Development and Characterization of Injection Moulding Mould for Ulna Implant

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Abstract. Metal injection moulding is a method by which metal parts are produced near net form by using metal feedstock. Current medical implants are products that must meet rigorous material, technology and functionality specifications. Corrosion resistance, bio-compatibility, bio-adhesion, bio-functionality and accessibility are the main medical desires of all medical implants. This work focused on the design and production of ulna plate implants using metal injection moulding. To be details on this, maximum stress and shrinkage of ulna implant components are studied. The size after demoulded from cavity was measured and compare to the cavity size. The range of shrinkage is observed by weights lost after debinding process that the result shows 0.1 gram decreased. The average maximum stress is 5.2749 MPa. Based on the result, the products are brittle after debinding process.

1. Introduction

Implant is a metal components of the body that are produced to substitute missing or damaged bones or joints. Modern medical implants are products that must meet rigorous material, technology and functionality specifications. Corrosion resistance, bio-compatibility, bio-adhesion, bio-functionality

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and accessibility are the main medical requirements of all medical implants. Ulna bone is very essential for an ideal motion in the human body. Rapid prototype method produces most human implants, but it is too costly to generate in mass production. Materials such as titanium, silicone and apatite are applied as common raw materials used to produce implant. Reduce of machining activity in producing complete products need to be considered in purpose to reduce manufacturing cost. Metal Injection Moulding (MIM) or Powder Injection Moulding (PIM) is one of the conventional manufacturing technology for fabricating this ulna implant near net shape outcomes [1]. In this study, the mold is designed to fabricate the implant components. The maximum stress of ulna implants component is measured via flexural test. Also, the correlation between the shrinkage effect of ulna implant components is investigated with cavity size. The research scope of this study is to design mold for MIM and study the correlation of injection molding material and cavity shape.

2. Literature review

Biomaterial can be defined as natural or synthetic materials that implied to support, enhance, or replace damaged tissue or biological function in human body. As known, the biomaterial engineering devices that implied in orthopaedics was called implants [2]. Purposing to meet the required characteristics which purpose to consolidate internal and external bone fracture fixation, the osteosynthesis of main implants like pins, screws, plates and nails are used with various shapes and forms [2]. The osseointegration (which referred as direct structural and functional connection between ordered, living bone and the surface of a load-carrying implant) of biomaterial is not depend only towards implant properties, but also on the host bone properties and its regenerative capability [3].

In United States of America, 280 000 of hip fractures, 250 000 wrist fractures and 700 000 vertebral are reported occur in each year which cost by $10 billion. Also, it was reported that more than 4 000 000 operations includes bone substitutions and bones grafting are conducted around the world every year, thus making the demanding of surgical market is crucial [4]. Secondary bone healing needs a degree of micro motion at the fracture area purposing to enhance the development of callus (tough bone tissues which grows around the end of the fractured bone during the healing process) formation [4]. Locking plates are intended to hold the fracture debris while allowing a restrained micro motion which allows a quick secondary bone healing. Whilst, the ulna-shortening osteotomy is a normal operation for multiple ulna-sided wrist disorders. Remarkably, the ulna plates are applied in ulna shortening osteotomy [5]. The implants applied in orthopaedic surgery should gratify numerous biomechanical and biocompatibility properties with referred to human body. The Ti-6Al-4V alloy able to be coated with alumina or zirconium ceramics which existing anti oxidant characteristics (bioinert ceramics), or by hydroxyapatite ceramics which have osteoconductive characteristics (bioactive ceramics). Mechanical strain should have a main effect on the interactions between biomaterials and bones [6-7]. Hydroxyapatite (HA) is known as bioactivity that commonly applied as an implant material in biomedical industries. However, its utilization is severely restrained because of the poor mechanical characteristics, which might results in discomfort of instability and reduce implant life cycle in presence of the body fluids, and local loading as compound stresses [8].

Metal injection molding (MIM) technology is become a greatly attractions among researchers purposing to produce small and intricate components in high volume mass production. Generally, there are four stages of this technology, likes mixing, molding, debinding and sintering. First, the fine metal powders are mixed with binders purposing to produce homogeneous feedstock. Next, the cool feedstock is crushed into small pellets form before undergoes the next MIM processing, which is the injection molding. This process is conducted in order to transform the molten feedstock into a required
shape metal components. The binder removal is necessary to be conducted without gratify the ability of producing the free defect brown components, so called debinding process. Lastly, the brown/debound components are sintered at high temperatures often near to the theoretical.

The work on cavity and core is by far the most significant. The work on cavity and core can be categorized regarding to its form whether it is a simple or complex nature. For example, the circular or rectangular cavity and core moulding is easier to be fabricated [9]. Runner connects the sprue via the gate with the cavity. The materials are melting and filling up throughout the cavity during moulding process at a given temperature and pressure.

Obviously, the runner dimension is depending on the maximum thickness of injected components and the type of material that will being prepared. The wider runner’s cross section resulting in thicker injected components. Fundamentally, the runner cross section should be around 1 mm larger than the thickness of injected components [10]. The molten feedstock fill up the mold cavity via a sprue which is mostly machined in the sprue bushing. It is commonly being the thinnest dimension of the whole system. Then, by considering various prerequisite, the size and location of sprue is decided. It should be small as possible, thus the material is heated without damage by shear. Also, it should be easy to demould during ejecting the implant components, and permitting automate runners separation from the mould, without leaving any blemish on the injected implant components. Besides, the gate is details designed in various configurations [10-11]. The parting line generation method is proposed for a triangular subdivision of the surface model components. In this method, a draw direction is firstly selected. Remarkably, the alloy steel is applied for fabricating the mould cavity and any plates which directly contact with moulding materials. As known, the alloy steels are able to be used in both states, whether it is soft or fully hard, depend on the applications [12]. The machining operations should be consist of four geometrically defined cutters (e.g., milling, turning, drilling and sawing) and geometrically undefined cutter (grinding, honing and lapping). Then, the modern tooling machine for fabricating the mould are performed by multi axial CNC control which highly precise for positioning systems. The deviates of ideal geometrical contour of the cavity surfaces, e.g., ripples and roughness, might diminish the appearance in the particular and form “undercuts”, which increase the necessary of releasing the force [10].

The binders selection is crucial to ensure the feedstock is well melting during injection molding process, which specifically for the melt front temperature difference and cooling time. According to velocity-related outputs, the powder and binders selection are crucial in order to control the maximum shear rate [13]. When shrinkage is decrease, the heating rate is increased, holding temperature is decreased and holding time is decreased. In reducing the shrinkage effects, the vacuum furnace is used to conduct debinding process, however it is useful for the length and width dimensions but not for thickness dimension [14]. The successful of the whole MIM processing is crucially depends on the rheological behavior of the feedstock. As known, the required behaviour is shear thinning, so called by pseudoplastic. For high powder loading of bimodal feedstock is more sensitive towards temperature. The flexure strength and green density of bimodal powder systems are proportionally to powder loading [15]. Besides, the wear resistance behaviour of the tested materials are very depending on the feedstock homogeneity, ability of work-hardening and plastic deformation [16]. The high volume ratios \( (A_s/V) \) samples need less time to perform debinding process due to larger solvent accessibility to extract the binders from the implant components. Higher volume ratios, \( A_s/V \) cause an increase in volumetric pore frequency due to capillary pressure effect, and the temperature plays a major role in solvent debinding by the changes of solubility and diffusion coefficient. The debinding optimization in MIM might enhance the rate production of MIM components, and minimizing defects that might be occured in subsequent processing [17].
3. Methodology

By using Solidwork software, the mold insert are drawn equal to the existing dimension, except for runner, cavity and gate system are differs. In this research work, the used material is Mild Steel AISI 1020, which also applied for, e.g., turning, milling, drilling and tapping operations, by practicing a suitable feeds, tool types and speeds. Two pieces of Mild Steel AISI 1020 plates are used in this research work, which dimension of 110 mm length x 80 mm width x 30 mm height. All the injected implant components should be milled and grind in order to obtain square shape components which accordingly to the present mould block dimensions.

In order to produce square shape of mould insert, the conventional milling machine is used. Impurities/unnecessary removal must be done for acquiring the close dimension of components, by clamping both cavity and core side to the clamping tool. The all sharp edges are milled until obtaining a chamfer which at least 5° angle. Next, the milling process is continued by making 45° angle chamfer with dimension of 3.5 mm heights, purposing to ensure that the components are feasible while fitting inside the present mould block.

Next, the components are being subjected to the process of finishing which conducted to gratify an accurate dimension of components. After completing the surface grinding processes, both cavity and core side are machined using CNC machine, in order to produce gates, runner, cavity and core in more precise dimensions and shapes. The components (workpieces) are drawn by Solidwork software and generated to CNC machine which performed using Mastercam software. Purposing to measure an accurate outside dimension of mould insert is fabricated, it was checked by employing Coordinate Measuring Machine (CMM), before it is fabricated inside the mould block. After completing the injection moulding process, the implant components are measured and being subjected for debinding process before undertakes the flexural ISO 178 test.

4. Result and discussion

The results observe according to the geometrical size of cavity side, core side and injected components which consist of length, width and thickness. The sample was tested by flexural ISO 178 test. The shrinkage was determined by measuring the injected components weight before and after debinding process.

4.1. Measurement of Original Mould Insert

Table 1 presents the measurement of original mould insert by using CMM. The measurement is taken to produce a new mould insert specifically for fabricating the ulna plate shape, using CNC milling machine. The original mould insert measurement consists of the length, width and thickness. Since the existing mould block does not have an original drawing, the measurement must be taken to ensure the new mould insert fit inside the mould block without any gaps which may resulting the damage towards the mould block and mould insert itself.
Table 1. The original mould insert dimensions

| Type   | Length (mm) | Width (mm) | Thickness (mm) |
|--------|-------------|------------|----------------|
| Cavity | 99.9549     | 69.9851    | 25.0356        |
| Core   | 99.9231     | 69.9878    | 15.0300        |

4.2. Fabrication of Core Side

Purposing to fabricate the core side, the CNC milling machine and surface grinder machine are used. The machining process consist of 4 tapping holes and 1 sprue bushing hole. In order to measure the core side, the CMM is employed purposing to ensure the precise dimension obtained is approximately same to the original core size. Table 2 tabulates the core side dimensions after machining process. Precise core side dimension is crucial in order to ensure the mould insert is fitted inside the mould block without any gap. The thickness between original core and fabrication core not equal because of there are several parts that need to fit inside the cavity.

Table 2. Core side Measurement

| Length (mm) | Width (mm) | Thickness (mm) | Hole Diameter (mm) |
|-------------|------------|----------------|-------------------|
| 99.5179     | 69.9655    | 18.1884        | 12.0311           |

4.3. Fabrication of Cavity Side using Ejector Pin System

In order to fabricate the cavity side mould, it was done by CNC milling machine, surface grinder and drilling. As known, the ejector pin holes are used for allowing the ejector pins for pushing out the injected implant components after the filling phase is completed. There are 5 ejector pins, which consist of 4 pins for ejecting the implant component and the other one pin is for ejecting the sprue runner. Table 3 tabulates the measurement of cavity side mould after the machining process. The mould insert is divided into two part, e.g., cavity side and core side. Then, the cavity side is consist of 5 ejectors pin hole, which made up of 4 holes for ejecting part and 1 for ejecting the sprue runner. Subsequently, the all dimensions are being compared. But, there are some errors regarding to the original mould insert and the fabricated mould insert. However, it was in acceptable range because the fabricated mould insert was still in the tolerances range of +/-0.5 mm.

Table 3. Cavity side measurement

| Specification | Dimensions (mm) |
|---------------|-----------------|
| Length (mm)   | 99.8915         |
| Width (mm)    | 69.9855         |
| Thickness (mm)| 25.1884         |
| Ejector hole Ø, Part (mm) | 1 2 3 4 5 |
| Sprue runner  | 5.0311          |
4.4. Result of Implant Components

The complete injected implant components are measured purposing to compare the cavity size of the mould insert, in regards to study the shrinkage effect. All injected implant components are placed on granite table and they are measured using digimatic calliper. It was taking 5 repetitions in measuring the shrinkage effect of the injected implant components with the mould cavity, and it was presented in Table 4. In this research work, hydroxyapatite, palm stearin and Low Density Polyethylene (LDPE) are chosen to be mixed and forming a homogeneous feedstock. Whereas, Table 5 presents the injection molding parameters which conducted by employing NP7 Real Mini of horizontal plastic injection moulding machine, Polymer and Ceramics Laboratory, UTHM.

| Samples   | Length (mm) | Width (mm) | Thickness (mm) |
|-----------|-------------|------------|----------------|
| Sample A  | 39.88       | 9.85       | 2.89           |
| Sample B  | 39.86       | 9.88       | 2.85           |
| Sample C  | 39.99       | 9.79       | 2.91           |
| Sample D  | 39.87       | 9.91       | 2.87           |
| Sample E  | 39.79       | 9.89       | 2.93           |

Table 5. Injection parameters

| Type                  | Machine setting |
|-----------------------|-----------------|
| Heating Temperature (°C) | Nozzle 165     |
|                       | Front 165       |
|                       | Medium 165      |
|                       | Rear 1 155      |
|                       | Rear 2 150      |
| Pressure (P), MPa     | 1.1             |
| Injection Velocity (%)| 25              |
| Injection Time (s)    | 3               |

4.5. Solvent Extraction

The weight loss of the palm stearin is measured and tabulates in Table 6. The injected implant components are soaked in heptane solution within 5 hours at 70 °C. The samples are weighed for each 1 hour. It can be seen that the all samples weight are decreased with regards to immerse time. It was found that weight loss recorded was in range of 0.09 g to 0.10 g. After the solvent extraction process, the injected implant components become more brittle and needs appropriate ways in handling it for the next subsequent processing.
Table 6. Products dimensions

| Samples | Weight before debinding (g) | Weight after 1 hours (g) | Weight after 3 hours (g) | Weight after 5 hours (g) | Average weight lost (g) |
|---------|----------------------------|--------------------------|--------------------------|--------------------------|-------------------------|
| Sample A | 1.182                      | 1.164                    | 1.128                    | 1.092                    | 0.09                    |
| Sample B | 1.172                      | 1.154                    | 1.118                    | 1.082                    | 0.09                    |
| Sample C | 1.201                      | 1.185                    | 1.149                    | 1.111                    | 0.09                    |
| Sample D | 1.191                      | 1.167                    | 1.129                    | 1.091                    | 0.1                     |
| Sample E | 1.210                      | 1.194                    | 1.162                    | 1.130                    | 0.08                    |

4.6. Flexural Test

The flexural strength is defined by the components ability to withstand the deformation under the given load. The flexural test is conducted in order to measure the green strength of the implant components. The 5 repetitions is made in order to obtain an accurate green strength data. Three types of data are recorded for this flexural test, i.e., maximum stress, maximum force and maximum displacement.

Table 7. Flexural test results

| Samples | Maximum force (N) | Maximum stress (MPa) | Maximum displacement (mm) |
|---------|-------------------|----------------------|---------------------------|
| Sample A | 37.4812           | 4.6852               | 0.6470                    |
| Sample B | 44.7000           | 5.5875               | 0.7720                    |
| Sample C | 38.9719           | 4.8715               | 0.6780                    |
| Sample D | 43.0688           | 5.3836               | 0.7880                    |
| Sample E | 46.7750           | 5.8469               | 0.6590                    |
| Average  | 42.1994           | 5.2749               | 0.7088                    |

5. Conclusion

This research work aims to design and fabricate the mould insert for metal injection moulding, in producing the ulna plate implant components. The maximum stress of ulna implant components are studied via flexural test and the shrinkage effect of ulna plate implant components are studied, which correlates to the cavity size. Since this is a preliminary research towards implants material, the material which compatibles to human bone are not covered in this research work, but only covered the design process, e.g., ulna implant component geometries after demoulded and debinding, and correlation between injection moulding material and cavity shape.
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