

Manufacturing Methods for Medical Prostheses– A Review

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ABSTRACT

The main objective of this paper is to review the manufacturing methods that can be used for fabricating medical prostheses. The medical prostheses have different functions and applications. Selection of manufacturing method is made based on the material, design, and mechanical properties of the prostheses. The conventional manufacturing methods that had been applied for manufacturing prostheses are machining, incremental sheet forming and investment casting. The combination of computer numerical control and additive manufacturing has been able to improve the process efficiency of these methods. However, direct fabrication by additive manufacturing has been able to replace the conventional method with better process efficiency and product accuracy.

INTRODUCTION

Prosthetics is a division of medicine that focuses on surgical procedures for replacing the body parts that have been removed due to illness or accidents with artificial components. The objectives of the artificial component are not only to replace the human part but also to restore its normal function. These technologies facilitate recovery and improvement of human biological functions continuously. There are two types of biomechanical prostheses, ready-made prostheses and custom-made prostheses. Ready-made prostheses are designed and manufactured in standard sizes. Unlike ready-made prostheses, custom-made prostheses are made to fit the patient. These prostheses can be fabricated by different manufacturing methods. The selection of suitable manufacturing method is made based on standard criteria such the design, application, and material. This paper will review the manufacturing methods that can be applied for fabricating medical prostheses for various applications using different types of materials.

MANUFACTURING METHOD

Conventional Manufacturing Methods

One of the conventional manufacturing methods that can be used to manufacture prostheses is machining. It is a method that involves material removal process that is conducted with a cutting tool. Machining used to be one of the main manufacturing methods for fabricating orthopaedic implants. Compared with advanced manufacturing technologies, machining is considered to be fairly cost effective and user-friendly. It can also be used to improve the surface finish of the finished product. This method is highly recommended for manufacturing implant components with simple designs. The combination of machining parameters can determine the quality of the

finished products (Ahilan, Kumanan, Sivakumaran, & Edwin Raja Dhas, 2013). Optimum working parameters need to be determined according to the working material in order to achieve the good surface finish. With the development of advanced manufacturing technologies, conventional machining was replaced by computer numerical control (CNC) machining. The aid of CNC has managed to reduce the process duration, making it more user-friendly with a minimum requirement of human input. Micromachining method, on the other hand is a method that uses laser aided technology (Wall, 2012) that has the ability to modify the surface structure of polymer components with micro-scale surface texture. It is also applied for manufacturing tiny implant components as well. 5 axis CNC have better flexibility in machining complex geometrical designs as compared to 3-axis CNC machine. The only limitation of machining is the deposition of raw material waste (Cronskär, Bäckström, & Rännar, 2013). Incremental sheet forming (ISF) on the other hand is a forming process of sheet metal through continuous forming. This method uses a rotating tool through a progressive increase in pressure and it is adaptable to CNC milling equipment (Fig. 1).

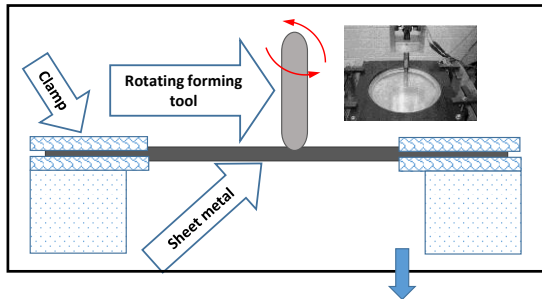


Fig. 1: SPIF schematic diagram (Ambrogio, De Napoli, Filice, Gagliardi, & Muzzupappa, 2005)

There are a few techniques of ISF such as single-point (SPIF), and two-point (TPIF). SPIF is a method that uses a single point contact while TPIF utilizes two points contact on the sheet metal. This method can produce asymmetrical product via spinning, flow forming, and shear forming. This die-less method makes the process more cost effective compared to machining. However, ISF processing time is directly dependent on the sheet thickness, material and part geometry. Determining the process parameters can be a challenge especially with a new material. Therefore, this method is more suitable for straightforward geometry and small-batch manufacturing. Ryutaro et. al (Hino, Kawabata, & Yoshida, 2014) had developed ISF by the application of laser and was able to improve the formability of the sheet material and reduce the residual stress on the finished product. Unlike ISF, investment casting is a manufacturing method that uses patterned moulds for casting (Pattnaik, Karunakar, & Jha, 2012). Molten metal is poured into the mould and left to cool to form solid metal. Investment casting used to be an alternative method for manufacturing metal medical implants. However, the conventional method for fabricating mould used to be expensive and time-consuming. To overcome this limitation, additive manufacturing was introduced for fabricating the mould. This combination has managed to reduce the lead time and has made the investment casting economically more effective. Compared with wax, silicone made mould are easier to remove from the solid product as well. One application of investment casting in manufacturing medical implants is in prosthodontics that focuses on designing and fabricating artificial implants for mouth parts including teeth. However, the quality of implant fabricated is depending on the quality of the mould. Good mould will produce an implant with excellent fit and reliability.

Additive Manufacturing Methods

Additive manufacturing (AM) is a manufacturing method by material deposition in layers that build a part based on standard tessellation language (STL) formatted file from computer-aided design (CAD) software. The product of AM can be designed by the digital scan of the part and from the conceptual part design. It is a direct and straightforward method that is more feasible and relevant for manufacturing medical implants. The AM has the flexibility of using a variety of available materials with desired customizations such as porosity and surface roughness as well. There are three types of AM method which are solid based, liquid based and powder based AM. Fused deposition manufacturing (FDM) is one application of solid based AM that eject thin filament through an extrusion nozzle on a moving platform as illustrated in Fig. 2.

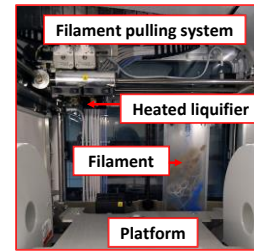


Fig. 2: FDM equipment

FDM is the most appropriate manufacturing method polymer based implant because it provides full control on the working parameters. FDM is known to be cost effective and user-friendly as well. However, due to the limited material available, FDM application for prostheses is limited as compared to metal based AM. Unlike solid based AM, liquid based AM is a solidification process of liquid raw material via curing. Some of the methods of liquid based AM are stereolithography (SLA), and continuous liquid interface production (CLIP). SLA's building process is known as photopolymerization. It is a process of polymer solidification by application of ultraviolet (UV) rays that act as a catalyst for the liquid resin reaction (Fig. 3). It is a continuous process of making the part layer by layer until a solid object is constructed.

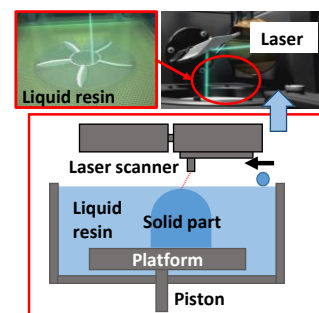
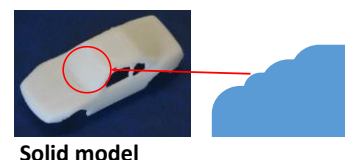


Fig. 3: SLA schematic diagram ("Stereolithography," n.d., "The Best SLA 3D Printers," n.d.)

SLA is known to have excellent dimensional accuracy and surface finish for polymer based products (Zhou, Ye, & Zhang, 2015). Due to this advantage, nano-SLA technology was developed for the purpose of manufacturing micro devices with complex geometry (Ha & Yang, 2014). Furthermore, micro-SLA (MSLA) that was developed could produce fine resolution scaffold with excellent mechanical properties that are similar to bone. This technology is showing great potential in the fabrication of customized tissue scaffold for cell regeneration. Continuous liquid interface production (CLIP) is another modified liquid-based AM that was developed to improve staircase effect (Fig. 4) (Januszewicz, Tumbleston, Quintanilla, Mecham, & DeSimone, 2016).



Solid model

Fig. 4: Staircase effect on finished product fabricated by SLA (Arni & Gupta, 2001)

CLIP deposits continuous liquid compound (Yang, Zeng, Vieira, & Olsson, 2016) that manipulates oxygen-comprised area, known as the 'dead zone' (Fig. 5). It is a small gap in between the oxygen absorbent window and the curing resin. Unlike SLA, CLIP promotes faster building process..

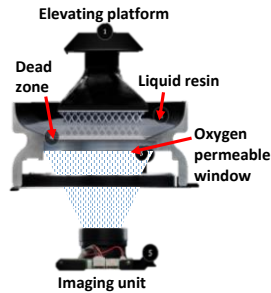


Fig. 5: CLIP equipment ("CLIP Process," n.d.)

This technology is relatively new and has the ability to process biological and elastic materials (J. R. Tumbleston et al., 2015) that are suitable for artificial tissue and cartilage. Unlike the previous two AM types, most of the powder based AM equipment are used in manufacturing metal based medical implant. The AM equipment that are working by using powder material are laser sintering, selective laser melting (SLM), electron beam melting (EBM), and laser engineered net shaping (LENS). Selective laser sintering (SLS) is a manufacturing technique that solidifies powder material through sintering. It is solidification process that uses thermal energy to fuse the powdered particles together at a temperature in between the melting temperature and half of the melting temperature (Kruth et al., 2005). SLS has a wide variety of process materials such as a polymer, metal alloy, and metal-ceramics mixture (Tiwari & Pande, 2014). Direct Metal Laser Sintering (DMLS) works specifically with powdered metals and metal alloys. Unlike SLA, SLS and DMLS built part does not require support structure because of the excess powder act as surrounding support (Fig. 6).

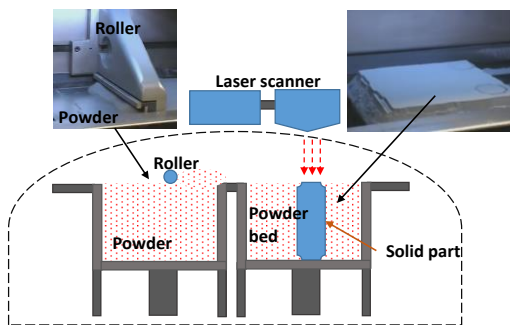


Fig. 6: General schematic diagram of DMLS ("3D Metal Printed Parts," n.d.; Frazier, n.d.)

SLM has a similar working principle to DMLS that employ full melting mechanism. This method is highly recommended for metals and as well as ceramics because it produces lightweight but strong and robust products. The pore structure of the part can also be customized. However, the working parameters need to be customized for different

materials, making this method more difficult to control (Pacurar & Pacurar, 2016). Another method which is EBM is known to produce high accuracy parts by utilizing electron beam to melt the powdered material (Fig. 7).

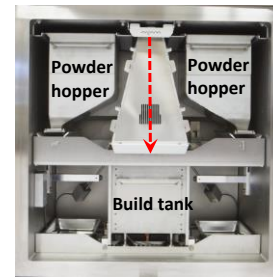


Fig. 7: EBM equipment and schematic diagram ("EBM Hardware," n.d.)

EBM is more time efficient and user-friendly compared to SLA because electron beam energy possesses higher density that increases building process (Parthasarathy, Starly, Raman, & Christensen, 2010). This method also has the ability to improve the material's mechanical properties and strength (Murr, 2015). Laser engineered net shaping method (LENS) is another type of AM that utilized powder material for building solid parts. Unlike the other method, LENS solidifies melted powder metal in a melted substrate (Cong & Ning, 2017). The process of melting the substrate and the powder metal is conducted by laser radiation as shown in Fig. 8.

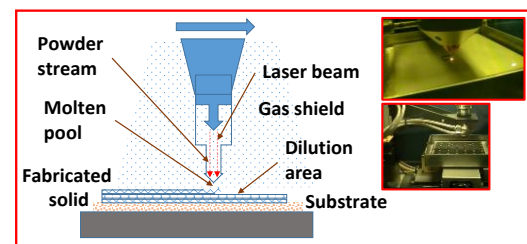


Fig. 8: LENS schematic diagram (Cong & Ning, 2017; "LENS 450 System," n.d.)

LENS has the flexibility of processing most type of powdered metal alloy and ceramic with high complexity and customized porosity (Mallik, Rao, & Kesava Rao, 2014; Niu et al., 2016). However, the final product is prone to surface deformation due to high solidification rate (Gu, Meiners, Wissenbach, & Poprawe, 2012). Due to this problem, a study on heat treatment was conducted and was proven to be able to enhance the hardness of the product (Cong & Ning, 2017).

CONCLUSION

Although conventional manufacturing technology had been enhanced by using computer-aided software, AM technology seems to catch up in manufacturing medical implants. Material removing methods have become less preferred due to the material waste and longer operation time. Furthermore, reversed engineered implants that focus on the geometrical accuracy are more suitable to be manufactured by AM. Integrated approach that was developed has able to increase the processing duration and decrease material waste as

well. Another obvious advantage of AM is its ability to customize the micro structure of the product according to the application. The porosity and strength of the implant could also be further enhanced by the advanced manufacturing method such as electro-discharge machining (Abdu Aliyu, Mohd Rahani, Abdul Rani, & Musa, 2015). Although the overall operation and AM equipment are still costly, this aspect is mainly subjective because it is closely related to the material selection and production volume (Campbell, Bourell, & Gibson, 2012). Besides, there is an obvious trend of equipment price decrement over the past decades (Emelogu, Marufuzzaman, Thompson, Shamsaei, & Bian, 2016). This has proven that the advanced technology will be more affordable in the future and despite this limitation, advanced manufacturing is still gaining recognition from the public. The equipment has become portable and more user-friendly as well. Soon, the medical officers should be able to operate the equipment from the hospital with minimum supervision from technical experts.

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