Fabrication of magnesium ecap based maxillary miniplate-typed implant through the method of micro forming

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Abstract. Research and study on a degradable implant for bone fracture fixation has received great attention. This had to do with a problem, which in some cases, require doctors to do re-surgery to remove the implant from the patient after the fractured bone was healed. The removal surgery could cause several problems, such as the need for another recovery period and the high cost of the removal surgery itself. Several methods are developed to control degradation rate to match with healing rate. One of such method is the grain refinement technique using severe plastic deformation. In this paper, a study of fabrication of a miniplate implant for maxillofacial region using magnesium which passed severe plastic deformation using Equal Channel Angular Pressing (ECAP) was performed. The micro-forming fabrication method is selected to form the miniplate. It is shown that the accuracy precision of the process was achieved with a reasonable result compare to the design. The most crucial part form miniplate design is the hole which shows low variation in diameter, 1.43 %. It shows that the method of micro-forming has great potential to fabricate miniplate using magnesium ECAP. Further work is necessary to conduct finishing process on the miniplate.

1. Introduction

Research on implants has led to the development of biomaterials, both metal and non -metal. While previous researches are focused on the biocompatibility itself, nowadays the standard material of implants has been established. Modern implants are proven enough to be biocompatible, with titanium as the leader of the structural metal implants, and other alloys or ceramics as wear resistant parts. The advance of biomaterial research has brought another inspiration, on how the implants are focused as a temporary solution, not a permanent one, as the previously mentioned titanium and ceramic implants will be permanently resided inside the body, unless removed surgically, which is quite common in the maxillofacial region (face and jaw area) implants. The second surgery required to remove the implant, will be somehow uncomfortable for the patient themselves and meticulous for the doctors. With that in mind, most patient will opt for leaving the implants inside the patient's body, as there is no direct medical side effect of the implants itself. Although, maxillofacial implants tend to affect patient's face proportions slightly, which for some, could be bothersome and not aesthetically pleasing. To refine the fixation method, there has been a proposal on how implants, especially for maxillofacial region, could

be made using materials found naturally in human body, so the implant itself could be degraded after bone healing has been done. Magnesium has been a leading material in this regard. With higher strength than most non-metal biodegradable materials, magnesium could provide more structural support and could be used for wider spectrum of implants.

However, magnesium has one weakness, which is a high degradation rate, which is much faster than the healing rate of the bone itself. Therefore, a method of lowering magnesium's degradation rate shall be implemented. There are 3 known method to lower magnesium's degradation rate. The First one is coating. Coating is done using other materials to coat magnesium, so that oxidation will not happen. Another method is alloying, which is combining two or more metals so that the strength and corrosion resistance is increased. The 3rd method is by using grain refinement, which is decreasing the grain size of the material itself, in its pure or alloyed state [1]. The first two methods are not too effective in this application as an implant. The first method, which is coating, will only protect and decrease degradation rate temporarily, as long as the coating present. When the coating is gone, the degradation rate will increase to the initial uncoated rate [2]. The second method, which is alloying, had a different set of problems. Metals used in the alloy, such as aluminum, which when degrade, could be released in a dangerous, toxic amount for the human body. The third method is the most feasible one, as the structure is uniform enough, and there are no alloying metals that will degrade with the magnesium itself [3], and smaller grain size means that degradation rate will drop. There are several methods of grain refining, such as hot rolling, cold rolling, forging, and ECAP (Equal Channel Angular Pressing), and based on the experiment performed by Wang in 2008, it is proven that ECAP method resulted in a more uniform, and overall better mode of degradation, as well as lower rate of degradation [4].

The ECAP method, developed by V.M. Segal in the 1970s, is a method to refine the grain through strain hardening [5]. The heated billet is passed several times through an angular channel, which will bend and straighten the billet itself. 1 pass is equal to one cycle.

This experiment aims to evaluate the method of micro forming in the manufacturing process of magnesium ECAP based miniplate for maxillofacial region, in terms of manufacturing accuracy using important dimensional parameters within the plate.

2. Experiment method

The experiment is done using magnesium that has been through six times ECAP procedure. The magnesium ECAP blanks then cut into rectangular plates of 24 x 3.5 x 0.85 mm dimension. The plates are cut into the outer profile, and then stamped using dies at 250˚C with the force of 21046 N. The heating process is done with a muffle furnace for 10 minutes, and the pressing itself is done using hydraulic press. This experiment parameters of the Mg ECAP itself are shown in Table 1.

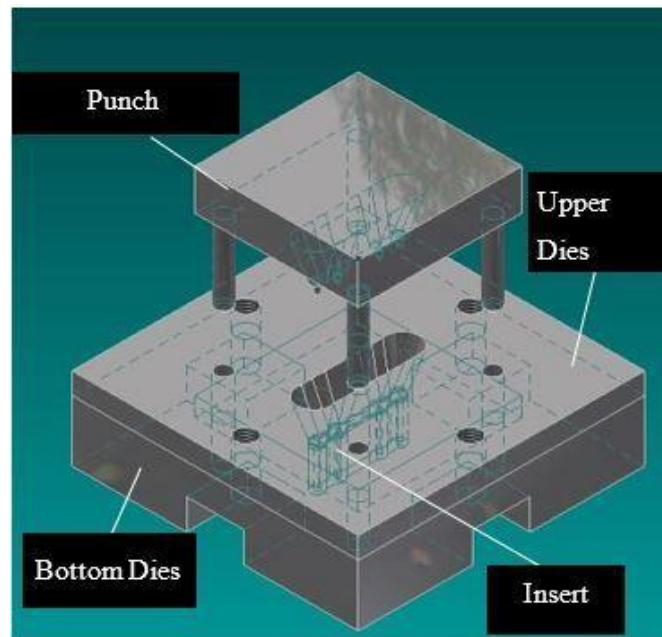**Table 1**. The parameters and values of ECAP process in this experiment [6].

Parameters	Values
Force (N)	25000
Temp (^oC)	350
Channel angle (^{o})	120
Passes	6 with 90° turn every pass

The influence of this process on the magnesium itself, is increase in yield and tensile strength, decrease in grain size, and decrease in degradation rate, as seen in Table 2.

The dies used in this experiment is presented in Figure 1, with SKD-11 as the material, consists of 4 parts, stacked on each other as shown in Figure 1 and sealed with 4 nuts and bolts. The plate blank was put inside the cavity from the oval hole, and closed using the punch (the top part). Both the dies and the blank inside are heated in a furnace to 250˚C. Finally, using a hydraulic press, the heated dies and blank were pressed with 21046 N of force. The plate is then extracted by removing the upper dies and the insert.

Table 2. The physical differences between unprocessed Mg and ECAP Mg [6].

Parameters	Pure Mg Without ECAP	Pure Mg ECAP
UTS(MPa)	147.09	186.33
Hardness (Vickers)	51.81	73
Corrosion Density(μA)	172	5
Grain Size(μm)	700	10

Figure 1. Dies used in this experiment.

The measurement of the result was done using Dino Lite camera, and measured using Dino Capture 2.0 software. The manufacturing process in this experiment is done in 5 samples. 19 data were taken from 5 samples, and each measurement was taken 3 times in each measured part.

3. Result and discussion
Figure 2 shows the plate resulted from the manufacturing process, with a standard pen for comparison.

Figure 2. The finished product, pen for scale.

The detailed measurement result of the plate's important dimensional parameters is shown in Figure 3. The important dimensional parameters are: Neck width, hole radius, chamfer radius, and outer circle radius. The measurement method could be seen in Figure 3, with each measurement is done 3 times and averaged.
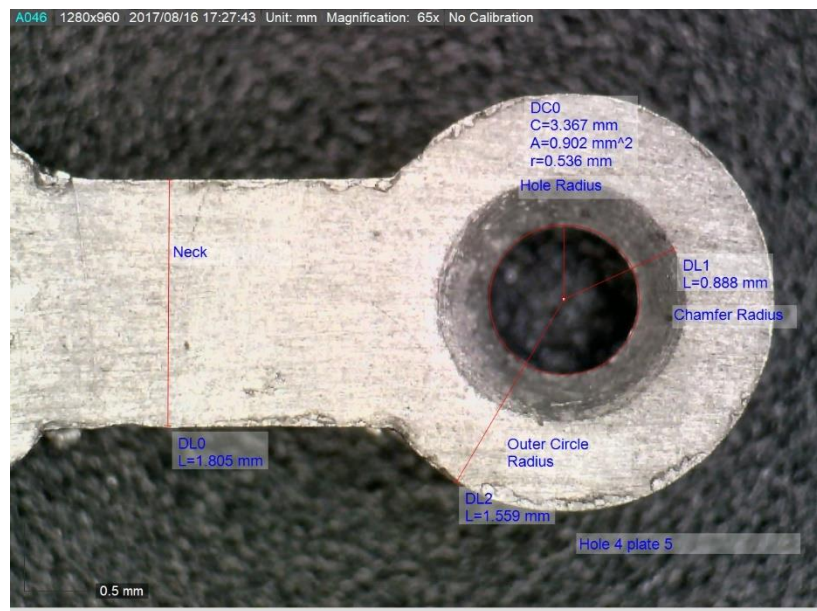

Figure 3. The measured example of the detailed parts of the plate. The part's names are written along the measurement line.
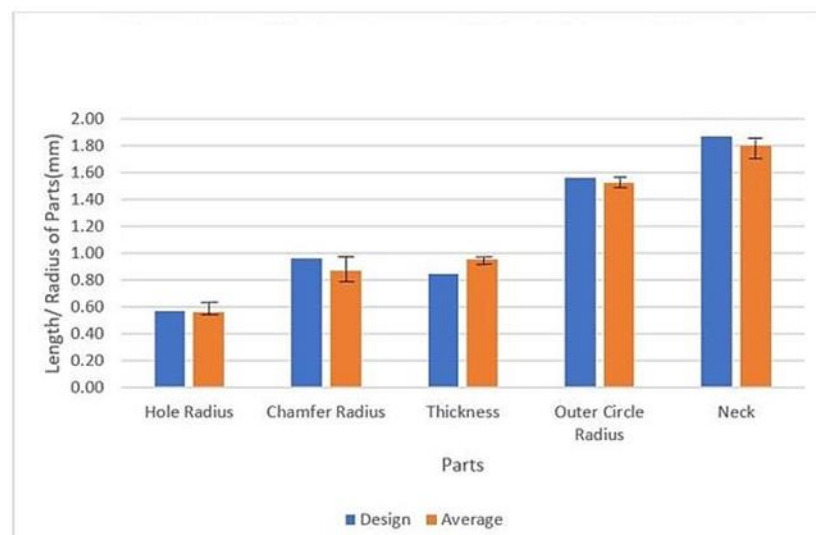

Figure 4. Comparison of Design, Average, Highest Value, and the Lowest Value of each parts measured.

The average result and range (maximum and minimum value) of all the measurement done in this experiment could be seen in Figure 4, and the average error percentage is shown in Figure 5. The formula of specific part's error percentage in this calculation is shown in equation (1),

$$\left|\frac{Designed\ part}{Average\ of\ result}\right| x\ 100\% \tag{1}$$

where: Designed part = length/radius of part according to design; Average of result = average length / radius of each parts resulted from the manufacturing process.
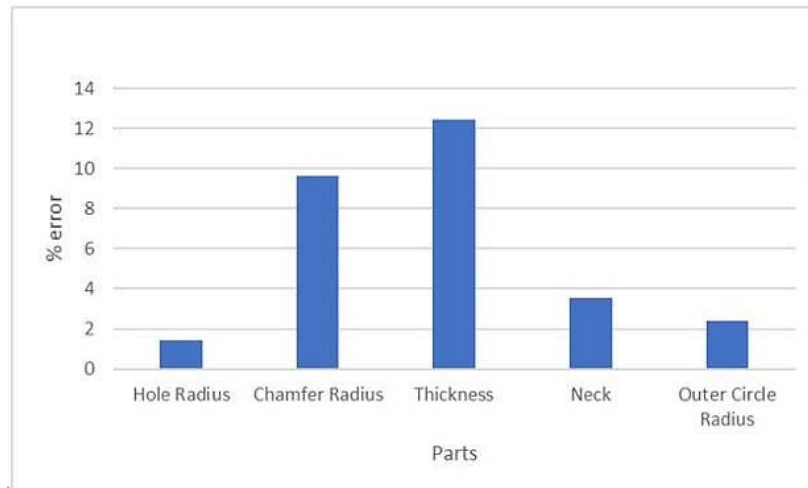

Figure 5. Average Error of each samples' detailed parts.

Table 3. Design, average, highest value, lowest value, average error measurement of the samples' detailed parts.

	Design (mm)	Average (mm)	Highest Value (mm)	Lowest Value (mm)	Average Error (%)
Hole radius	0.58	0.57	0.62	0.55	1.43
Chamfer radius	0.97	0.87	0.97	0.78	9.65
Thickness	0.85	0.96	0.96	0.94	12.47
Outer Circle	1.57	1.53	1.55	1.50	2.42
Neck	1.87	1.80	1.87	1.71	3.55

Looking at the detailed measurement of the samples, we could conclude, that the manufacturing result is quite accurate, based on the International Tolerance governed by ISO 286, in which, using the IT rating of 14, the most important part, the hole, is manufactured within the tolerance, which is 0.15 mm, from the International Tolerance Formula:

$$T = 10^{0.2x(ITG-1)}.\left(0.45x\sqrt[3]{D} + 0.001xD\right) \tag{2}$$

where: T = Tolerance in micrometers

   D = Geometric mean dimension in milimeters

  ITG = IT Grade, a positive integer [7].

We could see from the result in Figure 5 and Table 3, that the greatest error present is in the thickness, which is quite precise with the average of 0.96 mm. This is caused by the presence of flash that occur when the plate is stamped, and manufacturing limitation that happened in the manufacturing process of the plate itself. The targeted thickness of 0.85 mm is proven to be too thin for the machine too handle,

and increase in thickness is the solution to the problem. This thickness problem could be solved by sanding the plate itself until it reaches 0.85 mm. The thickness itself is not the main concern, as the increased thickness will also increase the tensile strength of the plate itself. The increased thickness also will not pose any problems regarding the space occupied either, because the average thickness of such plates is around 1 mm. The most crucial part, however, is the hole size itself. The hole size should fit the screw tightly so the force could be transferred optimally. Average error occurred in the hole section is very small, at 1.43%, making it the smallest error in the measurement, and still within the International Tolerance Standard. Another part's error, which is neck parts, came from the inconsistency of the machining process, which caused burr, and should be sanded down manually with hand. However, sometimes the sanding process just cut too much inside that it caused the neck width itself to decrease. This, could pose some problem for the plate's tensile strength itself. What should be done, is that to leave around one-millimeter excess in the sanding process, to ensure that the neck width will not be below the original design that will result in a decrease in strength.
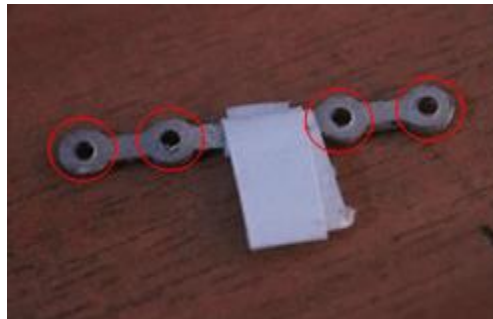

Figure 6. Flash formed during forming process.

As for the mode of failure, it is mostly ductile, as seen in Figure 6, where the ductile part resulted in flashes, that also contributes to the increase in thickness. In the actual manufacturing process, the flashes should be removed using sandpaper for optimum result as the bottom part of the plate is the part that will be in contact with the broken bones. The top and side part, should be sanded too, as both parts will be in contact with face's tissue, in order not to let the tissue scratched and wounded. The next experiment will be focused on the strength of the plate itself, so that the plate could be used in practical level, as clinical trials on the magnesium ECAP *in vivo* has shown promising results [8].

4. Conclusion
The miniplate made by magnesium for maxillofacial implant was successfully manufactured using microforming process. The forming process was focused on punching and tapering the magnesium miniplate. Microforming is proved to be an efficient method in shaping magnesium with high production rate.

The results of the magnesium miniplate shows an acceptable accuracy based on standard established by ISO 286 (International Tolerance). The most important part, which is the hole, is accurate enough and thus, will not interfere with the plate's functionality. The calculation based on physical properties of magnesium ECAP give an accurate guideline in designing parameters needed for manufacturing process. Further works is needed to improve surface finish of the magnesium miniplate.

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