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# Functional results of total-knee arthroplasty versus medial unicompartmental arthroplasty: two-year results of a randomised, assessor-blinded multicentre trial

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## ABSTRACT

**Objective** The primary objective of the trial was to assess the clinical effectiveness of medial unicompartmental knee arthroplasty versus total knee arthroplasty in patients with isolated medial osteoarthritis of the knee.

**Design** Prospective, randomised, 2 years, assessor-blind, multicentre, superiority trial.

**Setting** The patients were enrolled between December 2015 and May 2018 from the outpatient clinics of three public high-volume arthroplasty hospitals (Finland).

**Participants** We recruited 143 patients with symptomatic-isolated medial osteoarthritis of the knee needing an arthroplasty procedure. All the patients were suitable for both unicompartmental and total knee arthroplasties. Population was selected as the end-stage-isolated medial osteoarthritis.

**Interventions** All patients, randomized 1:1, received a medial unicompartmental arthroplasty or a total knee arthroplasty through a similar midline skin incision. Patients were blinded to the type of arthroplasty for the whole 2 years of follow-up.

**Main outcome measures** Primary outcome measure was between-group differences in the Oxford Knee Score (OKS) and secondary outcome Knee injury and Osteoarthritis Score (KOOS) at 2 years postoperatively. The changes within and between the groups were analysed with analysis of variance for repeated measurements.

**Results** The primary outcome was comparable for medial unicompartmental arthroplasty and total knee arthroplasty at 2 years. The mean difference in the OKS between the groups was 1.6 points (95% CI −0.7 to 3.9). In the KOOS subscales, the mean difference between the groups was 0.1 points (95% CI −4.8 to 5.0) for pain, 7.8 points (95% CI 1.5 to 14.0) for symptoms, 4.3 points (95% CI −0.6 to 9.2) for function in daily living, 4.3 points (95% CI −3.0 to 11.6) for function in sports, and 2.1 points (95% CI −4.8 to 9.1) for knee-related quality of life.

**Conclusions** The recovery after unicompartmental knee arthroplasty was faster compared with total knee arthroplasty, but unicompartmental arthroplasty did not provide a better patient-reported outcome at 2 years.

**Trial registration number** NCT02481427.

## Strengths and limitations of this study

- The study design is a parallel (1:1) multicentre, assessor-blind and randomised superiority trial of knee arthroplasty patients to assess the effectiveness of medial unicompartmental knee arthroplasty versus total knee arthroplasty.
- Only patients with isolated medial osteoarthritis who met the original indications for medial unicompartmental arthroplasty with the Oxford knee (Zimmer-Biomet, Warsow, Indiana, USA) were considered for the trial.
- Our primary outcome was the between-group difference in Oxford Knee Score at 2 years after surgery.
- Our secondary outcomes were Knee injury and Osteoarthritis Score 1–5 subscales, complications and revision rates according to Clavien-Dindo, change in the 15D score between groups, Knee Society Score and radiographic findings at 2, 12 months and 2 years after surgery.
- The changes within and between the groups were analysed with analysis of variance for repeated measurements.

## INTRODUCTION

Knee osteoarthritis is a common joint disease which may cause severe pain and lead to a reduced quality of life. The prevalence of painful osteoarthritis in people aged 60 years and over is 10% for men and 18% for women.[1] Total knee arthroplasty is the most frequently performed procedure for the treatment of painful severe osteoarthritis of the knee when conservative treatment is insufficient.[2 3] In 2014, over 680 000 primary total knee arthroplasties were performed in the USA, and the number of arthroplasties is increasing especially among younger patients.[4 5] Despite total knee arthroplasty being a highly successful

operation, as many as 20% of patients are somewhat dissatisfied with their outcome.[2 6]

Total knee arthroplasty is the most frequently performed procedure for the treatment of painful, severe medial osteoarthritis of the knee in Finland. However, in at least 25% of patients, the pattern of osteoarthritis is isolated medial osteoarthritis that could be treated with medial unicompartmental rather than total knee arthroplasty.[7] Medial unicompartmental arthroplasty has been associated with a shorter hospital stay, faster recovery time, lower cost, better functional outcome, and reduced perioperative morbidity and mortality compared with total knee arthroplasty.[8–11] Although several studies have reported good long-term results in single-centre series for medial unicompartmental knee arthroplasty, its survival has been inferior to that of total knee arthroplasty in national registries.[12 13] Therefore, whether patients should undergo unicompartmental or total knee arthroplasties at all is open to debate.

The primary objective of the Finnish Unicompartmental and Total Knee Arthroplasty Investigation trial was to assess the clinical effectiveness of medial unicompartmental knee arthroplasty versus total knee arthroplasty in patients with isolated medial osteoarthritis of the knee in a randomised, controlled, assessor-blind comparison. The hypothesis of the study was that unicompartmental knee arthroplasty is superior to total knee arthroplasty at 2 years in terms of the functional results.

## METHODS

### Setting and participants

The study design is a parallel (1:1) multicentre, assessor-blind and randomised superiority trial of knee arthroplasty patients to assess the effectiveness of medial unicompartmental knee arthroplasty versus total knee arthroplasty. All patients had isolated medial bone-to-bone knee osteoarthritis with a functionally intact anterior cruciate ligament. Three of the six largest public funded arthroplasty hospital of Finland were able to participate to the study. The patients were enrolled between 9 December 2015 and 28 May 2018 from the outpatient clinics of participating high-volume arthroplasty hospitals (a minimum of 800 hip or knee arthroplasties per year).

The patients were enrolled and operated on by one of four orthopaedic surgeons, all of whom had over 5 years' experience of medial unicompartmental arthroplasty and total knee arthroplasty. Before consenting to participate in the study, all patients were given both oral and written information on the study during their screening visit. The surgeons were not involved in the follow-up to ensure blinding. Before actual launch of the study in the study centres, the protocol was discussed in detail to ensure similar protocol adherence in all three centres.

The patients, physiotherapists, healthcare professionals involved in postoperative care on the ward, research personnel who collected and analysed the data, surgeons who followed up the patients, and the authors were blinded to the type of operation and study-group assignments.

Only patients with isolated medial osteoarthritis who met the original indications for medial unicompartmental arthroplasty with the Oxford knee (Zimmer-Biomet, Warsow, Indiana, USA) were considered for the trial.[14 15] Inclusion and exclusion criteria are listed below in more detail.

### Patient and public involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

### Inclusion criteria

- Painful medial knee osteoarthrosis with exposed bone on both femur and tibia (bone-on-bone osteoarthritis in weight-bearing radiographs, anteromedial osteoarthritis and medial joint line disapperance).
- Age between 45 and 79 years.
- Failed conservative treatment of knee osteoarthritis (physiotherapist-supervised exercise therapy and pain medication).
- Mechanical axis from 5 to 15 degrees varus (in standing long-leg alignment views).
- Functionally intact anterior cruciate ligament at inspection at the beginning of the operation.
- Full-thickness lateral cartilage present.
- Correctable intra-articular varus deformity in the knee on 20 degrees flexion.

### Exclusion criteria

- Rheumatoid arthritis or other inflammatory disorders.
- Osteonecrosis.
- Osteochondritis dissecans.
- Symptomatic hip or spinal pathology (registered in medical history or suspected in a clinical examination).
- Previous knee surgery other than diagnostic arthroscopy or medial meniscectomy.
- Previous infectious knee arthritis.
- Significant osteoarthritis of the lateral facet of the patella, patellar subluxation or concave patella.
- Previous ligament injury and instability (crucial or collateral ligaments).
- Range of knee movement within 15–100° (flexion deformity >15° or flexion range <100°).
- Patient is planned to undergo simultaneous bilateral knee arthroplasty.
- American Society of Anesthesiologists classification 4 or above.

### Randomisation and masking

The sequentially numbered, sealed envelopes for the study group (medial unicompartmental or total knee arthroplasty) were prepared by a statistician with no involvement in the clinical care of patients in the trial. Randomisation was performed on a 1:1 ratio with a block size of four (known only by the statistician). The randomisation sequence involved stratification according to

age (45–60 years or 61–79 years), sex, and preoperative Oxford Knee Score (OKS) (0–17, 18–27 or 28–48). If a patient was confirmed to be eligible for the trial, an envelope containing the study-group assignment (medial unicompartmental or total knee arthroplasty) was opened 2 to 24 hours before the operation. The assignment was not revealed to the patient or personnel outside of the operation room. The study nurse collected the primary-outcome forms by mail, and patients filled in the forms by themselves. Patients were given the option of filling these forms in at home with no time limit.

To ensure blinding, only the operating orthopaedic surgeon and the staff in the operating room were aware of the group assignment, and they did not participate in further treatment or clinical follow-up of the patient. A day before the surgery, the surgeon called the study nurse (who was not involved with clinical work or patients preoperatively), who opened the randomisation envelopes and informed the surgeon of the type of operation. The operations were performed in arthroplasty theatres and time slots, which allowed us to use any arthroplasty implant needed.

A midline skin incision was performed on all study patients and was equally long in both study groups. Postoperative and follow-up radiographs were stored with a personalised study number and assessed by the surgeon responsible for the surgery. None of the radiographs or surgery reports were linked to the patient's personal identification number after surgery. Immediately after the operation, the postoperative radiographs were digitally coded and blinded and were invisible to the general picture archiving database. The unblinded surgeon who performed the operation evaluated the radiographs to identify immediate complications, for example, fracture. At latter timepoints, radiological findings needing attention were translucent lines, changes in position of implant, breakage of implant, mobile-bearing dislocation, and malposition of implant, in addition to fracture. In these cases, the patient was unblinded.

To ensure blinding, the postoperative clinical examination was performed by an orthopaedic surgeon who had not participated in the surgery and did not see the radiographs.

If the patients needed an opposite-side operation later on, this opposite knee was operated on using the same prosthesis and same blinding protocol without randomisation. The second knee was not included in the study.

## Interventions

In this study, we investigated the supposed superiority of cementless unicompartmental knee arthroplasty, which is currently the most used type of this implant in Finland, and which has worldwide better results in arthroplasty registers compared with cemented model in terms of implant survival. The cemented total-knee replacement is the most widely used procedure of this type worldwide as a gold standard, and therefore, it was selected as a comparison.

### Total knee arthroplasty procedure

For the total knee arthroplasty group, the study implant was a Triathlon (Stryker, Mahwah, New Jersey, USA) cruciate-retaining device. The operation was performed through a standard medial parapatellar incision. An intramedullary guiding rod was used for alignment for the femoral and tibial saw cuts and component positioning. Soft tissue and ligament releases were performed if needed. Components were cemented in place using polymethyl methacrylate bone cement. The patella was not resurfaced. Intraoperative local infiltration analgesia (mixture consisted of ropivacaine HCl (Naropin; AstraZeneca Pty., Sydney, Australia), 2.0 mg/mL mixed with 30 mg ketorolac tro-methamine (Toradol; Roche Products Pty. Ltd., Sydney, Australia) and 10 µg/mL epinephrine) was used for postoperative pain management and no drain was used.[16] A tourniquet was used in the procedure and was released at the end of the procedure.

### Medial unicompartmental arthroplasty

For the medial unicompartmental arthroplasty group, the study implant was a cementless unicompartmental Oxford phase 3 mobile-bearing device with microplasty instrumentation.

To ensure blinding, a midline skin incision was performed similarly in both groups, which differs from the standard medial parapatellar skin incision of unicompartmental arthroplasties. After skin incision, the knee joint and fascia were opened with a standard Oxford minimally invasive incision.[15] If the anterior cruciate ligament was not macroscopically and functionally intact, or if there was remarkable osteoarthrosis of the lateral compartment, the procedure was changed to total knee arthroplasty. Intraoperative local infiltration analgesia, which was similar with total knee arthroplasty, was used for postoperative pain management and no drain was used. A tourniquet was used in the procedure and was released at the end of the procedure.

### Postoperative medication and rehabilitation

The postoperative treatment protocol was similar in both study groups. Patients were instructed to take acetaminophen and over-the-counter non-steroidal anti-inflammatory drugs for pain as needed. All patients received 40 mg subcutaneous injections of enoxaparin daily for thrombosis prophylaxis for 14 days postoperatively. Full weight bearing and free range of motion were allowed immediately after surgery. Postoperative rehabilitation was instructed by a physiotherapist according to a standardised protocol. All patients received the same walking aids and instructions for the same exercise programme.

All primary and secondary outcome scores were collected at outpatient clinics preoperatively from 2 weeks to 3 months before actual operation, and at 2 and 12 months and 2 years postoperatively. Two months time point was used to investigate immediate recovery of the patient. At 12 months time point, a patient has usually

achieved a steady state in terms of pain and functional result. However, a proportion of patients may recover even after that and therefore a minimum of 2 years follow-up has been suggested to investigate early results of arthroplasty.

### Outcome measures

#### Primary outcome

Our primary outcome was the mean differences in improvement between study groups in OKS at 2 years after surgery. The OKS have been previously validated for knee osteoarthritis patients and knee arthroplasty.[17]

The minimal clinically significant difference of the OKS was defined as 5 (SD 8–10).[17]

### Secondary outcomes

Secondary outcomes included OKS at 2 and 12 months, and Knee injury and Osteoarthritis Score (KOOS) subscales: pain, symptoms, function in daily living, function in sport and recreation, and knee-related quality of life at 2 and 12 months and 2 years after surgery. The KOOS consists of five subscales: pain, symptoms, function in daily living, function in sport and recreation, and knee-related quality of life. The KOOS is responsive to change following non-surgical and surgical interventions including knee arthroplasty.[18 19] The OKS and KOOS have been previously validated for knee osteoarthritis patients and knee arthroplasty.[17–19]

Other secondary outcomes were complications and revision rates according to Clavien-Dindo,[20] change in the 15D score between groups, Knee Society Score (KSS),[21 22] and radiographic findings at 2, 12 months and 2 years after surgery.

Clavien-Dindo is a classification of complications based on the type of therapy needed to correct the complication.[20] The 15D is a generic, comprehensive (15-dimensional), self-administered instrument for measuring health-related quality of life among adults.[21] The KSS is subdivided into a knee score that rates the stability, movement, alignment and stairs, contractures of the knee joint itself and a functional score that rates the patient's ability to walk and climb.[22] Radiographs were taken on the first postoperative day and at 2 and 12 months and 2 years and looked for signs of potential failures such as component loosening and periprosthetic fracture.

### Statistical analysis

The required sample size was calculated to detect potential between-group differences in the primary outcome. The primary outcome was the change in the OKS at 2 years. The trial was powered to detect a 5-point mean difference in the OKS (SD 10 points)[19] with 80% power at 5% significance level. A 10% dropout was assumed. Based on the power analysis, 140 patients (70 in each group) were needed for the trial.

Power calculations were also done to the secondary outcome (KOOS) to detect a 10-point difference in the KOOS (SD 20)[18 19] with 80% power at 5% significance level. A 10% dropout was assumed.

The trial was designed to investigate the theoretically superior functional outcome of medial unicompartmental arthroplasty over total knee arthroplasty. Baseline characteristics were described as the mean with SD for continuous variables and frequencies with percentages for categorical variables. A two-sample t-test was used to compare continuous variables between the study groups and a $\chi^2$ test or Fisher's exact test for categorical variables. The changes in the OKS, KOOS subscales, KSS and 15D within and between the groups were analysed with analysis of variance for repeated measurements using an unstructured covariance structure after adjustment for surgeon and stratification variables age, sex and preoperative OKS. The mean changes and between-group differences in the changes with 95% CIs were calculated from the baseline to 2 and 12 months and 2 years. Statistical analyses were performed on an intention-to-treat basis and used all available participant data. P values less than 0.05 were considered statistically significant. The SAS System for Windows, V.9.4 (SAS Institute, Cary, North Carolina, USA) was used for statistical analyses.

Both treatment methods are widely used in the treatment of anteromedial osteoarthritis of the knee. A complete interim analysis was not performed for the study, but the complication data were analysed after 50% enrollment.

## RESULTS

Between 9 December 2015 and 28 May 2018, a total of 143 patients were recruited and underwent randomisation. Seventy-two patients were assigned to the medial unicompartmental arthroplasty group and 71 to the total knee arthroplasty group (figure 1). Three medial unicompartmental arthroplasty patients did not receive their allocated device. One had lateral compartment osteoarthritis, two had a torn anterior cruciate ligament, all of which were revealed during surgery. Four patients, three from the unicompartmental and one from the total knee arthroplasty group, were lost to follow-up. The baseline characteristics of the two groups were similar with respect to age, sex, and body mass index (table 1). Clinically significant improvement from baseline to 2 years was seen in the OKS and KOOS in both study groups (figure 2 and table 2).

The functional outcome scores provided comparable scores for medial unicompartmental arthroplasty and total knee arthroplasty at 2 years. The mean difference in improvement of OKS between the study groups was 1.6 points (95% CI −0.7 to 3.9; p=0.175) at 2 years.

### Secondary outcomes

In the KOOS subscales, there were no mean differences in improvement between study groups in the pain score (0.1 points; 95% CI −4.8 to 5.0; p=0.9589), function and daily living score (4.3 points; 95% CI −0.6 to 9.2; p=0.0842),

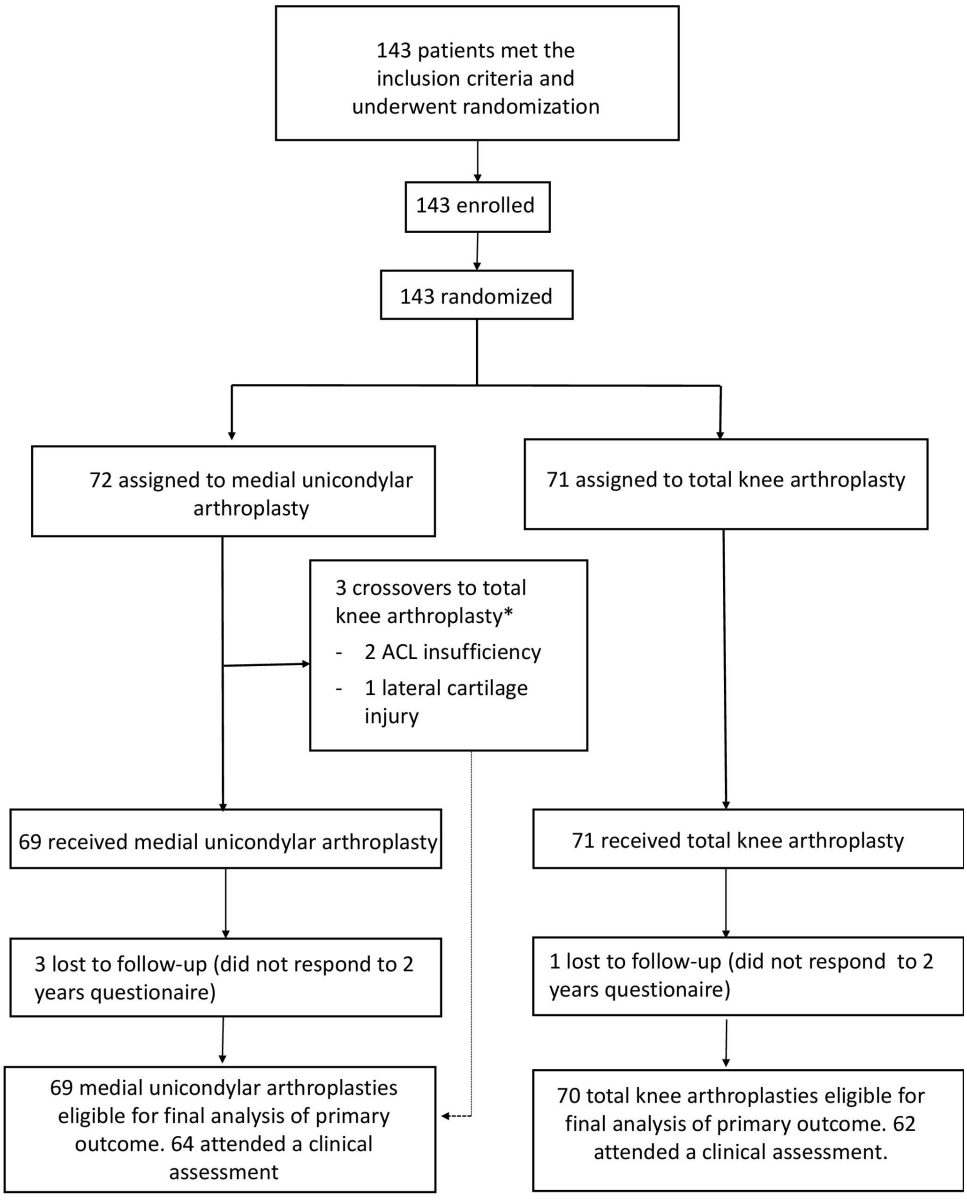


**Figure 1** Flow chart. *Included to final analysis according to intention-to-treat principles.

sports and recreation score (4.3 points; 95% CI −3.0 to 11.6; p=0.2452), and quality of life score (2.1 points; 95% CI −4.8 to 9.1; p=0.5472) at 2 years.

The mean difference in improvement of OKS between the study groups was 6.2 points (95% CI 3.5 to 8.9; p<0.0001) at 2 months and 3.2 points (95% CI 0.9 to 5.6 p=0.0067) at 12 months, favouring unicompartmental knee arthroplasty. In the KOOS subscales, there were differences between the study groups in the pain score (11.4 points; 95% CI 5.9 to 16.9; p<0.0001), symptoms score (12.6 points; 95% CI 6.1 to 19.1; p=0.0002), function in daily living score (12.5 points; 95% CI 6.8 to 18.1; p<0.0001), sports and recreation score (16.7 points; 95% CI 9.1 to 24.3;<0.0001), and quality of life score (8.9 points; 95% CI 2.3 to 15.6; p=0.0089) at 2 months and in the KOOS symptoms score (10.1 points; 95% CI 3.6 to 16.6 p=0.0025) at 12 months. In the KOOS symptoms score, the mean difference in improvement between study groups (7.7 points; 95% CI 0.02 to 15.3; p=0.0491) favoured unicompartmental arthroplasty at 2 years, but the difference was not clinically significant.

At 12 months, there were no differences between the study groups in the KOOS subscales sports and recreation score (7.0 points; 95% CI −0.9 to 14.9 p=0.0834), and quality of life score (6.6 points; 95% CI −0.6 to 13.8 p=0.0701). In the KOOS function and daily living score and in the pain score, the mean difference in improvement between the study groups was statistically but not clinically significant (7.8 points; 95% CI 3.0 to 12.7 p=0.0016) and (5.1 points; 95% CI 0.1 to 1101 p=0.0461), respectively.

Clinically significant between-group differences were found at 2 months in KSS and 15D: 22.7 points (95% CI 13.0 to 32.4; p<0.0001) and 0.028 points (95% CI 0.006 to 0.050; p=0.0132), respectively. There were no differences between the study groups in 15D, KSS, revisions,

Table 1 Baseline characteristics of patients by study group¶

| | Medial unicondylar arthroplasty (n=72) | Total knee arthroplasty (n=71) |
|---|---|---|
| Age | 63.3±7.3 | 62.9±8.5 |
| Male sex–No. (%) | 33 (46%) | 30 (42%) |
| BMI | 29.5±3.8 | 28.5±3.8 |
| Oxford Knee Score* | 25.0±6.55 | 26.1±6.5 |
| KOOS classification† | | |
| Symptoms | 53.8±16.4 | 53.6±17.1 |
| Pain | 50.0±12.2 | 49.7±12.5 |
| Function, daily living | 55.8±14.0 | 58.6±14.0 |
| Function, sports | 20.2±14.6 | 19.9±14.6 |
| Quality of life | 28.7±15.3 | 30.8±13.5 |
| Knee Society Score ‡ | 115.5±19.1 | 117.2±21.4 |
| 15D score § | 0.84±0.07 | 0.84±0.08 |

*The Oxford Knee Score contains 12 items. The score ranges from 0 to 48; a higher score indicates less severe symptoms.
†The Knee Injury and Osteoarthritis Outcome Score consists of five subscales: The score ranges from 0 to 100; higher scores indicate less severe symptoms.
‡The Knee Society Score is subdivided into a knee score that rates the stability, movement, alignment and stairs, contractures of the knee joint itself, and a functional score that rates the patient's ability to walk and climb. The maximum score is 200 and minimum 0; higher scores indicate better function of the knee.
§The 15D instrument is a generic health-related quality of life instrument. It contains 15 items. The maximum score is 1 (health) and minimum 0 (death).
¶Plus–minus values are means±SD. There were no significant differences in the baseline characteristics between the treatment groups.
BMI, body mass index; KOOS, Knee injury and Osteoarthritis Score.

infections, postoperative haematoma, postoperative fracture, instability or complications according to the Clavien-Dindo classification at 12 months or 2 years (table 3).

At 2 years, patients with total knee arthroplasty had more limited postoperative range of movement (ROM) needing manipulation under anaesthesia than patients with unicompartmental knee arthroplasty (5 vs 0 patients, p=0.0280). Three patients in the medial unicompartmental arthroplasty group and four patients in the total knee arthroplasty group needed revision arthroplasty. The reasons for revision were deep infection (three in the total knee arthroplasty group), instability of the knee or bearing dislocation (one in the total arthroplasty group and two in the medial unicompartmental arthroplasty group), and haematoma evacuation (one in the medial unicompartmental arthroplasty group) (table 3.)

The complication data were analysed after 50% enrollment. There were three complications, two in the total knee replacement (TKR) group and one in the unicompartmental knee arthroplasty (UKA) group. The steering committee evaluated these complications and decided that no further statistical analysis was needed.

## DISCUSSION

This is the first assessor-blind study comparing medial unicompartmental and total knee arthroplasty in the treatment of isolated medial osteoarthrosis. The lack of blinding has been identified to be a significant source of bias in clinical trials.[23] We found that patients treated with medial unicompartmental arthroplasty did not have better patient-reported outcome scores in OKS or KOOS compared with total knee arthroplasty at 2 years. Patients treated with medial unicompartmental arthroplasty had a faster postoperative recovery (better OKS and KOOS scores at 2 and 12 months) compared with patients treated with total knee arthroplasty. There was no difference in the number of revisions between the study groups.

### Comparison with other studies

To our knowledge, there are five earlier randomised trials comparing medial unicompartmental and total knee arthroplasty.[10 24–27] In the The Total or Partial Knee Arthroplasty Trial (TOPKAT) study, the largest of these randomised trials including 528 patients, medial unicompartmental arthroplasty provided good clinical outcome with lower cost and better cost-effectiveness at 5 years compared with total knee arthroplasty.[10] Even though the OKS, which was their primary outcome, was comparable between the study groups at 5 years postoperatively, patients had faster recovery in the unicompartmental arthroplasty group and were more likely to think that their knee was better than before surgery and would more often have the surgery again than patients in the total knee arthroplasty group (95% vs 90%, p=0.010; 91% vs 84%, p=0.010, respectively). Additionally, the unicompartmental arthroplasty group had a better EuroQol-5D visual analogue scale score at 5 years. The authors concluded that their results encourage offering medial unicompartmental arthroplasty to patients with isolated

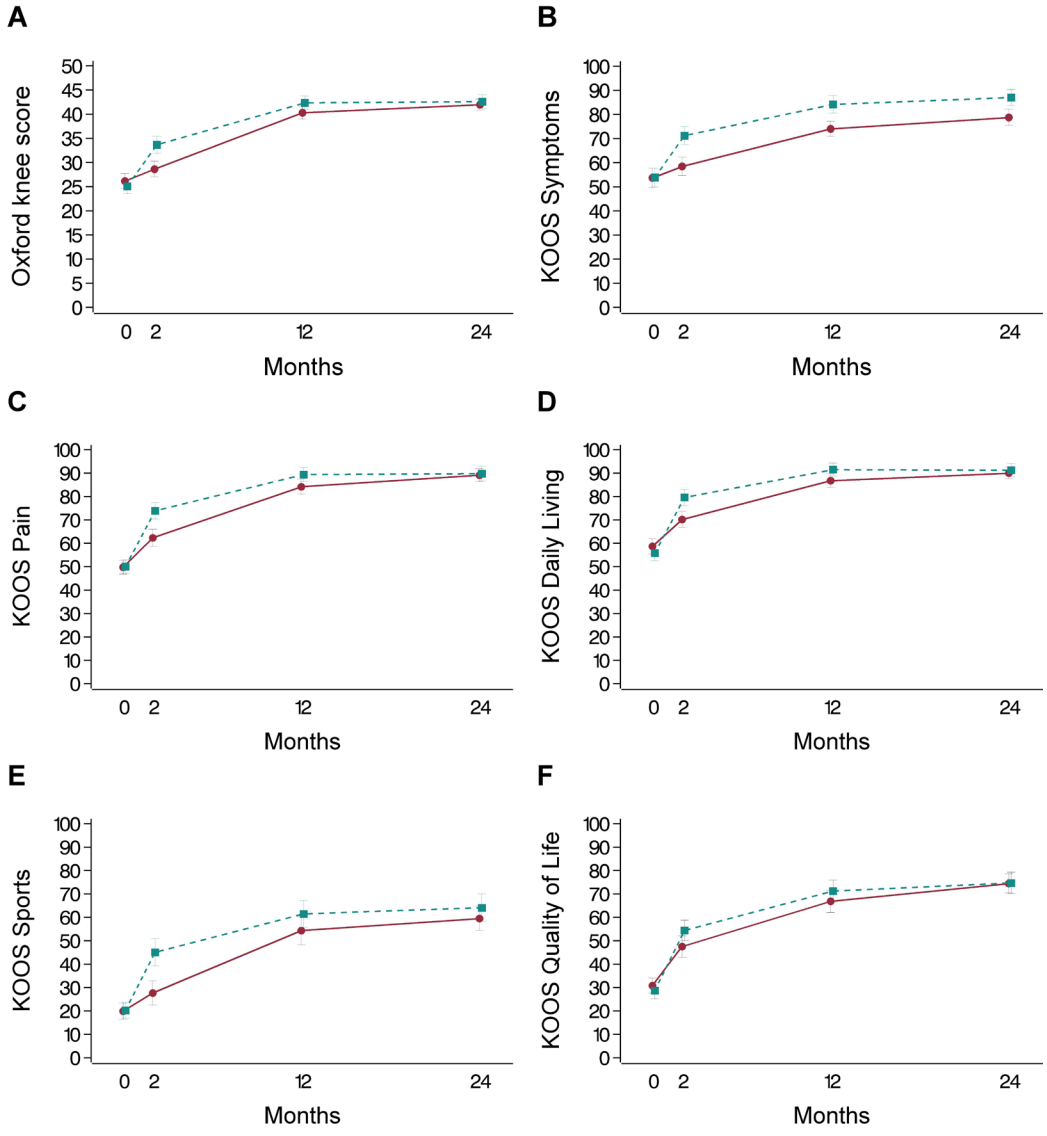


**Figure 2** Primary and secondary outcomes in the unicompartmental knee arthroplasty group and the total knee arthroplasty group. Values are means with 95% CIs. Unicompartmental knee. Arthroplasty total knee arthroplasty. KOOS, Knee injury and Osteoarthritis Score.

medial osteoarthrosis.[10] Although we did not assess cost effectiveness, faster postoperative recovery in our study supports the conclusions of the TOPKAT study.

Newman *et al*[25] compared fixed-bearing UKA to TKA and reported a better ROM after UKA. Sun and Jia[26] compared mobile-bearing UKA with fixed-bearing TKA and did not find a significant difference in (ROM) or KSS postoperatively after a mean of 52 months follow-up, but the TKA group had significantly more prevalent postoperative deep vein thrombosis and greater postoperative blood loss. Kulshrestha *et al*[27] reported similar outcomes compared fixed-bearing unicompartmental arthroplasty with total knee arthroplasty for patient with bilateral simultaneous arthroplasty. These earlier randomised control trials, except for TOPKAT, have reported single centre series, without adequate blinding, with relatively small number of participants.[24–27] As patient expectations have a significant effect on outcome in arthroplasty, assessor-blind studies in which patients do not know which implant they have received are vital in confirming patient-reported outcome results in medial unicompartmental compared with total knee arthroplasty.[6] In our study, both medial unicompartmental and total knee arthroplasty provided good to excellent short-term results in an assessor-blind setting. The medial unicompartmental arthroplasty group had better outcome results at 2 months, which suggests faster postoperative recovery. At 12 months, the medial unicompartmental arthroplasty group still had slightly better outcome scores in both the OKS and KOOS, although only one of the subcategories of KOOS was clinically significant. However, after 2 years the outcome scores were comparable. The findings of our study do not support a recent literature review and meta-analysis assessing differences in patient reported outcomes between unicompartmental and total knee arthroplasty in terms of better functional outcome of unicompartmental arthroplasty.[28]

**Table 2** Primary and secondary outcomes at 2 and 12 months and 2 years after surgery*

| | | | Improvement from baseline | | | |
|---|---|---|---|---|---|---|
| | | | | | Between-group difference | |
| **Outcome—adjusted mean (95% CI)*** | **Unicompartmental knee arthroplasty** | **Total knee arthroplasty** | **Unicompartmental knee arthroplasty** | **Total knee arthroplasty** | **Total versus unicompartmental knee arthroplasty** | **Adjusted p value** |
| Primary outcome (2 years) | | | | | | |
| Oxford Knee Score (OKS) $ | 41.2 (39.7 to 42.7) | 40.1 (38.7 to 41.6) | 17.4 (15.8 to 19.1) | 15.8 (14.2 to 17.5) | 1.6 (–0.7 to 3.9) | 0.1749 |
| Secondary outcomes | | | | | | |
| 2 months | | | | | | |
| OKS $ | 32.5 (30.6 to 34.4) | 26.8 (24.9 to 28.7) | 8.7 (6.8 to 10.6) | 2.5 (0.5 to 4.4) | 6.2 (3.5 to 8.9) | <0.0001 |
| Knee Society Score & | 157.1 (150.3 to 164.0) | 136.3 (129.4 to 143.1) | 45.4 (38.5 to 52.3) | 22.7 (15.9 to 29.6) | 22.7 (13.0 to 32.4) | <0.0001 |
| KOOS pain | 72.3 (68.5 to 76.0) | 59.9 (56.2 to 63.7) | 24.0 (20.0 to 27.9) | 12.6 (8.6 to 16.5) | 11.4 (5.9 to 16.9) | <0.0001 |
| KOOS symptoms | 70.0 (65.9 to 74.1) | 56.7 (52.6 to 60.8) | 17.4 (12.8 to 22.0) | 4.8 (0.2 to 9.4) | 12.6 (6.1 to 19.1) | 0.0002 |
| KOOS function, daily living | 77.7 (74.0 to 81.5) | 67.3 (63.6 to 71.0) | 24.0 (20.0 to 28.0) | 11.5 (7.5 to 15.5) | 12.5 (6.8 to 18.1) | <0.0001 |
| KOOS function, sports | 42.5 (37.0 to 48.1) | 24.9 (19.4 to 30.4) | 24.6 (19.3 to 30.0) | 7.9 (2.6 to 13.3) | 16.7 (9.1 to 24.3) | <0·0001 |
| KOOS quality of life | 52.4 (47.7 to 57.1) | 44.6 (39.9 to 49.3) | 25.6 (20.9 to 30.3) | 16.7 (12.0 to 21.4) | 8.9 (2.3 to 15.6) | 0.0089 |
| 15D score | 0.869 (0.852 to 0.886) | 0.838 (0.821 to 0.855) | 0.036 (0.020 to 0.051) | 0.007 (–0.008 to 0.023) | 0.028 (0.006 to 0.050) | 0.0132 |
| **12** months | | | | | | |
| OKS $ | 41.2 (39.6 to 42.7) | 38.4 (36.9 to 40.0) | 17.4 (15.7 to 19.0) | 14.2 (12.5 to 15.8) | 3.2 (0.9 to 5.6) | 0.0067 |
| Knee Society Score & | 182.3 (177.9 to 186.8) | 176.9 (172.6 to 181.3) | 70.6 (65.0 to 76.2) | 63.4 (57.8 to 69.0) | 7.2 (–0.7 to 15.1) | 0.0742 |
| KOOS pain | 87.8 (84.6 to 91.0) | 81.8 (78.6 to 84.9) | 39.5 (35.9 to 43.0) | 34.4 (30.8 to 37.9) | 5.1 (0.1 to 10.1) | 0.0461 |
| KOOS symptoms | 83.1 (79.5 to 86.7) | 72.6 (68.7 to 75.8) | 30.4 (25.9 to 35.0) | 20.3 (15.7 to 24.9) | 10.1 (3.6 to 16.6) | 0.0025 |
| KOOS function, daily living | 89.7 (86.7 to 92.7) | 83.9 (80.9 to 86.9) | 35.9 (32.5 to 39.3) | 28.1 (24.7 to 31.5) | 7.8 (3.0 to 12.7) | 0.0016 |
| KOOS function, sports | 59.5 (53.6 to 65.3) | 51.6 (45.8 to 57.4) | 41.6 (36.0 to 47.2) | 34.6 (29.0 to 40.2) | 7.0 (–0.9 to 14.9) | 0.0834 |
| KOOS quality of life | 69.4 (64.6 to 74.2) | 63.9 (59.2 to 68.7) | 42.6 (37.6 to 47.7) | 36.0 (31.0 to 41.1) | 6.6 (–0.6 to 13.8) | 0.0701 |
| 15D score | 0.894 (0.876 to 0.912) | 0.874 (0.856 to 0.893) | 0.060 (0.045 to 0.076) | 0.044 (0.028 to 0.059) | 0.017 (–0.005 to 0.039) | 0.1250 |
| **2** years | | | | | | |

Continued

**Table 2** Continued

| | | | Improvement from baseline | | | |
|---|---|---|---|---|---|---|
| | | | | | Between-group difference | |
| **Outcome—adjusted mean (95% CI)*** | **Unicompartmental knee arthroplasty** | **Total knee arthroplasty** | **Unicompartmental knee arthroplasty** | **Total knee arthroplasty** | **Total versus unicompartmental knee arthroplasty** | **Adjusted p value** |
| Knee Society Score & | 180.9 (175.6 to 186.1) | 178.6 (173.3 to 183.9) | 69.1 (63.0 to 75.3) | 65.1 (58.9 to 71.3) | 4.1 (–4.7 to 12.8) | 0.3585 |
| KOOS pain | 87.9 (84.7 to 91.0) | 86.8 (83.7 to 90.0) | 39.6 (36.1 to 43.0) | 39.4 (36.0 to 42.9) | 0.1 (–4.8 to 5.0) | 0.9589 |
| KOOS symptoms | 85.5 (81.9 to 89.1) | 77.0 (73.5 to 80.6) | 32.8 (28.4 to 37.3) | 25.1 (20.7 to 29.5) | 7.8 (1.5 to 14.0) | 0.0152 |
| KOOS function, daily living | 89.1 (86.2 to 92.0) | 86.9 (84.0 to 89.8) | 35.3 (31.9 to 38.8) | 31.0 (27.6 to 34.5) | 4.3 (–0.6 to 9.2) | 0.0842 |
| KOOS function, sports | 61.7 (56.1 to 67.2) | 56.4 (50.9 to 61.9) | 43.7 (38.6 to 48.9) | 39.4 (34.3 to 44.6) | 4.3 (–3.0 to 11.6) | 0.2452 |
| KOOS quality of life | 72.3 (67.9 to 76.8) | 71.3 (66.9 to 75.7) | 45.5 (40.6 to 50.5) | 43.4 (38.5 to 48.3) | 2.1 (–4.8 to 9.1) | 0.5472 |
| 15D score | 0.894 (0.875 to 0.912) | 0.889 (0.871 to 0.907) | 0.060 (0.044 to 0.077) | 0.058 (0.042 to 0.075) | 0.002 (–0.022 to 0.025) | 0.8739 |

*Adjusted means (95% CIs) from analysis of variance for repeated measurements. Analyses were adjusted for surgeon, age, sex and preoperative OKS.
KOOS, Knee injury and Osteoarthritis Score.

Table 3 Complications

| | Unicompartmental knee arthroplasty | Total knee arthroplasty | P value |
|---|---|---|---|
| Outcome | | | |
| Revision for any reason no. (%)* | 3 (4.2) | 4 (5.6) | 0.72 |
| Infection no. (%)† | 0 (0) | 3 (4.2) | 0.12 |
| Manipulation under anaesthesia no. (%) | 0 (0) | 5 (7.0) | 0.03 |
| Postoperative haematoma (needing surgery) no. (%) | 1 (1.4) | 1 (1.4) | 1.00 |
| Postoperative fracture | 0 (0) | 0 (0) | 1.00 |
| Mobile bearing luxsation or instability of the knee | 2 (2.8) | 1 (1.4) | na |
| Complications—Clavien Dindo‡ | | | 0.08 |
| Grade I no. (%) | 2 (2.8) | 2 (2.8) | |
| Grade II no. (%) | 0 (0) | 5 (7.0) | |
| Grade IIIa no. (%) | 4 (5.6) | 5 (7.0) | |
| Grade IIIb no. (%) | 0 (0) | 2 (2.8) | |
| Grade IVa, IVb and V no. (%) | 0 (0) | 0 (0) | |

*Revisions for infection included .
†Deep infections included.
‡Clavien-Dindo is a classification of complications based on the type of therapy needed to correct the complication. Grade I complications are any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions. Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside. Within grade II complications requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included. Grade III complications are those requiring surgical, endoscopic or radiological intervention. Grade IIIa intervention not under general anaesthesia and grade IIIb intervention under general anaesthesia. Grade IV complications are life-threatening complications (including central nervous system complications) requiring intensive care unit-management. Grade V complication is death.

In our study, there were three revisions in the medial unicompartmental arthroplasty group and four in the total knee arthroplasty group. The reasons for revision and complications reflect the differences between mobile-bearing unicompartmental knee arthroplasty and total knee arthroplasty. Patients in the total knee arthroplasty group had three infections and five knees underwent manipulation under anaesthesia, whereas there were no reoperations for these reasons in the unicompartmental arthroplasty group.[29] Further, in the medial unicompartmental arthroplasty group two patients had a bearing dislocation requiring revision, a complication that barely occurs in total knee arthroplasties or fixed-bearing unicompartmental arthroplasties in the short term. We acknowledge that the revision rate was higher than normal, but, the current study was not adequately powered to assess differences in the reoperation rate. More long-term data with larger patient data from randomised trials are needed to assess the later revision burden of medial unicompartmental knee arthroplasty.

## Strengths and limitations of this study

The main strength of our study is the assessor-blind setup. Despite the inferior survival of unicompartmental arthroplasty in registries, many orthopaedic surgeons and patients believe in the potential superior functional outcome of medial unicompartmental arthroplasty compared with total knee arthroplasty.[12 13 30 31] Given these expectations, a assessor-blind setup is the most reliable method for comparing these devices. Another strength of our study was that it was conducted in the public sector in publicly funded hospitals and the authors did not receive any grants or other funding from industry.[32]

We acknowledge that there were limitations in our study. First, 2 years is a relatively short follow-up time for an arthroplasty. However, one of the main potential benefits of unicompartmental arthroplasty is faster postoperative recovery, which can be assessed during the first two postoperative years. Short-term outcomes were our main interest, because assumed superiority of unicompartmental knee arthroplasty should become visible in the very first years after the operation. The limitation of short follow-up does could not be avoided, or it was not needed to avoid, but the mid-term and long-term results of the current study may be different. Second, there was only one uncemented mobile-bearing medial unicompartmental arthroplasty device and one cemented total knee device included in the study. Both implants are in the top five most-used implants in their categories worldwide and they were most used brands by the surgeons who operated on the study participants. To the best of our knowledge, there is no study reporting different functional results between different arthroplasty brands, but caution should be applied when extrapolating these results to other unicompartmental device types such as lateral,

cemented, or fixed-bearing unicompartmental devices. Third, we were unable to report the exact number of patients assessed for eligibility and the reasons for exclusion from outpatient clinics. The patients were recruited from the knee arthroplasty surgeons' outpatient clinic. In these outpatient clinics, the patient population is highly selected, and we thought that it would not be reliable to report the exact number of patients assessed for eligibility and the reasons for exclusion. Fourth, patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

## CONCLUSIONS

In conclusion, medial unicompartmental arthroplasty did not provide a better functional result compared with total knee arthroplasty at 2 years in a assessor-blind randomised study setting. Medial unicompartmental arthroplasty provided faster postoperative recovery than total knee arthroplasty. Our results support the use of medial unicompartmental arthroplasty in patients with isolated medial osteoarthrosis, but the better functional result of unicompartmental knee arthroplasty should not be part of a shared decision-making process. More long-term data from randomised trials are needed to assess the later revision burden.

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**Patient consent for publication** Not required.

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**Data availability statement** Data are available upon reasonable request. The data collected for this study, including deidentified individual participant data, will be made available to researchers on request to the corresponding author with investigator support, after approval of a proposal, with a signed data access agreement by emailing jani.knifsund@tyks.fi. The study protocol, statistical analysis plan and informed consent form are available with the publication.



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