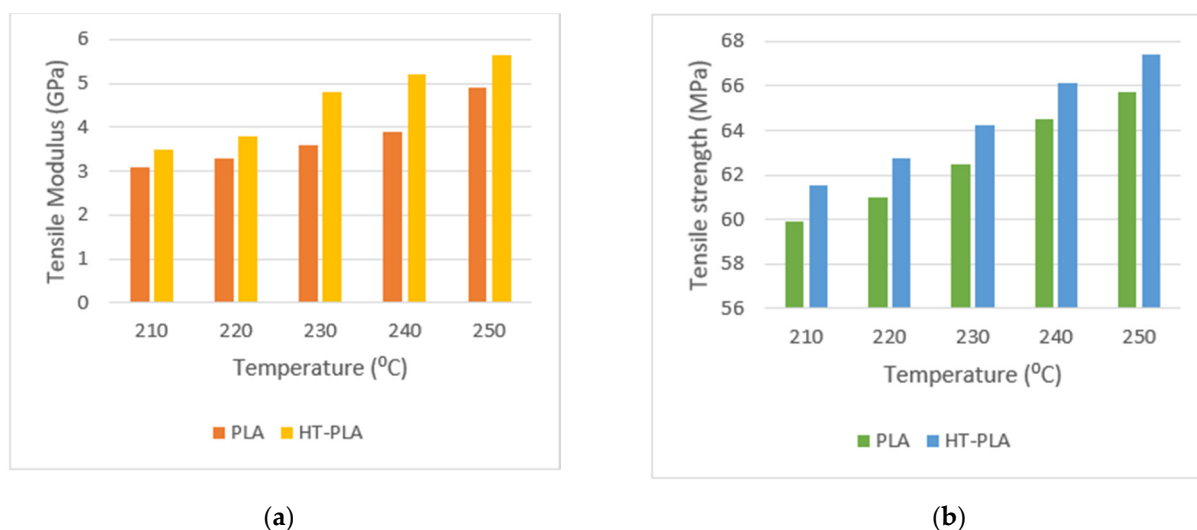

(**a**)　　　　　　　　　　　　　　　　　　　　(**b**)

Figure 11. Tensile modulus values (**a**) and tensile strength values; (**b**) in terms of printing temperature.

The model printed in HTPLA requires a complete annealing. The cooking phase takes place in a laboratory oven. The 3D printed model is heated for 30 min at 115 °C and remains at this temperature for one hour. Finally, it is left to cool for 30 min. After annealing, the HTPLA model can withstand up to 140 °C.

Due to the ability of HTPLA to withstand higher temperatures, sterilization of the cutting guide in an autoclave is therefore possible.

The cost of HTPLA is approximately 68.00 EUR/kg. 0.01 kg of material is required to make the surgical guide.

The printer used in this study cost about 250 EUR and has a working life of approximately 2000 working hours.

Table 3 shows a comparison between this procedure and the more common ones present in the literature for the case of cubitus varus deformity. This comparison concerns the cost of materials and printers used. Entry level printers, easily available on the market, were taken as a reference. The cheapest printing technology is the FDM procedure. Specifically, the printer used in this study is a Delta-type EZT3D and costs around € 250. The

most expensive printing technology is the SLS procedure, with prices ranging between 7000 and 145,000 EUR for a single printer.

Table 3. Cost comparison.

Printing Technique	Materials	Materials Cost (€/kg)	Printing Cost (€)
FDM	ABS	32.50	from 150 to 800
	PLA	37.30	
	HTPLA	68.00	
	PETG	45.30	
SLS	Nylon (PA12)	85.70	from 7000 to 145,000
SLA	Medical-grade resin	429.99	from 250 to 1000
SLA/PoliJet (Viper SLA Si2 3D System + Objet Eden 250)	Resin	58.99	13,500 + 41,000

Cheaper materials include PLA, Acrylonitrile butadiene styrene (ABS) and Polyethylene Terephthalate Glycol-modified (PETG). However, these materials are not suitable for autoclaving, which is considered the safest method of sterilization. The most expensive material is medical resin. Raydent Surgical Guide (Zortrax) resin was also considered for cost analysis.

Ultimately, the use of the FDM procedure and the choice of HTPLA as the printing material is the best, both qualitatively and economically.

The innovative process described is in-house, so the cost of the location infrastructure has not been considered.

Mainly, free open-source software (Invesalius, made by Centro de Tecnologia da Informação Renato Archer (CTI), Brazil; MeshLab, made by Visual Computing Lab of CNR-ISTI, Italy; Meshmixer, made by Autodesk, Inc. 111 McInnis Parkway San Rafael, CA 94903. USA) were used. Table 4 shows a comparison between our procedure and the more common ones present in the literature in terms of procedure used, software, material used for printing, sterilization process and printer used. It should be noted that most of the procedures use commercial software (such as Mimics which is the most widely used software in the biomechanical field) or closed source software. Furthermore, the sterilization method used for prototypes is often not mentioned or specified.

Table 4. Procedure comparison.

Ref.	Production	Informatic Procedure	Material	Sterilization	3D Printing Technology
THIS PROCEDURE	In-house	Invesalius, MeshLab/Meshmixer, PTC Creo	HTPLA	Autoclave	FDM
Zhang et al. 2011 [31]	In-house	Materialise Mimics, Imageware	Acrylate Resin	Sterilization is not mentioned	SLA
Murase et al. 2013 [32]	Nakashima Medical	Bone Simulator (ORTHREE), Magics	Resin	Sterilization is not mentioned	SLA/PoliJet
Barbier et al. 2019 [36]	In-house	Materialise Mimics	Nylon	The sterilization method used is not specified	SLS
Hu et al. 2020 [33]	In-house	Materialise Mimics 17.0	PLA	Sterilization is not mentioned	FDM

The estimated cost for a specialized operator is 20 EUR/h. The design phase of the CAD surgical guide requires 20–30 h. of work depending on the complexity of the case treated, while the printing of the guide obtained takes about 3 h.

Ultimately, with all above considerations made, the cost of the surgical guide made is around 485 EUR.

Proposed Improvements

The present study must be seen in the light of some limitations. The cost analysis was performed on a single targeted case of surgical guide made for a patient with cubitus varus. A comparison was reported between the innovative methodology used and the alternative innovative procedures present in the literature. However, no comparison was offered between the costs of the innovative methodology and the traditional planning procedure.

A future development of the simulation could involve the consideration of soft tissues for the surgical guide. In this way, it will be possible for surgent faithfully reproduce the anatomy of the affected part including muscular and nervous structures of the patient. This would increase the accuracy and effectiveness of the entire process.

Another possible future development could involve a more accurate filling of the bone model in the molding phase so as to obtain also the real density of the bone.

4. Conclusions

This work shows an innovative procedure aimed at prototyping a custom-made surgical guide for a pediatric patient suffering from deformity of the cubitus varus.

A study on the most common innovative procedures found in the literature has shown that, to date, no material has been found that offers the right compromise between good mechanical properties and low cost. Therefore, HTPLA was chosen, a new and innovative material that offers a good combination of the existing ones and allows to obtain an easily sterilizable and resistant product.

To obtain a cost-effective surgical guide, an in-house procedure, free and open-source design software (except Creo Parametric) and an entry level 3D printer were chosen.

Ultimately, it is possible to consider the methodology described as a low-cost procedure that can be used in any healthcare institution and which improves the quality of care.

As demonstrated by [31–33,36], the use of a customized surgical guide during surgery allowed to obtain an optimal cut of the bone wedge in a fully guided manner. In this way, the operations can be carried out straightforwardly even by less experienced surgeons, follow-on a lower risk for the patient.

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