# FDM-sourced Shinbone Cutting Guide in Polylactic acid-based Polymers: Heat Sterilization Effects on Part Quality

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## Abstract

Software for image analysis endorsed further developments in the medical area that would accept state of the art reengineering processes to reproduce actual internal organs and structures of the human body. Previous research on FDM produced elements in the medicine field shown important discoveries on orthopedics. Preoperative planning shown to be suitable for additive manufacturing solutions that could help to improve the efficiency on procedures lowering potential risks after surgery. Accurate and well thought planning is necessary to choose the best way for the practice and deliver the best results. Tooling customization has shown to help into achieving this result. Bone-related surgeries require customized cutting guides for better accuracy. The following work aims to deliver the opportunity to use variations of Polylactic acid (PLA) based cutting guides in actual surgery practices by means of sustaining a regular heat-sterilization procedure without compromising its tailor-made characteristics. This would be possible by means of a proved, reliable procedure for obtaining the prototype from traditional CT scan images. As a result, HT-PLA material composition and crystallization properties allowed to sustain a sterilization procedure in a way that does not compromise the reliability of the part, nor the safety of the procedure, so prototypes made with a similar process as the proposed one, can be used in actual surgery practices with safety.

## Keywords
HTPLA, FDM, 3D Engineering, Sterilization, Cutting Guide.

## 1. Introduction

The goal of this research is to develop an innovative, customized cutting guide that emerged from the study of the surgical guides made to date by the team, which is a collaboration between the Department of Industrial Engineering (DIN) of the University of Bologna and the Rizzoli Orthopedic Institute (IOR) of Bologna, both with the sole goal of finding useful engineering tooling and procedures ought to be applied in the medical field.

3D Printing manufacturing is an active field with recent developments in the biomedical engineering field; especially, in tissue engineering and generative medicine (Zhu et al., 2016). Also, several studies have different kinds of applications on 3D organs and tissues (Osti et al., 2019)(Yakof et al., 2018). 3D medical design can be the practical process for the surgical robot operations related to the manufacturing of organs and tissues in case of the doctor does not have a direct connection with the surgical area. (Osti et al., 2019).

The accurate training of medical professionals has turned out progressively more difficult, the traditionally accepted method of direct supervision has become more difficult given the high affluence of professional medical students. So, it is more challenging than before to educate medical students professionally by using traditionally accepted methods like direct supervision. (Waran et al., 2014) CT (Computed tomography) is a type of radiological method which shows the body layers with a scanning process based on their density that can manage the production of cross-sectional images of a particular space of a body. (Leonardo Frizziero, Liverani, et al., 2019)(Caligiana et al., 2020).

Further while, CT scans or MRIs are medical-oriented solutions for image obtaining. The aimed geometry from the medical images which are transformed from the DICOM format, which includes the X-ray data set, is extracted to produce the three-dimensional model. Studies on this matter by (Leonardo Frizziero, Santi, et al., 2019), also proved that this methodology is safe and cost-effective (L. Frizziero, Santi, et al., 2019) (Leonardo Frizziero et al., 2020)(Osti et al., 2019)in terms of reproducing an HTPLA used bone under its unique anatomical structure which is represented in the TC images of a human. The economic impact of this technology in the traditional workflow shows the process division on the radiograph area into the non-overlapping regions related to homogeneity and coherence. The elaboration of the problem affects the image subdivision. (Auricchio & Marconi, 2016)

Research analysis showed that a variety of anatomically accurate physical models were developed based on computed tomography (CT) and (magnetic resonance imaging) MRI data, using 3-dimensional (3D) printing technology (McGurk M, 1997) (Waran V, 2012). Moreover, CAD models based on patients with a determined pathology have been developed, and using FDM printing technology, and texturized models that resemble normal tissue structures have also been exposed (Waran V M. R., 2012). Thereafter, as this training procedures imply the use of expensive and complex surgical tools, special physical and cognitive skills for the performance of certain standard surgery procedures using real patient data are required.

**2.1 3D Printing for Surgery:**

Nowadays, healthcare providers have greater access to fast prototyping thanks to lower production costs; the use of 3D printed implantable devices on patients will be limited though, by excluding devices that require stringent regulation (e.g. prostheses, artificial organs with bioprinting techniques). Although the creation of Printing Centers near the operating rooms could be provided, these will not be performed on a large scale due to the slow development and regulation in this area. 3D printing will become mainstream as a technique of education and preparation of complex surgical procedures. (Deloitte, 2018). Other research findings suggest evaluating the application of 3D models in other surgical procedures; from educating patients before the procedure and as a tool for both before (Ferretti et al., 2021) and after surgery system, as models for professional training.

Appropriate predictive surgical planning is essential to achieve the ideal correction angle that will ensure a good functional result, osteotomy site, wedge position and size are the key points in performing an accurate correction that avoids joint line obliquity or creation of a new deformity (Jacobi et al., 2011). In order to improve accuracy in axis correction, navigation techniques have recently been used with good results (Pape & Rupp, 2007).

**2.2 Sterilization methods in medical industry.**

Heat is one of the oldest and cheapest ways to sterilize food, tools, equipment, etc. There are several basic ways to apply heat in sterilization; several techniques are commonly used to sterilize medical equipment: autoclave, ethylene oxide gas (ETO), hydrogen peroxide gas plasma, and gamma radiation according to the CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities, released in 2008. (Perez et al., 2012). Steam autoclave is the oldest, safest, most widely used and most cost-effective method for sterilization in the medical industry (McKeen, 2018).

Polymer products could be sterilized by few methods. To consider when selecting a technique, steam or dry-heat sterilization could degrade or melt some plastics. ETO leaves toxic residues; hydrogen peroxide and oxidizing agents that can oxidize or damage some materials. Radiation instead would alter the molecular structure of many polymers (cross-linking, scission), causing odor and discoloration, embrittle and degrade some materials, affecting bonding strengths that change its shelf-life (Rogers, 2012). There are publications regarding the intrinsic sterility of 3D printing manufacturing, due to the high temperatures and pressures reached during the process (Skelley et al., 2020), (Neches et al., 2016).

## 3. Objectives

- To make a material efficacy assessment of an optimized, polymeric FDM-produced surgical tooling for applications related to orthopedics that can withstand a regular heat steam sterilization process without substantial alteration in its dimensional and fit properties.

Table 1. Tested Materials claimed Mechanical Properties.

| | **Item** | **PLA** | **HTPLA** | **Related to** |
|---|---|---|---|---|
| | *Filament diameter* | 1.75 mm | 1.75 mm | |
| | *Specific Gravity* | 1.24 (g/cc) | 1.25 (g/cc) | (ASTM D1505) |
| **Mechanical Properties** | *Tensile Strength* | 47.8 Mpa | 40.8 Mpa | ISO 527, *(ASTM D638) |
| | *Tensile Modulus* | 2436 Mpa | 2190 Mpa | ISO 527, *(ASTM D638) |
| | *Yield Strength* | / | 90,9 Mpa | ISO 178, *(ASTM D790) |
| | *Elongation at Break* | 4.59% | 5% | DIN EN ISO 6892-1 |
| | *Impact Strength (v-notched Izod)* | 17.91 kJ/m2 | 25.31 kJ/m2 | ISO 180 (d), ISO 179(m), ASTM D256 (t) |
| **Thermal Properties** | *Melting Point* | 145-160 °C | 165-180 °C | (ASTM D3418) |
| | *Glass Transition (Tg)* | 60 °C | 55-60 °C | (ASTM D3418) |

## 4. Methods, Technology and Material

### 4.1 Materials

PLA is a biodegradable material as it could be made from renewable resources, giving good properties at a low cost as compared to other traditional biodegradable polymers used in medical applications (Hamad et al., 2015). It is used in a wide range of biomedical applications such as sutures,(Maharana et al., 2009), soft-tissue implants, tissue engineering scaffolds, drug delivery devices, (Langer, 1998), nails, pins, anchors, (DeJong et al., 2004), craniofacial augmentations in plastic surgery (Moravej & Mantovani, 2011), stents,(Erne et al., 2006), (Eyring, 1936), (Tsuji & Miyauchi, 2001), (Wiebe et al., 2014), screws (Lembeck & Wülker, 2005), and spinal cages,(da Silva Soares, 2008) to name a few. PLA sustains different load environments due to each application characteristics. Recently, PLA could be found in the market with a crystallization compound, enabling this plastic to further acquire mechanical improvements and stabilization towards temperature increasing. This is called HT-PLA. However, 3D printing process settings of HT-PLA are little studied in the literature(Hanon et al., 2021). Technical details about chosen filament materials is displayed in Table 1.

**4.2 Methods**

**4.2.1 From TAC Image to the Drawing Board, And 3D Printer**

The procedure started by gathering information from the TAC image from the lower part of the abdomen, which was scanned with InVesalius V3.0 Software, so a 3D mesh of the desired part is gathered (Figure 1); exported then to Stereolithography (STL) format afterwards, the obtained 3D mesh is then improved with software like MeshLab, Mesh Mixer, Blender V2.9. This process is necessary to achieve better part aesthetics, and less time from the printer. Cutting Guides were modeled around the scanned mesh so the fit with the actual bone is verified, therefore, customizing the tool for this surgery procedure.

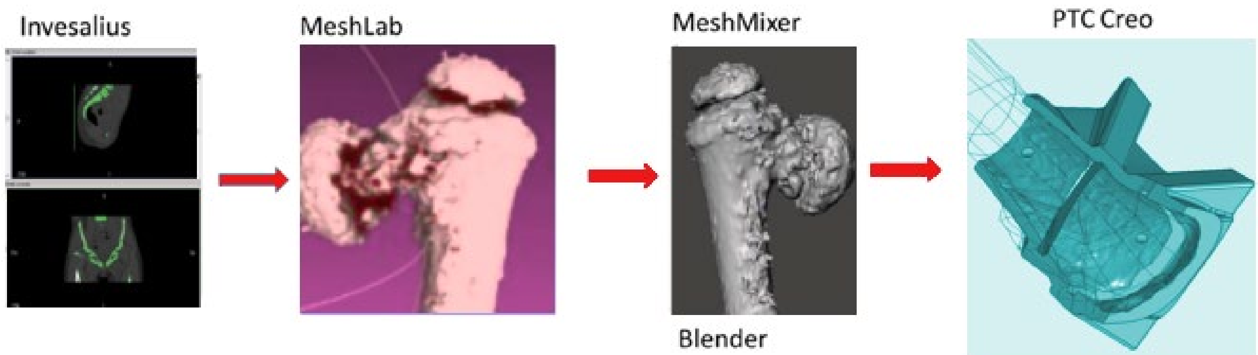


Figure 1. Process for Obtaining the Bone Cutting Guide

**4.2.2 FDM Process Parameters:**

All the specimens have been printed at the same speed, according to optimized parameters by means of the methodology proposed by (Ferretti et al., 2021). Therefore, a particular attention was made to certain printing parameters, which may influence the result. These parameters are:

1. *Extrusion Multiplier:* this parameter allows to determine the quantity of filament to add or decrease according to the standard quantity calculated by the slicing software and is fundamental since it allows to reduce any defects on the piece.
2. *Extrusion Width*: this parameter allows control the space of the centers of two adjacent filaments, as it is not possible to have precise control on the width of the single line.
3. *Outline Overlap:* this factor allows to set a percentile on how much to overlap the infill lines with the perimeters. It was chosen a value of 30%.

Both elements were printed in both filament materials accordingly as shown in Figure 2.

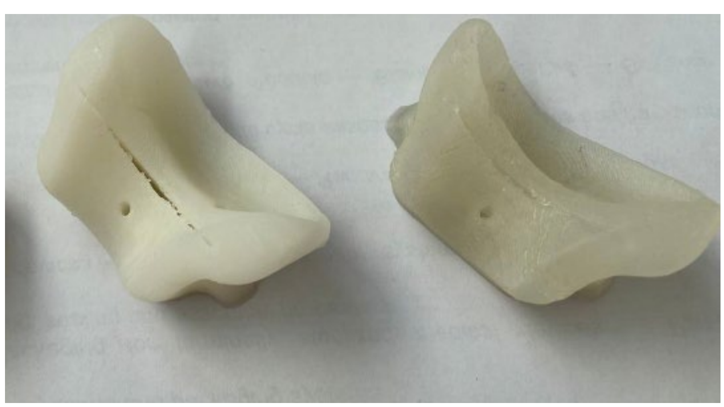

Figure 2. Cutting Guides printed by FDM in PLA (left), HTPLA (right)

**4.2.3 Heat Sterilization**
Sterilization by steam with autoclave is a process adopted by most hospital structures and in general when it is necessary to eliminate all the possible microorganisms present in a certain environment; it is the most used sterilization method because of its simplicity and effectiveness. Its use is rather simple, as there is a pump to remove the air, allowing the introduction of saturated steam.

The sterilization process follows various steps: conditioning, heating, washing, and drying. The actual cycle will be much longer than the heating time, with a duration of about 50 minutes total and maximum temperatures that are highlight between 134.7 and 134.9 °C for the true sterilization phase and own.

Sterilization test was performed by the IRCCS–IOR – Rizzoli Orthopaedic Institute, process of which is detailed on Table 2, the entire working cycle in which the parameters are concerned: time, temperature and pressure.

Table 2: Process of Heat Sterilization in Autoclave

| Process | Temperature (°C) | Pressure (kPa) | Time (min) |
|---|---|---|---|
| **Conditioning** | 79.6 | 93.4 | 22 |
| **Heating** | 134.7 | 300 | 6 |
| **Sterilization** | 134.8 | 311.9 | 4 |
| **Wash** | 134.8 | 311.8 | 2 |
| **Addition** | 20 | | 11 |
| **Drying** | 89.8 | 86.7 | 3 |
| **Drying** | 96.8 | 24.8 | 2 |
| **Ventilation** | 94 | 17.4 | 1 |
| **Total** | | | **51** |

**4.2.4 Autoclave Temperature Analysis results – Sterilization Test**
Each material gave a different response to the sterilization procedure. As all materials shown color differences after the process (Figure 3); HTPLA and PLA-sourced Guides shown a sunburn like coloration because of crystallization by the process. The Table 3 summarizes the 4 chosen dimensions compared on each (in mm) obtained for each material, with % error on the measurement. PLA and annealed HTPLA showed good performance overall.



Figure 3. Comparison View of Tested Masks Before and After Sterilization Process

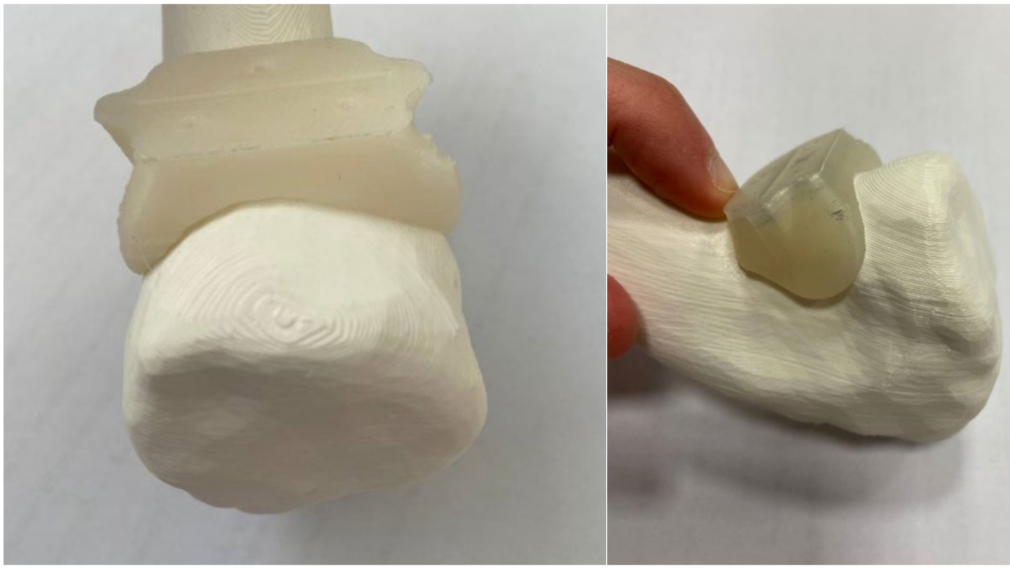

Figure 4. Fitting test of cutting guides after sterilization: PLA (left), HTPLA (right)

Table 3. Measurements Results Obtained After Sterilization Process

| Da | Design | HTPLA | PLA |
|---|---|---|---|
| media | **20** | **19.46** | **19.44** |
| deviation % | | 2.7 | 2.8 |
| **Db** | | | |
| media | **39.21** | **38.76** | **38.41** |
| deviation % | | 1.15 | 2.05 |
| **Dc** | | | |
| media | **40.35** | **40.56** | **40.03** |
| deviation % | | -0.52 | 0.79 |
| **Dd** | | | |
| media | **24.55** | **24.3** | **23.93** |
| deviation % | | 1.03 | 2.53 |

The resulting elements after sterilization were tested for fit with the actual shinbone, printed in FDM with methodology performed by (L Frizziero, Liverani, et al., 2019) as shown on Figure 4, PLA and HTPLA, proven to be materials suitable for this purpose: they are rather easy to print, have good mechanical characteristics and the resistance to heat sterilization is excellent. HTPLA has more performing characteristics overall than PLA, in fact being a modified PLA, able to resist better to high temperatures and stress.

## 5. Conclusion

Heat Sterilization procedure was performed on two polymeric surgery tooling elements; this process would modify the material's internal composition and could cause excessive material deformation or mechanical instability that would directly challenge the outcome of the procedure.

Thermoplastic materials could be importantly deformed if temperature exceeds its glass transition point. HTPLA includes a crystallization vehicle that causes the material to crystalize with temperature changes like the performed in this study. This phenomenon allowed HTPLA to show a lower deviation percentage that of the PLA.

Crystallization in HTPLA caused by heat treatment made this polymer material to become more fragile mechanically, but in the same way, can deliver a higher thermal stability, so its geometry was not compromised; giving the possibility of being used in different applications.

Dimensional results on printed parts depend directly on the correct choice of printing parameters, as mechanical and internal behavior of the element could be degraded if the internal stability of the material is not guaranteed.

## 6. Future Work

Further work is needed to answer the probable behavior of other polymer materials to heat treatment processes like this one. The influence of printing parameters in the stability of the printed part after heat tests.

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