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MANUFACTURE OF MEDICAL ORTHOPAEDIC IMPLANTS USING COMPUTED TOMOGRAPHY IMAGING AND RAPID PROTOTYPING

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ABSTRACT

The manufacturing method of an orthopaedic implant using computed tomography image of the bone, current enhanced designs and rapid prototyping technology is studied to produce the mould of casting. This method can decrease the complexity of process and production time which as a great impact on medical metal implants manufacturing as compared to the usual approaches. The aim of this study is to integrate the function of 2D imaging, numerical solution, and rapid prototyping method for reducing many of the initial processes cost and time that is based on orthopaedic implants production. The integrated method of using 2D images to 3D part model is applied, and final part produced applying rapid prototyping machine. The comparative results illustrate a significant time reduction in some production steps which is almost near quarter of the current manufacturing process by employing the presented integrated system and rapid prototyping process.

Keywords: tomography image, orthopaedic implant, customized mould production, medical imaging, DICOM converting.

INTRODUCTION

The production of medical implants is one of the most complicated procedures involving several steps such as casting or forging, machining, fine machining, polishing, and coating usually [1, 2, 3]. A typical process of creating a medical implant includes: (1) making the impressions for replicating the affected bone and duplicating the unaffected part, if appropriate; (2) taking an image of defected tissue to illuminate the issue and also to calculate the exact bone geometry; (3) re-designing the damaged part to best fit on the bone using region growing method; (4) prototyping the mould for implant production; (5) non-destructive testing on both mould and implant; (6) coating and sterilising of the implant; (7) surgery and implantation. Thanks computed tomography (CT) imaging and computer technology, the first 3steps in conventional methods are not time-consuming compared with prosthesis manufacturing time. The remained steps which are manufacturing process and final processing including polishing and coating involve8 days of working, which can nowreduceto3 days (every day consider as 8working hours).

CT imaging, computer-aided design/computer aided manufacturing (CAD/CAM), and rapid prototyping have been reported in detail [4-8]. However, none of these studies has focused on the use of integrated systems in quick mould design and manufacture. Furthermore, while most of the studies described the use of simulation in medical implants production and renovation of the missed part of damaged bone, extended experiments are still needed after settlement. CT scans are used to detect the defected bone, and healthy tissue which provide important benefits for manufacturing of a mould for the damaged bone implant. However, CT scanning it is not cheap, and might needlessly expose patients to radiation.

The other systems of 3-D surface translations, for example, laser scanning systems, is also used to gain 3-D images of the bone. However, surface scanning still requires the patient to remain seated for a couple of time, which in return leads to an experiment that may result in imperfect data collecting. In addition, it is not aimed at in vivo condition, hence, the application of 3-D scanners are not recognised for implantation inside the human body [9]. Figure-1 shows a typical example of both CT image and a 3-D scan in different tissues.

Figure-1. CT image and 3-D scan (up) CT scan of a damaged cartilage (down) 3-D scan of knee [10].

Current manufacturing processes of medical metal implants are based on the following procedure; the model will be shaped from the conventionalism plant production method, then the matching mould will be manufactured, after which the implant will be fabricated in a couple of days [11, 12]. Regarding this current methodology, the purpose of this study is to illustrate how the use of CT imaging, computer design systems, and rapid prototyping method can modify various introductory processes which are now used to produce orthopaedic medical implants.

METHODOLOGY

The plan of manufacturing of medical implants require a variety of industrial steps and is expected to reach a market volume of more than USD 4000 million/year which needs significant scientific and experimental investigation to advanced different production procedures appropriate for batch or low series industries. Some parts such as joints with complicated shapes and geometry are very challenging to produce using conventional manufacturing methods. A high-performance 5-axis CNC machine, for example, is required to machine these type of parts. The manufacturing time for a typical knee joint for instance is estimated to be about18 hours and, therefore, it is known as an expensive procedure. In addition, casting or forging have been found to manufacture the knee joint more economically. Nonetheless, these processes suffer from defects associated with inner porosity which in turn leads to lower fatigue and strength resistance which are the main parameters of low life span medical implants. Hence, rapid prototyping method with features of rapidity, development and accuracy have been effectively applied to fabricate those parts such as medical implants and structural examples [13].

Although CT scanning has been presented as a fairly high radiation dose technique, there was no other alternate in the early years. In addition, there was no special modality that can compete CT scanning in academic work in terms of diagnostic precision [14]. Therefore, in this study the CT images are collected from the hospital and, sent to computer directly in DICOM (Digital Imaging and Communications in Medicine) format. A converter system is employed to convert DICOM format to STL using manual segmentation method. The STL file then exported to CAD systems for future design and modification of the first draft as it is mentioned in Mok *et al*, (2015)too [15]. The 3D STL design is considered as a final part in prototyping, thus all the cavities for mould are designed and analysed. The final 3-D design with the help of CAM systems are exported to prototyping machine to manufacture the mould. This mould requires some final processes such as polishing and tension reduction.

RESULTS AND DISCUSSIONS

Computer tomography is often applied to take images for 2-D modelling methods. In the present study, the high resolution 2-D CT imaging permitted capture of the area of interest and helped to generate an STL format file for future engineering designation. Due to the high quality of imaging, the separation of the cartilage from bone, which the case study considers as a joint, is very precise. In addition, this advantage can be increased by positioning the patient optimally and employing digital

manipulation of the STL format file to generate extra undercuts on the tissue which were not combined with the 2-D CT Imaging computational file. This methodology, with the use of a CT scan is slightly more complicated. As impleimplant, such as a broken femur holder can be easily created using the process described in the present study. Figure-2 illustrates the differences in production time between conventional production steps and presented study procedures in 7 mentioned stages. As can be seen, there is a huge difference in the production time when rapid prototyping method is used. In addition, using computer techniques, there is significant time reduction in this step of the production.

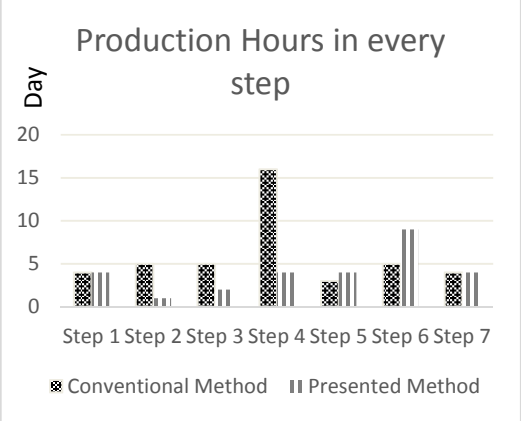

Figure-2. Comparison of 7 steps regarding the time of process.

The result of this study also shows that only one software suite does not deliver all of the required functions for the computational operation of the STL format file and mould manufacture; therefore, the 2-D files, which are in DICOM format, are exported and imported through 3different software packages to produce the final part. It should be considered that some data degradation may result if the export and import accuracies or resolutions are not defined properly in the altered software suites. In addition; it is found that a three cavity mould for the production of an orthopaedic implant due to the simplicity of recovery and ease in the engagement of a spongy device is very time efficient. The fabrication of the joints computationally has been considered because it was complicated and took several attempts.

The process of production also is time-consuming, 5 different manufacturing processes of implants are compared regarding the time of production. Figure-3 shows these differences and, illustrate that forging presents shorter time while the machining procedure is radically time-consuming. Prototyping mould also is time consuming after permanent mould casting and machining process, however, the variety of products can raise to an amount of batch production series applying this method.

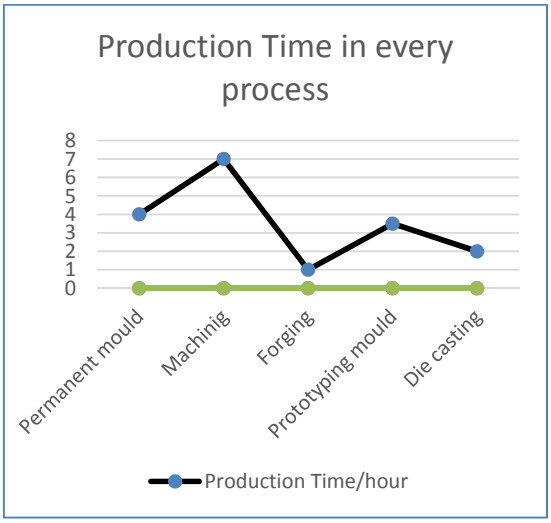

Figure-3. Time of production in 5 different manufacturing processes of bone medical metal implants.

Regarding the density of parts rapid prototyping method shows that it is potential to produce almost around 90% of original parts which is produced from block of material in machining. This amount also illustrates the complexity of powder arrangement in additive manufacturing process. It should be noticed that concentration of final produced part is based on the machine and purity of material as well.

In addition, in this research the surface quality (SQ) of products are measured. Based on the result, the SQ for implants which is manufactured by each process is presented in Table-4. Final part made by die casting and forging process show the lowest SQ while Machining and prototyping mould casting distinguish the higher SQ. In this table, the post processing such as polishing and coating were not considered.

Table-1. Surface quality of final part in each process.

Process	Surface quality
Permanent-mould casting	▽
Machining	▽▽
Forging	▽
Prototyping-mould casting	▽▽
Die casting	▽

CONCLUSIONS

A method for the production of Orthopaedic implants is defined by the use of 2D CT imaging, design

of CAD system, and rapid prototyping method. The implants were manufactured applying the rapid prototype castin combination with traditional techniques, which includes final polishing and coating. The implant is conceived, produced, and delivered to the patient in3 days, a significantly shorter period compared to the use of current procedures which employ casting, forging or machining process. Regarding the usage of described method in this study for fabrication of medical implants, a deliberated geometry is achieved for orthopaedic implants which can best fit the patient's defective or missing tissues.

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