Design for manufacturing of custom-made femoral stem using CT data and rapid prototyping technology

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Abstract: Rapid prototyping (RP) applications have an increasing trend, making the future of RP more and more promising. These applications may include design, development, and manufacture of medical devices and instrumentation, as well as prosthesis design, anatomical modelling, surgical planning and prosthesis fabrication. This paper provides a new methodology for design of custom-made femoral stem, providing high accuracy of femoral canal reconstruction via 3D modelling of femoral stem with optimal fill and fit. The result of this methodology is optimised load transfer, minimum stem micromotion, increase in initial stability and extended durability. In addition to
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in the above, the possibility of combining the stem with different modular necks to satisfy any type of femoral head shapes and facilitating the communication between designer and surgeon are other advantages. Applying RP technology has facilitated manufacturing of complex 3D femoral stems and has lead into time and economical benefits.

Keywords: MRP; medical rapid prototyping; custom-made femoral stem; fill and fit.


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1 Introduction

In recent years, with the development of modern imaging technology, computerised three-dimensional (3D) data processing and advanced engineering techniques, a prosthesis that fit the skeletal anatomy can be exactly designed via computer-aided design (CAD) techniques. The physical model of customised prosthesis or skull replica can be produced through subtractive or additive manufacturing processes, such as computer numerical control or rapid prototyping (RP), respectively (Singare et al., 2006). In
comparison to subtractive technologies, RP-based technologies, also called solid freeform fabrication, refer to new collection of manufacturing processes that can fabricate a complex 3D physical model of any object directly from 3D digital data like CAD model using a layer-by-layer building technique. In recent years, many RP technologies have been developed; most common types include stereolithography (SLA), selective laser sintering, fused deposition modelling and 3D printing. Moreover, advanced RP techniques which applying different metal powder alloys include laser engineering net shaping and electron beam melting (EBM) (Harrysson and Cormier, 2006; Kowalczyk, 2001; Rahmati et al., 2009).

Application of RP technology in medicine has been significantly developed and has opened new field in RP, known as medical rapid prototyping (MRP). Fundamentally, MRP includes manufacture of dimensionally accurate 3D physical models of anatomical structures of human body based on anatomical information derived from scanning data, such as computerised tomography (CT), magnetic resonance imaging (MRI) and laser scanning. MRP plays increasingly prominent role in medicine and covers different fields, such as diagnosis treatment, surgical training, surgical simulation, pre-operative planning, design and manufacturing of customised prostheses and surgical aid tools. Clinically, MRP models could be used in reconstructive operations such as craniofacial and maxillofacial surgery, dental implantology and especially orthopaedics (Gibson et al., 2005; He et al., 2006; Hieu et al., 2005; Kowalczyk, 2001; Liu et al., 2006; Singare et al., 2006; Winder and Bibb, 2005).

In the field of orthopaedics, especially in total hip replacement (THR) (Figure 1), there is a great quantity of requirements annually for femoral stems surgery (Jun and Choi, 2009). Femoral stems could be generally divided into two categories: standard and customised stems. To include the great variability of 3D shape of the femoral canal, customised femoral stems have been designed (Adam et al., 2002). Generally, to acquire information about the geometry specification of the endosteal femoral canal for production via CAD/computer-aided manufacturing (CAM) techniques, three various methods have been utilised that are intra-operative moulding, conventional radiography and CT imaging (Adam et al., 2002; Mathur et al., 1996; Ruya et al., 2005).

CT-based design is the most accurate procedure for 3D reconstruction of the femoral canal as well as design of customised femoral stems (Adam et al., 2002). However, the weak points of designs based on CT data may include: inadequate fill and fit, high slice thickness of 2–5 mm and slice spacing of up to 10 mm, which may lead into problems of distinguishing between cancellous bone and cortical bone in proximal area of the femur and hence neglecting septum calcar ridge in design. Moreover, long design cycle, hardship in consultation between designer or manufacturer and surgeon, and lack of simulation of designed stem with medullary canal (Adam et al., 2002; Bo et al., 1997; Guo et al., 2004; Kawate et al., 2008; Kim et al., 1998; Pawlikowski et al., 2003; Singare et al., 2006; Viceconti et al., 2001; Werner et al., 2000).

Due to the above-mentioned problems, this paper is aiming to provide a new methodology of designing customised femoral stem that could provide high accuracy of femoral canal reconstruction via 3D modelling of prosthesis stem with optimal fill and fit. The result of this methodology is optimised load transfer, minimum stem micromotion, increase in initial stability and extended durability. Facilitating the communication between the designer and the surgeon and having the possibility in combination of modular necks for satisfying all types of femoral head shapes are the additional advantages.
Figure 1  Schematic of cementless THR surgery: [10] (1) removing femoral head; (2) inserting acetabular component; (3) preparing femoral canal; (4) prosthesis inserted into femoral canal; (5) artificial hip (in place) and (6) follow-up of THR via radiograph image (see online version for colours)

2 Methodology

The proposed methodology is based on design criteria of intra-medullary of femur using exact 3D computer modelling of the femoral canal. The intra-medullar portion of the stem is constructed with the purpose of achieving optimal fill and fit in the distal and proximal femur. The designed femoral stem model is evaluated and simulated in the medullary canal and subsequently manufactured via RP technology, and the proposed methodology is shown in Figure 2. Finally, using different modular necks in the extra-medullar part, it is possible to restore the original geometry of the hip joint.

2.1 Custom-made femoral stem design

Modelling of human anatomy in a CAD-based environment is known as bio-CAD modelling. Bio-CAD model construction of interested tissue begins from the anatomic data acquisition via an appropriate medical imaging system (Sun et al., 2005). Hence, the custom-made femoral stem design approach is initiated from the non-invasive anatomic data acquisition of region of interest (ROI) via CT scan of the patient’s hip joint. Slice thickness and the resolution rate of CT images will influence the accuracy of modelling (Bibb and Winder, 2009; Mallepree and Bergers, 2009). Hence, the CT images were
acquired with 1 mm slice thickness and a resolution of $512 \times 512$ pixels and $0^\circ$ gantry tilt. After data acquisition, the CT data were exported as Digital Images Communications in Medicine format to the materialise interactive medical image control system (MIMICS) software (Hieu et al., 2005; Mimics, 2007).

**Figure 2** Proposed methodology for design and manufacturing of customised femoral stem (see online version for colours)

2.1.1 **Thresholding**

When the CT images were imported into MIMICS software, the segmentation was the first stage in separating the soft tissue from hard tissue by isolating the bone structure (hip area or ROI) using a proper threshold value. Threshold value known as CT number (a number value allocated to each pixel) is ~$200$–$2,000$ HU which satisfies the requirement for isolating in the case (Winder and Bibb, 2005). After segmentation technique, a region growing technique enables the created segmentation via thresholding to be split within the CT scans. After region growing, 2D contours of CT scans were
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stacked upon each other in 3D space and created the final 3D voxel model known as volume element (Figure 3). Thresholding of 700 HU was applied to separate the cortical and cancellous border and construct the femoral canal to design femoral stem which is based on intra-medullary criteria as shown in Figure 4.

**Figure 3** Isolating soft tissue from hard tissue via segmentation and region growing technique (thresholding value 200–2,000 HU) (see online version for colours)

**Figure 4** Cortical and cancellous bone border separation (thresholding value 700 HU) (see online version for colours)
2.1.2 *Intra-medullar-based design*

The design criteria was developed and evaluated to achieve optimal primary and secondary long-term stability and to restore physiological load transfer from the stem to the femur because of better fit and fill. These two features can enhance bone stock anchoring and optimum conditions for bone remodelling in the perimeter contact area between the stem surface and the bone. These characteristics can improve the patient’s life quality and increase the stem durability. To satisfy these conditions, this design phase was initiated with marking slices cross-sections by points. On the other hand, in this step every slice (distal to the lower resection level of femur in 20 mm above lesser trochanter) was marked to extract femoral canal by consideration of cancellous and cortical border obtained in density thresholding process by MIMICS software as earlier stated briefly (Figure 5). Based on thresholding, each image pixel that is below the specified threshold value would be removed by MIMICS. To determine the optimised threshold values in design stage, grey values must be determined along the CT slices. As shown in Figure 6, regarding the lesser trochanter level, its profile was extracted using a MIMICS option called ‘draw profile line’ which is applicable for the remaining slices.

A similar study done by Adam et al. (2002) has shown that higher grey values relate to cortical bone with higher density and lower grey values relate to cancellous bone with lower density, respectively. They also mentioned that due to noise, beam hardening and the partial volume effect, the HU values for cortical bone were scattered, leading to curved peaks of cortex in HU profile. In 1999, Aamodt et al. (1999) demonstrated that, in general, femoral canal preparation using conventional reamers for values of less than 600 HU is impossible. Another research conducted by Adam et al. (2002) has shown that constant threshold value cannot be applied to all; this is due to the relation between cortical bone density, patient specification and imaging parameters. They proposed a threshold slightly above the cancellous HU values in the two-third of the cortical peak to be chosen, which is usually between 600 and 800 HU to be used. They also stated that the thick internal septum of cortical bone in the lesser trochanteric area of femoral canal would remain after thresholding process. To satisfy all the above conditions, an average thresholding value of 700 HU was used in design process, as shown in Figures 4 and 6.

**Figure 5** Marking of slices by points from distal to proximal area for optimal fill and fit (two samples of marked distal (right) and proximal (left) slices) (see online version for colours)
The internal cortical septum, which is also known as femoral thigh spur, is a cortical bone ridge protruding from mediodorsal endosteal cortex into the medullary canal. However, it narrows the dorsal part of main femoral cavity and extends from lesser trochanter into the femoral neck, and it is in line with the neck longitudinal axis (Figure 7). Adam et al. (2002) have reported high density of cortical septum, and emphasise thickness of 3 and 35 mm length in different people, which is surrounded by cancellous bone in the lesser trochanteric zone. They have also found out that the femoral thigh spur can be visualised in lateral conventional radiographs, while the X-ray beam is aligned with the spur. This finding is common in different people regardless of gender and age. The septum thickness and the connecting trabecular bone are proportional with mass and density of cancellous bone. It seems that in old people, in particular for elderly females who suffer from bone hollowness, femoral thigh spur mass is less than young people (Adam et al., 2001; Decking et al., 2003). However, it is essential for support and primary stability of cementless THR stems; therefore, in stem design process, the femoral thigh spur must not be neglected.

After the slices were marked in MIMICS software, the points were exported to Geomagic, which is a reverse engineering software package (www.geomagic.com). After multiple steps, the point cloud was converted into a solid model and saved as Standard for Exchange of Product (STEP) format and exported to Catia software (http://en.wikipedia.org/wiki/CATIA). In Catia, the spline curves were extracted for stem design and possibility for inserting to the femoral canal during THR (Figure 8). To assure the reconstruction accuracy of canal femoral, the fitting deviation between designed model and point cloud data were evaluated using the Geomagic software as shown in Figure 9. The maximum derivation was 0.463832 mm and the average deviation was 0.041078 mm with the SD 0.069066 mm.
Figure 7  The femoral thigh spur (arrows) is highly dense and thick and cannot be removed from CT images by thresholding and it is essential for support and primary stability of cementless THR stems.

Figure 8  Using point cloud to extract spline curves for stem design via CAD techniques (see online version for colours)

Figure 9  Evaluation of fitting deviation between designed model and point cloud data (see online version for colours)
2.1.3 3D reconstruction of femur

Based on proposed methodology as shown in Figure 2, for completing the femoral stem design and the possibility of using modular neck after manufacturing, interface plane must be defined. In other words, interface plane or bone cutting surface is a surface that femoral head will be separated during THR surgery. Because of changeability stem design based on this cutting level position, it is a decisive factor in the design and must be done in consultation with the surgeon. Nowadays, utilising computer softwares in pre-planning and simulation of complex surgery especially orthopaedic surgery like THR has an increasing trend. On the other hand, in 3D virtual environments, surgeons and designers or manufacturers simulate complex surgeries and make decision based on virtual reality and different modelling techniques (Handels et al., 2001; Lee et al., 2006; Wong et al., 2007).

Among these softwares, the MIMICS can be used for pre-planning and simulation and making link between RP machines for bio-models manufacturing. MIMICS software is an interactive tool for the segmentation of CT and MRI images and 3D object rendering (Dhoore, 2006). After cutting femoral head via consultation with surgeon, the resulted model was converted into a surface tessellation language (STL) format and imported into Geomagic software to create free form surfaces of non-uniform rational B-spline patches. This is due to the fact that MIMICS is unable to export the model in standard CAD format like STEP; hence, Geomagic is used to convert it into standard CAD format. Next, the model was saved as solid CAD model using STEP format, and imported into Catia software, and using different CAD techniques, interface plane was determined as shown in Figure 10. Finally, the stem design was completed using the interface plane in order to enable to insert any modular necks as shown in Figure 11.

Figure 10 Assessment of interface plane via virtual reality and CAD techniques (see online version for colours)
2.1.4 Design evaluation

After the femoral stem was designed (Figure 11), the evaluation and canal fill and fit can be calculated in lateral and frontal view (Figure 12) or using the cross-sectional images at the five critical levels as explained in the following (Figure 13) (Nishihara et al., 2003):

**Level 1**: This is the lower corner of the femoral neck resection.
**Level 2**: This is the centre of the lesser trochanter.
**Level 3**: 1 cm distal from the centre of the lesser trochanter.
**Level 4**: This is the middle of femoral stem.
**Level 5**: 1 cm proximal from the femoral stem tip.

2.1.5 Modular neck technology

For restoring of normal hip biomechanics in THR for each patient, surgeons use modular neck technology. Since 1985, surgeons have been using modular necks for minor variations in cup position or stem anteversion, impingement issues, anatomic variation in version neck orientation, avoiding the use of elevated liners, independently adjusting limb length or offset and additional neck length options for ceramic bearings (Merloz, 2008). Following assessment of modular neck via consultations with surgeon, designed stem can be used with modular necks and finally the position of femoral head would be restored (Figure 11).
2.2 Femoral stem manufacturing

After the design phase, the STL file of model will be transferred to a RP machine, such as SLA machine or EBM machine, to produce custom-made femoral stem. However, the final stem will be made out of titanium alloy (Ti–6Al–4V) and the surface of the stem will be finished as follows: polishing the distal part to prevent any adhesion to distal bone then the proximal part will be grit blasted and coated with hydroxyapatite applied in 70 μm layers (air plasma spraying) (Philippe et al., 2005).

3 Discussion

Due to the variability of the femoral canal between one person and another, using traditional femoral stem design is not sufficient to assure accurate modelling of the proximal femur (Adam et al., 2002). To eliminate the problem, custom-made femoral stems using computer-aided reconstruction of 3D canal model of the femur were proposed. Computer analysis of the patient’s data acquired from CT scanning provides the precise individualised data which may be utilised to design and manufacture an optimal fill and fit stem by means of CAD/CAM technologies (Adam et al., 2002; Guo et al., 2004; Kawate et al., 2008; Pawlikowski et al., 2003). Hence, this research was conducted based on the CT scan data.

In-design based on intra-medullary 3D femoral canal reconstruction was done using MIMICS to assess optimal threshold between cancellous and cortical bone and marking slices to optimise fill and fit between hypothesised stem and the femoral canal. Eventually, after a number of steps, the femoral stem was designed. Moreover, during design the femoral thigh spur in the canal of the proximal femur above the lesser trochanter was not neglected. As above-mentioned, it will be playing an important role in force transfer and stability rate of the designed stem. Close contact between the femoral...
stem and the septum calcar may result in load transmission such as physiological condition (Dhoore, 2006; Wong et al., 2007).

Loosening of the femoral stem as a critical issue affects the femoral stem durability and the patient’s life quality. The major issues that result in loosening include biomechanical and biological subject (Guo et al., 2004). From biomechanics point of view, femoral stem was designed to present optimal fill as well as maximum congruence with the femoral canal, hence to decrease micromotion and to generate acceptable degrees of stress distribution in the bone tissue like its physiological ones. Other positive characteristics of stem include optimal fit easily being inserted and implanted in the medullary canal. These characteristics help to assure initial stability and to supply proper requirements for the bone ingrowth. Moreover, due to the biological fixation, implant loosening is reduced as well.

In spite of the desired and proper design of custom-made femoral stem for optimal fit, the femoral cavity should be accurately prepared for the stem to be inserted. Preparing the canal cavity for the femoral stem is a geometrical challenge for orthopaedic surgeons. This is due to the fact that making and executing a plan requires the exact location for cuts and holes, which is almost impossible to make a precise fit via manual surgeries. In industry area, the required accuracy and precision is to be achieved by robotics system. The goal of the system, also called computer-aided surgical planning and robotics (CASPAR), is to improve the prosthesis selection and sizing, accurate positioning of the prosthesis within the femoral cavity for inserting. The manual broaching and reaming as current techniques for preparing the femoral cavity has considerable inherent inaccuracy (Wu et al., 2004). Making a precise fit between the stem and the canal cavity using CASPAR, the femoral stem will receive uniform stress distribution during loading. Close intra-medullary femoral stem fit using robotics-assisted reaming decreases the stress concentration due to contact between the stem–bone interface, so lessening the pain after cementless total hip arthroplasty (Wu et al., 2004). Other advantages using CASPAR include lower risk of valgus or various malposition of prosthesis and preventing intra-operative femoral fracture (Nishihara et al., 2004).

Recently, developments in additive manufacturing using RP technologies have fundamentally modified the common techniques in such a way that most prostheses in diversity of biocompatible materials are fabricated by QuickCast technology or EBM indirectly or directly, and utilised in the patient body (Harrysson and Cormier, 2006; Harrysson et al., 2007; He et al., 2006). EBM technology fabricates the customised prostheses directly from the designed model as well as EBM machine is able to fabricate almost 10–15 customised prostheses in less than 15 hr in the biocompatible alloys, such as titanium or cobalt-chromium, at a rational cost. The finishing step in comparison with conventional prosthesis is very similar and would not add the overall cost significantly. One benefit of fabricating an orthopaedic prosthesis using EBM technology is the capability to produce the porous bony ingrowth surface simultaneously; otherwise, in relation to the sintering step of titanium or cobalt–chromium beads, it is normally done in multiple steps and would need manual labouring (Harrysson and Cormier, 2006; Harrysson et al., 2007). This will lead to additional saving in time and cost.
4 Conclusion

The novel methodology presented in this paper has the potential to design an anatomical femoral stem with extended durability. The designed stem using this technique provides the following benefits:

- 3D modelling and high accuracy of femoral canal reconstruction due to the smaller slice thickness and advanced modelling techniques
- in view of septum calcar ridge design leads to improvements in stability
- facilitating the communication between designer and surgeon.

Compared to the standard cementless femoral stem and the conventional custom-made stem, the present novel methodology of custom-made stem has the following advantages:

- optimal fit and fill of the stem
- improved physiological stress distribution on the proximal femur
- improvement in primary stability
- providing favourable conditions for bone remodelling
- safe and precise implantation
- excellent pre-operative planning.

Concerning the disadvantages such as time and cost of the stem design and need for surgical robot to perform the bone resection and preparing femoral canal, RP technologies namely QuickCast and EBM fabricate the customised femoral components quickly and economically.

References


