Application of Rapid Prototyping for Development of Custom–Made Orthopedics Prostheses: An Investigative Study

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Abstract: Recently, as the result of development in modern imaging, computerized three dimensional data processing and advanced engineering techniques, a prosthesis that match the skeletal anatomy can be accurately designed using computer aided design (CAD) where the physical model of prosthesis or skull replica can be produced through rapid prototyping (RP), rapid tooling (RT), and computer aided manufacturing (CAM) technology. This paper aims to describe CAD, CAM, RP systems and technologies for design and fabrication of custom-made hip prostheses. A novel methodology based on RP technology is applied to design and manufacture a custom-made hip prostheses. Results show that the RP models provide an accurate and useful tool for preoperative, surgical simulation and fabrication of such prostheses. Concerning the disadvantages such as time and cost for the hip prostheses design and need for surgical robot to perform the bone resection and preparing proper femoral canal, RP technologies fabricate the custom-made prostheses quickly, accurately and economically.

Keywords: Image Processing- Custom-Made Hip Prosthesis- Medical Rapid Prototyping


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1 INTRODUCTION

Rapid prototyping (RP) technologies are the most widely applied and known fabrication methods that are based on additive fabrication principles [1]. RP represents a new set of manufacturing processes that can fabricate a representative 3D physical model of any shape directly from a Computer aided design (CAD) model using a layer by layer building technique. Currently, leading RP technologies include stereolithography (SLA), selecting laser sintering (SLS), fused deposition molding (FDM), 3D printing (3DP) and electron beam melting (EBM). These differ in the manner of layer deposition techniques, speed, accuracy and building materials and the suitability of applications [2,3]. In recent years, the application of RP technology in medical area has grown tremendously and an entirely new field, known as medical rapid prototyping (MRP) is emerging. MRP basically involves manufacture of dimensionally accurate 3D physical models of human anatomy derived from medical image data. This 3D physical model can enhance interpretation, visual and physical evaluation, and aid in the rehearsal and planning of the surgical steps before a surgical operation is carried out. Combining the technologies of RP and rapid tooling, it is possible to fabricate complex 3D physical objects and medical prostheses in a wide range of materials and sizes, from plastics to metals and biocompatible materials, and from large models to microstructure. MRP is now a multidiscipline field, which draws resources from the fields of medical imaging, design and manufacturing, biomaterials, tooling and bioengineering (Figure 1). MRP plays an important role in diagnosis treatment, surgical planning, medical education, design and manufacturing of custom prostheses and surgical tools. The clinical application of MRP models could include reconstructive operations like oral and maxillofacial surgery, dental implantology and especially orthopedics [4,5].

Fig. 1 A flowchart for design and manufacturing of prostheses, surgical aided tools, and medical devices [6]

Fig. 2 Schematic of total hip replacement (THR) surgery [7]: 1) Removing femoral head  2) Inserting acetabular component  3) Preparing femoral canal  4) Prosthesis inserted into femoral canal  5) Artificial hip (in place)
In the field of orthopedics, especially in total hip replacement (THR) there is a great quantity of requirements for prostheses in surgery every year (Figure 2). Prostheses could generally be divided into two categories: standard and customized prostheses. To accommodate the great variability of the three-dimensional shape of the femoral canal, custom femoral prostheses have been designed. The rational for such prostheses (custom-made hip prostheses) is to fit the prostheses to the femurs rather than shaping the femurs to fit the prostheses (standard prostheses) [8,9].

Basically, three different methods have been used to obtain information about the geometry of the femoral canal for CAD/CAM production that are intraoperative molding, conventional radiography and computerized tomography (CT) imaging [8,9,10]. The most accurate method for design of custom femoral prostheses is CT imaging and 3D reconstruction of the femoral canal. The weak points of designs based on CT are [11,12,13,14,15]:

- Slice thickness of 2-5 mm and slice spacing of up to 10 mm, which may result in problems of dividing cortical from cancellous bone in the proximal part of the femur, and neglecting septum calcar ridge in design.
- Calculations of design parameters such as leg length, femoral offset, and anteversion angle, in 2D view, leads to errors in the real measurement.
- Lack of proper designed prosthesis matching with abnormal hip joint such as dysplasia patients.
- Long design cycle.
- Difficulty in consultation between the designer and surgeon.
- Designer experience dependence.

Due to the above problems this paper is providing a new methodology for customized hip prosthesis to provide a 3D modeling of prosthesis involving intra-medullary section with better fill-fit and extra-medullary section for restoring original femoral neck. Combination of this novel methodology with RP technology, facilities manufacturing of custom-made hip prosthesis and provides time and economical advantages.

2 METHOD AND MATERIAL

The proposed methodology is based on design criteria of intra-medullary and extra-medullary of femur by using precise three dimensional computer modeling of the femur (Figure 3). The intra-medullar part of the prosthesis is constructed with the aim of achieving the best possible contact with improved bone tissue in the proximal femur (Figure 4). Through individual design of the extra-medullar part it is possible to restore the original hip joint geometry (Figure 5). After design, the simulation and canal fill and fit rate can be calculated using the cross-sectional images in the five critical levels (Figure 6) or in the lateral (Figure 7) and frontal view (Figure 8). Finally, the accepted CAD model of custom-made hip prosthesis will be manufactured via RP technology (Figure 9).

Fig. 3 Proposed methodology for design and manufacturing of custom-made prosthesis via RP

Fig. 4 Different steps for design of intra – medullar portion
This research is conducted based on the CT images. For the purpose of design based on Intra-Medullary, the reconstruction of a three-dimensional canal using MIMICS software for edge-detection of the canal based CT image data for designing the stem of prosthesis was achieved. Subsequently, the data were analyzed and the stem prosthesis was designed. The canal of the proximal femur above the lesser trochanter was mainly composed of cancellous bone sectioned obliquely on the CT scans, making the relative contrasts in this region unclear. Femoral calcar existed in this region and played an important role in the force transfer and stability of the prosthesis, therefore, contours of the calcar lateral canal could not be neglected in the design process of the prostheses. In extra-medullary design using 3D modeling, the upper part of femur was designed to achieve maximum restoration based on reverse engineering techniques.
3 DISCUSSION

Due to the fact that the endosteal canal varies significantly from person to person, thus, using standard size of pre-designed prosthesis, is not sufficient to achieve a high degree of accuracy in terms of modeling the proximal femur. Therefore computer assisted reconstruction of a three-dimensional canal model of the femur is a very promising approach to produce custom-made hip prostheses. Computer analysis of the data obtained from CT slice and CT scans data, provide the accurate individualized data which was used to design an optimal fit and fill hip prostheses via CAD/CAM. Moreover, it is a general experience that the use of custom-made hip prostheses offer greater possibilities to achieve ideal antversion, medial femoral head offset and leg length correction while other types of hip prostheses possess high abnormal shape of the upper end of the femur. Use of custom femoral components enable optimization of the hip biomechanics and eliminates the need for highly modular femoral stems [16,17].

The downside of applying custom designed prosthesis components is the time and cost associated with the design as well as the need for surgical robot to perform the bone resection and canal preparation of femur insertion. However, by growing and streamlining custom-made prostheses application, based on a CT scan, could lead to reduction in the overall time and cost. To fabricate custom designed implant components at a reasonable cost, has always been a problem and has discouraged its application in the past. Recent developments in layer fabrication using RP technologies can radically change the situation. Recently most implants in variety of biocompatible alloys are available and are produced via QuickCast Technology or Electron Beam Melting technology. Electron Beam Melting (EBM) technology fabricates the custom designed components directly from the CAD model of designed custom-made prostheses. It is capable of fabricating 10-15 custom prosthesis components in less than 15 hours in either titanium or cobalt-chromium at a reasonable cost. The finishing operation is very similar to conventional prosthetic fabrication and would not add the total cost significantly. One advantage of fabricating a femoral prosthesis component using EBM technology is the ability to produce the porous bone ingrowth surface simultaneously, otherwise associated with the sintering operation of titanium or cobalt-chromium beads, it is normally done in multiple steps and would require manual laboring, Which leads to additional savings in time and cost.

4 CONCLUSION

In this study, a novel method to design medical customized hip prostheses, based on sectional medical images and RP technology is presented, and highlights the following benefits:
- 3D modeling and high accuracy of femoral canal reconstruction due to the smaller slice thickness
- 3D modeling of prosthesis neck axis and aligning it with the standard neck in order to restore the original neck position of hip joint
- In view of septum calcar ridge in design, leads to improvements in stability
- Facilitating the communication between the designer and surgeon

Compared to the standard cementless hip prosthesis and the conventional custom-made prosthesis, the present novel methodology of custom-made prosthesis has the following significant advantages:
- Optimal fit and fill of the prosthesis
- Improved physiological stress distribution on the proximal femur
- Improvement in primary stability
- Providing favorable conditions for bone remodeling
- Optimization of the biomechanics of the hip joint via individual neck design
- Safe and precise implantation
- Excellent pre-operative planning

Concerning the disadvantages such as time and cost for the prosthetic design and need for surgical robot to perform the bone resection and preparing femoral canal, rapid prototyping technologies namely EBM technique, fabricates the custom implant components quickly and economically.

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