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Medical Implant Production using Three-Dimensional Printing as a Potential Manufacturing Process in Medical Application

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ABSTRACT

Three-dimensional printing (3DP) is one of the rapid prototyping (RP) technologies that can be a potential manufacturing process in medical application such as implant manufacturing. 3D printing is a layer manufacturing technique and can act as direct production of medical implant. In this research, implant manufacturing process by using MakerBot Replicator 2X 3D printer is proposed as improved alternative of the previous conventional implant production method. This study attempted to investigate the production time and production cost of medical implant manufacturing as compared to the conventional methods. As compared to the conventional method of implant manufacturing, the production time is much shorter than expected and the production cost is more affordable. The results show that 3D printer which is MakerBot Replicator 2X is feasible for direct production of implant manufacturing.

Keywords: *Medical implant; Medical application; Three-dimensional printing; MakerBot Replicator.*

Introduction

Rapid prototyping (RP) technology or currently termed as three-dimensional printing (3DP) can fabricate models with complex geometric forms directly from computerized model, making it very versatile for reconstruction of the

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complex human body [1]. The ability of RP is providing detailed information of the anatomical in a layered format to be used in reconstructing the 3D image. By conventional method of casting or handcrafting, the fabrication of customized implants to fit everyone is challenging [2]. By layer-based nature of RP technologies, the creation of complex freeform shapes is very feasible, hence allowing customization to fit each patient. The main process chain for the production of an anatomic facsimile model (AFM) is shown in Figure 1. The process chain starts with medical indication by medical doctor. Next, data acquisition are obtained either by computed tomography (CT), nuclear magnetic resonance (NMR), positron emission tomography (PET), single-photon emission computed tomography (SPECT) or ultrasonic processes (US). CT scanner is used for reproducing bone structures. Magnetic resonance imaging (MRI) is an application of NMR to show soft tissue in similar manner as the US process. PET and SPECT are both for the reproduction of blood circulation and metabolic disorders. Data acquisition is done by radiologist. Then, Mimics and 3-Matic is used in 3D reconstruction by radiologist and computer specialist. 3D images are reconstructed from the measured values. Implant is produced using rapid prototyping process by RP engineer and computer specialist. Lastly, RP engineer model maker and medical doctor will continue to the implantation process and patient monitoring.

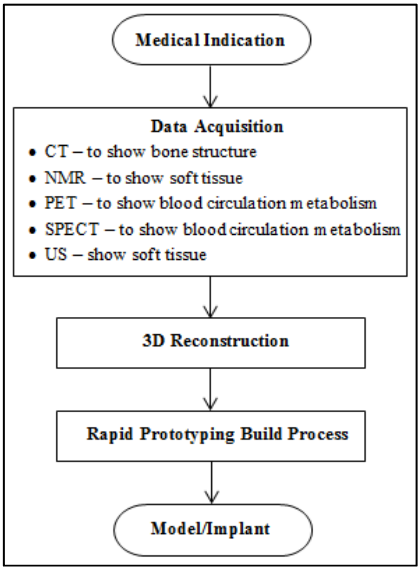


Figure 1: Main process chain for the production of an anatomic facsimile model (AFM) [3].

The conventional method is the most complicated procedure and usually the procedures include casting or forging, machining, fine machining, polishing and coating [4]. This study targeted to produce the implant as a substitution of the hard tissue by using three-dimensional printing (3DP) which is MakerBot Replicator 2X (Makerbot Corporation, USA) as improved from the previous conventional methods. MakerBot Replicator 2X is an affordable 3D printer that adopted and inspired by fused deposition modeling (FDM) technology. Therefore, the purpose of this study is to evaluate the production time and production cost of medical implant manufacturing as compared to the conventional methods.

Methodology

Materials selection

Material used in this study is polymethyl methacrylate, (PMMA). This is because PMMA is already established in medical application and researchers from previous and recent studies are mostly use PMMA in medical implant, although produced by conventional method [5]. In addition, PMMA is biocompatible material and highly recommended by surgeons [6]. PMMA has density of 1.18 g/cm^3 and tensile strength of 72 MPa [7]. By using 3D printer which is MakerBot Replicator 2X, the material must be in filament form. Therefore, PMMA filament was purchased from rigid.ink, United Kingdom (refer Figure 2). The diameter of PMMA filament is 1.75 mm with tolerance of 0.03mm.

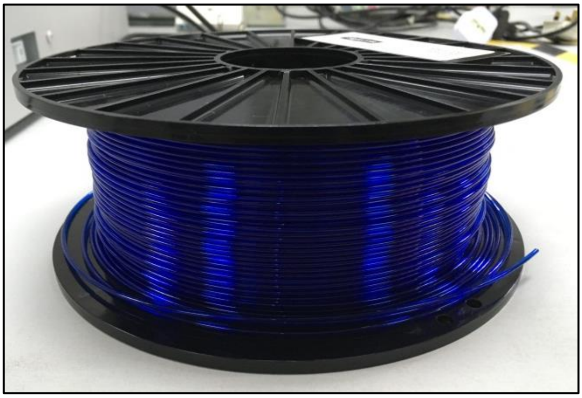


Figure 2: Polymethyl methacrylate, (PMMA) filament.

Parts selection

Three dimensional models have been widely used for preplanning craniofacial and maxillofacial surgery, surgery, spinal surgery, neurosurgery, cardiovascular surgery and visceral surgery [8]. The majority of the medical application of RP has been in the dental surgery field and maxillofacial reconstruction [9]. Cranioplasty is defined as the method of treatment of skull defects. This method required to protect the underlying brain, correct major aesthetic deformities or both [10]. Parietal part was used in this case study and was printed by 3D printer. The parietal bone of human skull is illustrated in Figure 3.

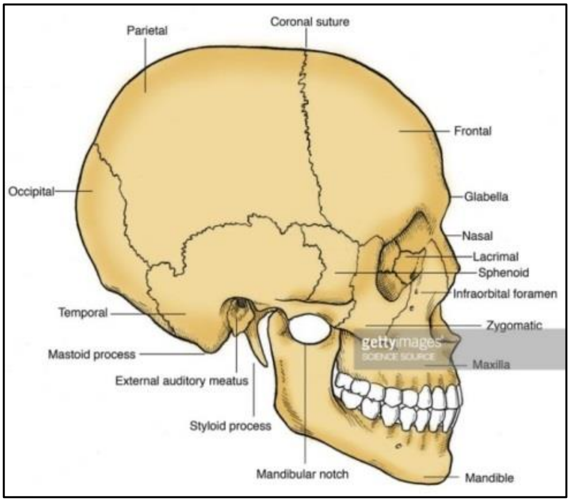
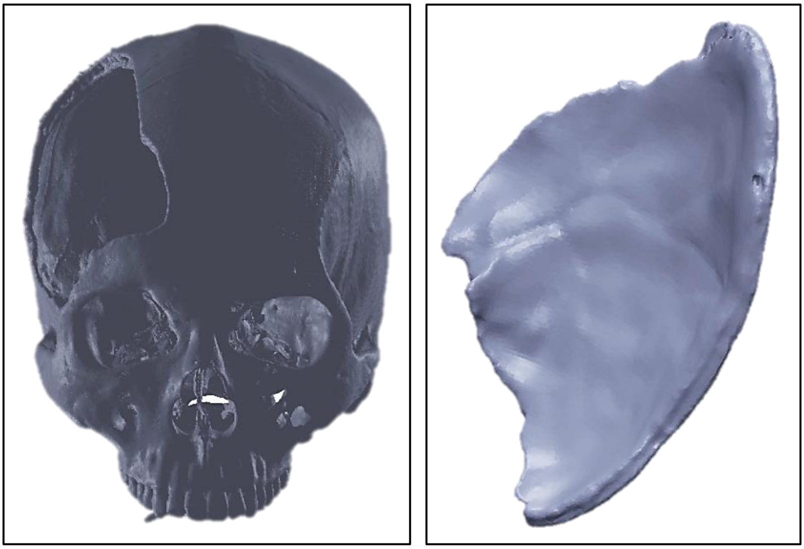


Figure 3: The illustration of human skull [11].

Methods selection

The manufacturing of medical implant models using RP technology began with the data acquisition. Medical scanner was used in acquisition of three dimensional shape data of both internal and external human body structures. Computer Tomography (CT) is commonly used in medical imaging to obtain anatomical information for reproducing bone structures [3]. 3D images were reconstructed from the measured value by using special image analysis processes and were generated into stereolithography or standard tessellation language, (STL) file format. The special programs such as Mimics (Materialise) and 3-Matic (Materialise) were used. In this study, the STL file as shown in Figure 4 was provided by School of Dental Sciences, Universiti Sains Malaysia.



(a) (b)

Figure 4: (a) A patient with a skull defect and (b) designed implant.

Then, this STL file was converted into a list of commands that 3D printer could be able to understand and perform. Through this study, the program used to slice the 3D model is Makerware program. After 3D model was sliced, then the data was sent to the printer which is MakerBot Replicator 2X through USB connection (refer Figure 5).

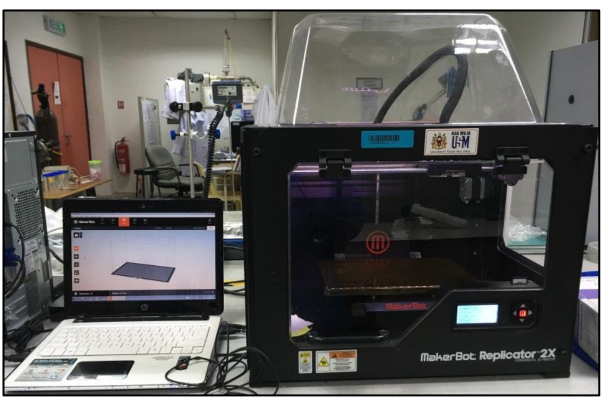


Figure 5: 3D printer (MakerBot Replicator 2X) used in this study and controlled by Makerware program.

A 3D implant model was printed at the printing platform layer by layer. The processing parameters in Makerware program are summarized in Table 1. Kapton tape was used as a platform surface for 3D printing PMMA filament. The kapton tape acts a base layer and was protected the platform surface, while glue stick was applied on the tape to provide adhesion. Before start the printing, the platform was heated up to desired temperature as a countermeasure to reduce warpage and for the filament to stick on the platform. For this implant model, there has supports and raft to support the 3D model during the printing process. Supports and rafts can be either other materials or PMMA itself. In this study, the supports and raft used commercial acrylonitrile butadiene styrene (ABS) filament (Makerbot Corporation, USA).

Table 1: Processing parameter of 3D printer (MakerBot Replicator 2X) in Makerware program.

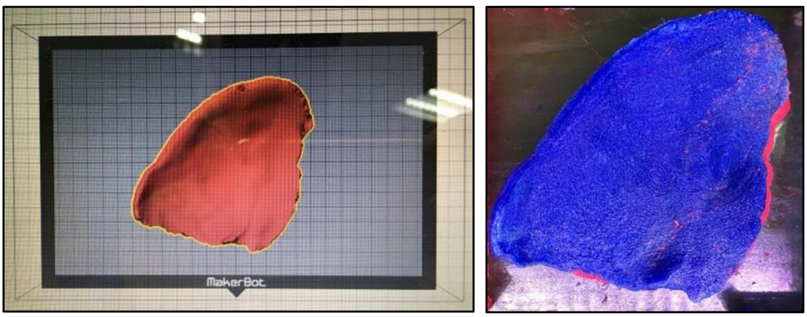
Parameter	**Setting**
Resolution	High
Infill	100 %
Number of shells	2
Layer of height	0.2 mm
Right extruder	Acrylonitrile butadiene styrene (ABS) filament
Left extruder	Polymethyl methacrylate, (PMMA) filament
Right extruder temperature	230 °C
Left extruder temperature	250 °C
Platform temperature	110 °C
Supports and raft	Right extruder
Speed while extruding	40 mm/s
Speed while travelling	60 mm/s

After printing was done, the 3D implant model went through the surface finishing process or known as post-processing method. Then, the process was continued to the next level which is implantation process and patient monitoring were done by RP engineer model maker and medical doctor. At the end of this study, manufacturing process, production time and production cost of implant manufacturing were studied to compare with conventional methods.

Results and Discussion

Methods selection

The 3D implant model were successfully fabricated and printed by using three-dimensional printing (3DP). MakerBot Replicator 2X was used and controlled by Makerware program. During printing process, the processing parameters in Makerware program given by manufacturer were used and there has no alteration of the initial setting. The designed implant and the printed implant are shown in Figure 6.



(a) (b)

Figure 6: (a) Designed implant in Makerware program, (b) printed implant by MakerBot Replicator 2X.

The weight of the filament used to print the implant was 98.99 g and the weight of the printed implant was 60 g. The volume of the part of skull that was removed was 55.5 cm^3 approximately. The weight of bone removed is 119.3 g approximately by assuming the density of human bone is 2,150 kg/m^3 [12]. Therefore, the weight of printed implant was 49.7% of the portion of bone removed. The RP model can be used directly or as a master model. However, in this study, printed implants by MakerBot Replicator 2X was proposed as a direct product. All the phases in procedure of implant production are based only on CT data and linked to CT report automatically. So that, the human errors and its leakage will be reduced and make the surgery results become more successful [1]. The accuracy of the model is limited because of their machining process [2]. In the conventional method, the accuracy is very difficult to obtain, while in RP technology provides very accurate model of the joint of the patient [13].

Production time

The production time for medical implant manufacturing by using three-dimensional printing (3DP) were summarized as shown in Table 2.

The manufacturing process starting from data acquisition by CT medical scanner, 3D reconstruction by Mimics and 3-Matic and lastly rapid prototyping build process by MakerBot Replicator 2X. The production time of medical implant manufacturing depends on the case study. Usually, the cycle time for data acquisition is around 7 to 10 seconds, while the cycle time of 3D reconstruction is 30 minutes to 2 hours depends on the defects of each case. In this study, the cycle time to fabricate 1 unit of medical implant for the data acquisition and 3D reconstruction was approximated 2 hours. Although, the estimated time given by Makerware program for printing a 3D implant model is 11 hours 24 minutes, the actual cycle time was 8 hours 15 minutes. The total cycle time for medical implant manufacturing was 10 hours 15 minutes for this case.

Table 2: Production time for medical implant manufacturing by using MakerBot Replicator 2X.

Operations	**Cycle time (minutes)**	**Cycle time (hour)**
Data acquisition (CT medical scanner) 3D Reconstruction (Mimics and 3-Matic)	120	2
Rapid prototyping build process (MakerBot Replicator 2X)	495	8.25
Total cycle time (in minutes)	**615**	
Total cycle time (in hour)		**10.25**

Production cost

The production costs of medical implant manufacturing depend on the case study which means it differs for each case. The costs of material used in this study were shown in Table 3. The production costs to fabricate the medical implant by using three-dimensional printing (3DP) were summarized as shown in Table 4.

Table 3: Material costs for medical implant manufacturing by using MakerBot Replicator 2X.

Materials	**Unit price (MYR)**	**Quantity**	**Cost (MYR)**
Polymethyl methacrylate (PMMA)	186.36 (£33.95 GBP) per kg	1 kg	186.36
Shipping	93.04 (£16.95 GBP)	-	93.04
Total cost			**279.40**

Table 4: Production costs for medical implant manufacturing by using MakerBot Replicator 2X.

Components	Descriptions	Cost per unit (MYR)
Variable cost		
Direct materials	Polymethyl methacrylate (PMMA) at MYR 279.40/kg	27.94
Direct labor	Data acquisition and 3D reconstruction at MYR 1000/month for 1 staff	100.00
	RP build process at MYR 1000/month for 1 staff	100.00
Fixed cost		
Machine tools and fixture	Data acquisition and 3D reconstruction at MYR 400/unit	400.00
	RP build process at MYR 2/g	200.00
Total direct cost		**827.94**
Overhead charges	MYR 96.60/month	9.66
Total unit cost		**837.60**
Total 10 units costs	MYR 837.60 x 10 units for a month	**8,376.00**

In this case study, the weight of the filament used to print the implant was 98.99 g and approximate to 100 g. So, the weight of the printed implant was considered in calculating the production costs. The weight of the printed implant was measured and the weight was 60 g approximately. Table 4 shows the production costs for a month and 10 units of implant were assumed to be produced in a month. This is because the total cycle time of medical implant manufacturing is 10 hours 15 minutes (see Table 2) which means 2 days of working hours to produce 1 unit of medical implant. The currency was referred to the current currency (April 2017). Overhead charges refer to all costs that cannot be attributed in producing the products [14]. Overhead charges can be maintenance expenses. Maintenance expenses included the expenses in maintaining and repairing the equipment such as changing the kapton tape. The production cost for 1 unit of medical implant is MYR 837.60 or $196.67. Then, the production cost for a month that produced 10 units is MYR 8,376 or $1,966.66.

Comparison on production time and production cost to the conventional method

Production cost of implant manufacturing depends on the size of cranial defect [15], implant material [16], complexity [16] and manufacturing process [17]. Reducing in production time of implant manufacturing resulted in decreasing of the production cost [8]. In this study, the affordable 3D printer (MakerBot Replicator 2X) is used. As compared to the others professional 3D printers that cost at least $50,000, the cost of simpler models such as MakerBot Replicator 2X is between $300 and $3,000, depends on the printer specifications [18, 19].

In medical implant manufacturing, the parts fabricated by using the conventional method such as injection molding cannot be customized and only suitable for large-scale manufacturing. This is because of the expensive tooling [18]. Large amounts of materials are wasted by using the conventional method which is CNC milling machine [20] and resulted in disadvantage for this process. In this case study which is medical implant manufacturing using MakerBot Replicator 2X, the production time was 10 hours 15 minutes for 1 unit production. This shows the production time of medical implant by using 3D printer (MakerBot Replicator 2X) is much shorter than conventional methods. By using conventional method, the prototype is produced in a few days to a few weeks [13] compared to the implant production using the RP technology which is in a couple of days [4]. Implant that produced by the RP technology is conceived, produced, and delivered to the patient in 3 days, much shorter period compared to the implant manufacturing by conventional methods [4]. The production cost of medical implant is MYR 837.60 or $196.67 for 1 unit. Most of the production cost for medical implant produced by the conventional method is over expensive to the poor. 3D printer (MakerBot Replicator 2X) is a RP technology that anyone can afford to use with a reasonable price [6]. This shows that 3D printer gives more advantages in medical implant manufacturing.

Table 5 shows the comparison of the production time and production cost between different manufacturing processes in implant manufacturing. Lead time is the production time required to manufacture the implant. The production cost is the total cost for the manufacture of the implant excluded the surgical cost. This table proves that implant manufacturing using 3DP (MakerBot Replicator 2X) is practically better in production time and production cost compared to other manufacturing processes.

Table 5: Comparison on production time and production cost between different manufacturing processes in implant manufacturing.

Manufacturing process	**Case study**	**Lead time**	**Production cost**	**Ref.**
Selective laser melting (SLM)	Dental implant	Low	High	[22]
Milling	Dental implant	Low	High	[22]
CNC milling machine	Hip arthroplasty implant	40 minutes for 3g material	$447.64	[23]
CNC milling machine	Cranial implant	Not reported	$7,000 - $8,000	[17]
5-axis CNC machine	Knee joint	18 hours (3 days consider 8 working hours)	High	[4]
Casting	Knee joint	8 days consider 8 working hours	High	[4]
Casting	Dental implant	High	Average	[22]
Forging	Knee joint	8 days consider 8 working hours	High	[4]
Machining	Knee joint	8 days consider 8 working hours	High	[4]
Molding	Cranial implant	Not reported	$40,000 - $50,000	[17]
Gypsum molding	Cranial implant	Not reported	$2,347.97 - $3,521.95 (Cost of the production of gypsum mold)	[15]
Gypsum molding	Cranial implants	Not reported	$704.39 - $939.19	[15]

RTV silicone rubber molding	Not reported	0.5-2 weeks	$1,000 - $5,000 (Cost of the tooling)	[24]
Aluminum-filled epoxy	Not reported	1-4 weeks	$3,000 - $35,000 (Cost of the tooling)	[24]
Sprayed material	Not reported	2-4 weeks	$2,000 - $15,000 (Cost of the tooling)	[24]
Kirksite	Not reported	3-6 weeks	$4,000 - $15,000 (Cost of the tooling	[24]
3D Keltool	Not reported	1-6 weeks	$2,000 - $5,000 (Cost of the tooling)	[24]
Not reported (From USA market)	Dental, oral and maxillofacial implant	Not reported	$400 - $1,500	[16]
Not reported (From China and India market)	Dental, oral and maxillofacial implant	Not reported	$100 - $500	[16]
Not reported (From China, India, Australia, South Africa, UK, and the USA market)	Xenografts	Not reported	$2,000 - $3,000	[16]
Not reported (From China, India, Australia, South Africa, UK, and the USA market)	Breast implant	Not reported	$1,000 - $2,000	[16]

Conclusion

The study reveals improvement in the current implant manufacturing and produces better fabrication method of implant manufacturing using 3D printing technique. According to the finding in this study, the production time of implant manufacturing is much shorter than expected and the production cost is affordable compared to the conventional method. This study indicates that MakerBot Replicator 2X 3D printer gives more advantages compared to conventional method and could be a potential manufacturing process in direct production of patient specific implants. As three dimensional printing is getting more accessible and affordable in recent years, using 3DP technology for medical implant production is looking very promising.

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