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APPLICATIONS OF THE ADDITIVE MANUFACTURING TECHNOLOGY TO MANUFACTURE THE KNEE IMPLANTS

PRIMJENA ADDITIVE MANUFACTURING TEHNOLOGIJE ZA IZRADU IMPLANTATA KOLJENA

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ABSTRACT
The paper presents an application of the Additive Manufacturing (AM) technology using the Objet 3D Printer to develop femoral component of total knee endoprosthesis patterns for investment casting process. The goal of the paper is to outline the manufacturing technology intended for prototype production with the use of PolyJet technology and investment casting technology for use in orthopaedics and the surgery of knee arthroplasty. At present the research is focused on the preparation of STL data and verification of the production technology of prototypes made using PolyJet photopolimer materials. The wax model of knee implant obtained by Precision Casting Foundry (LPO) Ada was used as an initial model in this research and the production of knee implant prototypes was carried out in the Center for Numerical Simulation and Digital/Rapid Prototyping at the University "Eftimie Murgu" Resita, Romania.

Keywords: Additive Manufacturing, PolyJet, prototypes, knee implant, patterns, investment casting

SAŽETAK
Rad predstavlja primjenu Additive Manufacturing (AM) tehnologije uz korištenje 3D pisača za pripremu modela endoproteze koljena za izradu postupkom preciznog livenja. Cilj ovog rada je opisati tehnologiju proizvodnje namijenjenu za proizvodnju prototipa uz korištenje PolyJet tehnologije i tehnologije preciznog livenje za korištenje u ortopediji i kirurgiji koljena. Trenutno je istraživanje usmjereno na pripremu STL podataka i verifikaciju tehnologije proizvodnje prototipa izrađenog pomoću PolyJet polimernih materijala.Voštani model koljena implantata izrađen u livnici preciznog liva (LPO) Ada služio je kao početni model u ovom istraživanju za proizvodnju prototipa implantata koljena koje je provedeno u Centru za numeričke simulacije i Digital/Rapid prototyping na Univerzitetu "Eftimie Murgu" Resita, Rumunjska.

Ključne riječi: Additive Manufacturing, PolyJet, prototip, implantat koljena, model, precizni liv

1. INTRODUCTION

The most recent approaches to technological innovations include technological innovations of products and processes as competition factors as well as the new information and flexible manufacturing technologies having new properties. Modern development and design of new products and technologies is based on CAD/CAM/CAE technology application.
Additive Manufacturing is a procedure of direct prototype production by means of the gradual addition of individual material layers. The procedure, based on 3D CAD file, is relatively known nowadays. Additive Manufacturing technology is the most frequently used name for a technology family: Rapid Prototyping (RP), Rapid Tooling (RT), Rapid Manufacturing (RM) and Reverse Engineering (RE). [1]
When the application of AM technology started in investment casting, the parts produced within the first AM systems were applied as meltable wax models in order to shorten the time and costs of casting. Economic benefit which the AM meltable models provide is reduced to individual and small series production due to high AM material costs.
The latest researches in technology of development of AM meltable models are redirected to development and application of Rapid Tooling technology which ensures fast development of tools/ molds for meltable wax models development in investment casting. The name Rapid Investment Casting (RIC) is AM technique application in investment casting. Additive Manufacturing technology is optimal for the manufacturing of customized implants. These are the reasons why AM technology have such an important role in medicine.

2. INVESTMENT CASTING OF METAL IMPLANTS

The main feature of technological process of producing cast products by investment casting is to inject an easily melted model mass under pressure in tools made of metal or other material: after solidifying in the tool, the mass assumes the shape of a cast piece. The injecting system is made in other tool. The model of cast piece is joined to the injecting system model after it has been removed from the model tool. Since the models are of small dimensions, more models are joined on one injecting system which makes a wax sprue. Several layers of suspension are applied on the prepared wax sprue, which form a solid shell after drying. The shell is made by melting the model assembly and is then put into special boxes and sprinkled with sand or grains. [2]
The box containing the shell is heated in a furnace to a relatively high temperature and then is cast. After cooling down, the cast pieces are removed from the shell and then detached from the injecting system and cleaned. If necessary, thermal treatment of cast pieces is performed. Investment casting is used for making cast pieces of ferrous, non-ferrous and light metals. Investment casting produces high quality and geometricaly complex near net shaped metal parts with tight tolerances cost effectiveness in case of mass production. The economic benefits of investment casting are limited to mass production.
Limitations of traditional investment casting [3]:

- Traditional investment casting requires the production of metal tooling for the injection of wax material to produce sacrificial patterns which leads to cost justification problems for prototyping, pre-series, customized and single casting and small and medium quantity production.
- Major part of the total lead time is consumed in production of metal tooling required for wax pattern generation.

- Before committing to manufacturing, numbers of design iterations are performed by tool makers by evaluating different mould design which further incorporate an additional cost and lead time.

There are several companies producing medical implants using stainless steel alloys in the Serbian market. This production is mainly carried out by machining or forging. CoCr based alloys are used more in the area of knee and hip joint replacement production in the foundry industry at present. CoCr alloys have been utilised for many decades in making artificial joints. They are generally known for their excellent wear resistance.

A very strict certification regarding the material quality causes problems to foundries. Knee implants are produced in different sizes, for the left and right knee separately. Producers are trying to satisfy each inividual patient's needs at a surgery. [4]

In this paper we used a meltable wax model of femoral component for total endoprosthetic knee obtained by Precision Casting Foundry Ada and Fig. 1 shows tool for meltable wax model with injected wax pattern and knee implant metal cast pieces. The material of metal implants is CoCrMo alloy.

(a) *(b)*

Figure 1. Tool for meltable implant model with wax pattern (a), metal cast pieces (b) (Courtesy of the Precision Casting Foundry Ada)

The cost involved in designing and fabrication of metal tooling for wax injection process can be overcome by using AM techniques to fabricate sacrificial patterns for investment casting. Additive manufacturing also facilitates to reduce the overall lead time involved in production of prototype casting with excellent quality. By employing AM-fabricated patterns to produce the prototypes, there is no need to commit to production tooling for single part or small quantity production. [5]

Additive Manufacturing technology provide various cost effective solutions by which preseries casting can be produced very economically. Presently, almost all commercialised AM techniques have been employed to produce casting patterns with varying success and many AM solutions in investment casting are being used by various industries and researchers. The use of Additive Manufacturing in investment casting is in three basic forms. Fig. 2 shows the three basic approaches used as rapid casting solutions in RIC.

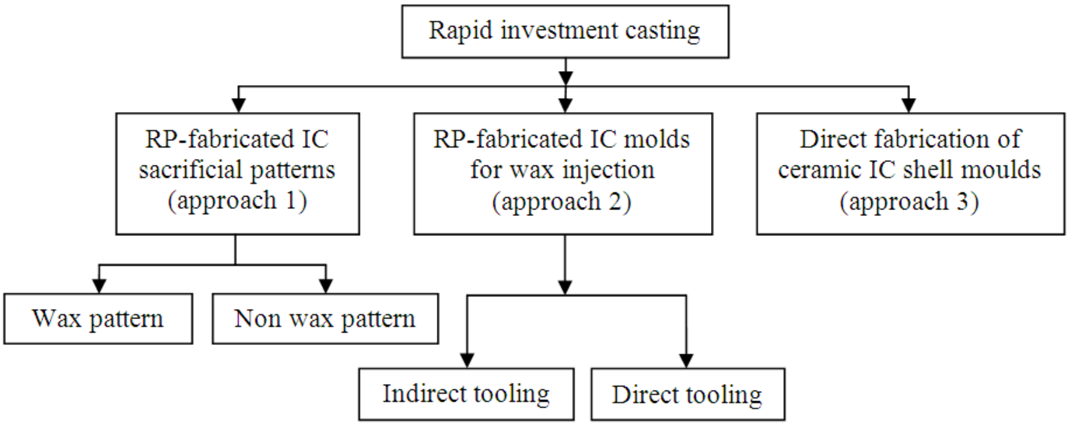


Figure 2. Rapid investment casting approaches, [3]

3. THE DESCRIPTION OF THE 3D PRINTER

Objet Geometries machines build parts layer by layer combining inkjet technology with photo-polymerisation (UV curing) process, as shown in Fig. 3.

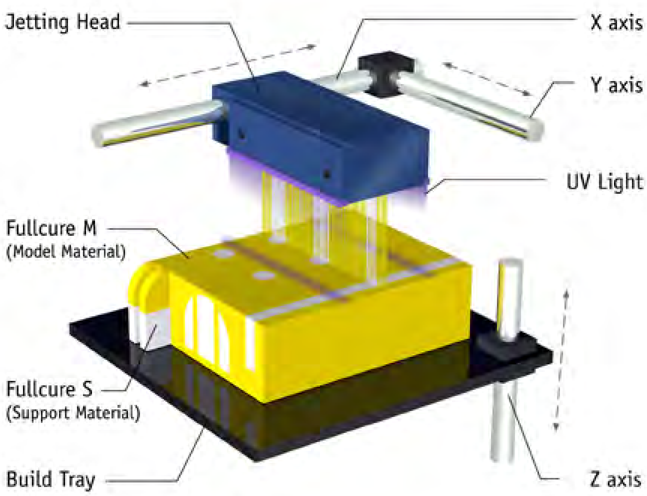


Figure 3. Polymer jetting printing process

Objet 3D Printer Multifunctional Desktop 30, Fig. 4(a), used in this study has maximum print size defined by the parallelepiped 294 mm x 192.7 mm x 148.6 mm, with a resolution of 600 dpi in the X, Y axis respectively 900 dpi in Z axis. The layer thickness on Z-axis direction is 28 microns. Accuracy can vary depending on the geometry, orientation and size of the object, up to 0.1 - 0.2 mm. The models do not require further finishing, but can still be processed by drilling, soldering, metal coating, painting. The wall thickness is 0.6 mm and minimum diameter of the holes is 1 mm.

(a) *(b)*

Figure 4. Equipment: 3D printer Objet 30 (a), Objet Waterjet System (b)
(Courtesy of the Center for Numerical Simulation and Digital/Rapid Prototyping, University "Eftimie Murgu" Resita, Romania)

The range of material model (material used to print the full part of a model) available include Objet FullCure materials: VeroWhite, VeroBlue, VeroBlack, VeroGray, DurusWhite, TangoPlus, TangoBlack and FullCure®720. In this research VeroBlack – FullCure870 material was applied, and its properties are shown in Table 1.

Table 1. Material properties VeroBlack - FullCure870

Property	**ASTM**	**Units**	**Metric**
Tensile Strenght	D638-03	MPa	51
Elongation at Break	D638-05	%	18
Modulus of Elasticity	D638-04	MPa	2192
Flexural Strenght	D790-03	MPa	80
Flexural Modulus	D790-04	MPa	2276
HDT, °C @ 0.45MPa	D648-06	°C	47
HDT, °C @ 1.82MPa	D648-07	°C	43
Izod Notched Impact	D256-06	J/m	24
Water Absorption	D570-98 24 hr	%	1
Tg	DMA, E″	°C	63
Shore Hardness (D)	Scale D	Scale D	83
Rockwell Hardness	Scale M	Scale M	81
Polymerization density	ASTM D792	g/cm^3	1.17
Ash content	USP281	%	0.005

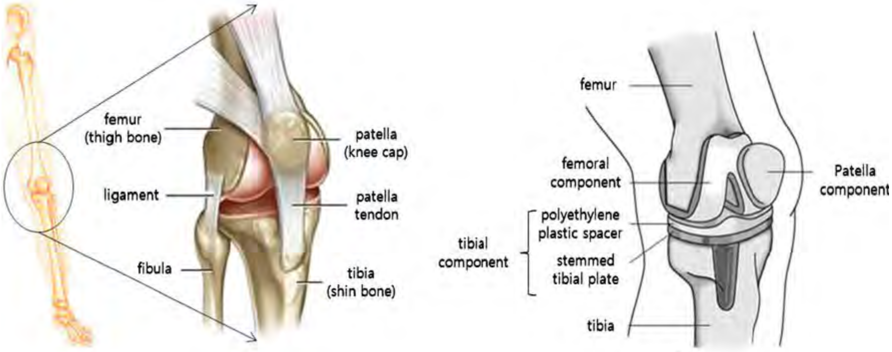
As support material (material used to print a model empty space) FullCure®705 Support a non-toxic gel-type photopolymer was used, that can be easily removed by Objet Waterjet System, Fig. 4(b), the equipment being included in the printer configuration. Waterjet use pressure water jet to remove material support.

4. THE CAD MODEL OF THE KNEE IMPLANT

The knee is one of the most sophisticated joints of the human body. As the knee is a major weight bearing located between the end of femur and the top of the tibia, it is likely to be afflicted with chronic diseases or any other severe injury. If the joint suffered from a severe disease, normal daily activities are mainly restricted or even impossible. In this case, total knee replacement (TKR) surgery may be applied to replace the damaged part of the knee with an implant and recover the normal articular cartilage functions. One of the most important aspects of TKR surgery is to design better knee implants in the operation.

The knee joint consists of three bones: the femur, the tibia, and the patella as shown in Fig. 5(a). The two major bones related to TKR surgery are the femur and the tibia.

Similarly, a knee implant consists of the femoral, the tibial, and the patellar component as shown in Fig. 5(b). The metal femoral component displaces the bottom of the femur and has a groove so the patellar component can glide up and down smoothly. [6]



(a) *(b)*

Figure 5. Knee bones. Anatomy of the normal knee (a), knee implants (b), [6]

The 3D CAD solid model of the knee implants was obtained using a Reverse Engineering process. Phases of obtaining 3D CAD model based on wax pattern of knee implant:

- Generating the point cloud of the knee implant by non-contact 3D Scanner Noomeo Optinum (Fig. 6) and Numisoft software.
- The obtained point cloud processing and conversion into mesh model in Geomagic Wrap software.
- Mesh model processing and transfer into neutral CAD format in Rapidform XOR software.
- Model import and conversion into 3D CAD solid model in SolidWorks software.

Figure 6. 3D Scanner Noomeo Optinum

(Courtesy of the Center for Numerical Simulation and Digital/Rapid Prototyping, University "Eftimie Murgu" Resita, Romania)

The geometry of the knee implant is presented in Fig. 7. The maximal dimensions of knee implant are 65 mm x 63 mm x 61 mm.

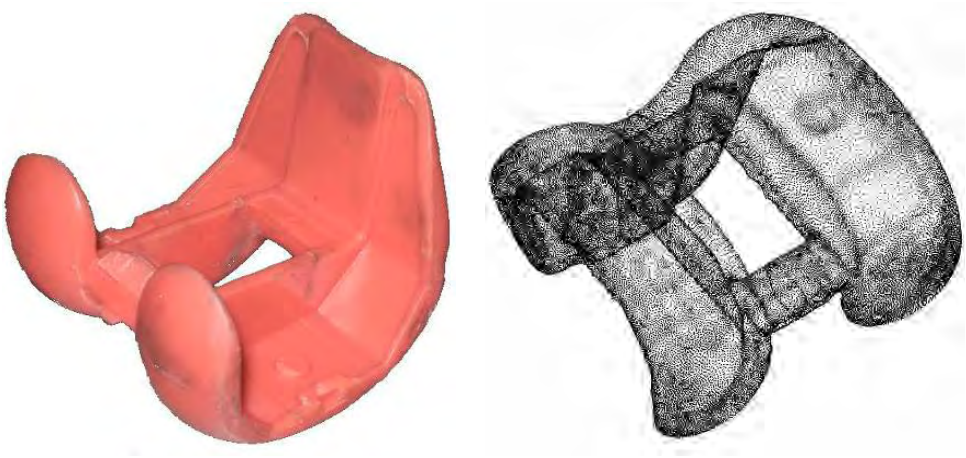


Figure 7. The wax pattern and point cloud of the knee implant (1.729.003 points)

The CAD geometry of the knee implant was exported on an STL file, resulting in 40368 triangles, as shown in Fig. 8.

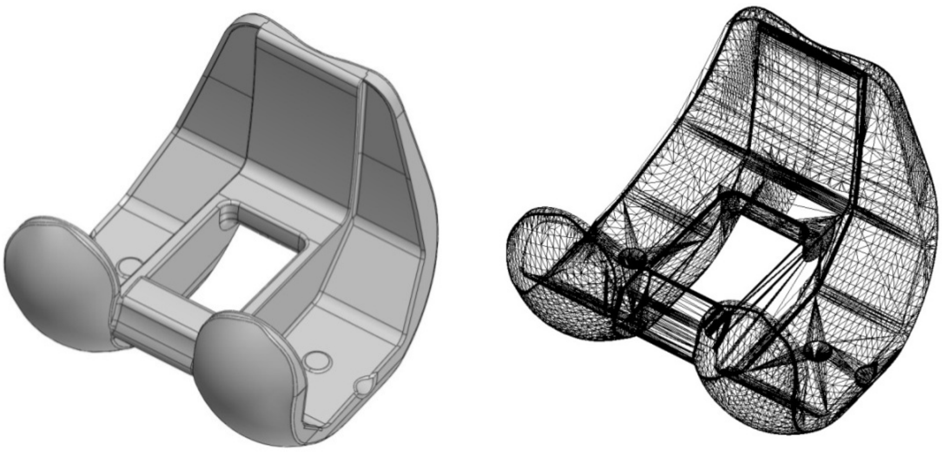


Figure 8. The SolidWorks and STL model of the knee implant (40368 triangles)

5. THE PRINTING PROCESS

The implant prototypes were produced in the 3D printer Objet 30 polyjet machine and its production took place in the Center for Numerical Simulation and Digital/Rapid Prototyping. Models that are saved in a CAD program as STL files may be inserted into the Objet Studio tray. Fig. 9 and Fig. 10 show the STL files loaded in Objet Studio software. The orientation of models on the build tray affects how quickly and efficiently they will be produced by the 3D printer, where and how much support material is used, and whether or not model parts will have a gloss finish. To minimize printing time [7]:

- the longest dimension of a model must be placed along the X-axis;
- the smallest dimension of a model must be placed along the Z-axis;
- the tallest model must be placed on the left of the tray.

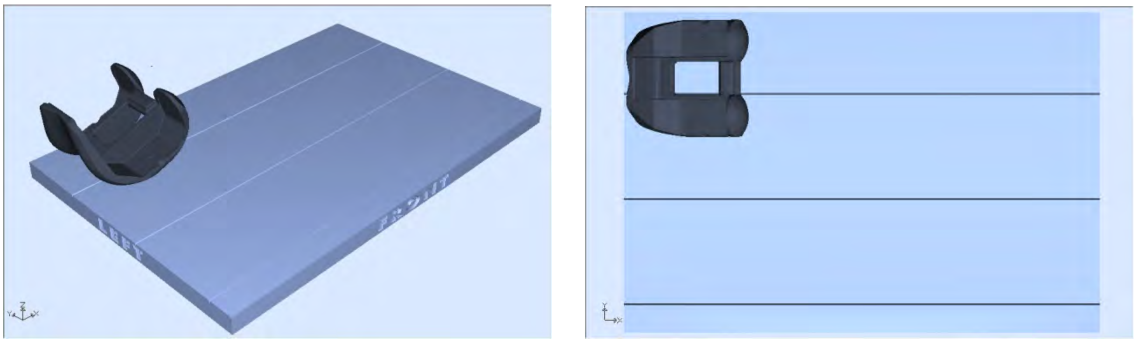


Figure 9. The STL file of the knee implant loaded in Objet Studio software

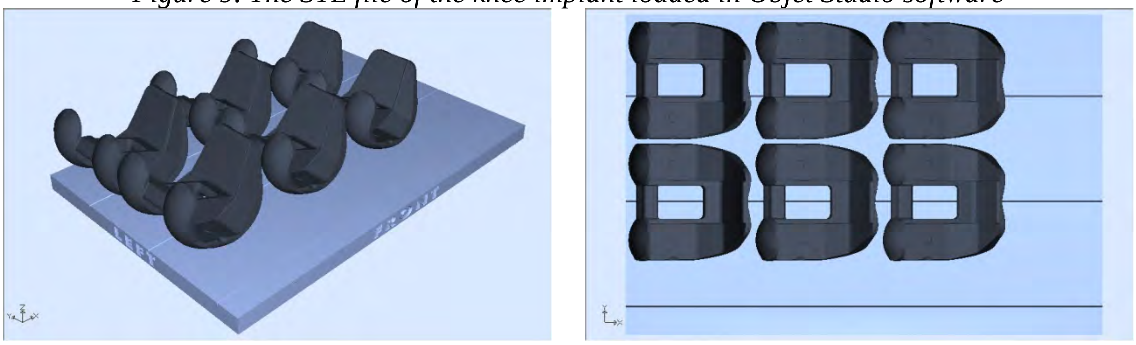


Figure 10. The 6 STL files of the knee implants loaded in Objet Studio software

When a tray is ready to be printed, it is sent to Job Manager, where it is placed in the print queue. When the job reaches the head of the queue, Job Manager preprocesses the tray file to create slices, and feeds them to the 3D printer. The printing parameters for the two case study are shown in Table 2.

Table 2. Printing parameters for the knee implant

Parameter	**UM**	**Knee implant 1 piece**	**Knee implant 6 pieces**
Material	-	VeroBlack	VeroBlack
Model Material	g	123	708
Suport Material	g	118	678
Printing Time	h/min	16 h 37 min	29 h 07 min
Layer Thickness (Z-axis)	μm	28	28
Triangles number	-	39164	234960

Objet Studio software offers the following additional features [7]:

- dividing objects - to produce objects larger than the build tray by dividing the model into separate parts.
- choosing the support strength - when producing models, support material fills some hollow and empty sections. Objet Studio allows to adjust the strength of the structure formed with the support material.
- smartcast - filling models with support material - many objects placed on the build tray from STL files are "solid". This means that, when printed, the model will be completely filled with model material. Often, especially with large objects, this is unnecessary. Instead, the model can be filled with support material, which is less costly. It is also advisable to fill models with support material when preparing them for investment casting, since this material burns off more quickly during the process of making the cast. Objet Studio enables to print objects on the build tray with an outer shell of model

material and a center filled with support material. This feature of Objet Studio is called "Smartcast/Hollow".

For optimal efficiency, the two knee implants were decreased in the ratio 1:0.6 and manufactured along with a number of other parts. Fig. 11 shows the different stages in the printing of the knee implants. Fig. 12 shows the removal of the support material with Objet Waterjet System from the knee implants.

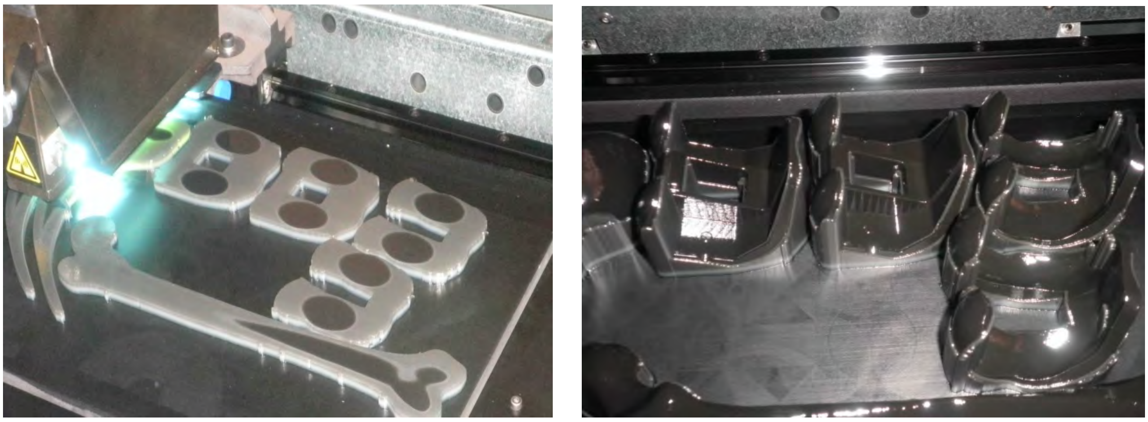


Figure 11. The different stages of the knee implants printing

Figure 12. The support material removal with Objet Waterjet System

Fig. 13 shows the final shape of the two knee implants, produced with 3D printer Objet 30.

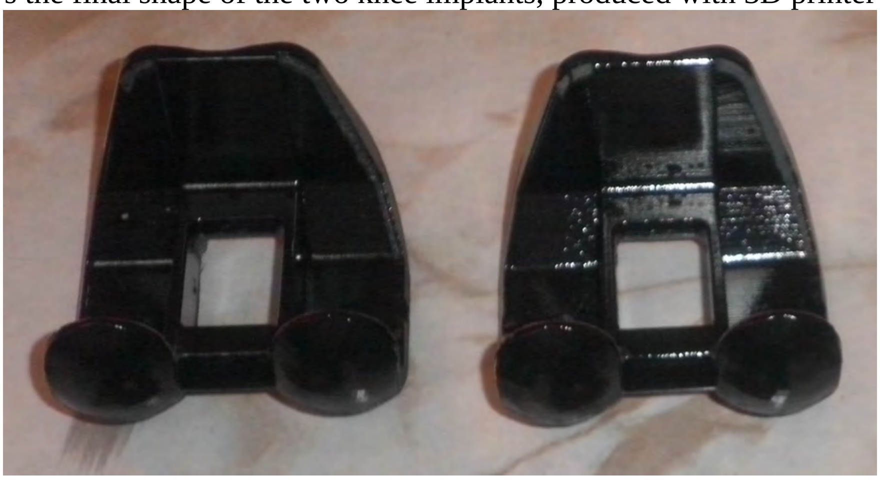


Figure 13. The final shape of the two knee implants

Additive Manufacturing technology is used to produce the pattern for investment casting. The acuracy of the produced patterns is compatible with the accuracy of those used in medical field, especially for orthopedic surgery. The use of this semi-finished product is double. Firstly, it is possible to use this pattern as non wax pattern for investment casting. Secondly, by using the PolyJet patterns it is possible to make a silicon mould and with it cast the wax patterns in the vacuum chamber. Investment casting technology is applied hereafter.

6. CONCLUSION

The application of Additive Manufacturing technology in the medical field is an invaluable contribution of engineering technology to orthopedic surgery field. The PolyJet technology can be used to create complex objects, like knee implants, and to use these objects for investment casting process as non wax pattern or for AM-fabricated molds for wax injection (indirect tooling). The following advantages are important: surface quality, smoothness details, great level of accuracy and reduced manufacturing time. Advances in Additive Manufacturing material will undoubtedly produce ″clean″ parts that can be used directly as implants.

The paper ends with a hope that in the future, Rapid Investment Casting solutions will emerge with the capability to provide dimensionally more accurate and better surface finish of medical implant castings of any size, shape and material with more speed and lower costs.

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