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Patient-Specific Design and Biomechanical Evaluation of a Novel Bipolar Femoral Hemi-Knee Prosthesis

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Abstract

While total knee replacement is successful, hemiarthroplasty is necessary for some young, obese and active patients who are especially not suitable for unicompartmental or total knee prostheses. Hemiarthroplasty also provides an opportunity for children with bone tumors. The design of hemiarthroplasty should be patient-specific to reduce contact stress and friction as well as instability, compared to conventional hemi-knee prosthesis. A novel bipolar hemi-knee prosthesis with two flexion stages was developed according to a healthy male's knee morphological profile. The motion mode of the bipolar hemi-knee prosthesis was observed through roentgenoscopy *in vitro* experiment. The biomechanical properties in one gait cycle were evaluated though finite element simulation. The bipolar hemi-knee prosthesis was found to produce knee flexion at two stages through X-ray images. The first stage is the motion from upright posture to a specified 60° flexion, followed by the second stage of motion subsequently to deep flexion. The finite element simulation results also show that the designed hemi-knee prosthesis has the ability to reduce stresses on the joint contact surfaces. Therefore, it is possible for the bipolar hemi-knee prosthesis to provide better biotribological performances because it can reduce stresses and potentially wear on the opposing contacting surface during a gait cycle, providing a promising treatment strategy in future joint repair and replacement.

Keywords: hemi knee prosthesis, custom-design, bipolar mechanism, finite element analysis, biomechanics

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1 Introduction

The increasing need for artificial knee replacement with the aging population and trauma has become more urgent over time. It is generally quoted that there are 200,000 to 300,000 cases of total knee replacement surgery just as a result of accidents each year. Total Knee Arthroplasty (TKA) has been clinically approved for effective treatments to knee joints with serious damage or deformity like severe rheumatoid arthritis and osteoarthritis. However, the current total knee replacement strategy cannot meet the needs of some special patients because of its limitations, such as a major surgical trauma, and limb length inequality for adolescents when they grow up after operation. For some children or other obese patients, resection of their distal femur, meniscus and proximal tibia of the knee will make their articular epiphysis severely damaged and loss the normal growth of the lower limb. Therefore Hemi Knee Arthroplasty (HKA) has been subsequently developed with the mini-incision technique for preservation of bone stock, improved range of motion, reduced surgical complications, reduced hospital stay, and decreased cost[1,2].

The HKA was especially suitable for the adolescents with a major surgical trauma at the endpoint of the femur or tibia of the knee, but to preserve their meniscus and the counter bone[2–4]. The special demands of the geometric shape and motion mode of the hemi-knee implants, which significantly affect the wear and friction as well as the exercise capacity of the postoperative patients' knee, impose significant challenges of the design.

Currently, patient-specific hemiarthroplasty provides a promising feasible solution[5,6]. The design procedure starts from the three-dimensional patient-specific knee model by reverse engineering and the computed

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tomography data. Then a set of prosthesis with the matched size and the surface bearing to the patient's knee was designed and optimized to minimize wear and friction as well as improve stability[7–12]. The integrated Computed Aid Design and Finite Element Analysis (CAD-FEA) process has been proven to be effective and efficient[13,14]. Harrysson *et al.*[12] evaluated a custom-designed orthopedic implants using CAD-FEA method to demonstrate a more even stress distribution on the bone-implant interface of the custom-implants compared to the conventional implants, potentially reducing uneven bone remodeling and premature loosening.

In addition, a bipolar femoral head in the hip joint hemiarthroplasty (HA) has been developed to provide some benefits such as a better range of motion and less acetabular wear when compared to the unipolar one[15,16]. Different from the unipolar femoral head with a single articulation between the prosthesis and acetabulum, the bipolar head has a second articulation between the inner smaller head and the polyethylene liner. Such a mechanical design in theory reduces frictional stress on the acetabular surface and thereby acetabular erosion which causes pain and impaired hip function.

Considering the above two design technologies of patient-specific implants and bipolar mechanism[12–18], a bipolar femoral hemi-knee prosthesis with two flexion stages was developed to minimise wear and friction as well as improve stability. The motion mode and characteristics of the designed hemi-knee joint implants under static and gait loading conditions were analyzed through finite element method and *in vitro* experiments.

2 Materials and methods

2.1 Materials

The high-resolution CT scans (Scanner: SOMATOM Sensation 32, Siemens, Germany) of the limbs for a healthy 24-year-old male volunteer was carried out with 1 mm cut at the Xijing Hospital affiliated to the Fourth Military Medical University (FMMU), PR of China. Consent was obtained from the volunteer before the study. Axial CT slices were reconstructed with the 1 mm increment and were imported to a workstation in Digital Imaging and Communications in Medicine (DICOM) format. The reconstructed knee model, combined the femur and the tibia, was established, based on the male volunteer CT-scans through our previous reverse engineering study[3,18] using Mimics software (Materialise, Belgium), Geomagic software (Raindrop, US) and Pro/Engineering software (PTS, US).

Two voluntarily donated cadaver joint specimens were obtained from the Xijing hospital and used for the *in vitro* experiment. This study was approved by the ethical committee of Xijing Hospital. A Link Endo-Model rotational knee system was purchased from LINK Co., Ltd. (German) and used as a control of a unipolar system. A bipolar hemi-knee prosthesis was designed and fabricated from medical grade stainless steel in this study, including a patient-specific bearing surface with a base, an intramedullary nail, an axis pin and a bridging plate. All these components were manufactured using a five-axis CNC machine tool and commissioned by Chunli Zhengda Science and Technology Co., Ltd. (Beijing, China).

2.2 Prosthesis design

The schematic diagram of the motion of the proposed bipolar prosthesis is shown in Fig 1. The bipolar motion was divided into two stages during a gait cycle in order to reduce the friction of contact surfaces between the femoral hemi-knee prosthesis and the contralateral tibial plateau. The first stage occurred in the initial small-angle gait flexion, from 0˚ to bipolar angle defined in Fig. 1, through an inherent hinge when the tibial plateau was on the relatively static position to the bearing articular surface of the bipolar femoral prosthesis. The second stage occurred in the large-angle gait flexion (more than the bipolar angle) through an intramedullary nail pushing the variable convex plate on the base when the whole femoral prosthesis slid relatively to the tibial plateau.

A patient-specific femoral hemi-knee joint prosthesis with a bipolar mechanism, shown in Fig 2, included four main components of intramedullary nail (a),

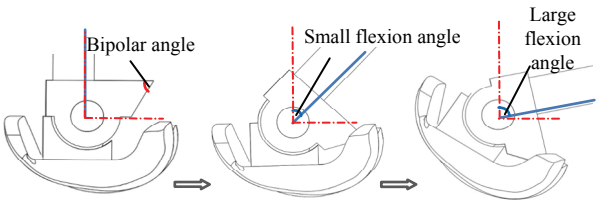

Fig. 1 Motion mode of the bipolar femoral hemi-knee prosthesis. (a) Upright posture of flexion 0˚; (b) initial small-angle flexion at the first stage of motion; (c) large-angle flexion at the second stage of motion.