博士論文（要約）

Patient-specific Finite Element Musculoskeletal Model-based Knee Prosthesis Design

(患者個別有限要素筋骨格モデルに基づいた人工膝関節の設計)

舒 利明

With an aging society aggravating, it is indispensable to maintain the walking function as a basic movement for improving quality of life (QOL) and supporting the realization of independent lives of elderly people. Around 26% of the elderly experience pains caused by osteoarthritis or rheumatoid arthritis, which make walking difficult. Therefore, total knee replacement surgery (TKR) started to be performed in 1968 in which a part of damaged bone was excised and replaced with a metal joint implant, and the number of domestic artificial joint replacement surgeries has doubled in the past 10 years. Although improvements in the surgical materials and techniques have greatly enhanced the effectiveness of this procedure, it has been still reported that 11%–19% of primary TKR patients are unsatisfied with the surgical outcomes while approximately 6% require revision surgery due to operative complications and wear of implant. The incompatibility between the highly standardized geometric structure of the knee implant and the various characteristics of patients results in highly variable surgical outcomes and in turn affects patient's satisfactions. To face this challenge, the research aims to create a novel subject-specific knee prosthesis design approach and an in-silico simulator that can predict the postoperative performance after TKR surgery.

It are important to understand the joint kinematics and contact mechanics performance of normal knee joint and TKR knee for improving the knee prosthesis design and satisfaction of patient. A PID controlled explicit FE knee simulator with a high mimicked soft tissues structure was developed and experimentally evaluated based on a grand challenge dataset. The predicted results show a good agreement on tendency and magnitude (Flexion-extension rotation: $RMSE$=0.56°, R^2=0.99; Internal-external rotation: $RMSE$=0.68°, R^2=0.93; Anterior-posterior translation: $RMSE$=1.54mm, R^2=0.89; Medial-lateral translation: $RMSE$=0.62mm, R^2=0.56) with in-vivo measured fluoroscopic experimental results on TF kinematics. Then, the verified knee simulator were used to predict the mechanics of healthy knee and four kinds of knee prosthesis design. The comparison results of TKR and normal knees confirm that the medial pivot design could improve the kinematic behavior with no paradoxical anterior motion, which was found in the other three designs during squatting. An enlarged contact area and a lower peak contact pressure are observed on the medial side of the medial pivot prosthesis. Conversely, on the lateral side of the medial pivot prosthesis, the contact area and peak contact pressure are equal to those of the unconstrained prosthesis, which could potentially result in wear. Overall, although the medial pivot prosthesis may restore normal kinematic function of the knee, the further in-vivo analysis and long-term studies on the femoral internal rotation and high contact pressure on the lateral side are still required. Those results provide the fundamental design idea for patient-specific knee prosthesis design in the following chapters.

The prerequisite for designing a user-satisfaction knee implant is to understand the body's dynamic mechanism and the internal mechanical characteristics of the joint. Concurrent use of finite element (FE) and musculoskeletal (MS) modeling techniques is capable of considering the interactions between prosthetic mechanics and subject dynamics after a TKR surgery is performed. We presented a methodology to develop a subject-specific FE-MS model of a human right lower extremity including the interactions among the subject-specific MS model, the knee joint model with ligament bundles, and the deformable FE prosthesis model. In order to evaluate its accuracy, the FE-MS model was compared with a traditional hinge-constraint MS model and experimentally verified over a gait cycle. Both models achieve good temporal agreements between the predicted muscle force and the electromyography results, although the magnitude on models is different. A higher predicted accuracy can be found in the FE-MS model on comparison with the MS model and previous researches on the total tibiofemoral (TF) contact force. The *in-vivo* contact mechanics including the contact area, pressure, and stress were synchronously simulated. The new approach outlines a high-precision knee joint biomechanics analysis and provides an in-vivo method to apply individualized treatment and prosthesis design in TKR.

Subsequently, the methodology of patient-specific knee prosthesis design with consideration of both the patient-specific anatomical structure and biomechanics characteristics was created based on the analysis of the above comparison and the anatomical measurements of healthy knee. Patient-specific design could improve the TKR performance including the improvement of the coverage ratio between bone and implant and the contact mechanics between implant components. Current researches related to patient-specific knee prosthesis designs are mainly mimicked the anatomical structure of femoral condyle, but it is still questionable of kinematics and long-term performance due to the change of the material compared with normal knee joint. What's more, the end-stage knee osteoarthritis patients are usually associated with the large bone deformation and wear, and the CT-based anatomical data would not be adapted to those patients. Hence, an anatomical analysis of the health knee based on CT data was conducted to understand the anatomical characteristics. Then, the anatomical data from osteoarthritis patient was used to mate and map the healthy knee joint model for prosthesis design. Finally, a patient-specific knee prosthesis was designed based on the patient data and the concept of surface-guided for deep flexion and natural kinematics. The new design would be enabled to improve the satisfaction of patients after TKR.

It is helpful to understand the critical design parameters on implant performance for improving the performance of patient-specific knee prosthesis. Combination with the design of experiment method and finite element knee simulator were used to access to the relative contribution of each design parameter to the kinematics and contact mechanics of TF and PF joint of TKR knee. 12 design parameters were selected and analyzed in the knee simulator during deep squatting. The design parameters that have the largest influence on anterior translation, posterior translation, internal rotation, external rotation, medial TF contact area, lateral contact area and PF contact area are tibial medial sagittal conformity (C_{tms}), patellar coronal conformity (C_{pcc}), tibial lateral coronal conformity (C_{tlc}), C_{tms}, and C_{tlc}, respectively. On the basis of sensitivity analysis, the design parameters were optimized. The optimal patient-specific knee prosthesis design was firstly virtually evaluated under the ideal alignment and patient condition during gait cycle and deep squatting. However, the clinical investigations presented the substantial variation in TKR performance of kinematics and contact mechanics for different patient and TKR surgery. Compared to the subjective-specific variation, the surgical factors show a stronger influence on TKR mechanics during deep squatting. The simulation results also confirm the high robustness of the current patient-specific knee prosthesis.

In conclusion, the study has presented recent advancements in knee simulator and patient-specific knee prosthesis design to improve the satisfaction of patients with knee disease. However, the future research on in vitro and clinical in-vivo experiments is preferred, in order to ensure the practicality and advancement of design.

In addition, the bone excision method was also studied in the appendix. Although orthopedic oscillating saws (OOSs) have been widely used for plane processing in orthopedic surgery such as knee and hip replacement, sawing has been still associated with bone breakthrough and necrosis problems. It has been proposed that deepening cut depth and reducing cutting speed could perform high-efficiency and low-temperature sawing based on the crack propagation characteristics of the bone. In order to better understand the mechanism of bone cutting, firstly, a novel low-frequency elliptical vibration assisted bone cutting device was created and used to analyze the bone cutting force, chip, crack propagation and temperature rising mechanism during the cutting experiment. The XFEM was used to analyze the crack propagation under conventional and elliptical vibration assisted cutting. Then, a novel elliptical vibration assisted OOS was designed to carry out the proposal. In order to reduce the large cutting forces due to the large cutting depth, a series of experiments was also conducted to investigate the influence of processing parameters on cutting forces. It was demonstrated that cutting forces are significantly reduced by increasing the vibration frequency and vibration amplitude, and decreasing the sawing speed in the current design. The new design could minimize the cutting forces during sawing and allow surgeons to have better control over the sawing process.