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ABSTRACT

Introduction Unicompartmental knee arthroplasty (UKA) is one of the most effective surgical procedures for treating isolated medial compartment knee osteoarthritis. However, previous studies have regarded patellofemoral osteoarthritis as a contraindication for UKA. In contrast, most current research shows that damage to the articular cartilage of the patellofemoral joint, even to the extent of full-thickness cartilage loss, has no influence on the outcome of UKA.

Methods and analysis Study settings: This study is a prospective cohort study that will compare the Forgotten Joint Score and Lonner patellofemoral joint score of patients who have undergone UKA; the patients will be divided into two groups (with and without patellofemoral joint osteoarthritis (PFJOA)). Primary objective: Long-term follow-up will be used to evaluate the effect of the operation on the above-mentioned scores in both the groups. Secondary objective: We will divide the patients from the with PFJOA group into three subgroups according to the localisation of patellofemoral cartilage lesions (medial zone, lateral zone and central zone). We aim to compare knee joint scores among these groups and clarify the impact of different wear sites on clinical efficacy. We will use CT to explore the potential mechanism through which UKA affects patellofemoral joint-related parameters (lateral patellar tilt, lateral patellar shift and tibia tuberosity-trochlear groove distance). We will also record mid-term/long-term post-surgery complications.

Ethics and dissemination This study's protocol is in accordance with the Declaration of Helsinki. This study was approved by the Ethics Committee of Xuanwu Hospital. The results of this study will be disseminated in international peer-reviewed journals.

Trial registration number ChiCTR2000030310.

BACKGROUND

Description of the condition

Osteoarthritis (OA) of the knee is a serious degenerative disease characterised by symptoms/signs such as articular cartilage degeneration, subchondral bone hyperplasia and

Strengths and limitations of this study

- The large number of patients included in this study will decrease the likelihood of biases and improve the power of the results.
- Evaluation of surgical outcomes through mid-term to long-term follow-up and use of the knee function scoring system (especially the Lonner patellofemoral joint score for the patellofemoral joint).
- We will also use CT to explore the potential mechanism through which unicompartmental knee arthroplasty affects the patellofemoral joint-related parameters. Use of MRI could add more qualitative assessment of the patellofemoral joint articular cartilage and combined location of wear on the patella and trochlea.
- Both Forgotten Joint Score-12 and Lonner patellofemoral joint scores are relatively subjective scoring systems.
- This study is a medium-term to long-term study. Loss of cases to follow-up or death is inevitable.

synovitis. It is one of the main causes of pain and disability in the elderly and often leads to a decline in patients' quality of life.¹⁻³ OA alters normal joint metabolism, resulting in increased chondrocyte breakdown and reduced synthesis.

OA has been recognised as a global public health problem; it causes enormous economic burdens, apart from other issues.² It is now increasingly recognised that concurrent OA leads to an increase in patient mortality. Increased mortality in patients with OA is caused by its effects that influence the course of chronic diseases such as cardiovascular, obesity and diabetes. The cumulative sites of OA include the knees, hips, ankles, hands and spine. In addition to a series of

clinical symptoms, OA, especially symptomatic knee OA, increases the incidence of cardiovascular events and all-cause mortality.²

Description of the treatment

Unicompartmental knee arthroplasty (UKA) is one of the most effective surgical procedures for treating isolated medial compartment knee OA. Compared with total knee arthroplasty (TKA), UKA can provide better physiological function, quicker recovery, shorter hospital stay and fewer perioperative complications, especially in early OA.⁴⁻⁷ Recently, the incidence of UKA has increased rapidly worldwide. Through strict case selection, improvement of surgical techniques and improvement of prosthesis design, the long-term efficacy of UKA is now close to or even better than that of TKA.⁴⁻¹³ Several recent literature analyses have found that the efficacy of UKA is based on strict case selection, so it is essential to appropriately select the indications for UKA.

Why is it important to conduct this prospective study?

Previous studies have regarded patellofemoral OA as a contraindication for UKA.¹⁴ Most current research shows that the damage to the articular cartilage of the patellofemoral joint (PFJ) to the extent of full-thickness cartilage loss has no influence on outcome of UKA.^{9 11 15} There is no correlation between preoperative anterior knee pain or medial PFJ degeneration and the clinical outcome.¹⁶ However, severe damage to the lateral side of the PFJ with bone loss and lateral subluxation of the patella are known to have an adverse impact on the post-operative curative effect. Degeneration of the lateral PFJ may be a risk factor affecting the outcome.¹⁶

Since Kozinn and Scott¹⁴ first established the guidelines for UKA surgery, degenerative changes in the PFJ have been considered a contraindication; this opinion was reinforced by Stern *et al.*¹⁷ However, some studies demonstrated no correlation between the preoperative state of the PFJ and the outcome; the debate is ongoing.^{15 16 18 19} Beard *et al* reported a group of patients who had UKA (824 knees), of which 128 knees had confirmed PFJ degeneration. In the longest known follow-up period 7 years, no patients underwent revision surgery for PFJ degeneration, and no significant difference was seen in the postoperative functional scores (Oxford Knee Score and American Knee Society Score).¹⁸ Hamilton *et al* analysed the long-term results of a group of patients, some of whom had anterior knee pain and patellofemoral joint osteoarthritis (PFJOA), all of whom were managed with UKA.¹⁶ This study provided evidence that patients with the previously reported contraindications did as well as, or even better than, those without the contraindications. Therefore, these contraindications should not apply to UKA. The Oxford group reports performing UKA regardless of PFJ degenerative changes, provided there is no bone loss or lateral facet grooving. They found that medial OA of the PFJ does not affect outcome scores or survivorship of their mobile-bearing UKA design.

Several studies have suggested that OA progression in the PFJ is the most common reason for revision of UKA to TKA.²⁰⁻²² However, these studies have a limitation in their use of non-specific scoring systems for PFJ symptoms.

OBJECTIVES

Primary objective

The primary objective of this study is to evaluate the mid/long-term survivorship and the curative effect of UKA in patients with combined medial compartment knee OA and PFJ arthritis. We aim to use the Forgotten Joint Score (FJS-12)²³ and Lonner patellofemoral joint score²⁴ to evaluate the general condition of the patients' knees before and after surgery. According to the presence or absence of PFJOA, all patients will be divided into two groups. We will record the mid/long-term clinical outcome and the revision rate to evaluate whether the presence of PFJOA affects the mid/long-term efficacy of the procedure.

Secondary objectives

1. We will divide patients into three groups according to localisation of the patellofemoral cartilage lesions (medial zone, lateral zone and central zone). We will then compare the knee joint scores among the groups and clarify the impact of different wear sites on clinical efficacy.
2. We will use CT to explore the potential mechanism through which UKA affects PFJ-related parameters. Before and after surgery, we will use the lateral patellar tilt (LPT), lateral patellar shift (LPS) and tibia tuberosity-trochlear groove (TT-TG) distance to measure the change in the parameters of the PFJ.
3. We will record mid-term/long-term surgery complications.

METHODS AND ANALYSIS

Study design

The study will be performed in a joint surgery centre in Xuanwu Hospital, Capital Medical University. This study is a prospective cohort study comparing the scoring assessment carried out preoperatively and postoperatively with consecutive patients who have undergone UKA. The study design is shown in [figure 1](#).

Patient and public involvement

The study patients or general public were not involved in the development, planning, recruitment, conduction or burden assessment of this study. Patients are informed about the surgical risks and other procedures related to this study. Patients are also informed about other treatments for early OA, including arthroscopy, high tibial osteotomy and non-surgical treatments. After completion of the study, an information letter about the results will be provided for study participants.

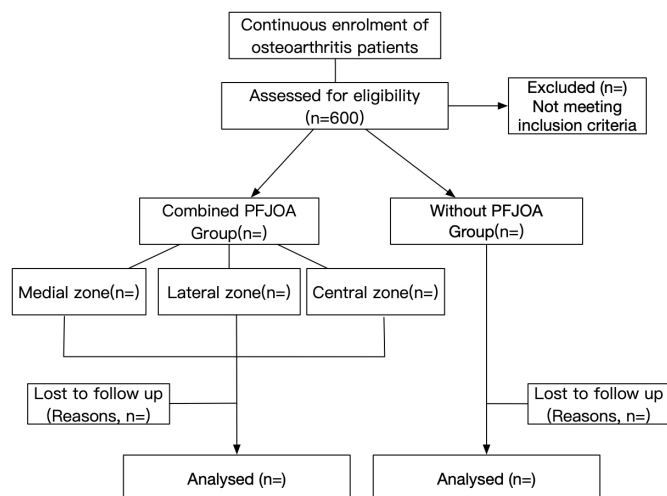


Figure 1 Flow diagram. PFJOA, patellofemoral joint osteoarthritis.

Patient enrolment and eligibility criteria

1. All patients diagnosed with anteromedial osteoarthritis (AMOA) of the knee, based on history, physical examination and radiographs.

Radiographic definitions of AMOA:

- ▶ Anteroposterior radiographs demonstrate loss of articular cartilage medially by showing that the condyles articulate ‘bone-on-bone’; or varus-stressed radiographs showed full-thickness loss of cartilage (bone-on-bone contact) between the medial femoral and tibial condyles.
- ▶ The lateral radiographs demonstrate an intact medial articular surface at the back of the tibial plateau and the femoral condyle.
- ▶ Valgus-stressed radiographs show full-thickness cartilage of the lateral compartment.
- ▶ Valgus-stressed radiographs show intra-articular varus deformity manually correctable in 20° flexion.

2. The indication criteria for UKA were:

- ▶ Older than 55 years; a correctable varus deformity;
- ▶ Relatively intact knee ligaments. Especially, the anterior cruciate ligament (ACL) and medial collateral ligament should be functionally normal. We usually observe the stage of ACL deterioration intraoperatively. If the ACL deterioration is less than grade 2, Oxford UKA can be performed. ACL grade:
 - Normal.
 - Loss of synovial covering, usually starting distally.
 - Longitudinal splits in the substance of the exposed ligament.
 - Friable and fragmented with stretching and loss of strength of the collagen bundles.
 - Absent or ruptured.
- ▶ Intact lateral compartment.
- ▶ Almost normal range of motion.
- ▶ No inflammatory disease.
- ▶ PFJOA is accepted (PFJOA is not considered to be a contraindication, with the exception of patients with

subluxation, bone loss and the formation of grooves in the lateral side of the PFJ).

ASSESSMENTS

Preoperative phase

Before surgery, all patients had standard-view radiographs taken (anteroposterior and lateral radiographs; full-length standing and patella tangential view) and underwent MRI to evaluate the ligament, meniscus and lateral compartment. The MRI could add a more qualitative assessment of the PFJ articular cartilage and combined location of wear on patella and trochlea. Both before and after surgery, all patients received CT scans to evaluate the patellofemoral indices.

Postoperative phase

All patients were operated on by the same group of doctors. The patient was placed in the supine position; a tourniquet was applied to the proximal thigh on the operative side. All patients underwent the standard Oxford UKA surgical procedure (minimally invasive Oxford UKA, using the Oxford Microplasty instrumentation) (Oxford Unicompartmental Phase 3, Biomet, Warsaw, Indiana, USA). All patients received an analgesic intra-articular cocktail mixture injection containing ropivacaine, parecoxib sodium, oxycodone, epinephrine and tranexamic acid. Patients received an intravenous infusion of drugs to control pain for 3 days after surgery (flurbiprofen axetil or parecoxib sodium). They then took oral medication to control pain according to their condition. All patients routinely underwent drainage tube placement at the site of surgery; the tube was removed on the first day after surgery. All patients received low molecular weight heparin as an anticoagulant from 1 day after surgery until 2 weeks after surgery. All patients could get out of bed on the first postoperative day and could perform some weight-bearing activities with the aid of a walker. All patients could walk with full-weight bearing 2 weeks after surgery.

Post-hospital phase

Clinical and radiographic follow-up was performed within 3 months and then at 6 months and 1 year. We used the FJS-12 and Lonner patellofemoral joint score to evaluate the general condition of the patients’ knees before surgery and 3 months, 6 months and 1 year after surgery. Subsequently, the knee function score will be reviewed once a year, based on the score at the last follow-up (for the study timeline, see [table 1](#)).

OUTCOMES AND MEASUREMENTS

Primary outcomes

Both patient groups (with and without PFJOA) are to be assessed using the FJS-12 score and Lonner patellofemoral joint score through a mid/long-term follow-up period (at least 5 years). The PFJ was assessed intraoperatively. The surgeons performed intraoperative assessment

Table 1 Study timeline

	Enrolment	Allocation	PE	KFA	X-ray	CT	MRI	Complication
Eligibility screening	●							
Informed consent	●							
Preoperative assessment			●	●	●	●	●	
Operation information		●						
1 month			●	●	●	●		●
3 months				●				
6 months			●	●	●			
1 year			●	●	●			●
2 years			●	●				●
3–4 years				●	●			●
5 years			●	●				●
6–8 years				●	●			●
10 years			●	●	●			●
15 years			●	●	●			●

KFA includes FJS-12 and Lonner patellofemoral joint score.

FJS-12, Forgotten Joint Score-12; KFA, Knee Function Assessment; PE, physical examination.;

of the PFJ cartilage status for each knee, using the International Cartilage Repair Society (ICRS) classification based on chondral defect severity: normal (no changes, grade 0), superficial lesions (grade 1), partial thickness loss less than 50% (grade 2), more than 50% cartilage thickness loss (grade 3) and extensive full-thickness loss (grade 4).²⁵ If the ICRS grade is ≥ 2 , we believe PFJOA is present.

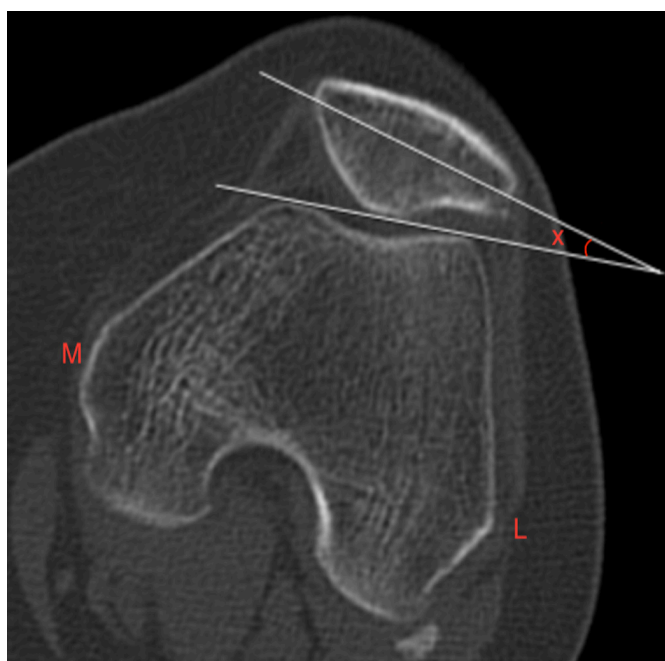


Figure 2 CT scan to measure lateral patellar tilt.

Forgotten Joint Score-12

The FJS was developed by Behrend *et al* in 2007. This new patient report outcome measures provides a very appealing concept; the ability for a patient to forget about their artificial joint in everyday life.²³ The original FJS is a 12-item questionnaire that asks patients questions based on their ‘awareness’ of their artificial joint during everyday activities.²³ The FJS scales the answers from 1 to 5. These scores add up to give a score out of a maximum of 60, which is then converted into a percentage.

Lonner patellofemoral joint score

We prospectively analysed PFJ pain and functional change using the patellofemoral scoring system devised by Lonner.²⁴ This system has considerable value when addressing the treatments directed specifically at patellofemoral arthritis. This scoring system includes two parts, pain assessment and functional assessment. The items are summed up to give a total score ranging from 0 to 100, with a high score indicating a good outcome.

Secondary outcome measurements

1. Enrolled patients were divided into the with PFJOA group and without PFJOA group. Then we divided the with PFJOA group into three groups according to localisation of the patellofemoral cartilage lesions (medial zone, lateral zone and central zone). The patients were assessed using the FJS-12 score and Lonner patellofemoral joint score through a mid/long-term follow-up.
2. Before and 1 month after surgery, all patients underwent a CT scan to evaluate the patellofemoral indices, including LPT, LPS and TT-TG distance.

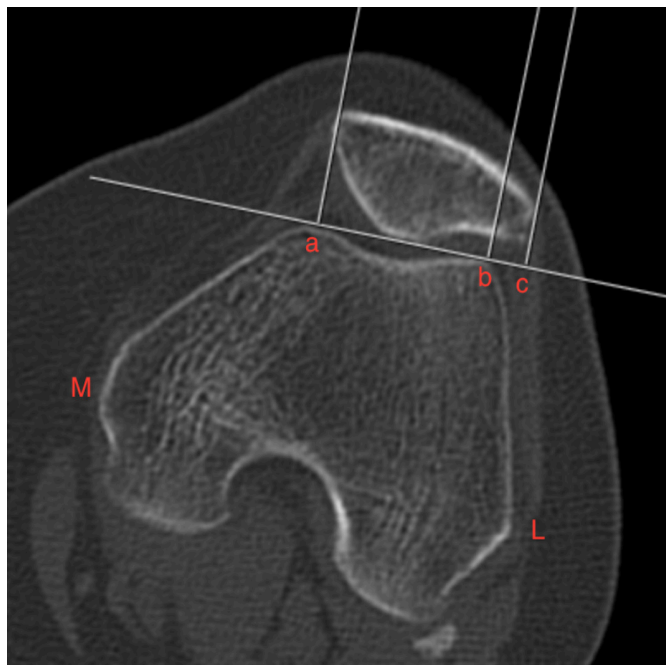


Figure 3 CT scan to measure lateral patellar shift.

The angle 'x' represents LPT (figure 2), defined as the angle between a line tangential to the anterior femoral condylar surfaces and a line intersecting the widest bony portion of the patella.

LPS (figure 3) is defined as the ratio between the distances bc and ab, where ab is defined the distance between the summits of the medial and lateral femoral condyles and bc is defined as the distance between the summit of the lateral femoral condyle and the point where a line from the lateral edge of the patella is

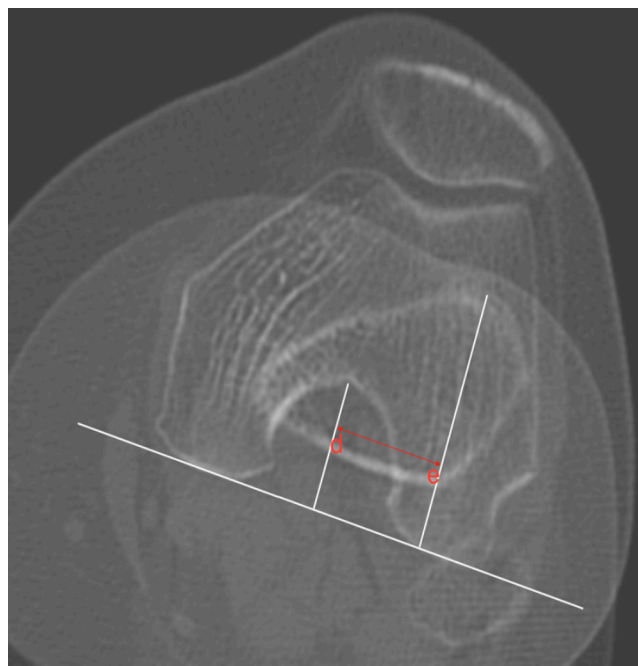


Figure 4 CT scan to measure the tibia tuberosity-trochlear groove distance.

perpendicular to the line tangential to the anterior femoral condylar surfaces.

How to measure TT-TG distance (figure 4): first draw a line tangential to the posterior epicondyle and perpendicular through the deepest point of the trochlea. Then draw another line parallel to the trochlea line through the most anterior portion of the tibial tuberosity. The distance between these two parallel lines (de) is the TT-TG distance.

After performing CT scan, the changes in the patellofemoral parameters before and after surgery were compared in all patients.

- Through clinical follow-up, we will record mid-term/long-term complications such as implant loosening, wearing dislocation, progression of arthritis and need for revision surgery. Information on whether the patient has undergone revision arthroplasty or another knee surgery will also be recorded.

SAMPLE SIZE CALCULATIONS AND POWER

Based on previous studies,²⁶ the SDs between the FJS-12 score of the with and without PFJOA groups were 29 and 26, respectively. The mean FJS-12 score of the with and without PFJOA group was 71 and 77, respectively. Setting the significance level (alpha) at 5% and the power (1-beta) at 80%, patients are needed in each group, resulting in a total study population of 286 patients. This number has been rounded up to 300 by the research group.

DATA MANAGEMENT AND STATISTICAL ANALYSIS

Data management

The study data are stored in the Department of Orthopaedics, Xuanwu Hospital, Capital Medical University and are in accordance with relevant data privacy regulations. The registration descriptions are enclosed with the Ethics Committee statement. Access to the data is only available to the personnel participating in the study; no information is provided to non-examiners. For computer analysis, all personal data are encoded so that patients are unidentifiable when processing or reporting the results.

The data of this study will be collected using the Raw Data Sheet and the Case Report Form (CRF)/Electronic CRF (eCRF).

The study coordinator is responsible for recording the study data in a CRF/eCRF. The investigator is responsible for ensuring that all CRFs/eCRFs are completed, reviewed and approved. All the researchers must sign the CRF/eCRF. These signatures will serve as proof that the information contained in the CRF/eCRF is true. At any time, the researcher is ultimately responsible for the accuracy and authenticity of all clinical and laboratory data entered into the CRF/eCRF.

Patient information during the cohort study must be recorded in the CRF/eCRF in an anonymous form,



identified only by the patient number and the initials of the phonetic alphabet. Exceptions can be made where patients must be identified for safety or regulatory reasons.

The CRF/eCRF should be filled out based on the original documents. Fill in 'not done' for missing data; fill in 'not applicable' for unavailable data; fill in 'unknown' for unknown data.

If the CRF/eCRF needs to be modified, the researchers must keep track of the changes. Modifications should be approved and signed by the researcher and, if necessary, the reason for the modification should be mentioned. The research auditor will review the completeness and accuracy of the CRF/eCRF and guide the testers in making the required corrections and additions. After the test, the research centre will send the CRF/eCRF to the statistical department of the Contract Research Organization (CRO) company for statistical analysis.

Statistical analysis

Data will be analysed with statistics software (latest version of SPSS; IBM). We will use propensity score for comparison of preoperative and postoperative patellofemoral indices and clinical score of the two groups. We will use an interobserver and intraobserver intraclass correlation to verify the reproducibility and accuracy of the measured patellofemoral indices. We will use analysis of variance for comparison of the clinical score among the three groups. Cox regression will be used additionally in the long-term follow-up.

ETHICS AND DISSEMINATION

This study protocol is in accordance with the most recent version of the World Medical Association Declaration of Helsinki. This study was approved by the Ethics Committee of Xuanwu Hospital. The report of the study will be disseminated via scientific forums including peer-reviewed publications and presentations at national and international conferences.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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