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PRECISION MOLD OF PROTOTYPE TITANIUM ORTHOPEDIC IMPLANT USING METAL INJECTION MOLDING APPROACH

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MIDC's researchers in fulfilling Industry Development Programme have taken a step to develop technology in the design application of orthopedic implants to help suppress the rate of imported medical devices in Indonesia. This research objective was to make a prototype plate for a jawbone connector that meets the geometric specifications with the metal injection molding approach. The jawbone connector plate has a very small size of about 2 mm x 20 mm x 0.5 mm that needs precision mold with certain geometric specifications. MIM approach was used, from the literature reviews that show MIM is the appropriate process for manufacturing implants. The phases of MIM were done according to the standard reference which is making raw materials or feedstock, gatting system design, flow simulation, precision mold producing, mold testing, injection process, debinding, sintering, and mechanical product testing. The results of this study were precision molds with several variants and were test using plastic polypropylene to see the performance of the mold. The researchers then produce the jawbone connector implant using feedstock material. The test result conducted in MIDC successfully shows that the mold can produce shapes that match the required geometry.

Keywords: *Metal Injection Molding, Orthopedic Implant, Precision Mold, Duralumin, Gatting System.*

1. INTRODUCTION

All of the industrial centers include Metal Industry Development Center (MIDC) are encouraged to develop technology and human resources for the design application of medical devices and bionics (artificial organs) which combine aspects of biological, material, cognitive and micro/nanoelectronic health. As in Presidential Instruction Number 6, the year 2016, state that Ministry of Industry need to increase the availability of basic chemical materials and components such as medical devices that support health as an outlined in the Medical Devices Industry Development Programme in RIPIN (*Rencana Induk Pembangunan Industri Nasional*) from 2015 until 2035 [1]. This action was taken due to 90% of medical devices in Indonesia were still imported, while the national medical equipment market has a high growth of around 12% per year. Therefore, domestic industries are expected to seize the opportunity, thereby reducing the entry of imported medical devices [1, 2].

An orthopedic implant is a component that was used as a bone connector that fractured due to injury. Orthopedic implant categorized into two which are temporary (plate and screw) and permanent type (hip bone, knee, shoulder, spine, toe, etc). The best material currently used for orthopedic implants is titanium which has higher specific strength by the ratio of mechanical strength to weight, than stainless steel, light and has high biocompatibility [3]. Titanium's modulus of elasticity was low and closer to the bone, which made it more preferred as an implant material for long-term use than other materials. However, titanium material has difficulty in the design machining and casting process due to its character of high reactive to oxygen and caused the material to brittle easily [4,5]. Lots of effort was done to minimize this weakness include increasing its mechanical power using the Metal Injection Molding (MIM) approach as one of the solutions. [4]. In this study, MIM approach was used based on its superiority between other techniques, shown in the literature reviews.

Studies related to Near Net Shape (NNS) manufacturing processes have been widely published since 2

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decades ago as it emerges as alternative methods for the production of a range of titanium components. Several alternative processes have been developed to provide low-cost titanium. NNS alternative methods that are available include forging (hot, cold, precision, closed die forging), forming (flow forming, hydroforming, semi-solid metal casting, semi-solid metal extrusion), casting (sand, investment, centrifugal, high and low-pressure casting), additive layer manufacturing and powder technologies (hot isostatic pressing and metal injection molding) [6]. Marini et al [7] showed that most of the research conducted was related to the type of metal material and powder technologies. Lower et al [8] have also conducted studies related to conventional material such as metal and plastic processes and had identified that powder injection molding has assessed technology, ecological and economic feasibility that match technical requirements with biological characteristics.

MIM is a manufacturing process of precision components that developed from the plastic injection molding process where thermoplastic material that was melted by temperature and rubbed in the barrel was then injected into a mold to produce a product [9]. This process can be applied to various types of materials include materials that are both metals and ceramics such as superalloys, stainless steels, titanium, carbide, zirconia, etc. MIM process was chosen based on factors of production quantity, the complexity of product shape, dimensions or weight of the product and type of material. Manufacturing components using the MIM process can significantly reduce manufacturing costs, increase design flexibility and materials, with high mechanical properties, good surface finish product and produce a large amount of production. Another advantage of the MIM process is that the dimensions and shape of the product resemble the final product, therefore the advanced process (machining) can be minimized and reduced production costs [10].

MIM process consists of four stages which were mixing, injection molding, debinding and sintering [11]. The metal powders and binders are mixed in a mixer and then were made in pellets to facilitate the injection process. The pellet was then inserted into the injection molding machine hopper to be melted and then injected at a certain pressure so that it filled the mold cavity. The results of this process called green compact were then removed by the debinding process through either chemical or heat treatment. Then the sintering process was done to solidify the product and increase the strength of the metal powder. Sintering is carried out under the melting temperature of the material [12]. During the process, diffusion of atoms occurred so that the powder will coalesce and the pores between the powders shrank. After the sintering process, the product dimensions will be reduced by 12-20% depending on the composition of the powder and binder. The specific gravity of the product after sintering is 97-99.5% of the specific gravity of the material [13].

The purpose of this study was to make a prototype plate for the jawbone connector that meets the geometric specifications with the MIM approach. Long term achievement of this study was to retrieve implant products that meet with geometric and mechanical strength with accurate specifications to help reduce import subsidies. In the early stage of the research, it will be limited to geometric aspects of dimensions and properties, while the aspects of biocompatibility and design of the product are still not carried out. In the aspect of geometric and dimensions, the implant will be checked whether it achieves the required standard size, and in the aspect of properties, the results of the MIM will be tested for strength through tensile strength test to see whether the mechanical properties which are tensile strength meet the prerequisites.

2. MATERIALS AND METHODS

The method used in the process of making a prototype jaw bone implant is reverse engineering. Reverse engineering is the process of rediscovering technology, working principles, or systems of a product in the form of tools and machines in whole or in part through an analysis of the structure, functions and ways of working, and interpretation of how this product is made [14].

Phases in reverse engineering include information gathering, understanding of the objects, thorough function analysis, and part analysis, work function analysis, worst case user scenario, external load, internal load distribution, environmental conditions, measurement, and geometric modeling, designing the geometric model with basic dimensions that are ready for production, function analysis, strength analysis according to the problem based on the geometry components in the initial design and assembling the product. Last but not least, evaluation of the product need to be done, as well as the improvement and preparation of massive product production [14].

The research took place at MIDC, Politeknik Bandung (Polban) and the University of Indonesia (UI). Machines used in this research include the 3-AXIS CNC Machine which was used to make precision molds and test aids mold and Small Injection Molding Machines which was used to test precision molds with plastic materials. Plastic materials were used for initial testing before using the feedstock. This research was limited to the design and manufacture of prototype plates with the MIM process for applications in the jawbone as shown in Figure 1.

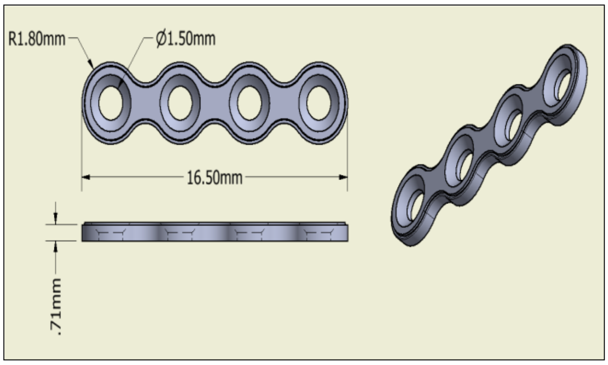

Figure 1. Orthopaedic jaw bone implant plate in the smallest dimension.

Creating a mold was an initial phase to produce mass production. The quality of a product was determined by this phase. Therefore, the mold designing process needs to be done in an appropriate and specific measurement before continue to the next step [9]. The material used for precision mold in this research is Duralumin which also called Duraluminium or Dural. The main alloys consist of 4.4% copper, 1.5% magnesium, 0.6% manganese and 93.5% aluminum. The strength of the material is 450 MPa (65 ksi), with variations depending on composition and temperature. The material used for the implant component is Titanium base alloy Ti CP grade 2 [15].

The first process that carried out was the manufacturing of the feedstock, which is the process of mixing powder and binder between the material (Stainless steel-binder and Titanium-binder). This mixing process used a remix machine in BBLM. The feedstock is consists of metal powders and binders. The metal powder's size required in the MIM process is 22µm-45µm. Diverse in metal powder sizes will cause an impact on the homogeneous and solidity of the feedstock when injected. Binder as an additive to metal powders consists of polymer, wax and additive agent [15, 16].

Based on the literatures, types of polymers used in the process of making feedstock are PE and PP polymers, the type of wax used are beeswax or paraffin wax, and additives used are dispersants, stabilizers or plasticizers. The binder in the MIM process needs to be free from any residue during the debinding or sintering process or else it will cause defects in the product. It also needed to have a low melting point so that it would not damage the green part (injection result) or brown part (debinding result). The binder may not react with powder metal which will cause damage to metal powders and binder composition [16].

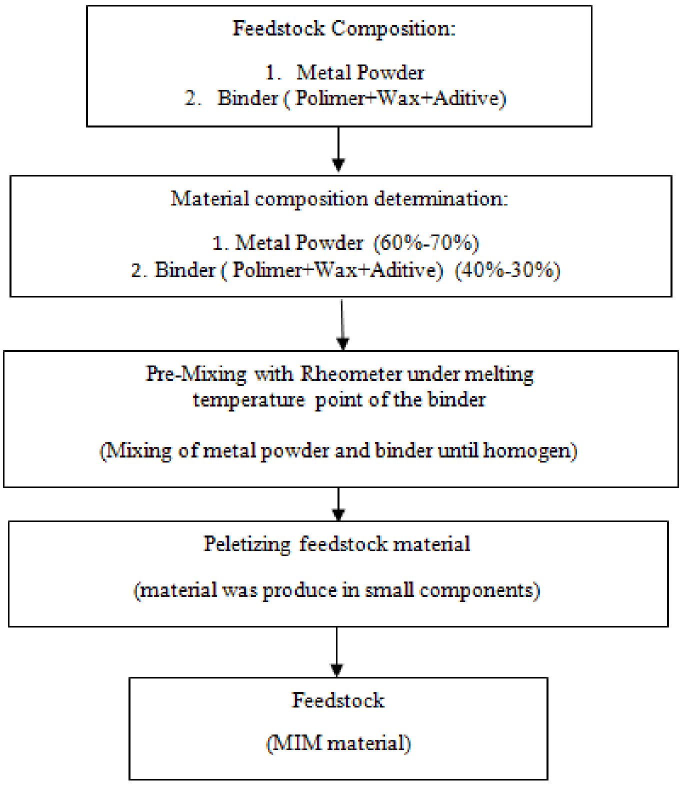

Figure 2. Feedstock production process outline.

The composition of metal powders and binders is mathematically calculated to determine the right composition for the manufacture of the feedstock [17]. The composition between metal powder and binder used in this research was 60% -70% and 30% - 40%. The composition was determined by the size of the metal powder and the type of binder to be added. Metal powders and binders were then mixed (premixing process) using a rheometer device with a rotation of 50-200 rpm in 10-30 minutes so that it can be evenly homogeneous at temperatures below the melting point of the binder. The feedstock was removed from the rheometer and small pellets are formed.

Temperature, length of stirring time, size of metal powder, type of binder and binder composition can highly affect the quality of the feedstock. Multazam et al [18] shows that the higher temperature tends to result in a percentage sintering porosity and wear rate decreases where at the optimum temperature, the product has shown smooth surface and decreased in the amount of porosity significantly to increase density. Feedstock that was made of pellets will facilitate the injection process and the addition of binders was intended to facilitate flowability during the injection process. These feedstock pellets were then left until they were frozen to be processed by injection into metal molds [19]. The schematic outline of the feedstock production process was shown in Figure 2.

3. RESULTS AND DISCUSSION

The precision mold designing process includes designing of the sprue, runner, and gate. Factors to be considered were the amount of cavity, size, gate position and cavity position, runner shape and its position, sprue shape and its position, as well as parting line. In this study, researchers used special software to determine the size, gate shape, and cavity position. The concept of a gatting system was made in a parametric application that can draw 3D which was the Inventor Software 2016 (trial version). The results of the concept are simulated and assessed to determine which are the best.

The variance of the gatting system that has been made in this research shown in Figure 3 where the first design (a) of single cavity runner with triangle cross-section and rectangle-shaped gate, the second design (b) runner with a single cavity in cylinder cross-section and circle-shaped gate, and the third design (c) with single cavity runner in a cylinder shape and rectangle gate cross-section shaped.

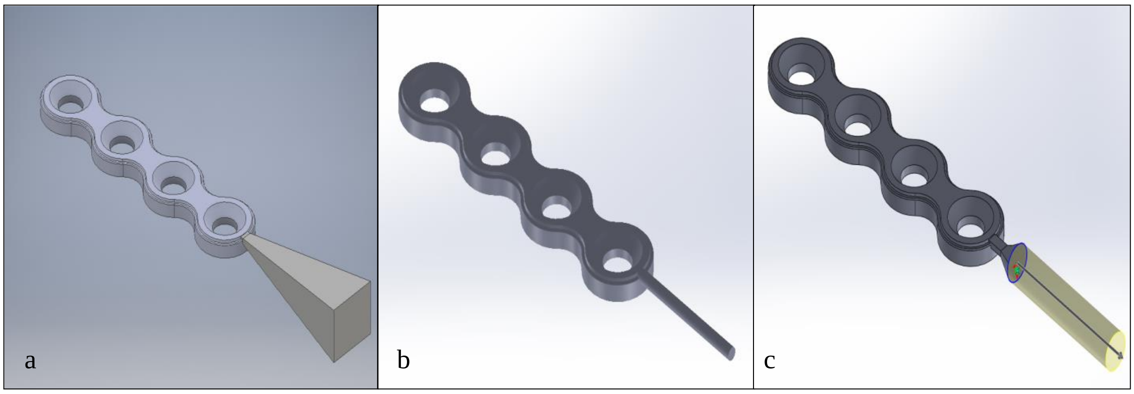

Figure 3 (a-c). Variance of runner and gatting system design for simulation test.

Then, the Moldflow Adviser software (Trial version) was used to find the best gate from the aspect of fluid flow in finding the best flow location. Flow simulation needed to see whether the product results will show defects or not. The simulation results then must be compared with empirical results, so that in the future the results of this process can be more accurate.

The input parameter used in the software flow simulation is at volume range: 354.359 mm3 (Relative Error = 0.006793%) with mold temperature 50℃ (material mold: steel) and barrel temperature was set on 220℃. The result of simulations showed that fill time suggests by the software is 21 seconds to make the perfect filling as in Figure 4.

Filling pressure is also important to see how much engine specifications are needed. The required pressure of 17.37 Mpa for the engine thrust to produce pressure needs to be calculated to see the amount of clamping force according to the formula below. Clamping force must not be too high because it will lead to a deflection of the mold and cause a gap in the parting line. Illustration of the pressure seen in Figure 5.

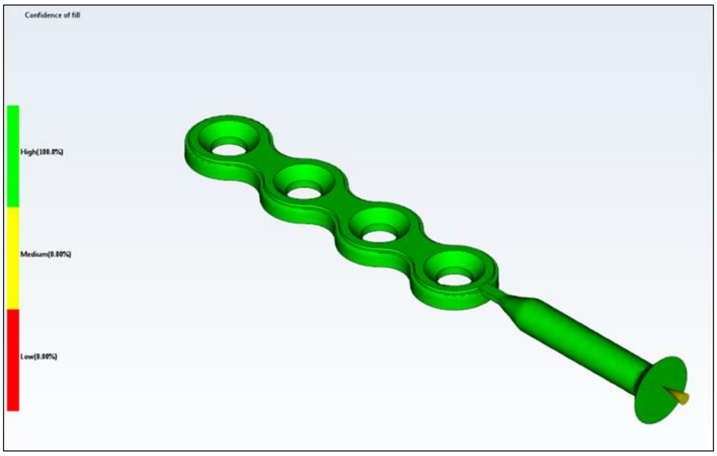

Figure 4. Confident fill simulation.

With P = 17.37 Mpa and A=3.14R²=3.14 x 0.01x0.01=0.000314 m²

F = p.A = 17370000 x 0.000314 = 5454.18 Newton = 545.4 Kg = 0.54 TON

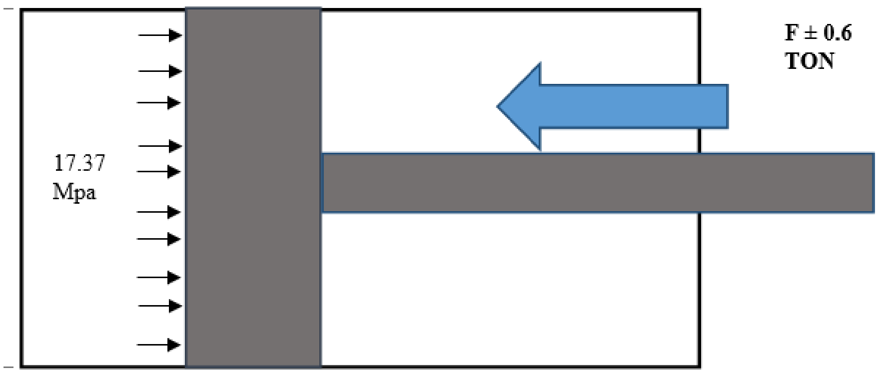

Figure 5. Illustration of filling pressure and clamping force.

The raw material that needed to be molded is usually in a large form. To obtain material optimization, a cutting plan and simulation are needed where the material must be cut according to the size of the mold. The machining process of Roughing to generate G-CODE CNC is one of the dominant processes in mold manufacturing and is carried out by a 3 AXIS CNC machine as shown in Figure 6 (a). The electrode machining process is then carried out to make a cavity on the precision mold that used the EDM process with an electrode made from copper. The EDM process is a non-conventional machining process to get features that cannot be done by 3 axis CNC machines. The results of the EDM process are shown in Figure 6 (b). The technique used to cut mold that suit the design is 3D parting line.

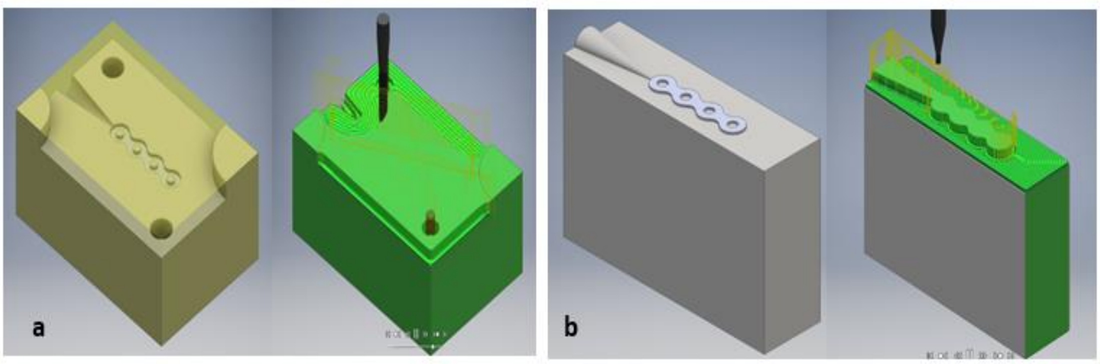

Figure 6 (a). Simulation and G-CODE Raughing with CNC 3 AXIS. **(b)**. Simulation and generate G-CODE results in EDM process.

Result of the molds from the gatting system variance that has been made before by software shown in Figure 7. Four molds with different variances especially in the sprue cross-section design were produced to define which one has the best flow in. Researchers wanted to prove the effectiveness of the gatting system and compare the simulation results from software and the test results with plastic material. 7 (a) show mold's runner design in triangle cross-section and rectangle-shaped gate, 7 (b) is mold runner's design with cylinder cross-section and circle-shaped gate, 7 (c) mold runner's design is about the same with (b) but the runner was designed to bend 90^0 , and 7 (d) mold runner's design was built with cylinder runner shape and rectangle-shaped gate.

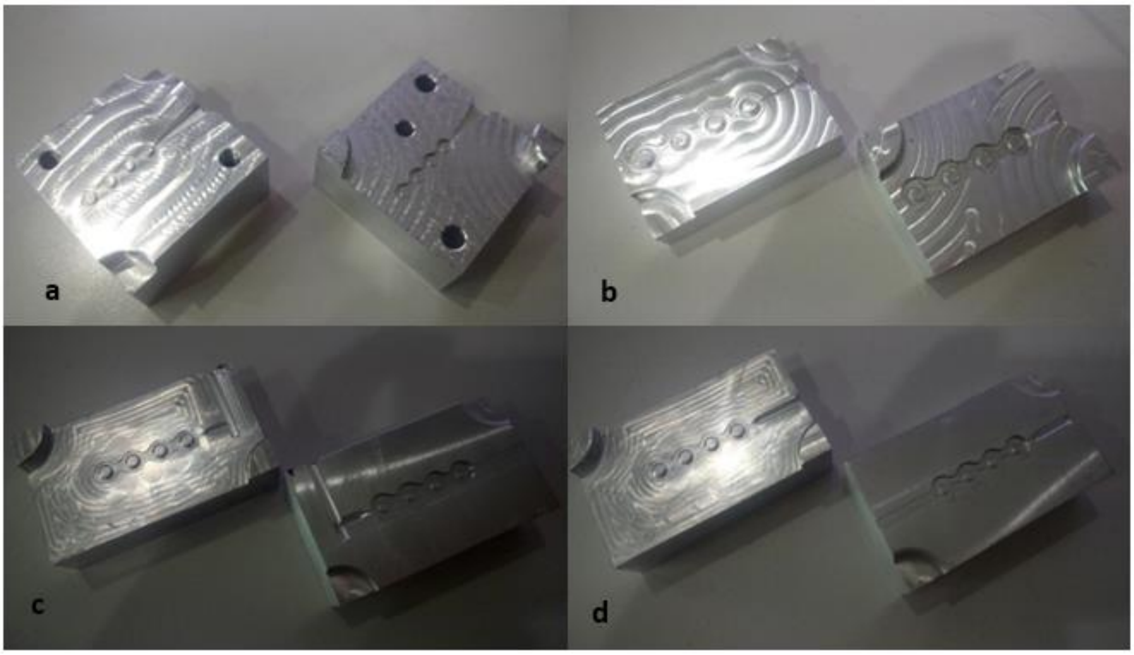

Figure 7. Manufactured molding in 4 variance (a – d)

After molds were produced, they were tested by mold manufacturing tests, conducted by the researchers as in Figure 8. The test must be carried out to see the strength value of the products that have been made.

Figure 8. Mold manufacturing test.

The researchers used plastic material before using feedstock at the initial stage of testing. The material used for testing was polypropylene for its low cost, to see the quality of the flow entering the mold from the gatting system. All of the 4 variances of mold were tested to see the volume cavity, runner shape and dimension. The test delivered by a plastic injection machine with a maximal volume capacity of 125000 mm3, and maximal pressure, P = 6 Bar. The result of plastic material testing from the mold design of figure 7(a) showed in Figure 9 (a). The plastic product of mold design 7(b) showed in Figure 9(b). Mold design 7(c) failed to give any product due to filling process clogged at the gate. Mold design 7(d) showed as in Figure 9(c).

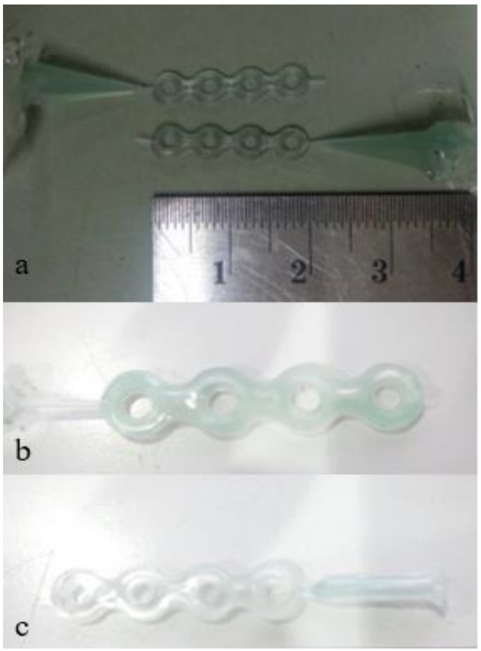

Figure 9 (a-c). Result of initial plastic products from variance mold designs.

After the initial stage of testing, we used feedstock material to produce the plate as in Figure 10. When using the feedstock, we realize that the MIM machine needs to have a larger clamping force, mold heater, controlled temperature, controlled flow and volume of material, and the barrel needs to be horizontal.

Figure 10. Result of mold from feedstock material

Certain aspects need to be evaluated and confirmed to make sure the product meets the requirements. After tested with plastic materials, it can be concluded that from the aspect of the mold, the injection hole must be adjusted to the injection machine standard, the optimal gate position should be fit with the parting line where the parting line must be in the position that does not damage the visual and function of the product, the ejector needs to be available to release the product and make sure that there is no air trapped in the mold.

From the gatting aspect, the volume at the gatting system must be confirmed right on flow, the gate must be easily cut, and the product flow must be balanced. MIM machine aspects that need to be re-checked are that the optimal clamping force at 1.1 Ton, the machine was completed with the mold heater with an optimal temperature of 50℃ and material temperature inside the barrel at 170℃. We also need to make sure that material volume can be arranged at the MIM machine, filling time of material is 21 second and mold pressure set at 17 Mpa.

Parameters that can be influenced the flowability are viscosity, gatting system, heat transfer and the pressure setting. Wax poly-propylene was mixed with the metal powder as the flow material where the melting temperature point at 160℃ and the optimal viscosity achieved at 170℃. The total volume of the cavity, runner dan gate implant was set at 354.359 mm3 (Relative Error = 0.006793%), so that the feedstock can be filled completely into the cavity. When the fluid enters the mold, there will be phase changes from liquid to solid phase. The product must be in liquid form until all the fluid enter the cavity before the turn into solid. The initial temperature of the barrel and mold can affect this phase and molding process.

4. CONCLUSION

This research shows that precision orthopedic implant molds can be made by the MIM approach with different mold variants. The mold that has been made shows that we can produce an implant in the shape that meets with the required geometry. The results of this study are precision mold with several variants with geometric dimensions and mechanical properties meet the target requirements.

MIM technology can be used in making components, not only for manufacturing implants but for other technologies such as weapons, electronics, etc. Therefore, research about component manufacturing using MIM technology must continue to be developed.

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