Machine Dynamics Research
2016, Vol. 40, No 3, 67-78

Application of FFF Method in Orthopedics

Anna Kiełbus*[1], Karolina Furyk – Grabowska[3], and Ksenia Ostrowska[2]

[1]Cracow University of Technology , *Product Engineering Institute*
[2]Cracow University of Technology , *Laboratory of Coordinate Metrology*
[3]3D FLY

Abstract
As a part of realization of international project "3DCENTRAL - Catalyzing Smart Engineering and Rapid Prototyping" the cooperation with 3DFly enterprise and Lewkowicz Orthopedic Studio has been started concerning production of hand epithesis with use of method Fused Filament Fabrication (FFF). In the article, two different cases of producing the epithesis was described, as well as the process of creating the cover of the lower extremity adjusted to the patient's needs.

Keywords: rapid prototyping, FFF method, 3D print, 3DCentral, epithesis, orthopedics.

1 Introduction

As a part of realization of international project "3DCENTRAL - Catalyzing Smart Engineering and Rapid Prototyping", which main purpose is leading to European perfection in international cooperation in technology, innovation, transfer and business efficiency in terms of intelligent engineering and rapid prototyping, the actions leading to create specialized support program in this field - support web, are made. This project is carried out with 11 partners from 6 different countries, which are: Italy, Slovenia, Austria, Hungary, Germany and Poland (represented by Małopolska region). Main fields of the projects are: virtual reality, intelligent materials, 3D scanning and rapid prototyping.

One of the actions taken in terms of the created support web in the field of rapid prototyping is the project of creating a hand epithesis using Fused Filament Fabrication (FFF) method. Cracow University of Technology has started the cooperation with 3DFly enterprise and Lewkowicz Orthopedic Studio (http://lewkowicz.com.pl/).

Rapid prototyping is creating physical 3D objects layer after layer directly from models in the computer which are created with CAD software. For the first time this method has been used in 1980s as stereolithography (SLA) (Venuvinod and Ma,

*kielbus@mech.pk.edu.pl

2013). One must remember that currently the term of rapid prototyping does not only mean creating prototypes, which is why you can often see the term "3D print". No one is surprised anymore by the information from science world, media or press about possibility of printing elements like implants (Corney et al., 2005), prosthesis of the injured organ or tissue, which can be inserted into human body (El-Ghannam et al., 2013).

Created networks of cooperation (Mielck et al., 2016) aimed at sharing knowledge and experience among in producing limbs prostheses. Often the web is created by individual person for whom professional prosthesis is too expensive. The particular case are parents of children with amputated limbs. The price of prosthesis is quite high and the child needs to change prostheses due to growing up. One of the first projects of the hand was model created by Mick Ebeling for 14-year old boy Daniel Omar from South Sudan. Most of the projects of the prosthesis of the upper limb are not individualized.

No limb significantly lowers the quality of life of the patient. In order to make it better, cosmetic prosthesis, which is an anatomical portrait of the limb, may be used. It perfectly reproduces the healthy limb, helping the patient in coming back to normal life. The main purpose of the hand epithesis is replacing it in the visual way. Its task is to reconstruct the anatomical details such as nails, fingerprints, blood vessels, hair, etc. The authors has described cases of producing epitheses for two patients. Step by step, the process of creating a cover of prosthesis of lower limb adjusted to patient's expectations was described.

The natural appearance of epitheses and adjusting the cover of prosthesis to individual needs of client are challenges that meet the engineers. Currently manufacturers focus on using the 3D print technology in medicine. It relates not only to creating "artificial organs", but also to creating whole kind of medical help, epitheses, prostheses (rehabilitation supplies) or medical gear. The possibility of creating epitheses, orthoses, prostheses using the 3D print technology is a chance for a "normal life" to many people.

The main purpose of the reasearch was designing and creating a prototype of hand epithesis and cover of the prosthesis with FFF method. Currently it is one of the most common methods of accretion manufacturing which is embedding of the melted material layer after layer, more commonly known as FDM (Fused Deposition Modeling) which was patented by the Stratasys company. Because this name was patented, currently the producers of printing devices in a very similar technology use another names. The example of such solution is Layer Plastic Deposition (LPD) technology, which is used by Zortrax or technology based on Rep-Rap project, where the process of printing was named as Fused Filament Fabrication (FFF), which was used to create the mentioned elements. Process of producing elements using the FFF method is based on a few basic steps common for all of the accretion manufacturing methods (Fig. 1).

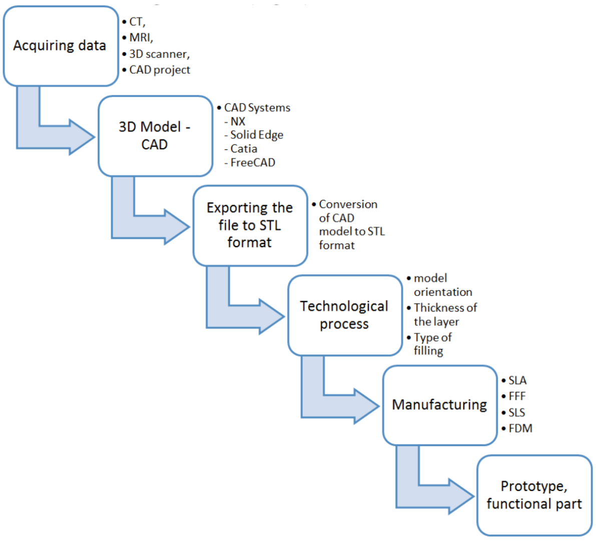

Fig. 1. Scheme of the process of manufacturing using accretion methods.

Method FFF comprises creating a 3D element layer after layer from ductile material (filament) given by the heads equipped with heated orifices. (Fig.2.). After laying given layer the work table lowers itself and the process is repeated (Wichniarek, 2014).

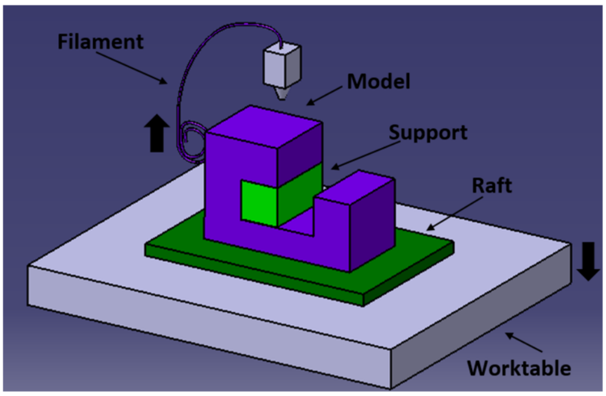

Fig. 2. Scheme of the FFF method.

The complexity of produced elements often results in construction requiring the usage of support, then in each layer, apart from construction material, the support material called the support is placed.

In the FDM print method two types of supports are recognized:

- support created from the same material as the main model, it is specially designed to be easy to remove, for example to be ripped off or cut off with a knife

- support created from the material which has other properties than construction material which makes it easy to remove, for example by dissolving in the water (Sęp and Budzik, 2015).

The construction materials used in FFF method because of the commonness and low price are usually ABS (Acrylonitrile Butadiene Styrene) and PLA (Polylactic). These materials have similar physical properties like weight and resistance to attrition. Market of available materials used in FFF method is still developing. Thanks to that this method can be used in more and more kinds of industry. Dynamic development of the growth methods for medical use has resulted in the development of the biocompatible materials at the same time (Bibb et al., 2014). One of the most common biocompatible materials is PCL (Polycaprolactone) (Chia and Wu, 2015). It is a biodegradable material with low melting and vitrification temperatures. PCL has found its use mainly in tissue engineering as the material used for creating scaffolds and because of its ability to decay step after step due to hydrolysis of ester bonds it is used to produce medicine and surgical threads (Karbowski et al., 2014). Next material used in medicine is thermoductile ABS -M30i of the Stratasys company. This biocompatible material is used to construct prototypes, functional parts which are sterilized during exploitation, so it can be used in pharmaceutics or medicine. Very similar material of Stratasys company is PC-ISO material, which because of its high durability is used in creating medical devices. In order to use FFF method effectively it is necessary to use certain filaments of which constant development helps in foreseeing that in the future the use of the accretion manufacturing in the medicine will be more common.

2 Research methodology

2.1 Manufacturing of epithesis

The process of a epithesis design is strictly connected to the type of after-surgery field, which will be prepared by the doctor managing the amputation surgery. Everything depends on type of the loss, which results in process of designing the epithesis strictly connected to patient's preferences, as this product must be individually adjusted. In presented cases, designed and created epithesis was a reproduction of the whole hand directly connected to prosthetic funnel. First case concerned a person which had specific establishments concerning epithesis to ease everyday actions. The person was equipped in wooden funnel and the epithesis was supposed to fulfill following assumptions:

- easy disassembly - patient worked as a worker. In his job epithesis made with 3D technology was changed to more durable, however less aesthetic epithesis made of resin or the hammer end,
- adequate shape - epithesis was meant to enable holding the steer of the bicycle,
- time of the epithesis manufacturing - maximally 72 hours,
- color - matched to the skin color as much as possible.

Assumptions listed above, especially the time limits resulting from the patient's situation were different from the second described in this article, where the main assumption of the patient was getting an epithesis with higher mechanical properties (more impact resistant) as well as lowering the time and the price of the prosthesis manufacturing.

2.2 Epithesis manufacturing step by step

There are four basic steps of epitheses creation (Fig. 3):

- preparation of the gypsum model - pre-execution of the model excludes scanning errors caused by patient motion .
- scan of the model - in the described cases was taken scans of a healthy hand and stump. In the other cases, such as skull reparation, was taken data from computed tomography (Haq and Haq, 2015).
- preparation of the CAD model - resizing and smoothing of the model, etc . ,
- printing of real 3D model - the step consists of several steps as e.g. finishing.

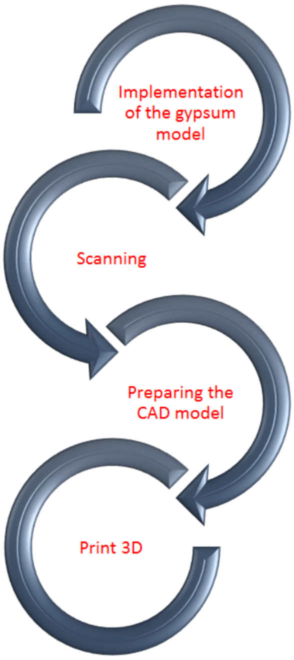

Fig. 3. Steps of manufacturing of epitheses.

The first step was taking measures. In this purpose the imprints of the stump (case 2) and the healthy hand were made (the setting of the hand was adjusted to patients' needs). Next, the measurement of the gypsum models was made with the coordinate measuring arm ROMER Absolute Arm of the Hexagon Metrology company, and in the case of the first patient the healthy hand was scanned, based on which the CAD model was created.

Fig. 4. The process of creating a healthy hand imprint.

The second step consists of analysis of cloud of points and data processing. Use of cloud of points as a set of dimensions consisted in reading characteristic dimensions through cooperating with the machine computer software PC-DMIS of the Wilcox Associates company, basing on which the certain CAD models were created. In the second case two models were designed:

1. Project of epithesis with funnel

2. Project of epithesis decreased in the thickness by the amount of 0.5 [mm], on which the sillicon was put in the last step

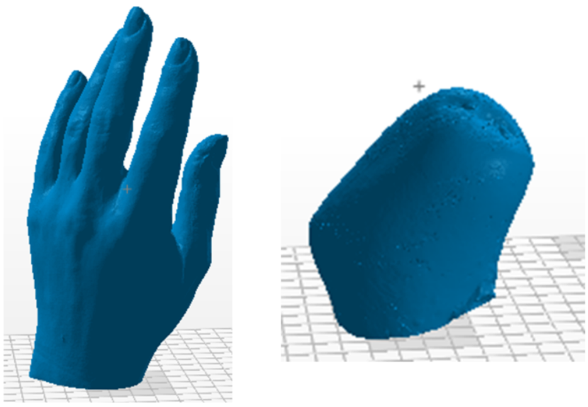

Fig. 5. CAD models of hand and stump.

The third step was consisting of printing the designed models. In this step the important aspect is right choice of materials. One of the most used materials is PLA (due to price and vast color choice). One needs to pay attention to elastic materials, such as Fiberflex 40D of the Fiberlab company (Sęp and Budzik, 2015) or materials of the Ira3D company called Gummify Skin (gum filament giving the effect of the artificial skin) (Bibb et al., 2014), which is currently getting used more and more in the technology of printing using the FFF method.

The described prototypes were made of two different materials. In the first case HD PLA (Fiberlab) material was used, while in the second case the Fiberflex 40D and ABS-X materials of the Future Innovative Technologies company were used.

In the process of manufacturing parts of complex shapes it is vital to choose the right printing parameters. In the first case the print of a single layer thickness 0.19 [mm] was used. In the phalanges part and the forearm 80% of the filling was used, while in the metacarpal part 50% of the filling was used. After printing, the model was accordingly to the producers information tempered for 15 minutes in the temperature of 80 [°C]. Due to this the material aside from higher mechanical durability is also resistant to temperatures up to 140 [°C]. For the print the Maker Bot Replicatior Z18 device was used.

In the second case for the elastic material the thickness of the single layer 0.19 [mm] and filling of 50% were used. In the case of ABS-X material the same parameters as in the first case were used. For the print the 3D Kreator Motion printer was used.

Fig. 6. Printed models of epitheses - on the left HD PLA material and on the right Fiberflex40D material.

The fourth step - finishing of the printed elements:

- for the first patient the finishing consisted of delicate smoothing of the model and mounting the insert,

- for the second patient the finishing of model was needed in the case of print from the ABS-X material where the sillicone layer was placed.

The last step consisted of checking the accuracy of manufactured parts and mounting of the epithesis.

Fig. 7. Epithesis mounted in a wooden funnel.

2.3 Creating of the covers

Currently, aversion to using prosthesis in public space and fear of the social isolation of the disabled people are slowly fading and these people more and more often talk about their disability openly and consciously. It is because of the possibility of using a 3D printing technology that disabled people show their individualism and strength through creating their individual cover showing their lifestyle and personality.

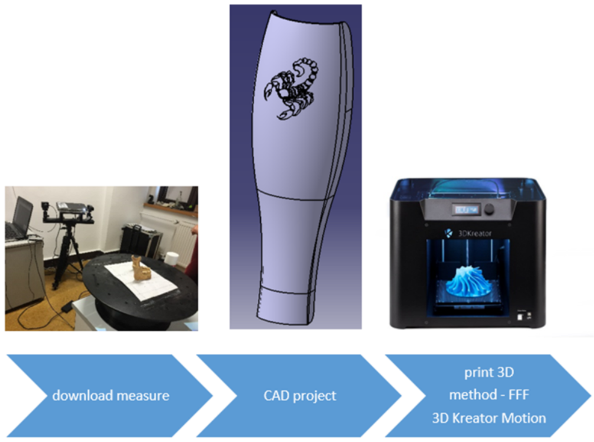

Fig. 8. Cover manufacturing step by step.

Process of creating a cover starts from getting characteristic measures through 3D scanning or mechanical measure of the healthy leg (Fig .8). Next, basing on the taken measures the cover project with patient's demands is made. In the last phase the real model is made. One of the most popular methods due to the financial advantages is covering the prosthesis with special sponge. In this method the skeleton of the leg's prosthesis is flooded in special sponge, which is then shaped by prosthetist, making it similar to healthy limb. On the real cover, a thick cosmetic stocking of the skin color is placed. Another more expensive, but certainly more realistic option is accessory silicon cover, which from the appearance and touch point of view is very similar to human skin. The last described method, which main advantage is individualized manufacturing of the cover of prosthesis is using the 3D printing. How efficient and needed it may be shows the national polish action "For prosthesis" led by Mrs Magdalena Baranowska. On the webpage of her project she shares a full methodology of creating covers in 3D printing technology (http://naproteze.blogspot.com/). The process of creating cover of prosthesis in FFF technology can be presented in a few steps:

First step was consisting of measuring dimensions of the prosthesis. In described case the patient had a leg prosthesis with the knee prosthesis Ossur TotalKnee 200. Characteristic dimensions were acquired as the result of measuring of knee prosthesis and the healthy leg and were consulted with patient.

Second step is project of cover Fig. 9, where shape and appearance are dependent on the patient demands and technological possibility of the method used for creating it. Main goals of the project were:

- possibility of an easy disassembly of the cover,
- streamlined shapes adjusted to healthy leg together with the scorpion project,
- project made entirely using the 3D printing technology,
- Easy-to-process material enabling entire smoothing.

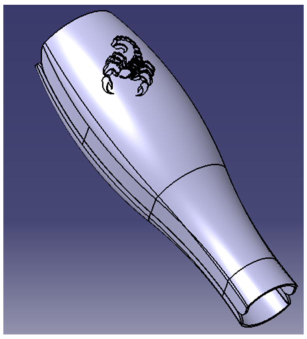

Fig. 9. CAD project of the prosthesis cover.

As a material ABS-FX of the Future Innovative Technologies company was used. It is a material of higher plastic flow and viscosity factor, which is characterized by small shrink. For creating the cover a 3D printer Kreator Motion was used with these parameters:

- Thickness of a single layer 0.29 [mm] - In the further step the model will be processed, which is why it is not necessary to use thinner layer,
- filling of 100%.

Last step is finishing which consists of bonding (cover was only printed in parts), grinding, chemical processing and painting.

3 Conclusions

The presented process of manufacturing of epitheses and cover projects show that modern methods of manufacturing, such as FFF method, create new possibilities in terms of designing and creating personalized orthopedic supplies. However, it needs to be said that the project is concerning a living person, which is why the cooperation with the patient even after mounting epithesis or cover is very important. In all of the described cases the patients were satisfied with the products that were created for them, which does not mean that after a longer use of the product they will not have a few comments that should be immediately included in further projects of that kind. To the advantages of the using 3D printing in the orthopedics it should count: speed - mounting is the first case took 48 h, low price, possibility of choosing the right material, individualizing of the project.

References

Bibb, R., Eggbeer, D., and Paterson, A. (2014). *Medical modelling: the application of advanced design and rapid prototyping techniques in medicine*. Woodhead Publishing.

Chia, H. N. and Wu, B. M. (2015). Recent advances in 3d printing of biomaterials. *Journal of biological engineering*, 9(1):4.

Corney, J., Hieu, L., Zlatov, N., Vander Sloten, J., Bohez, E., Khanh, L., Binh, P., Oris, P., and Toshev, Y. (2005). Medical rapid prototyping applications and methods. *Assembly Automation*, 25(4):284–292.

El-Ghannam, A., Hart, A., White, D., and Cunningham, L. (2013). Mechanical properties and cytotoxicity of a resorbable bioactive implant prepared by rapid prototyping technique. *Journal of Biomedical Materials Research Part A*, 101(10):2851–2861.

Haq, A. and Haq, R. (2015). *Characterization and development of polycaprolactone (PCL) /montmorillonite (MMT) /hydroxapaptite (HA) nanocomposites for fused deposition modelling (FDM) process*. PhD thesis, Universiti Tun Hussein Onn Malaysia.

Karbowski, K., Banach, M., Czepko, R., Masłowski, P., and Sujka, W. (2014). Inżynieria rekonstrukcyjna w modelowaniu wyrobów medycznych. *Mechanik*, 87.

Mielck, A., Kilian, H., Lehmann, F., Richter-Kornweitz, A., and Kaba-Schönstein, L. (2016). German cooperation-network 'equity in health'—health promotion in settings. *Health Promotion International*.

Sęp, J. and Budzik, G. (2015). Możliwości aplikacyjne technologii rapid manufacturing w przemyśle lotniczym. *Mechanik*, 88.

Venuvinod, P. K. and Ma, W. (2013). *Rapid prototyping: laser-based and other technologies*. Springer Science & Business Media.

Wichniarek, R. (2014). Badania wskaźników techniczno-ekonomicznych wyrobów wykonanych przyrostowo. *Rozprawa doktorska, Poznań*.