Research on the Association Between the Inclination of the Proximal Tibiofibular Joint Surface and Medial Compartment Knee Osteoarthritis

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Study Protocal

Study Design and Patient Selection

This case-control study (Level III Evidence) will be performed in line with the principles of the Declaration of Helsinki.

The study will be performed to compare the inclination angle of the PTFJ surface in participants with and without medial compartment knee osteoarthritis. A sample size power analysis was conducted before the study, which revealed that a minimum of 39 subjects per group was needed to achieve statistical significance with two-sided α=0.05 and 1-ß=0.80 and an assumed mean difference between two groups=65% of the standard deviation. The participants will be enrolled at the outpatient clinic of our hospital. The patients with medial compartment knee osteoarthritis will be enrolled at first. The anticipated number of patients is 40, and the female-to-male ratio is expected to be 1:1. Then, the participants of the control group will be enrolled and matched for sex and age (within 5 years) to the patients. The control-to-patient ratio is expected to be 1:1.

Inclusion criteria for participants of the patient group will be: (1) minimum age of 50 years, (2) symptomatic knee osteoarthritis according to the American College of Rheumatology criteria for the classification and reporting of osteoarthritis of the knee joint, (3) predominance of self-reported pain over the medial aspect of the knee, (4) radiographic evidence of medial compartment knee osteoarthritis with an Ahlbäck score of grade Ⅰ or greater, and (5) radiographic evidence of lateral compartment with Ahlbäck classification grade 0. We will exclude participants with any previous

surgery, severe trauma, inflammatory joint disease, or tumors in the affected limb.

Our controls will be participants aged 50 years or older, without knee osteoarthritis according to the American College of Rheumatology criteria for the classification and reporting of osteoarthritis of the knee joint, and with radiographic evidence of the knee with Ahlbäck classification grade 0. Exclusion criteria will be a history of previous surgery, severe trauma, inflammatory joint disease, or tumors in the affected limb.

All participants should give signed informed consent before enrolment.

Radiographic Examination

Standing anteroposterior knee radiographs and special PTFJ radiographs will be taken for the participants in both groups. The standing anteroposterior knee radiographs will be obtained with the knee extended. The PTFJ radiographs will be acquired with the knee of the participants in approximately 45°-60° of internal rotation. In this projection, the PTFJ articulation can be clearly visible.

Radiographic Evaluations and Measurements

For the standing anteroposterior knee radiographs, radiographic knee osteoarthritis will be evaluated by using the Ahlbäck grading scale, and the femorotibial angle (FTA) will be measured. For the PTFJ radiographs, the degenerative joint disease of the PTFJ will be staged with the Kellgren-Lawrence staging system, and the fibular inclination angle (FIA) and the tibial inclination angle (TIA) of the PTFJ surface to the longitudinal axis of both fibula and tibia will be measured separately. The horizontal type of PTFJ will be defined as the inclination

angle ≤ 20°, and the oblique type will be defined as the inclination angle > 20°.

Radiograph annotations will be deleted. Each participant will be assigned a random and unique number, and participants of the two groups will be mixed. All radiographic evaluations and measurements will be carried out in a blinded, independent, and random fashion by a radiologist, who do not know the study hypothesis, with tools of the digitized picture archiving communication system (PACS, RADinfo Technologies Co.,Ltd, Hangzhou, China). Additionally, 20 participants per group will be randomly selected. The FIA and TIA of the 40participants will be measured again after 1 month by the same radiologist and an orthopedic surgeon who do not know the study hypothesis. The intraobserver reliability and interobserver reliability in the FIA and TIA measurement will be assessed by using an intraclass correlation coefficient (ICC).

Statistical Analysis Plan

Statistical analysis will be performed with SPSS (v25.0; IBM Corp). $P < .05$ will be considered significant. Demographics, laterality of included knees and FTA will be compared between the patient and control groups by using two-sample *t* test or χ^2 test. Paired-samples *t* test will be used to compare the difference between the FIA and TIA of all participants.

Any differences of the FIA and TIA between the patient and control groups will

be assessed with the two-sample *t* test. Furthermore, the participants of each group will be separately grouped into sex subgroups and into two age subgroups. The old age subgroup of each group will include approximately 20 participants with earlier ages, and the remaining participants with higher ages will form the older age subgroups (The number of participants in each subgroup will be as close as possible to 20). The two-sample *t* tests will be repeated for each sex subgroup and age subgroup in isolation. The odds ratios (ORs) for risk factors of medial compartment knee osteoarthritis will also be calculated by using binary logistic regression analysis.

The PTFJ types will be compared between the two groups by using the χ^2 test. The PTFJ osteoarthritis grades will be compared between the two groups by using the Mann-Whitney *U* test.