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Exploitation of the additive manufacturing process to produce replacement Knee Exo-prostheses

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Abstract:

The knee exo-prosthesis constitutes a clinical solution that allows a leg amputee to regain the use of his feet. It is associated with a socket that adapts to the stump, a stem and a foot playing the role of the tibia and the natural foot. Several types of knees exo-prosthesis are marketed: single-axis, four-bar polycentric, six-bar polycentric, etc. This study is focused on a single axis exo-prosthesis (type 3A 17). The purpose of this paper is to improve the function of a worn and defective single-axis knee exo-prosthesis by renewing damaged parts.

To reduce the cost of the prosthesis and decrease its impact environment, the additive manufacturing process such as the fused deposition modeling (FDM) is envisaged.

The exo-prosthesis is composed of two large parts, one in titanium and the others are made in plastic. The aim of this study is to produce the plastic parts related to the Knee prosthesis by FDM process using polylactic acid (PLA) material.

Interface pressure tests and mechanical tests showed that the FDM part could be considered as an exo-prosthetic repair solution leading to successful walking. A comparative study between a marketed prosthesis and a used prosthesis with a plastic part obtained by FDM was performed to show the effectiveness of this solution in terms of cost, realization speed and ecological production.

The proposed work is a potential way to establish a green manufacturing approach reducing the cost and environmental impact of the lower limb prosthesis.

Keywords: Knee exo-prostheses, Additive Manufacturing, Mechanical propriety, Green Manufacturing, FDM

1 Introduction

The prosthetic knee joint of the exo-prosthesis is an external medical device used in the prosthetic low limb. They are manufactured specially for persons having a low limb amputation. The most common causes of the low limb amputation are vascular disease, infections, accidents, diabetes, and traumas as depicted by some authors [1] [2] [3] [4] [5].

The prosthetic leg is composed of 3 main modules: the socket module, knee module and the foot module as shown in Fig. 1 [6] [7].

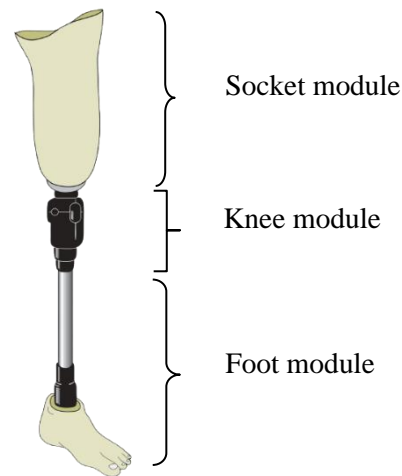


Fig 1- Prosthetic leg modules

The socket module contains a socket made from resin material and an adapter connecting the knee module. The last module that ensures the kinematics of the joint and allows transmitting the load to the tibia. The foot module containing a stem and a foot.

This paper is focused on knee module which is the most important part in motion [7] [8]. It is the widest joint in the human body and the most complicated one. This module is also the most fragile because it carries a lot of weight and strain while allowing flexible motion. It carries the body weight during the walking phase, the sitting phase, and the climbing phase.

Nowadays, there are many different systems, types and models of knee prostheses. There are two categories of exo-prostheses based on kinematics: the single-axis knee joint and the multi-axis or polycentric knee joint.

A single-axis knee has a single center of rotation that functions similarly to a hinge [9] [7]. It is a simple, more durable, available and inexpensive choice. In contrast, the multi-axis knee joint or polycentric knee has multiple axes of rotation. It is designed to be stable and flexible during the stance and swing phase [10].

Additive manufacturing is a new process that could be used for the manufacture of prostheses [11], even with some concerns about their robustness. As well as a large range of human prosthesis the prosthetic knee joint must be produced to conform and mimic the natural size, weight, and motion [10]. That is why a prototyping of each patient is very important to insure a successful prosthesis. The most suitable technologies to make customizing prosthesis is the additive manufacturing or the 3D printing specially with its capacity to create complicated structures quickly and at a lower cost than the traditional fabrication [12] [13] [14]. Many technologies and techniques can be used in the additive manufacturing. For our aim, three technologies were the most popular. The Fused Deposition Modeling (FDM), the Selective Laser Sintering (SLS) and the Polymer Material Jetting (Ply Jett) [12].

This work focuses on FDM technology, the most common and available 3D printing technology. This technique uses deposits of molten polymer layers to create specimens, prototypes, and products. [7] [15] [16]. Two materials are commonly used in the FDM technology: the Acrylonitrile Butadiene Styrene (ABS) and the Polylactic Acid (PLA). The Polylactic Acid (PLA) is very easy to use biomaterials. It is safe and free from any toxic materials and it is very suitable to be used in printing

biomedical devices and all lightweight products. It has less environmental impact compared to other polymers [17] [18].

Much research has focused on the capability and performance of using FDM technology in the fabrication of endo-prostheses and exo-prostheses such as knee prostheses [7] [9], orthoses [19], elbow braces [20], trans-tibia joints [19]. However, there is little information on the benefit of 3D printing in the maintenance and repair of worn and defective prostheses.

According to the data of the Tunisian orthopedic fitting center, a large number of patients with knee exo-prostheses who suffer from the repetition of the failure of their prosthesis. In addition, we do not yet have the idea of maintaining and repairing the defective prostheses. Therefore, we have a large amount of waste from defective prostheses. For this reason, and in order to establish a green manufacturing system, this work focuses on studying the exploitation of additive manufacturing to produce a knee replacement joint for exo-prosthesis.

The aim of this study is to reuse the defective single axis Otto Bock type knee by producing knee prosthesis parts using the FDM process to reduce the cost and reduce the scrap rate. The work consists of two main parts. The first step consists of studying the prosthetic knee joint. A finite element analysis will be developed. The second step concerns the realization by FDM of the plastic sheath, of the prosthesis, the part most exposed to wear and failure. A comparative study between the commercialized and reproduced knee joint is presented next. We will show that additive manufacturing could be an alternative in the biomedical field.

2 Finite Element Analysis of the Prosthetic Knee

This section covers the modeling and simulation of the plastic sheath of the single-axis knee prosthesis under study. SolidWorks 2021 software was used for modeling and the STEP file was imported into Abaqus 6.14 for finite element simulation.

The single-axis Otto Bock 3A17 knee shown in Fig. 2 is considered the most basic knee because of its simple design. It has one center of rotation that works like a door hinge. It is the lightest and most durable option available and is economical due to its simplicity but has no stance control [7].

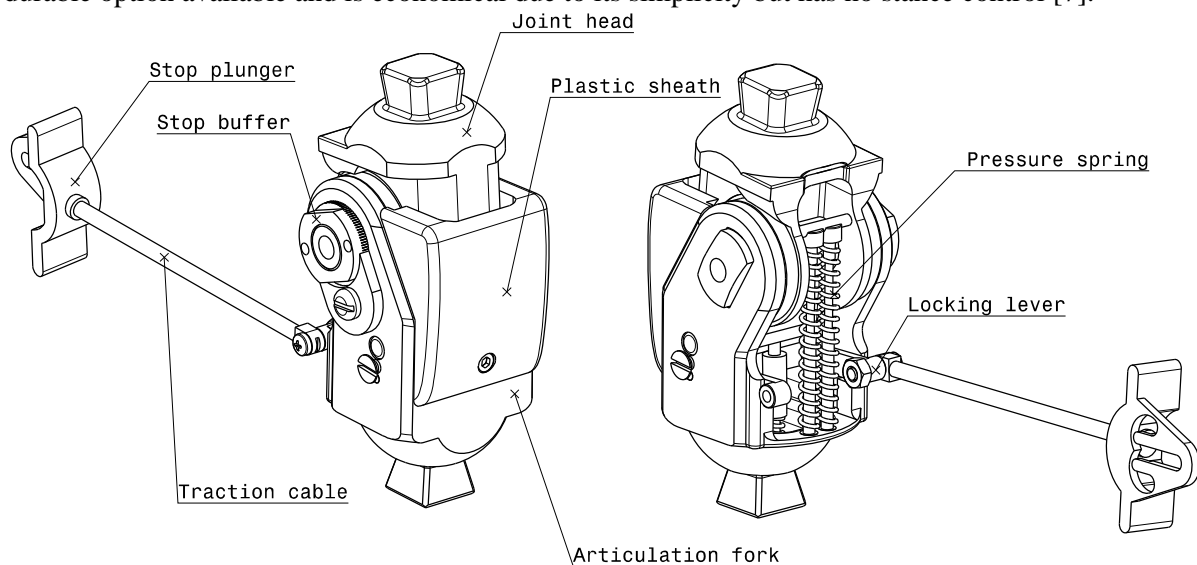


Fig 2- Single-axis knee

This prosthesis is composed of two principal parts: the joint head and the articulation fork pivoting in relation to each other. A stop plunger can fix the joint in a considered position through a locking lever, a traction cable, a pressure spring and using the stop butter.

In this work we considered the PLA printed material is an isotropic one even The FDM printed material is anisotropic (orthotropic) especially when the printing strategy directly affects the behavior of the printed material. In a work in progress, we are studying the anisotropy of the material through a design of experiment.

To conduct the simulation study, we considered the normal gait of a patient in monopodal support. The load applied to this artificial joint corresponds to the weight of the patient (\vec{W}_p) (Fig. 3.a). If the load applied to the knee prosthesis is transmitted to the lower limb, it will largely pass over the plastic sheath. We have therefore chosen as boundary conditions an applied load equivalent to a patient of mass 70 kg and an embedding at the backside of the sheath as shown in Fig. 3.b.

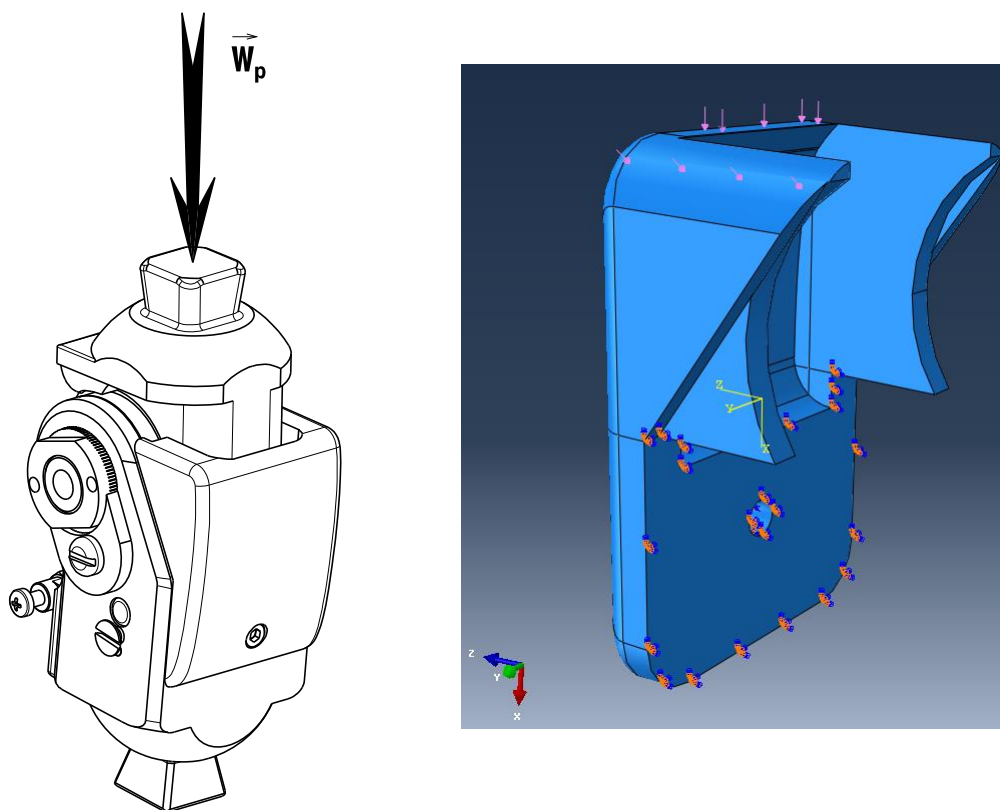


Fig 3- (a) Load applied in the Knee, (b) Boundary conditions on the plastic sheath

In addition, the initial plastic sheath of the prosthesis is made of polyethylene (PE HD) by the injection molding process. This process requires the use of an exorbitantly expensive injection mold; its use to produce small series of parts is not envisaged. Additive manufacturing is a technique for the rapid production of prosthetic parts, eliminating the cost of tools (mold).

Table 1 summarizes the mechanical properties of the used materials implemented to Abaqus software for the finite element analysis applied to the plastic sheath of the Knee prosthesis. These include the PE HD and PLA constituting an alternative to the polyethylene initially used as the material of the plastic sheath.

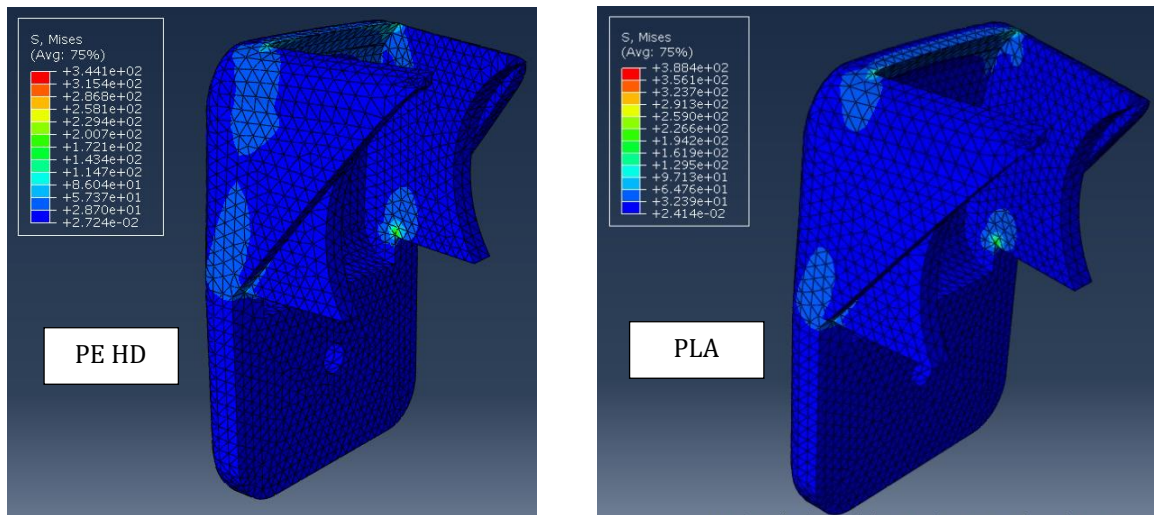
The finite element analysis relates to the evaluation of the stresses, deformations and maximum displacements at the level of the plastic sheath.

Examples of iso-values of stresses and displacements related to the plastic sheath for the two materials HDPE and PLA are presented in Fig. 4. Table 2 presents the maximum values of the stresses, deformations, and displacements of the plastic sheath.

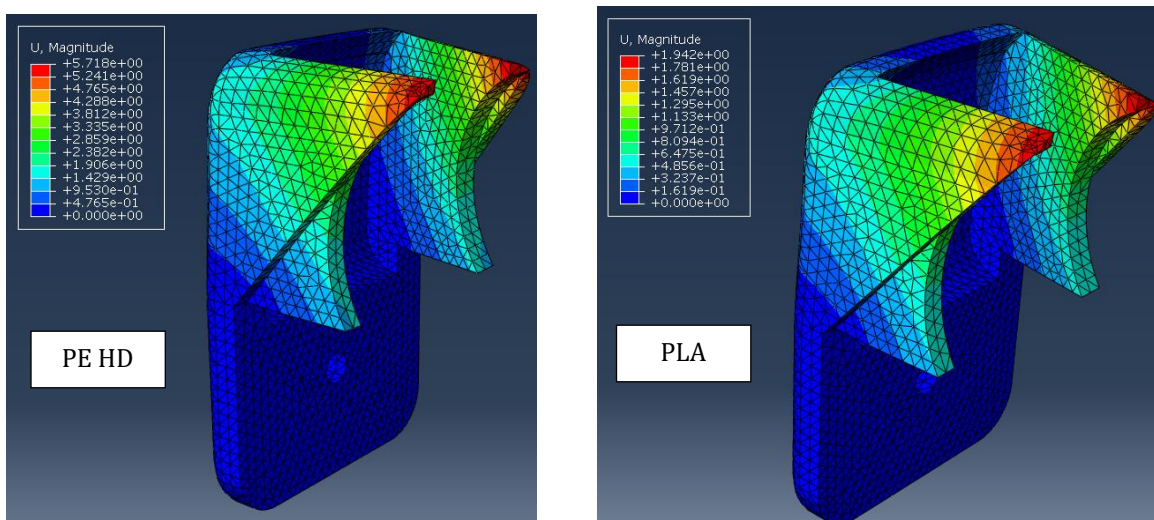
The Numerical models in the Fig. 4. showed a high stress concentration and an appearance of plastic zones. The solution can be the reinforcement of stress concentration zones and the reduction of singularities.

Table 1- Mechanical properties of the used materials

Material	Material Properties			
	Young Modulus E (MPa)	Density ρ (g/cm ³)	Poisson's Ratio ν	Yield Stress σ_y (MPa)
PE HD	1200	0.940	0.46	75.8
PLA	3500	1.24	0.36	60



(a)



(b)

Fig 4- (a) Stress iso-values, (b) Displacement iso-values

Table 2- Finite Element results

Material	Finite element results		
	Maximum Stress σ_{Max} (MPa)	Maximum strain ε_{Max}	Maximum displacement U_{Max}
PE HD	$3.441 \cdot 10^2$	$1.0491 \cdot 10^{-1}$	5.718
PLA	$3.844 \cdot 10^2$	$5.419 \cdot 10^{-2}$	1.942

The comparison between results related to PE HD and PLA shows an increase of maximum stress about 10% for PLA, a decrease of 80% and 66% of maximum strain and displacement respectively for PLA. This shows that PLA has a higher resistance than PE HD.

2 Materials and methods

This section presents the methodology and materials used to achieve this work. First, the process of the 3D printing has been developed and explained and second, the materials and equipment specification has been presented.

3.1 Process of 3D printing new plastic part

The Basic idea of this work is to reproduce a used prosthetic knee joint based on FDM process to help patient after the failure of their old knee prosthesis. The aim is to reproduce the plastic sheath of the single axis knee joint. This part can be manufactured according to two processes.

The first process is the plastic molding who's the mold cost is very expensive, and the availability of a customized mold can take a lot of time. The second process is the FDM that can ensure the low cost of the knee prosthesis, the availability and the speed of realization to guarantee the short time of waiting.

Many causes can defect the knee prosthesis like a shock from accident, the wear and tear after using or the weight increases of the patient and the creep [21]. The Fig. 5 bellow shows a defective knee joint that contains a creep and wear marks.



Fig 5- Faulty sheath of the prosthetic knee joint

The FDM process includes six steps: the first step is to prepare a 3D printable file of the desired part via a 3D modeling software: SolidWorks with the appropriate size. The second step consists in converting the 3D printable file into STL file or AMF file. The third step is to upload the STL or AMF file into the computer managing the 3D printer in the Creality slicer and choose the size, the

orientation in the landscape. In our study, we choose two different orientations: the external area coincides with the build plate and his opposite. We will decide which is the better [22].

The next step (step 4) is the 3D printing set up. Filling up all printer parameters. Many scientific workers showed that the printing parameters like the infill density, the infill strategy, the raster angle, the wall thickness, and the top and bottom thicknesses have a key role in the mechanical proprieties of the final product[23] [24] . That is why we must choose the appropriate set up as showed in the Table 3 to enhance the strength of the printed product and to ensure a successful test after manufacturing and the other parameters are followed from the recommended standard profile. A very important parameter in our case is to add a support to our design to guarantee a successful printed product.

Table 3- Printing parameters

Parameters	Unit	Value	Parameters	Unit	Value
Wall thickness	mm	1.32	Printing parameters	°C	200
Top/bottom thickness	mm	0.8	Build plate parameters	°C	60
Infill density	-	100%	Print Speed	mm/s	50
Infill pattern	-	Cubic	Support placement	-	Everywhere
Raster Angle	°	45			

The Fifth step is the printing and building the 3D product. It's an automatic step that can took few hours, in this step the PLA will be heated, fused, and deposited in the build plate layer by layer to have the final product. After heating phase, a small withdrawal can be present. The final step is to remove our product from the Creality CR5-Pro and remove the Support to get the final product.

3.2 Materials and equipment

The principal equipment of this study is the Otto Bock single axis prosthesis knee joint (type 3A 17). Our initial product is divided in two parts: a titanium part and a polyethylene part. The main characteristics of this product were presented in Table 5.

Table 4- Characteristics of the Otto Bock Single axis knee joint

Reference	Activity Level	Weight	Material	Max Angle
3A 17	K1	530 g	Titanium /Polyethylene	120°

The plastic sheath of the prosthetic knee joint was made using the FDM process with Creality Cr5-PRO printer shown in Fig 6. The used material is the PLA, which is a thermoplastic biomaterial polyester, which can be produced from bio resources. It is presently considered as a suitable solution for different biomedical application. Its cost is moderately low and possesses superior process-ability. PLA is considered a good compromise to reduce the impact on the environment due to the production and use of petrochemical polymers. Many works were realized to evaluate the characterization of virgin and printed mechanical proprieties of PLA such as [25] [26] [27].



Fig 6- Creality CR5-Pro Printer used to manufacture the plastic sheath

3 Results and discussion

In this section, we present our experimental results arising from the additive manufacturing, starting by a study of the reproduced prosthetic knee.

According to the Tunisian orthopedic equipment center, many patients suffer from the expansive price of prosthesis and their repetitive defective especially in the Knee module. That is why the objective of our study is the reproduced prosthetic knee joint to help patient to repair their lower limb amputation with a lower cost and faster speed.

Fig. 7 shows the photos of the plastic sheath obtained by FDM process. A better surface was obtained considering two different orientations: printing on the front view (curved face side) and the rear view (headset side). From an aesthetic point of view, the headset side seems to be better than the first one since that the roughness of the curved face side is smaller than the second orientation. However, this strategy has the biggest waste rate.



Fig 7- The manufactured plastic sheath by FDM

The dimensional accuracy of the printed part was measured using slide caliper. The main dimensions are the width and thickness of the final sample compared to the CAD dimensions. Eq. (1) was used to calculate the gap between designed and obtained plastic sheath.

$$Gap (\%) = \frac{(\text{measured dimension} - \text{CAD model dimension})}{\text{CAD model dimension}} \times 100 \quad (1)$$

This gap between the designed dimensions and the obtained ones varies between 0.54 % and 1.81 %.

Mainly this gap is due to withdrawal coefficient also the cooling rate of PLA, thermal expansion rate, printing position, printing orientation and temperature can affect this error [28]. In our work, we consider this withdrawal coefficient in the CAD model from the beginning to obtain the exact dimensions.

In the following, we present a brief comparison between the marketed plastic sheath made from PE HD and made from PLA in term of cost, realization speed, availability, and environmental impact.

In case of failure of the plastic part, the prosthesis will be completely replaced, although the metal part of the prosthesis is still functional. This incurs additional expense for the patient. The replacement of the plastic parts seems to be a solution allowing optimizing the cost and the expenses.

The cost of a new single axis prosthetic knee from Otto Bock company can cost 10-15 time expensive than the 3D printed one thanks to the local availability, the material costs... In addition, in term of manufacturing technologies also the 3D printed knee using PLA has a lower cost than the knee using PE HD. Many parameters can cause this difference in prices: the fabrication process, molding process or the plastic injection process has an upper cost because the necessity of customized molds and very expansive equipment.

Another advantage of the additive manufacturing used to produce the plastic sheath is the realization speed and the availability of customized product compared to traditional process. For the environment impact by studying the life cycle assessment of the PLA material and Polyethylene Materials as presented by some authors [29].

5 Conclusion

Previous studies have highlighted the possibility of using the FDM process in the production of prostheses. The current research represents further insight into the use of rapid prototyping in biomedical applications, particularly in the production of prosthetic knee joint replacement.

Through this study, we have shown that Additive manufacturing seems to be an interesting alternative in the maintenance of prosthetic parts. This could reduce the cost of the prosthesis and the expenses.

From an environmental point of view, FDM seems to be a way out compared to injection molding which has environmental waste.

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