Journal of Fundamental and Applied Sciences

ISSN 1112-9867

Available online at http://www.jfas.info

Research Article

Special Issue

DEVELOPMENT OF TI-6AL-4V BASED-MINIPLATE MANUFACTURED BY ELECTRICAL DISCHARGE MACHINING AS MAXILLOFACIAL IMPLANT

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Published online: 24 February 2018

ABSTRACT

Fracture in maxillofacial region is the most commonly encountered case of trauma in oral and maxillofacial surgical field. The handling, in this case, is by fixation method using miniplate which is locked by some screws. This research aims to fabricate the Ti-6Al-4V based-miniplate prototype as maxillofacial implant product. Electrical discharge machining (EDM) was employed as a method to manufacture the prototype. In this research, ultrasonic cleaning, rotary tumbler polishing, and brushing were applied as techniques to improve the roughness of prototype manufactured by EDM. The results showed that the prototype has been successfully produced within acceptable geometric tolerance. Ultrasonic cleaning and rotary tumbler polishing provided the significant increase of the surface roughness of prototype for each 90% and 67%. On the other hand, the single cycle bend test took the better results of mechanical performances. Both *K* and *EIe* have the excellence for each 64% and 26% compared to the imported product.

Keywords: miniplate, implant, maxillofacial, Ti-6Al-4V, electrical discharge machining.

1. INTRODUCTION

The basic concept of maxillofacial trauma management is based on some essential principles concerning in the healing of fractured bones, namely adequate of vascularization, anatomical reduction, and immobilization of bone segments (Champy, Härle, & Terry, 2009).

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doi: http://dx.doi.org/10.4314/jfas.v10i3s.65

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Handling of fracture can be done by closed reduction or open reduction. In the open reduction, fixation using miniplate and screw is required which is applied to fracture bone fragments until the bone cleavage process is complete (Ehrenfeld, Manson, & Prein, 2012).

The fixation system is used to acquire fracture fragment stabilization to restore the function of the maxillofacial bone well. This system was introduced by Arbeitsgemeinschaft für Osteosynthesefragen (AO) in 1958, where initially the screw and miniplate materials used were made of chromium, cobalt and stainless steel (McEwan & Muzaffar, 2014).

There are several methods employed in maxillofacial implant production. In this research, the miniplate was fabricated using electrical discharge machining (EDM) method. The advantages of machining are the use of Computer Numerical Control (CNC) machines, whose software is programmed to produce certain components in large quantities with the same product quality and closer dimensional accuracy. However, the machining process has its disadvantages in that it takes longer and the cost is more expensive than other methods (El-Hofy, 2013). EDM has its advantages compared to machining in that cavities with thin walls, and fine features can be produced, the use of EDM is not affected by the hardness of the work material, and the process is burr-free (El-Hofy, 2013).

Development of industries in Indonesia has experienced significant growth. The manufacturing industry has played a crucial role in the national economy. The contribution of the manufacturing industry to Indonesia's Gross Domestic Product (GDP) is the largest (Kemenperin, 2014). Unfortunately, this has not been followed by the development of the industry of medical devices. The primary factor of these problems is the limited research to develop medical devices as locally-made products. This has led to 90% of medical equipment including implant products in Indonesia is still imported (Kemenkes, 2005). This research aims to develop miniplate implant with the lower price compared to imported miniplate. Thus, one solution could be offered to reduce the dependence of imported implant products by developing a locally-made miniplate implant that can be reached by all classes of Indonesian people.

2. METHODS

2.1 Manufacturing and material preparation

In this research, the material used was Ti-6Al-4V titanium alloy. Prior researchers showed that Titanium alloys have been used extensively in the implantation field. Its excellent combination of biocompatibility, mechanical properties, chemical stability, and high corrosive resistance was the main reason for the selection of Ti6Al4V titanium alloys as implant material (Geetha, Singh, Asokamani, & Gogia, 2009; Prasad, Ehrensberger, Gibson, Kim, & Monaco, 2015).

The design of the miniplate prototype made in this research referred to the geometry or shape of the existing products of miniplate that have been widely used. The design was modified based on the needs and input of the maxillofacial surgeon as E. Febriani has researched (Febriani, 2015) with emphasis on how to acquire rigid internal fixation to achieve a good interaction between miniplate, screw, and maxillofacial bone. Shape and size referred were the type of non-locking miniplate with a straight form and 4 of holes.

The manufacturing process was using EDM Agie Charmilles Form 20. There are two main parameters of EDM process, namely voltage and amperes. Voltage is the pressure that makes amperes flow in the form of a spark. Amperes are the sparking electricity. The voltage used in this study was about 100 VDC, while the electricity was 50 amperes.

2.2 Geometric analysis

In this study, the geometric analysis was performed to determine the geometric deviations between the planned design and the results of the prototype produced. There were several sections of the area measured as shown in Fig. 1 (red circle). The measurement was using a digital micrometer and dino-lite digital microscope.

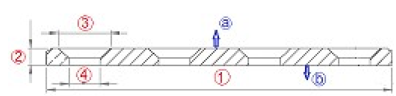

Fig.1. Sections of area of the miniplate for analysis of geometry (red circles); surface roughness (blue circles)

2.3 Surface roughness and topography observations

The surface treatment was employed to determine the surface roughness of prototype produced by using several techniques. The first method was the polishing by using a steel brush. The prototype was mechanically polished for 30 minutes. The second method was ultrasonic cleaning process. Al2O3 was added to take effect on the surface roughness of the prototype. The prototype was cleaned on Digital Ultrasonic Cleaner for 4 hours. The last treatment was by using rotary tumbler polisher, Kyngty KT 6808. Sintered Al2O3 was used as polisher balls. This process was done for 8 hours. These methods were chosen because of their low costs as techniques of implant surface treatment that can provide significant results.

The prototype surface roughness was evaluated by using Surfcom 2900SD3. There were two essential parameters of surface roughness observed. R_{max} is the difference between the highest and lowest point of the profile in the evaluated region. R_a is average deviation of the roughness profile from the mean line below:

$$Ra = \frac{1}{n}\sum_{i=1}^{n} |y_i| \qquad (1)$$

After that, topography observation was performed by using scanning electron microscope (SEM) FEI Quanta 650 at the accelerating voltage of 10 kV.

2.4 Single-cycle bend testing

The mechanical test performed referred to ASTM F382-99 on standard specification and test method for metallic bone plates. Single-cycle bend testing was conducted in determining the miniplate mechanical performance characteristic compared to imported product. The single cycle bend testing was done by the test configuration as shown in Fig 2. The test method measured the bending stiffness, *K* (N/mm); bending strength (N-m); and bending structural stiffness, *El* (N-m2) of miniplate (International, 2003).

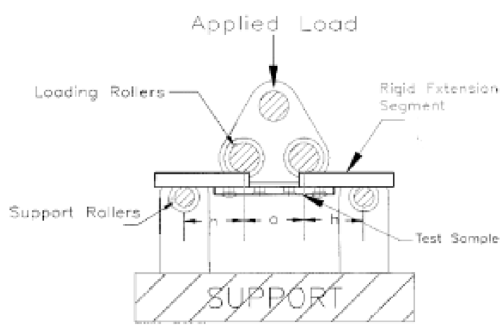

Fig.2. The configuration of Single cycle bend test; *a* is the center span distance, and *h* is the loading span distance.

The bending structural stiffness is the miniplate's normalized effective bending stiffness that takes into consideration the effects of the test setup's configuration when tested. The miniplate's bending structural stiffness is determined by the following expression (International, 2003):

$$EI - \frac{(2h+3a)Kh^2}{4} \qquad (2)$$

where *K* is the maximum slope of the linear elastic portion of the load versus load-point displacement curve for a miniplate when tested.

The bending strength of miniplate is the bending moment necessary to produce a 0,2% offset displacement in the miniplate when tested. This performance is calculated from the expression (International, 2003):

$$\text{Bending strength} = \frac{F \max .h}{2} \qquad (3)$$

where F_{max} is the fracture load.

3. RESULTS AND DISCUSSION

3.1 Prototype manufacturing

The fabrication process of the miniplate prototype was carried out in two stages. The first stage was the manufacturing process to make the outer profile of miniplate. This process was done by wire-cutting EDM method. Fig. 3a shows the configuration of miniplate profile resulted by the wire-cutting process.

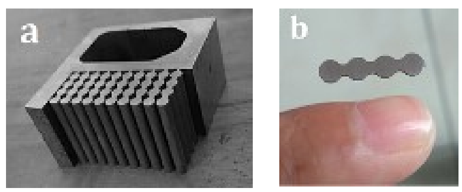

Fig.3. a) The configuration of miniplate profile resulted by wire-cutting process; b) specimen resulted by slicing process

After the miniplate profile was formed, as shown in Fig. 3a, the next step was slicing process or cutting into parts according to the thickness of miniplate, thus obtained several pieces of miniplate as shown in Fig. 3b. Afterwards, making four-holes profile was carried out using EDM machine. The result of prototype manufacturing is shown in Fig. 4.

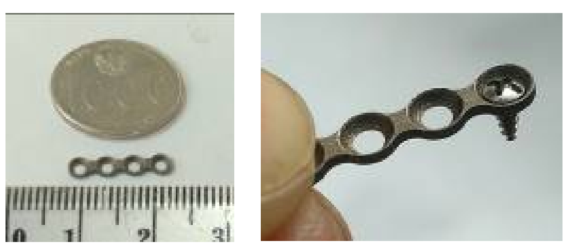

Fig.4. The fabrication result of miniplate prototype

3.2 Geometric analysis

The dimensions of the previously planned-design were compared to the prototype manufactured. The comparison results are shown in Table 1., which is the average result of the geometric measurement.

The result indicates that there are dimensional differences between the previously planned design and the manufactured prototype. However, the differences are not significant and still within an acceptable range of geometric tolerances. This means that the manufacturing method used, EDM, could provide the precise results.

Table 1. The result of geometric measurement

Section	Design (mm	Prototype (mm
1	16.50	16.51
2	0.82	0.82
3	2.77	2.79
4	1.97	1.99

3.3 Surface roughness and topography observations

The surface roughness of the implant plays a vital role in influencing the higher BIC values. High BIC values determine the success of implant osseointegration. Macrophages and osteoblasts exhibit behavior more favorably attached to rougher surfaces than smooth surfaces such as on implants manufactured by the machining process (Chehroudi et al., 2010; Gallo, Holinka, & Moucha, 2014).

A huge number of the experimental investigations (Ellingsen, Johansson, Wennerberg, & Holmén, 2004; Grassi et al., 2006; Le Guéhennec, Soueidan, Layrolle, & Amouriq, 2007; Sul et al., 2009; Vandamme, Naert, Vander Sloten, Puers, & Duyck, 2007; Wennerberg & Albrektsson, 2009) have demonstrated that the implant surface topography influenced the bone response; smooth (Ra <0.5 µm) and minimally rough (Ra 0.5–1 µm) surfaces showed less strong bone responses than rougher surfaces. Moderately rough (Ra 1–2 µm) surfaces showed stronger bone responses than rough (Ra >2 µm).

Surface roughness was measured in two sections, as shown in Fig. 1 (blue circles), for different types of prototype and the results are summarized in Table 2. Benchmark EDM + ultrasonic cleaning specimens proved to have the highest Ra. This method significantly increased the original roughness achieved by previous EDM process. Further, it also took the highest percentage of roughness increase about 90%.

Benchmark rotary tumbler polishing specimens also proved an excellent increase enough of surface roughness. On the other hand, benchmark polishing specimens could not increase the surface roughness of specimens. Even there were found some specimens that experienced a decrease in surface roughness than before.

Table 2. Surface roughness

EDM – electrical discharge machining, UC – ultrasonic cleaning, RTP – rotary tumbler polishing

Condition	R_{max} (μm)		R_a (μm)	
	Mean	Std. dev.	Mean	Std. dev.
EDM	6,72	1,01	1,01	0,11
EDM+UC	12,05	2,05	1,92	0,18
EDM+RTP	11,15	2,34	1,69	0,19
EDM+Brushing	7,83	0,87	1,25	0,05

As the easiest and fast method used to acquire the excellent surface roughness required in implantation, ultrasonic cleaning is recommended as a better method for surface characterization. In addition, this technique can clean debris and contaminants on the prototype surface.

Furthermore, all benchmarks of surface treatments were subjected to SEM observations. Micrographs are depicted in magnification of 500x. Fig. 5 is the comparison of the surface micrographs after several processes. Fig. 5a is the surface micrographs of the original EDM specimens. Quantitatively, this surface has a roughness of 1.01 μm. Fig. 5b and 5c show the specimen surface after rotary tumbler polishing and ultrasonic cleaning processes. These processes severely damaged the material. Drops of resolidified metal, debris and craters are well visible. Sintered-Al2O3 used in these methods successfully increased the surface roughness of the prototype to moderately rough. Visually, we can conclude that these surfaces have higher surface roughness than the original EDM and brushing process. Micrograph of the specimen surface after brushing depicted in Fig. 5d. It appears that the specimen surface is much smoother compared to ultrasonic cleaning and rotary tumbler polishing. This process was able to scrape debris and contamination of Cu on the surface of the specimen.

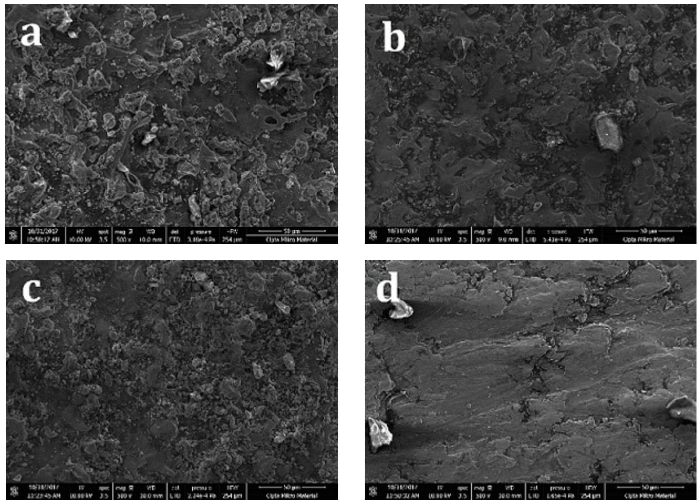

Fig.5. The comparison of micrographs of the surface. (a) original EDM; (b) after rotary tumbler polishing; (c) after ultrasonic cleaning; and (d) after brushing process

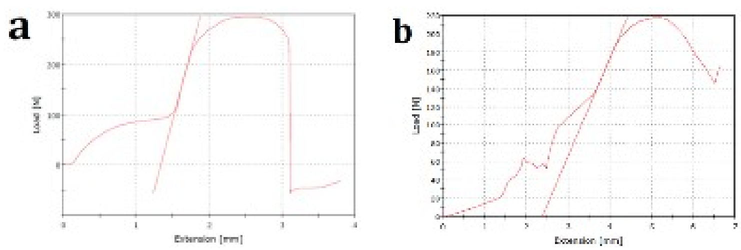

Fig.6. Diagrams of bending test result: a) miniplate prototype; b) imported product

Table 3. The comparison of mechanical performance characteristics of prototype and imported products

Specimen	K (N/mm)	EI_e (Nm^2)	Bending strength (Nm)
Prototype	128,57	10,52	12,81
Imported product	46,06	3,77	9,48

3.4 Single-cycle bend test

The jig created based on the configuration as in Fig. 2 was loaded on the press machine. The bending test results for the specimen of miniplate prototype produced are shown in Fig 6a. It indicates that the required F_{max} reaches almost 300 N while the distance traveled by the bending probe from the point of contacting sample until F_{max} reached is 2.6 mm. These results are then compared with the results of bending tests for imported product specimens as shown in Fig. 6b.

As shown in Fig 6b, the results of imported product indicate a lower yield with F_{max} of 220 N and extension of 5.2 mm. With h of 8.7 mm and a of 8.6 mm, the comparison of mechanical performance characteristics of miniplate prototype and imported products specimens are shown in Table 3 below.

From Table 3, it can be concluded that the miniplate prototype produced has the advantage of all the mechanical performance characteristics resulted by single cycle bend test with the percentage of 64% for bending stiffness and bending structural stiffness and 26% for bending strength. This shows that the miniplate prototype produced has excellent mechanical performance characteristics as implant product in medical application.

4. CONCLUSION

This research was conducted on the production of Ti-6Al-4V based-miniplate prototype as maxillofacial implant product. The results show that prototype has been successfully produced with acceptable tolerances in geometrical characteristics. Ultrasonic cleaning and rotary tumbler polishing techniques added with sintered-Al2O3 provided significant effects of surface increase with the percentage of 90% and 67% from the original EDM *Ra* of 1.01 µm. On the other hand, the single cycle bend test took the better results for each mechanical performance characteristics. Both *K* and *EIe* have the excellence percentage of 64% compared to the imported product when bending strength is 26%.

ACKNOWLEDGMENT

The authors would like to thank Indonesian Endowment Fund for Education (LPDP), Ministry of Finance; and Ministry of Research and Higher Education, Republic of Indonesia, for sponsorship and research grant “Hibah Inovasi Perguruan Tinggi 2017”.

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How to cite this article:
Qosim N, Supriadi S, Whulanza Y, Saragih A S. Development of ti-6al-4v based-miniplate manufactured by electrical discharge machining as maxillofacial implant. J. Fundam. Appl. Sci., 2018, *10(3S), 765-775.*