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Similar migration in computer-assisted and conventional total knee arthroplasty

A multicenter, parallel-group, randomized controlled trial involving 54 patients

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Patients and methods

This RSA study was part of a larger RCT investigating clinical and radiological outcome after total knee replacement operated with either CAS or CONV technique (Gøthesen et al. 2014). 192 patients were included in the trial, allocated randomly to CAS (n = 97) or CONV (n = 95). The first 54 patients operated were marked with RSA markers.

Patients were randomly parallel-assigned to either CAS or CONV (allocation ratio: 1:1). Due to the slow recruitment rate, the age criteria for inclusion were changed after 6 months, from 60–80 years to 50–85 years. Ultimately, eligible patients were men and women 50–85 years of age who were in need of a TKA, with primary, secondary, or inflammatory arthritis of the knee and with ASA category 1–3.

Exclusion criteria included severe systemic disease, severe neurologic disorder, a history of cancer, dementia, BMI > 35, previous fractures of the shaft of the tibia or femur, severe pre-operative valgus position of the knee (> 15º from the mechanical axis of the knee), previous osteotomy of the tibia or femur, knee injury less than a year preoperatively, severe stiffness of the ipsilateral hip, ipsilateral hip replacement, and allergy to metals. For patients with bilateral knee replacements, only the first knee evaluated in the recruitment period was included in the trial.

The recruitment period was 2009–2011, and patients were identified in 4 orthopedic clinics in Norway. 8 surgeons performed the knee replacements. They were all experienced in TKA (defined as having performed > 100 CONV procedures), and each surgeon had carried out at least 10 TKAs using CAS before recruiting patients into the trial. We used a block randomization method in order to ensure that each surgeon operated an equal number of patients in each of the 2 study groups.

The trial was designed and conducted according to the CONSORT statement guidelines for reporting of parallel-group randomized trials (Schulz et al. 2010).

Intervention

A cemented cruciate retaining (CR) Profix total knee prosthesis (Smith and Nephew, Memphis, TN) was implanted in all patients using Palacos R+G cement (Heraeus, Hanau, Germany). We used keeled implants in all patients with tibia size 3 or more; smaller sizes had a 5-cm metaphyseal stem (Table 1). We used the “measured bone resection” femur first technique (Whiteside and Arima 1995, Dennis et al. 2010) in all cases, and the principles of TKA and ligament balancing according to Whiteside (2002) were applied. No patellar resurfacing was performed. The tibial component was implanted with a view to achieving a 4º posterior slope and neutral alignment in the frontal plane. In the CONV group, conventional instruments and intramedullary rods were used, both in the femur and tibia. The femoral component was inserted in neutral alignment in the frontal plane (referring to the mechanical axis, the surgeon could choose between 5º and 7º valgus cutting blocks with reference to the intramedullary rod) and the sagittal plane (referring to the anatomical axis), or optionally with 4º flexion of the femoral component. In the CAS group, neutral alignment was aimed for in the frontal plane, and an individualized flexion of the femoral component and 4º slope of the tibia was...
allowed in the sagittal plane. The CAS technology used was the VectorVision knee software, version 1.6.93616, with the Kolibri system (Brain-LAB, Munich, Germany).

Tranexamic acid (10 mg/kg) was administered intravenously 10 min before surgery and repeated 10 min before release of the tourniquet. No drains were used. The operated knee was positioned in 90° flexion for 2 h to minimize bleeding. Antithrombotic medication was administered 4 h postoperatively and once daily for 17 days (5000 IE dalteparin by subcutaneous injection). Antibiotic prophylaxis (cephalotin, 2 g) was administered intravenously 30 min before surgery, then after 4, 8, and 12 h. The skin incision was closed with staples. All patients started weight bearing and standardized exercises on the first postoperative day. Postoperative epidural catheter was used for pain control in the first 2 days.

For the RSA analysis, 6 tantalum-sphere markers (diameter 0.8 and 1.0 mm) were inserted at operation into the plastic component of the tibia. 9 markers (1.0 mm in diameter) were spread out into the tibial metaphysis before the tibial base was cemented (Figure 1). As the CAS procedure requires extra incision in the mid-tibia, a sham incision was used in patients operated with the CONV technique.

Objectives and outcomes

The patients and observers (physiotherapists and radiologist) were blinded as to which surgical procedure was used. The follow-up period was 24 months, with scheduled follow-up visits at 3, 12, and 24 months.

192 patients were included in the main study. Of those, 54 were enrolled in the present RSA study. 6 patients were excluded: 1 withdrew from the study, 3 were revised (all CONV), 1 because of fracture of the proximal tibia and 2 because of deep infection. 2 could not be analyzed further with RSA (both CAS) because of an insufficient number of visible markers on the radiographs (Figure 2). In all, 48 patients were available for final RSA analysis at 2 years (Table 1). 3 patients did not show up at the 3-month RSA follow-up and 4 patients did not show up at the 1-year RSA follow-up. Due to inferior quality of stereo radiographs, 4 patients could not be analyzed at 3 months postoperatively.

Clinical outcome was evaluated with Knee Society score (KSS), knee injury and osteoarthritis outcome score (KOOS), EQ-5D, and a visual analog scale (VAS) for pain. Clinical outcome at 1 year has been published together with radiographic findings for the main study (Gøthesen et al. 2014).

The index RSA examination was done on day 6 or 7 and RSA examinations were repeated at 3, 12, and 24 months after surgery. The patient was supine with the knee positioned inside a biplane calibration cage (cage 10; RSA Biomedical, Umeå, Sweden) according to the technique described earlier (Henricson et al. 2008). 1 gantry-mounted X-ray tube and 1 portable X-ray tube were used to obtain 2 simultaneous exposures at a 90° angle. For radiographic imaging, we used high-definition digital plates (Agfa CR MD 4.0) and for plate reading we used the ADC compact digitizer (Agfa).

The investigator involved in the RSA measurements (KH) was blind regarding patient allocation. Sometimes, however, the holes in the tibia and femur made by the fixator pins used to secure the navigation towers were revealed on the images being measured. RSA measurements were possible if
3 or more markers could be identified in each segment from repeated examinations.

Translation and rotation of the tibial component relative to tibial bone was calculated using the markers in the tibia as the fixed reference segment and the markers in the polyethylene insert as the moving segment (UmRSA Digital Measure version 6.0; RSA Biomedical). The movements of the implant were measured along and around a medially directed axis (x-axis, anteroposterior rotation (AP)), longitudinal axis (y-axis, internal-external rotation), and sagittal axis (z-axis, varus-valgus rotation) of the knee. To ensure proper stability and distribution of the tantalum markers, the upper limit for the mean error of rigid-body fitting was set at 0.25 and the upper limit for the condition number was set at 100 (Valstar et al. 2005, Henrikson et al. 2008). To ensure identical points of measurement of the translation, standardized positions on the tibial tray were defined as described previously (Nilsson et al. 1991). Translations were expressed as the maximum total point motion (MTPM), subsidence, and lift-off. MTPM represents the 3-D vector of the prosthetic marker that moved the most and corresponds to the magnitude of the migration only (Ryd et al. 1995). For each implant, the largest negative value for y-translation was called maximum subsidence and the largest positive y-translation was called lift-off. The calculations were performed according to the orthogonal right-hand coordinate system.

**Statistics**

The numbers included in the study were determined by power analyses, claiming 0.1 mm as a clinically relevant between-group difference, with a repeatability of 0.1 mm in the RSA measurements. A group sample size of 17 would achieve 80% power to detect a difference of 0.1 between groups with an estimated standard deviation of 0.1 and with a significance level (alpha) of 0.05, using a 2-sided, 2-sample t-test. To ensure proper sample sizes at 2 and 5 years, we chose to calculate the standard deviation (SD) of the medians difference and the corresponding CI for the median difference for each migration and clinical parameter were calculated as described by Campbell and Gardner (1988). Differences in age, sex, Charnley category, and diagnosis were assessed by Pearson’s chi-squared test. Any p-value less than 0.05 was considered significant.

Statistical evaluation was performed using SPSS software version 21.0 and the R package.

**Ethics and registration**

The study was registered in the trial database at ClinicalTrials.gov (identifier: NCT00782444) on October 30, 2008. The trial was approved by the regional committee for medical and health research ethics, Bergen, Norway, on September 29, 2007 (ref. no. 2007/12587-ARS).

**Results**

**Implant migration**

The tibial components in both groups migrated most during the first 3 months after surgery (Tables 2 and 3) and then appeared to stabilize. The difference in MTPM during the first 3 months, and between 3 months and 2 years was not statistically significantly different between the study groups (p = 0.8 and p = 0.1, Mann-Whitney test) (Figure 3).

No tibial components migrated more than 0.1 mm between 12 and 24 months. The component that migrated most had an MTPM of 0.09 mm during the second year of observation. There were no outliers.

The total rotational migration (in degrees) was similar between groups at all 4 follow-up times (Tables 2 and 3). There was no trend of any 1-directional migration pattern; we found an even distribution between positive and negative migration values in both groups.

There were no statistically significant differences between the groups for maximal subsidence and lift-off between 3 months and 2 years (Figures 4 and 5).

The mean error of rigid-body fitting was 0.12 (95% CI: 0.11–0.13) and the condition number was 30 (95% CI: 34–40).
Radiographic findings
The main aim was to achieve a neutral alignment on long-axis radiographs. 10 patients ended up with a mechanical axis that deviated more than 3º into varus or valgus from this axis. 4 of these were CAS-operated TKAs and 6 were CONV-operated TKAs. These 10 patients were classified as outliers. When comparing outliers to neutrally aligned knees, we found no significant difference in MTPM between 3 months and 2 years (p = 1.0).

Discussion
We measured the degree of migration for TKA operated using CAS or CONV technique and we found no statistically significant differences in mean MTPM, subsidence, lift-off, or rotational movements between the 2 groups. Earlier studies have indicated that early migration correlates with later loosening of TKA. Our results indicate that the risk of loosening should be similar in both groups. Neither of these techniques is superior. According to Valstar et al. (2012), there is grow-
ing awareness that new joint replacement prostheses, cement, and surgical techniques should be thoroughly evaluated before general release onto the market and that RSA studies should play an important role in this evaluation.

**Strengths and limitations**

To date, no RCTs have directly compared CAS and CONV technique using radiostereometry. The main strength of our study is that it was an RCT designed to directly compare migration of CAS- and CONV-operated TKAs. The number of patients was sufficient for us to evaluate whether there was a statistically significant difference in implant migration between the 2 groups (Kärrholm et al. 1994, Ryd et al. 1995, Valstar et al. 2005). The trial was designed to study migration in TKAs in patients aged 50–85 years. The main limitation is that the number of patients was too low for us to evaluate subgroups (age groups, implant sizes, and alignment) within the study population.

**Current knowledge**

Ryd et al. (1995) used RSA as a predictor of mechanical knee implant loosening. Migration of more than 2 mm between 1 and 2 years was considered to be “continuous migration”, with an increased risk of aseptic loosening. Pijls et al. (2012) confirmed that migration measurements from RSA tests can predict subsequent loosening of knee prostheses.

A recent Cochrane review concluded that cemented implants migrate less than uncemented ones, with lower displacement in cemented implants when evaluating MTPM at 2 years (Nakama et al. 2012). However, cemented implants showed a higher risk of aseptic loosening due to a continuous migration pattern. The uncemented components stabilized after an initial period of early and greater migration, whereas the cemented components showed no tendency to stabilize over time. 1 publication found a cemented tibial component to be stable without continuous migration after 5 years (Henricson et al. 2013), and another after 2 years (Tjørnild et al. 2014). In the present study, all the implants were cemented. No implant migrated more than 0.2 mm between 1 and 2 years. All implants showed early migration and stabilization, with similar migration patterns.

In a registry-based study, de Steiger et al. (2015) found that computer navigation reduced the overall rate of revision and the rate of revision for loosening/lysis following TKA in patients less than 65 years of age. We found higher MTPM in patients younger than 65 who were operated with CAS rather than CONV, but this difference was not statistically significant (p = 0.2), probably due to low power.

In a study from the Norwegian Arthroplasty registry (NAR), the main conclusion was that the short-term risk of revision was either the same or higher for CAS, and depended more on prosthesis brand (Gothesen et al. 2011). The frequency of use of CAS in Norway peaked at 21% in 2008, but it was 8% in 2015 (NAR 2015).

**Clinical relevance**

This is the first RSA study to have directly compared CAS- and CONV-operated TKAs. RSA studies play an important role in the documentation of new techniques in joint replacement surgery, and some authors propose that this should be mandatory before larger clinical trials can be initiated.

**Conclusion**

We found similar migration of the tibial component in TKAs operated using computer-aided surgery and in TKAs operated using conventional technique.

GP, OG, AA, KGN, and OF planned the study and analyzed the data. AMF and OF supervised the analyses. KH analyzed RSA images. All the authors contributed to writing the manuscript.

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