Developing The Custom-made Femoral Component of Knee Prosthesis using CAD/CAM

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Abstract: The femoral component of knee prosthesis is a biomedical element with complex surface, and the design and production is a complicated task. In this paper, the femoral component of knee prosthesis is studied based on the reverse engineering (RE) system and multi-axis machining. The knee joint 3D geometric model is obtained by using the Mimics software with the computer tomography (CT) medical images and magnetic resonance image (MRI) firstly. The necessary constrains based on surgical experience are integrated into the CAD system. In the process planning of NC machining, the cutting sequence for rough and finish machining is arranged. Through the application of CAM software, the interference-free toolpath and the cutter location file for multi-axis NC machining are generated. The cutting simulations with solid model are performed to verify the generated toolpath and NC program. It is also verified through the real cut on a five-axis machine tool.

Keywords: knee prosthesis; femoral component; reverse engineering; multi-axis machining

1. Introduction

Each year, over two million osteoarthritis joints are replaced with artificial joints worldwide. The main reason for replacing any arthritic joint with an artificial joint is to stop the bones from rubbing against each other [1]. The components of prosthesis are often anatomically shaped or contoured designs versus basic geometric shapes, as shown in Figure 1. They are produced as a family in a range of sizes that can be selected at surgery to match the patient requirements.

In the design of stem and knee prosthesis, Kendrick et al. [2] investigated the cross-sectional design of the femoral stem at the level of the femoral isthmus with respect to its effect on the rotational stability of the bone-stem interface. Four cross-sectional designs – a fluted stem, a finned stem, a porous-coated stem, and a slotted fluted stem were implanted in 12 cadaveric femurs and loaded in torsion. A knurled stem, cemented into each specimen at the conclusion of testing, acted as a control stem. Based on the experiments presented in this study, implants with a solid fluted distal stem are recommended for use in revision arthroplasty to provide rotational stability, even in the absence of significant metaphyseal support for the prosthesis.

Sathasivam and Walker [3] determined the femoral and tibial bearing surface geometries which will induce the least destructive fatigue mechanisms in the polyethylene whilst conserving the laxity of the natural knee. Sixteen knee designs were generated by varying four parameters systematically to cover the range of contemporary knee designs. Sathasivam et al. [4] concentrated on condylar knees with intercondylar stability. In this study, a constrained condylar was designed with special attention to laxity, stability and strength. The design was parameterized such that for a custom case, only the A-P and M-L dimensions of the knee were required. Special software was written and interfaced with CNC machines. Liu et al. [5] investigated the effects of malalignment on stresses in tibial polyethylene component of total knee protheses. The greatest increase of contact stress and von Mises stress was occurred in the high conformity flat-on-flat design of knee prosthesis under the severest malalignment condition. The high conformity curve-on-curve design of knee prosthesis has the minimal risk of polyethylene wear under the malalignment conditions. Tomaso et al. [6] dealt with the design of a new knee prosthesis achieved by means of a concurrent engineering procedure. The aim of this study is to demonstrate that part of the developed process can be facilitated through the use of methods based on the computational codes and computer aided design techniques. Lee et al. [7,8] presented an integrated approach of CAD/CAM for the concurrent development of custom-made femoral stem and the femoral component of knee prosthesis. The solid modeling, rapid prototype and virtual multi-axis machining are used in the system to establish the interface among conception, design and manufacture. Chen et al. [6] adopted the Mimics software to obtain CT image to construct the complete knee actual 3D geometric model. In this study, the critical dimensions needed for the complicated femur resection in custom-made total knee arthroplasty, including critical dimensions of anterior femur resection, distal femur resection and posterior condylar resection was analysed and...
The cutter location file of the free-form surface was generated by the sculptured method. Two popular milling approaches, the conventional point cutting method and the flank cutting technique can be adopted. The flank milling can be efficiently applied to machine the ruled surface, which is performed by employing the side of a cutter to touch the desired ruled surface. For the complex surface of knee prosthesis, the milling process of the point cutting method is the better than the flank milling. In the study of tool path generation, Chiou and Lee [10] present a machining potential field (MPF) method to generate tool paths for multi-axis sculptured surface machining. The machining potential field is constructed by considering both the part geometry and the cutter geometry to represent the machining-oriented information on the part surface for machining planning. The largest feasible machining strip width and the optimal cutting direction at a surface point can be found on the constructed machining potential field. Yoon et al. [11] presented a local condition for collision-free 5-axis milling of sculptured surface. A new method is established to find the locally millable cutting positions by using the Dupin indicatrices of cutter surface and designed surface at the contact point. Lee et al. [12] integrated the reverse engineering technology and CAD/CAM system to generate the geometrical model and the product for femoral component of knee prosthesis. The system implemented is from surgeon requirements to the completion of manufacturing. The solid modelling, rapid prototype and virtual machining are used in the system to establish the interface among conception, design and manufacture.

In the research for postprocessor of machine tools, Sakamoto and Inasaki [13] classified the configuration of five-axis machine tools into three types. Lee and She [14] developed a postprocessor for three kinds of five-axis machine tools. The analytical equations for NC data were obtained using the homogeneous coordinate transformation and inverse kinematics.

In this paper, the femoral component of knee prosthesis is developed based on the RE technology, CAD/CAM system and multi-axis machining. The femoral component of knee prosthesis was designed according to the surgical procedure. A cutting simulation software, VERICUT®, is used to simulate the cutting processes and kinematics. The real cut is also performed with aluminum alloy and demonstrates the practical application.

2. Geometric modelling for femoral component of knee prosthesis

2.1 Artificial knee replacement

Artificial knee replacement is made up of three main parts. The femoral component replaces the bottom surface of the femur and the groove in which the patella fits. The tibial component replaces the top surface of the tibia. The patellar component replaces the surface of the patella where it glides in the groove on the femur (Figure 1). To develop the implant, the surgeon and the engineer determine the basic requirements and design criteria using either patient X-rays, the computer tomography (CT) scans or magnetic resonance image (MRI). To provide the best fill and fit femoral component to each individual patient, the shape is of major concern. The goal for the femoral component design was to define a product that met manufacturing requirements and surgical expectations.

2.2 Geometric reconstruction of anatomic features

The design procedure of the femoral component of knee prosthesis is based on the following steps: 1. obtaining the anatomic data according to CT of a healthy knee; 2. reconstructing the 3D CAD solid model of the knee; 3. designing the knee prosthesis by means of CAD techniques. The anatomic data of knee are obtained through CT scan. The scanner data (DICOM) is translated into full 3D CAD models via Mimics® software, as shown in Figure 2. By means of creating and modifying these segmentation masks in Mimics, the 3D CAD models of the knee are obtained (Figure 3). The model will be the anatomical reference for the design of the prosthesis. It is also the base for the surgical instrumentation design and the surgical operation planning.

2.3. CAD design of the femoral component

In this study, the femoral component of knee prosthesis is designed according to the surgical procedure. Through the application of the model of the knee and the CAD/CAM software (UG NX), the surgical procedure is simulated (Figure4). Through the coordination of the specialized doctor's discussion, the critical dimension and the positioning
analysis which needed for the total knee replacement are conformed under the cases with different specific knee skeleton characteristic shape and the damage situation.

The basic cutting concept is based on anterior reference cutting for the femur. The mechanical axis and the anatomic axis have to be determined in joint replacement surgery firstly. The measured angle between the mechanical axis and the anatomic axis is used to determine the approximate resection angle of the distal femur. With the help of the cutting guide, the surgeon cuts several pieces of bone from the end of the femur. The flexion and extension gaps of the distal femur can be prepared by 3° external rotation to maintain the parallelism in flexion and extension.

The tibiofemoral surface of femoral component of knee prosthesis is built according to the articular surface of a normal knee (Figure 5a). In order to consider the assembling design for metal femoral component attach to femur and manufacturing requirement, the surface model is modified as shown in Figure 5b.

**Figure 4.** CAD simulation of the surgical procedure for the femur.

**Figure 5.** The geometric modelling of femoral component of knee prosthesis.

3. CAM for the femoral component of knee prosthesis

The femoral component of knee prosthesis has to be machined on five-axis CNC machine tools because of their complex shapes. Compared with traditional three-axis machining, five-axis machining offers many advantages, for instance, the number of set-ups including the exchange of jigs and fixtures is reduced. Because of the two additional degrees of freedom in rotation, it can be used to machine complex workpieces which contain overlapped surface. The best combination of scallop height, surface roughness, workpiece accuracy can be obtained by adjusting the tool orientation during the toolpath generation. Thus, five-axis machining is widely used in the machining of aerospace parts, turbine blades, impellers, dies, molds and spatial cam. However, five-axis machining also suffers from some problems, including the complex tool movements and the insufficient support by CAD/CAM software. As for toolpath generation, specifying the tool orientation and the toolpath distribution are the main problems in CAM stage for five-axis machining of complex free-form surface.

3.1 Toolpath generation for multi-axis machining

Machining sequences and cutter location (CL) files can be created in the manufacturing module of UniGraphics NX software, which is the same CAD/CAM environment in that the solid model was created. In specifying tool location (position and orientation) for multi-axis machining within CAD/CAM software, two constraints, i.e. collision and gouging, are the major consideration. In the setup environment of manufacturing module for the femoral component, an alike femoral component workpiece (red portion) is built first and then assembled with the manufacturing model, as shown
in Figure 6. The machining features are selected based on the Surface Area drive method. The position and the orientation of the milling tool can be specified by the functions of Tool Axis and Projection Vector. The generated CL file can be verified through the function of solid cutting simulation built in this module. Figure 7 shows the cutting simulation of finish machining by multi-axis machining operation.

The generated toolpath is converted to the analytical NC code expression by the postprocessor, taking account of the kinematic description of the multi-axis machine tool. In this study, the postprocessor (table-tilting type five-axis machine tool) built by the UG/Post Builder is used in this system to establish the interface between design and NC machining (Figure 8).

Figure 6. Manufacturing model is assembled with the workpiece model.

Figure 7. Cutting simulation of finish machining for the femoral component.

Figure 8. Display of configured table-tilting type five-axis machine tool (UG/Post Builder).

4. Results and discussions
4.1 Geometric modelling

Using the commercial CAD/CAM system (Unigraphics NX), the complicated surface geometry of the femoral component of knee prosthesis is developed. The solid model of custom-made femoral component considering the soft tissue geometry built by Unigraphics NX software is shown in Figure 9.

Figure 9. Solid model of a femoral component built by Unigraphics NX.

4.2 Multi-axis toolpath generation and cutting verification

To maintain surface quality, the machining errors must first be identified. In this study, the option of cut step is set to Tolerances (chordal deviation) and the stepover (path interval distance) is specified as Scallop Height. For rough and semi-finish milling, a ball end mill with a diameter of 10 mm is applied in consideration of the gouging problems. Figure 10 reveals the toolpath generation and the cutting simulation of finish machining with ball end mill simulated by UniGraphics NX.

The toolpath generated from UniGraphics NX is converted into NC program by the postprocessor of table-tilting type five-axis machine tool. To avoid the risk of human error, the generated NC program is verified before actual machining. The CNC machine tool and controller are modelled to perform realistic 3D simulation. Figure 11 presents the process of cutting simulation. The simulation results demonstrate that the collision between the shank and workpiece surface does not occur. In order to demonstrate the applicability of the machining method, the femoral component was cut using a 5-axis machine with aluminum alloy (Figure 12). The machined allowances are specified as 0.05 mm and 0.01 mm respectively for the semi-finish and finish process. Figure 13 shows the assembling test of the machined femoral component and the cut femur. The physical model of cut femur is made directly from a solid model by rapid prototyping.

Figure 10. Multi-axis toolpath generation for the femoral component. (UniGraphics NX)
5. Conclusion

This paper integrates the reverse engineering technology and CAD/CAM system to generate the geometrical model and the product for femoral component of knee prosthesis. The system implemented is from surgeon requirements to the completion of manufacturing. The solid modelling and multi-axis machining are used in the system to establish the interface among conception, design and manufacture. Through the application of CAM software, the interference-free toolpath and the cutter location file for multi-axis NC machining are generated. The postprocessor built by the UG/Post Builder are used in this system to establish the interface between design and manufacture. The NC programs are verified through solid cutting simulation and real cut. The designed knee prosthesis will meet the research requirements and surgical expectations.

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