Study of Making Implant Plate and Screen of Femur Bone Internal Fictation From Hydroxyapatit Bovine And Polymer Biodegradation Material Using 3D Printers On Mechanical Strength

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Abstract. Traffic accidents in Central Java contribute to fractures or fractures of 1,770 people. Broken bones that often occur in the femur or thigh bone. Recovery of fractured femur or fracture using internal plate and screw fixation. Metal implants and screws have deficiencies in implant migration, discomfort, pain, allergies, and large costs. From this deficiency, biodegradation polymer materials are now being developed. Strength without taking after bone healing, reducing operating costs, traumatic patients, comfortable, and painless, but has a lack of low mechanical strength and lack of precision. From the background above, research is focused on making high precision implant plates and screws from CT-Scan image data of patients using 3D printing machines in femoral bone applications. The research method uses screw extrusion method for making 3D printer filaments to make plate and screw internal fixation implants. Materials used by PLLA, PLC, HA bovine and PLA by testing mechanical properties. The results for the composition of the filament biodegradation mixture for the most optimal filament are F1 code test specimens with a percentage of synthetic polymer content and Ha Bovine 80:20. The best density and porosity are owned by the test specimen F1 / 300N code. The density of 0.365 g/cm³ with 2.750% porosity makes the buckling strength better and the maternal degradation is longer. Melting temperature (Tm) that corresponds to a 3D printer machine is the F3 test specimen code at 305°C melting temperature. So that this test specimen supports 3D printer machines.

Keywords; Femur, Filament, Implant, Broken, Bone.

1. Introduction

Factors causing high fractures are caused by traffic accidents, sports, fights, animal attacks and others[1]. Traffic accidents contribute the highest fractures. Of the 45,987 events that fell in Central Java, traffic accident cases contributed 20,829 and had 1,770 fractures[2]. Whereas based on data from the medical records of Roemani Hospital Semarang, the number of fracture sufferers was 1 year, from May 2011 to April 2012 as many as 32 patients were fractured [3]. Broken bones that often occur in the femur or thigh bone. Many internal fixation devices are applied to the recovery of fractured or broken femur bones [4]. The fractured femur bone for recovery requires stabilization devices in the form of internal plate and screw fixation[5]. The main function of internal fixation is to maintain fracture reduction during bone healing [6].
This fixation requires having good strength and stiffness to stabilize and support fractures [7]. Plate and screws are made from rigid biocompatible materials, such as stainless steel, cobalt chromium, titanium and composite materials [7] [8]. Stainless steel, cobalt chromium, titanium for internal fixation have reliable mechanical strength, but have deficiencies in implant migration, discomfort, and pain in patients [9] [10]. In addition, it can cause lymph nodes (regional lymph nodes) and allergic reactions [1]. After the bone healing process, it is necessary to operate metal implant fixation, and large funds are needed [10]. In patients experiencing psychic trauma for surgery again[11].

Learning from the lack of internal plate and screw fixation from metal, biodegradation polymer materials are now being developed [12] [13]. The advantages of internal fixation of biodegradation polymers are without post-bone recovery, reducing operating costs, traumatic patients, comfortable, and without pain [8][9]. But it has a deficiency in low mechanical strength [14][15]. Plate and screw implants from poly (L-lactide) (PLLA) and Polyglycolic acid (PGA) casting methods. PGA polymers for degradation times are faster and mechanical strength is rapidly decreasing [16]. PLLA for longer degradation times and stable mechanical strength. The disadvantage of this method is that the mold adjusts bone size and results in less precision. Petteri V in 2009 have made implants from the PLDLA / TMC polymer. This material has a stable strength in the body for a long time, but the buckling strength is low [17].

Low mechanical strength and lack of precision in implants affect bone remodeling [18]. Advanced techniques using fused deposition modeling (FDM) machines have the ability to make implants directly and have high precision [19]. Polymers and composites of ceramics are often used in FDM processes [20]. FDM is able to process patient's Computed Tomography Scanner image data. These data can be directly printed according to broken bones [21]. Hutmacher in 2000 making FDM filaments from PCL-HA (Hydroxyapatite) composites has a compressive strength of 0.16-4.33 MPa [22]. Meskinfam in 2011 uses hydroxyapatite from bovine (HAb) and PLA from cassava for the manufacture of FDM filaments, but low mechanical strength and high melting temperature. Mixing PCL 80%, HAb 10% and PLA 10% increases mechanical strength and decreases melting temperature [12]. Saifudin AA and Solechan in 2015 made FDM filaments with a ratio of PCL + PLA (cassava starch) 90% and 10% HA bovine able to increase mechanical strength and degradation time[23]. From the background above, research focused on making high-precision prototype plate implants and biodegradation screws from CT-Scan image data of patients using the FDM method 3D printing machine on the femoral bone application. Materials used by PLLA, PCL, HA bovine and PLA. It is expected that the price of plate and screw fixation implants will be cheaper and reduce dependence on imported materials.

2. Research Methodology
Raw materials include PLLA, PCL, PLA, HAb, and vinyl silane coupling agents. The first step is the creation of a biodegradable 3D printer filament for internal fixation of plates and screws. The first step is the manufacture of biodegradable polymer (PB) with a ratio of the percentage composition of a mixture of PLLA, PCL, and PLA namely 50:30:20, 50:45:15, and 50:40:10 with a total weight of 5 grams and added 1 gram of vinyl silane compatible. The composition ratio of the percentage of PB and HAb material is F1 code with a ratio of 80:20, F2 code with a ratio of 85:15, and G3 code with a ratio of 90:10. The process of mixing the material using a hot plate magnetic roder at a temperature of 140oC and a rotation speed of 400 rpm. PB composites are made of pellets with a diameter of Ø 1.50 mm and a length of 2 mm using syringes or syringes whose ends are removed. The second step is to make PB Composite Pellet for 3D filament filament printer, Ø diameter 1.75 mm 300 mm using extruder screw machine. The heating temperature is controlled at 160°C for 10 minutes with an extruder pressure of 100 N at a rate of 4 mm/min.

Filaments are installed in 3D printing machine making in 2013 Brand UP Plus1 made in Australia. The internal plate and screw fixation 3D printing process to be installed on the femur bone from the CT Scan results in the patient. The manufacturing process from start to finish is shown in Figure 1. The third step is the manufacture of plate-shaped test specimens. The density and porosity tests refer to the ASTM D792-13 and ASTM C 20-92 standards, while the TGA test refers to the standard ASTM E1131-
08. The results of the internal fixation plate testing were printed in 3D compared to the commercial internal fixation plates purchased for import.

Figure 1. The flow of making internal plate and screw fixation for the femur bone

3. Results and Discussion

3.1. Density and Porosity Tests
Density and porosity tests use ASTM D792-13 and ASTM C 20-92 testing standards. Plate-shaped test material with a length of 20 mm, width of 10 mm, and thickness of 3 mm. Material specimen code F1/100N means F1 code for 100N pressure, F1/200N means F1 code for 200N pressure, while F1/300N means F1 code for 300N pressure. Porosity and density tests were carried out on composite matrix granules by calculating based on dry weight (Dw), wet weight (Ww), preparation volume (V). Porosity is a Ww-Dw slice divided by V x 100%, while density is the ratio between Dw and V. The composition of 3D printer filaments consists of PLLA, PLC, PLA, HAb, and compatibility Viny silane. The addition of bovine HAb material increases density and decreases porosity. Besides that the addition of bovine HAb causes changes in the surface morphology of the composite matrix. Bovine HA and extruder screw pressure result in narrowing of the pore matrix and increasing density as shown in Table 1.

Table 1. Density and Porosity in the internal fixation plate

| Code on Material Composition | Dry weight / Dw(g) | Wet weight/Ww (g) | Volume / V (cm³) | Density / ρ (g/cm³) | Porosity (%) |
|-----------------------------|-------------------|-------------------|-----------------|---------------------|--------------|
| F1 /100 N                   | 0.0603            | 0.0645            | 0.25            | 0.313               | 3,708        |
| F2 /100 N                   | 0.0578            | 0.0635            | 0.25            | 0.309               | 4,208        |
| F3 /100 N                   | 0.0563            | 0.0627            | 0.25            | 0.301               | 5,083        |
| F1 /200 N                   | 0.0582            | 0.0641            | 0.25            | 0.331               | 3,458        |
| F2 /200 N                   | 0.0541            | 0.061             | 0.25            | 0.326               | 3,875        |
| F3 /200 N                   | 0.0503            | 0.0579            | 0.25            | 0.319               | 4,167        |
| F1 /300 N                   | 0.0505            | 0.057             | 0.25            | 0.365               | 2,750        |
| F2 /300 N                   | 0.0497            | 0.0574            | 0.25            | 0.353               | 2,375        |
| F3 /300 N                   | 0.0476            | 0.0574            | 0.25            | 0.343               | 2,266        |

The increase in internal fixation plate density is due to increasing HAb mixture and increasing screw extruder pressure. The composition of the material F1/300 N has the highest density of 0.365 g/cm³ with a composition of 80% synthetic polymer and 20% HAb material. The increase in the composition of the synthetic polymer and the decrease in the bovine HA make the density decrease. For the lowest density in the material composition code F3/100 N with a density of 0.301 g/cm³ in the composition of a mixture of 90% synthetic polymer and 10% HAb. Looking at the results of the density of the internal fixation plate material composition shown in Figure 2. The increasing density will decrease from the material porosity [24]. The highest density has the lowest porosity. In addition, the highest extruder
screw strength for porosity is lower. Material composition code F1/300 N has a density of 0.365 g/cm³ with porosity of 2.750%. The decrease in the composition of the HAb mixture increases porosity. The composition of the mixture F2/100 N has a porosity of 4.208%. The synthetic polymer material has an effect on porosity.

![Material Composition](image)

**Figure 2.** The density of some plate mixtures is internal fixation

The composition of the synthetic polymer mixture is the lowest, i.e. 80% has a low porosity with a value of 3.708%, 3.458% and 2.750%, how can it be carved in Figure 3. Extruder screw pressure is also very influential on porosity, the greater the extruder screw pressure, the smaller the porosity. The smallest porosity is owned by the composition of the mixture F1/300 N with porosity 2.750 g/cm³.

![Material Composition](image)

**Figure 3.** Microstructure of Specimen AISI 316L Stainless steel (a) before shot peening, (b) after shot peening

3.2. *Thermo Gravimetric Analysis* TESTER

TGA test results to get a mass reduction in temperature and time. The temperature or semi-liquid temperature of the biodegradation filament is obtained from the TGA test results. Semi-liquid temperature obtained for setting the temperature on a 3D printer machine. 3D printers work to remove semi-liquid or thermoplastic flow to form scaffolds[25]. TGA testing was carried out on three specimens with a sample weight of 13.9210 mg and TGA mode of 100°C in a mixture composition of 90:10 (code F3), 85:15 (code F2), and 80:20 (F1 code). The composition of the mixed F3 code shown in Figure 4a. The graph diagram shows a mass reduction of 3 steps. The first step is to reduce the mass at a temperature of 305°C by 4.11% or 4.2364 mg. The second step at a temperature of 381°C there was a mass reduction of 26.33% or 9.42466 mg, and the third step temperature of 500°C occurred a mass reduction of 8.695% 10.6598 mg. The composition of the mixture of code F2 with a HAb content of 15% shows a
longer melting time and a small mass reduction, how is shown in Figure 4b. The first step is the mass reduction at a temperature of 309°C by 47.46%, the second step temperature 384 °C by 18.57%, and the third step temperature 500 °C mass reduction 19.62%.

![Figure 4. TGA test results for F3 code, and b) F2 code](image)

Increasing the composition of the Ha bovine material mixture for melting time and the higher melting temperature, while reducing the small mass. This occurs in the composition of the F1 code with the TGA test shown in Figure 5. The first step of mass reduction at a temperature of 314°C is 34.48%, the second step is temperature 388 °C by 31.58%, and the third step temperature is 500 °C mass reduction 10.37%. The difference in melting point temperature and mass reduction in the filament specimens of 3D printer biodegradation was caused by the composition of Ha bovine, composition. The more content of Ha bovine, the lower the mass and the higher the temperature. This is because the bovine HA has a high melting point of 954°C [26]. Another decrease in mass is due to the relationship of dehydration of the specimen and initial moisture loss resulting in a decrease in mass[16]. TGA test results look for several semi-liquid temperature test specimens to be likened to 3D printer liquefier temperature during processing time. 3D printers are capable of setting at temperatures of 150-350°C [27].

![Figure 5. TGA test results of mixed composition specimens of F1 codes](image)

4. Conclusion

a. The best internal fixation plate density and porosity is owned by the test specimen F1/300N code. The density of 0.365 g/cm3 with 2.750% porosity makes the buckling strength better and the material degrades longer.
b. Melting temperature (Tm) which corresponds to a 3D printer machine, namely the F3 test specimen code at 305°C melting temperature. So that this test specimen supports the 3D printer brand UP.

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