

Trabecular metal tibia still stable at 5 years

An RSA study of 36 patients aged less than 60 years

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Background and purpose Clinical results of total knee replacement (TKR) are inferior in younger patients, mainly due to aseptic loosening. Coating of components with trabecular metal (TM) is a new way of enhancing fixation to bone. We have previously reported stabilization of TM tibial components at 2 years. We now report the 5-year follow-up of these patients, including RSA of their TM tibial components.

Patients and methods 22 patients (26 knees) received an uncemented TM cruciate-retaining tibial component and 19 patients (21 knees) a cemented NexGen Option cruciate-retaining tibial component. Follow-up with RSA, and clinical and radiographic examinations were done at 5 years. In bilaterally operated patients, the statistical analyses included only the first-operated knee.

Results Both groups had most migration within the first 3 months, the TM implants to a greater extent than the cemented implants. After 3 months, both groups stabilized and remained stable up to the 5-year follow-up.

Interpretation After a high initial degree of migration, the TM tibia stabilized. This stabilization lasted for at least 5 years, which suggests a good long-term performance regarding fixation. The cemented NexGen CR tibial components showed some migration in the first 3 months and then stabilized up to the 5-year follow-up. This has not been reported previously.

The optimum mode of fixation of the tibial component in total knee replacement (TKR) for young people is still to be determined. Overall, the clinical results of TKR in younger patients are inferior, mainly because of revisions for aseptic loosening (Furnes et al. 2002, Harrysson et al. 2004, Julin et al. 2010, W-Dahl et al. 2010). However, recent data from Australia appear to show that more modern uncemented designs have similar cumulative revision rates to those of cemented designs

(Graves et al. 2011). Numerous studies using radiostereometric analysis (RSA) on cemented tibial implants have shown a common pattern of fixation with continuous migration of the implant in relation to bone (Nilsson et al. 1999, 2006, Carlsson et al. 2005). This is a concern, since it indicates an unstable interface that may very well end up in aseptic loosening. Hydroxyapatite (HA) coating of the implant has been shown to improve uncemented fixation by eliminating the continuous migration after the initial settling (Nelissen et al. 1998, Regner et al. 1998, Carlsson et al. 2005, Nilsson et al. 2006).

Trabecular metal (TM) has several theoretical advantages. The porosity and modulus of elasticity are similar to those of trabecular bone (Bobyn et al. 1999a). High proportions of bone ingrowth and sufficient biological fixation have been shown experimentally in animal studies (Bobyn et al. 1999b, Bullens et al. 2010) and in a retrieved human specimen (D'Angelo et al. 2008). Excellent long-term clinical results of uncemented TM acetabular cups have been reported (Macheras et al. 2009, 2010). Short- and medium-term clinical results of TM tibial components are encouraging (Helm et al. 2009, Unger et al. 2011). In an RSA study, TM LPS tibial components stabilized within the first postoperative year (Wilson et al. 2012) and inducible displacement was lower than for cemented tibial components in another RSA study (Wilson et al. 2010).

We have previously presented the 2-year results of an RSA study comparing TM CR tibial components with cemented NexGen CR tibial components in patients less than 60 years of age (Henricson et al. 2008). That study showed that the TM implants—after an initial settling during the initial 6 weeks to 3 months—stabilized up to 2 years. We also found that in contrast to what has been found for cemented tibial components, the cemented NexGen CR implants did not show continuous migration. We now present the 5-year results.

Table 1. Summary of demographics and clinical data at baseline. Median (range)

	Trabecular metal	NexGen cemented
Total no. of knees	26	21
Preoperative varus deformity	20/26	11/21
No. of knees (only first knee in bilaterally operated)	22	19
Sex, F / M	11 / 11	12 / 7
Weight, kg	88 (65–120)	86 (67–117)
Age	54 (33–59)	56 (44–59)
Knee flexion, degrees	103 (75–125)	105 (80–135)
Extension deficit, degrees	5 (0–20)	5 (0–15)
Knee Society		
knee score, max. 100	36 (13–69)	42.5 (26–63)
pain score, max. 50	15 (0–20)	20 (0–20)
function score, max. 100	62.5 (0–90)	70 (45–90)

Patients and methods

The study was originally designed as a randomized clinical trial between uncemented cruciate-retaining TM tibial components and cemented cruciate-retaining tibial components of the NexGen Option design (Zimmer, Warsaw, IN) in patients aged less than 60 years. For logistical reasons, however, it was changed to a comparison of 2 consecutive series of patients in succession who were operated on by the same surgeon (Henricson et al. 2008). The study was approved by the Ethics Committee of Umeå University.

Inclusion criteria were primary or secondary osteoarthritis of grades III–V (Ahlbäck 1968) with clinical symptoms requiring surgery, age below 60, and body weight of less than 120 kg. The exclusion criteria were ongoing or previous infection and malignant disease. Consecutive eligible patients were chosen from the waiting list and all agreed to participate. First, the TM implants were inserted (22 patients, 26 knees) and then the cemented tibial implants were inserted (19 patients, 21 knees). 6 patients underwent simultaneous bilateral TKR, 4 with the TM tibia and 2 with the cemented tibia (Table 1). The femoral component was either a cemented or an uncemented NexGen implant, which has been the subject of another study (Gao et al. 2009). The femoral component had a titanium fiber-mesh non-articular surface.

The posterior cruciate ligament was retained in all cases, but was balanced with partial release when needed. The proximal tibia was cut using an intramedullary guide, aiming for a perpendicular cut in the frontal plane and a posterior slope of 7°. The resected proximal tibia was covered with a thin layer of morcellised autograft before insertion of the implant (Bloebaum et al. 1992). When the patella had substantial osteoarthritis and was eroded, producing a concave articular surface, a patellar component was used (3 patients in each group).

For the RSA analysis, 6 tantalum-sphere markers (diameter 0.8 and 1.0 mm) were inserted at operation into the polyethylene of the trabecular metal monoblock implant. The modular

cemented NexGen CR tibial tray was equipped by the supplier with four 1.0-mm tantalum markers encased in titanium rods, attached to the undersurface of the tray and 1 at the tip of the stem, thus obviating the potential risk of movement between the polyethylene and the tray components if markers were used in the polyethylene. 9 markers, 1.0 mm in diameter, were spread out into the tibial metaphysis in all knees.

Postoperatively, the patients were allowed full weight-bearing immediately, but with the help of crutches for the first 6 weeks.

Clinical evaluation was carried out preoperatively, at 6 weeks, and at 3, 12, 24 months and 5 years postoperatively using the knee and pain scores of the Knee Society (Insall et al. 1989). All the clinical examinations were performed by one of the authors (AH). The presence and the size of radiolucent lines were analyzed on the RSA radiographs as described by the Knee Society (Ewald 1989).

The stereo radiographs were not obtained with the aid of fluoroscopy, but were taken under controlled circumstances and they were repeated until the beam was shown to be tangential to the interface, thus permitting analysis of potential radiolucent lines.

The initial RSA examination (reference examination) was performed at mean 4 (2–7) days after the operation. Subsequent examinations were at 6 weeks, at 3, 12, and 24 months, and at 5 years postoperatively with the patient supine and with the knee inside a biplanar calibration cage (Cage 10; RSA Biomedical, Umeå, Sweden). At the reference examination, the knee was positioned with its anatomical axes parallel to the cardinal axes of the calibration cage.

RSA was performed using UmRSA software (RSA Biomedical) according to the technique described earlier (Henricson et al. 2008). The RSA radiographs were digital, with a spatial resolution of 223 dpi. The upper limit for mean error of rigid-body fitting (a measure of marker stability) was set at 0.30, and it was actually 0.16 (95% CI: 0.12–0.20) for the markers in the tibia and 0.09 (CI: 0.06–0.12) for those in the implant. The condition number is a measure of the quality of dispersion of the markers in each segment; the lower the value, the better the dispersion. The maximum tolerable condition number was set at 100, and the mean was 33 (CI: 29–38) for the tibia and 24 (CI: 22–26) for the implant. To detect potential deformation of the tibial component between surgery (postoperatively) and 3 months, the change in mean error of rigid-body fitting between these times was calculated.

The relative movements of the tibial component in relation to bone were recorded using the markers in the tibia as the fixed reference segment. The rotations were expressed about the transverse axis (x-axis, anteroposterior (AP) rotation), longitudinal axis (y-axis, internal-external rotation), and sagittal axis (z-axis, varus-valgus rotation) of the knee. In order to ensure that there were identical points of measurement for the translations, standardized positions on the tibial tray were defined as described previously (Nilsson et al. 1991). Transla-

tions were expressed as the maximum total point movement (MTPM) (Ryd 1986), subsidence, and lift-off. In each implant, the largest negative value for y-translation was called maximum subsidence, and the largest positive y-translation lift-off. If all points of measurement displayed negative y-translation, the implant showed 0 mm of lift-off, and if all points displayed positive y-translation, subsidence was 0 mm.

The repeatability of the measurements was calculated based on double examinations performed on each patient at all follow-up visits, as described by Ranstam et al. (2000). Significant rotations at the 95% significance level were $> 0.25^\circ$ (transverse), $> 0.26^\circ$ (longitudinal), and $> 0.17^\circ$ (sagittal). The corresponding values for significant subsidence and lift-off were > 0.11 mm.

For patients with bilateral operations, only the first-operated knee was included in the statistical calculations.

All knees could not be analyzed by RSA at all times. In the TM tibia group, the postoperative radiographs were not obtained in one knee and therefore no further analysis was possible. 1 knee was revised at 19 months postoperatively and could therefore not be analyzed further. 1 patient died 4 years postoperatively for reasons not related to the knee replacement, and 1 patient moved abroad and could not attend the 5-year examination. In the NexGen CR group, the RSA radiographs at 12 months were of insufficient quality for analysis in 1 patient and another patient could not attend the follow-up examinations at 2 and 5 years due to Alzheimer's disease.

Thus, at 5 years 18 patients (18 knees) in the TM tibia group and 18 patients (18 knees) in the NexGen CR group were analyzed by RSA.

Statistics

Since the main interest of the study was the amount and progression of migration, only absolute values were analyzed in parameters where both negative and positive values were possible (the sign being an indication of the direction of the movement).

The migration data were not normally distributed, as tested by the Shapiro-Wilk and Pearson tests for normality, and therefore median and interquartile range are given. (After log transformation of the data, normality was achieved and mean and 95% CIs could be calculated and then re-transformed back to the original scale. These data are given in the tables and in the 2 figures for easier visual display). For statistical analysis, the median difference and the corresponding CI for the median difference for each migration and clinical parameter was calculated as described by Campbell and Gardner (1988). There is statistical significance between groups when the CI for the median difference does not include 0. In addition, Mann-Whitney U test was used. For comparison of migration over time from 3 months to 5 years in each group, Wilcoxon signed-rank test was used. Any p-value of < 0.05 was considered significant.

Results

Implant migration

The migration for the TM implants was larger than for the NexGen CR implants already from 3 months and onwards (Tables 2 and 3), and it was statistically significantly larger for all parameters of migration except lift-off (Table 3). Calculations with all knees in each group included (i.e. the second knee in bilaterally operated patients) were also done and the differences—relative to when the second knee in bilaterally operated cases was excluded—were very small (usually a change in the second decimal). In both groups, the migration occurred after surgery up to 3 months and then appeared to stabilize; the change in migration between 3 months and 5 years was not statistically significant ($p = 0.2$ – 0.7 , Wilcoxon signed-rank test). The only notable exception was (internal-) external rotation for the TM implants, which did not reach a steady state until 12 months postoperatively and later. We could not detect any significant deformation of the trabecular metal implants; the mean change in rigid-body fitting from after surgery to 3 months was 0.065 (0.044 – 0.098) mm, and there was no change in condition number (which is another measure of rigid-body rigidity).

Since both groups of implants showed all migration during the first 3 months and then stabilized, a separate analysis with 3 months as a reference was done (Table 4). The differences in medians between the 2 groups for the respective parameters of migration were not statistically significant (Table 5, see Supplementary data).

There were no significant differences between the groups for maximal subsidence when using 3 months as a reference (Figure 1). Similar results were found for MTPM (Figure 2).

Radiographic findings

Postoperatively, thin (< 1 -mm) radiolucent lines were found in 9 TM knees. In 7 of these knees, the radiolucent lines were located at the most anterior, posterior, lateral, or medial centimeter of the tibial tray—and in 2 knees, centrally between the pegs. At 24 months, all radiolucent lines but 1 had disappeared; this line had disappeared at 5 years.

In the NexGen group, 10 knees showed thin (< 1 -mm) radiolucent lines at 24 months. All lines were located at the most peripheral centimeter of the tibial tray and were not progressive. At 5 years, thin radiolucent lines could be detected in only 5 knees, located at the most medial, lateral, and anterior centimeter of the tibial tray. None of these lines were progressive.

Clinical findings

Both the Knee Society knee score and the Knee Society pain score improved up to 24 months in both groups and then stabilized (Table 6, see Supplementary data). There were no statistically significant differences between the groups. There were no statistically significant differences concerning preoperative HKA angles between the groups ($p = 0.1$, Mann-Whitney U test).

Table 2. Migration up to 5 years with postoperative examination as reference. In patients operated bilaterally, only the first-operated knee was included

	Trabecular metal				NexGen cemented			
	Median	IQ range	Mean	95% CI	Median	IQ range	Mean	95% CI
X-axis rotation [flexion-extension] (degrees, absolute value)								
3 months	0.61	0.22–1.08	0.35	0.19–0.63	0.08	0.03–0.26	0.09	0.04–0.17
24 months	0.52	0.34–1.06	0.47	0.32–0.71	0.10	0.06–0.19	0.11	0.07–0.18
5 years	0.55	0.22–1.00	0.43	0.26–0.69	0.15	0.10–0.26	0.15	0.10–0.25
Y-axis rotation [internal-external] (degrees, absolute value)								
3 months	0.31	0.14–0.68	0.28	0.15–0.50	0.11	0.06–0.21	0.14	0.08–0.25
24 months	0.41	0.20–0.94	0.41	0.26–0.65	0.11	0.05–0.21	0.13	0.06–0.16
5 years	0.49	0.23–0.75	0.43	0.28–0.65	0.14	0.08–0.22	0.13	0.10–0.18
Z-axis rotation [varus-valgus] (degrees, absolute value)								
3 months	0.37	0.20–0.81	0.30	0.16–0.56	0.09	0.04–0.16	0.07	0.04–0.13
24 months	0.37	0.07–0.74	0.28	0.13–0.54	0.09	0.06–0.19	0.10	0.07–0.16
5 years	0.41	0.18–0.74	0.31	0.18–0.54	0.14	0.07–0.27	0.11	0.07–0.19
MTPM (maximum total point motion, mm)								
3 months	0.98	0.61–1.57	0.85	0.60–1.20	0.27	0.18–0.35	0.29	0.19–0.44
24 months	1.07	0.63–1.69	0.95	0.72–1.29	0.22	0.11–0.52	0.25	0.17–0.35
5 years	0.89	0.67–1.57	0.95	0.71–1.26	0.41	0.27–0.59	0.37	0.29–0.49
Maximum lift-off, mm								
3 months	0.00	0.00–0.19	0.19	0.11–0.31	0.09	0.04–0.18	0.12	0.08–0.20
24 months	0.00	0.00–0.12	0.20	0.09–0.48	0.11	0.04–0.23	0.13	0.09–0.19
5 years	0.04	0.00–0.19	0.18	0.10–0.31	0.18	0.05–0.30	0.12	0.04–0.32
Maximum subsidence, mm								
3 months	0.82	0.52–1.44	0.72	0.48–1.07	0.07	0.00–0.18	0.11	0.06–0.21
24 months	0.82	0.46–1.44	0.72	0.50–1.02	0.06	0.03–0.13	0.08	0.05–0.14
5 years	0.72	0.49–1.56	0.69	0.44–1.07	0.12	0.00–0.18	0.16	0.11–0.22

IQ range: interquartile range; 95% CI: 95% confidence interval for the mean.

Table 3. Median differences and 95% CI of migration between Trabecular metal (TM) and NexGen cemented (NG) tibial components with postoperative examination as reference. In patients operated bilaterally, only the first-operated knee was included

	NG – TM at 3 months			NG – TM at 24 months			NG – TM at 5 years		
	median difference	95% CI ^a	p-value ^b	median difference	95% CI ^a	p-value ^b	median difference	95% CI ^a	p-value ^b
X-rotation	–0.32	–0.60 to –0.06	0.004	–0.35	–0.65 to –0.21	< 0.001	–0.38	–0.54 to –0.09	0.003
Y-rotation	–0.15	–0.41 to –0.02	0.02	–0.28	–0.51 to –0.13	< 0.001	–0.33	–0.48 to –0.14	< 0.001
Z-rotation	–0.26	–0.52 to –0.13	< 0.001	–0.21	–0.48 to –0.03	0.02	–0.32	–0.52 to –0.08	0.005
MTPM	–0.63	–1.01 to –0.26	0.001	–0.74	–1.05 to –0.47	< 0.001	–0.56	–0.97 to –0.31	< 0.001
Max. lift-off	0.05	0.00 to 0.11	0.1	0.06	0.00 to 0.17	0.06	0.10	0.00 to 0.19	0.05
Max. subsidence	–0.74	–1.08 to –0.46	< 0.001	–0.68	–1.13 to –0.40	< 0.001	–0.64	–1.15 to –0.42	< 0.001

^a 95% confidence interval of median difference

^b Mann-Whitney U test.

Complications

3 patients with persistent anterior knee pain received a secondary patellar component, 1 in the NexGen group and 2 in the TM group. 1 of the patients in the TM group improved dramatically whereas the other 2 patients did not improve. 1 patient with a TM tibia, who had the patella replaced secondary, had to be revised 19 months postoperatively because of persistent pain and stiffness of the knee. The reason for the

pain was unclear, and at surgery both components were found to be firmly fixed to bone.

2 patients in the TM group had neurological complications. 1 with a previous proximal tibial osteotomy had peroneal neuralgia but no paresis, and was relieved after release of the nerve. The other had pain and paraesthesia along both the peroneal nerve and the tibial nerve. The symptoms declined during follow-up but were still present at 5 years.

Table 4. Migration up to 5 years with 3-month examination as reference. In patients operated bilaterally, only the first-operated knee was included

	Trabecular metal				NexGen cemented			
	Median	IQ range	Mean	95% CI	Median	IQ range	Mean	95% CI
X-axis rotation [flexion-extension], (degrees, absolute value)								
24 months	0.13	0.06–0.31	0.13	0.08–0.23	0.07	0.05–0.13	0.07	0.05–0.11
5 years	0.14	0.07–0.35	0.14	0.08–0.24	0.10	0.04–0.21	0.08	0.04–0.15
Y-axis rotation [internal-external] (degrees, absolute value)								
24 months	0.09	0.07–0.24	0.12	0.09–0.17	0.11	0.06–0.20	0.12	0.09–0.17
5 years	0.13	0.07–0.29	0.14	0.10–0.21	0.15	0.06–0.28	0.11	0.07–0.19
Z-axis rotation [varus-valgus] (degrees, absolute value)								
24 months	0.15	0.07–0.25	0.13	0.08–0.23	0.12	0.05–0.22	0.09	0.05–0.15
5 years	0.10	0.04–0.35	0.10	0.06–0.19	0.19	0.05–0.30	0.12	0.07–0.19
MTPM (maximum total point, Motion, mm)								
24 months	0.26	0.20–0.38	0.28	0.21–0.36	0.24	0.21–0.40	0.25	0.19–0.32
5 years	0.42	0.22–0.45	0.31	0.22–0.42	0.40	0.21–0.48	0.26	0.14–0.46
Maximum lift-off, mm								
24 months	0.11	0.05–0.22	0.13	0.08–0.19	0.11	0.05–0.20	0.10	0.06–0.17
5 years	0.11	0.05–0.22	0.13	0.07–0.22	0.19	0.05–0.30	0.17	0.11–0.26
Maximum subsidence, mm								
24 months	0.13	0.02–0.26	0.15	0.11–0.22	0.09	0.02–0.15	0.08	0.05–0.13
5 years	0.11	0.02–0.24	0.11	0.06–0.21	0.08	0.03–0.14	0.09	0.05–0.14

IQ range: interquartile range; 95% CI: 95% confidence interval for the mean.

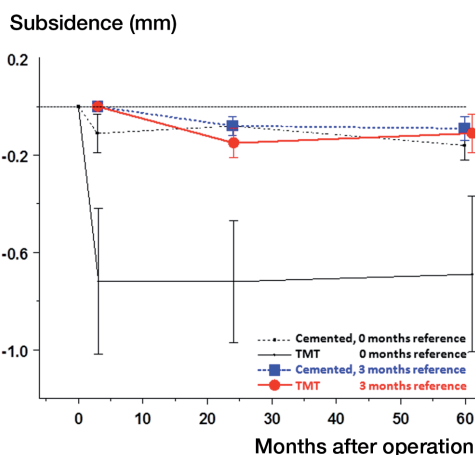


Figure 1. Maximum subsidence of the tibial component in the 2 groups, with postoperatively and 3 months as reference. Mean with 95% CI (whiskers).

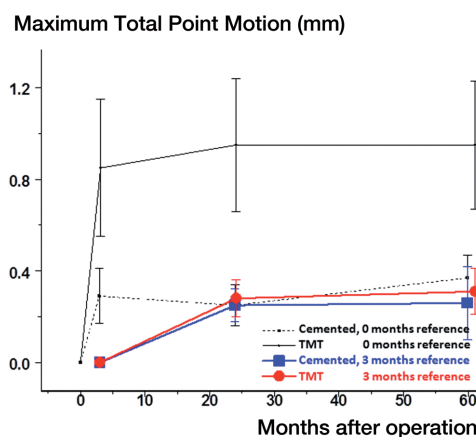


Figure 2. Maximum total point motion (MTPM) of the tibial component in the 2 groups, with postoperatively and 3 months as reference. Mean and 95% CI (whiskers).

Discussion

In the search for better long-term fixation, TM components have been introduced. In order to investigate the performance of trabecular metal tibial components, we started this study to compare TM tibial implants and standard cemented components in patients less than 60 years old, using RSA as a surrogate measure of long-term performance. At the 2-year follow-up of these patients, we found that the TM implants had shown a large degree of migration during the first 3 months and that they had then stabilized (Henricson et al. 2008). We interpreted this as being a good sign, as this pattern of early migration and stabilization for uncemented implants has been

found to be compatible with osseointegration and good long-term results (Bellemans 1999). However, we expressed the need for longer follow-up to determine whether this stabilization would last.

The present 5-year results corroborate the previous findings after 2 years. The TM components were still stably fixed to bone and showed no further migration between 2 and 5 years, indicating a benign interface between implant and bone. The absence of any radiolucent lines at the interface is also an indication of this.

The large degree of early migration of the TM implants is a common finding with all uncemented implants at the knee (Nilsson et al. 1991, 1999, 2006, Wilson et al. 2012). The area

of the exposed bone trabeculae of the cut proximal tibia is only about one quarter of the total surface area of the tibia, and the cutting process may create irregularities of as much as 1.4 mm (differences between the highest and lowest points) (Toksvig-Larsen and Ryd 1991). The quality of bone may also vary between patients (Li and Nilsson 2000). Moreover, the cutting process generates heat and therefore necrosis of the most proximal bone trabeculae, which will eventually be resorbed (Toksvig-Larsen et al. 1990). Thus, the implant will subside until the bone is strong and wide enough to support the implant. As these factors vary between patients, the amount of initial migration will also vary, as can be seen in the large dispersion around the median or mean values in this report. We do not know when this early migration actually takes place, since there were no RSA examinations between the initial postoperative examination and those at 6 weeks and 3 months. It may well be that most of the initial migration occurred early after surgery and then stopped. During this period of early subsidence, the prosthesis-bone interface is potentially unstable. The high friction between the trabecular metal and bone may therefore be a beneficial factor in stabilizing the interface, as indicated by the absence of migration once the initial settling has taken place (Zhang et al. 1999). The early subsidence is probably also the cause of the disappearance of the postoperative radiolucent lines, even though the gap-sealing property of trabecular metal has been shown by Bragdon et al. (2004) and Rahbek et al. (2005).

Dunbar et al. (2009) found what they believed was a deformation of the trabecular tibial component in 5 cases, between the immediate postoperative examination and the next (6-month) investigation, and which they stated resulted in a higher migration. We could not detect any deformation between the postoperative examination and that at 3 months, the time period in which the trabecular metal implants migrated the most. The very small change in rigidity of the markers in the polyethylene (0.065 mm) and the absence of change in condition number are strong arguments against a clinically relevant deformation.

Irrespective of the magnitude of the foregoing initial migration, early stabilization lasting up to 5 years indicates a benign and mature interface, and may be compatible with osseointegration—as shown by an *in vitro* RSA study in sheep (Belle-mans 1999). Moreover, clinical loosening has been found only in implants with continuous migration over time (Grewal et al. 1992, Ryd et al. 1995).

The cemented implants also showed early migration and stabilization, but the magnitude of migration was much smaller. Bone cement acts as a filler and accommodates the imperfections of the bone at the time of surgery. The early migration seen in these implants is therefore probably the result of resorption of the necrotic proximal bone trabeculae. In contrast to previous cemented knee implants studied with RSA (Nilsson et al. 1991, 1999, 2006, Carlsson et al. 2005), the cemented NexGen implants did not show continuous migra-

tion after the initial settling, indicating a benign bone-cement interface. The degree of migration was also less than that of other cemented designs examined by RSA. To our knowledge, we are the first authors to describe this phenomenon in cemented tibial components. There is no obvious explanation for this. The kinematic behavior of the NexGen design has been shown to be closer to that of the normal knee than other cruciate-retaining designs, which might reduce stresses at the fixation interface (Bertin et al. 2002). These findings may be the RSA migratory-pattern equivalent of long-term implant survival, since the cemented NexGen implant has the lowest risk ratio for revision in the Swedish Knee Arthroplasty Register (Sundberg et al. 2011).

Since the magnitude of initial migration differs between uncemented and cemented fixation, comparison of the 2 concepts using the magnitude of migration only—and not taking the pattern of migration over time into consideration—will not be meaningful. A statistically significant difference in the magnitude of migration already at 3 months will of course still be significant later if both implants stabilize after 3 months. This is in principle analogous to the situation with *in vivo* measurements of polyethylene wear in hip arthroplasty. The penetration of the femoral head during the initial 3–6 months is generally accepted as being a sign of “bedding in” or “creep”, and not wear. Consequently, the size of the initial migration of the tibial component (with documented stabilization thereafter) is more a consequence of the local bone quality of the individual at the time of surgery than an indication of the quality of fixation in the long run. It is therefore of interest to calculate and compare the migration of the 2 groups of fixation with 3 months as baseline. In doing so, one can see that the magnitude of migration was very similar between the groups, i.e. that for uncemented fixation with TM was the same as that for cemented fixation (Table 4; Figures 1 and 2; Table 5, see Supplementary data).

The TM tibial plate has a much lower degree of stiffness than the titanium alloy tray (Florio, personal communication). This may be the explanation as to why the lift-off of these trays was lower than for the NexGen trays, and was in fact at or below the precision level of RSA. Previous RSA findings have shown that the pattern of initial migration (i.e. in the first 3 months) of the stiffer titanium or chromium-cobalt alloy tibial components is a combination of subsidence at one edge and lift-off from the cut tibial surface at the opposite edge (teeter-totter effect), thus creating a gap between the cut bone and the implant (Nilsson et al. 1999, 2006). The high elasticity of the trabecular metal tray may prevent lift-off at the edges, and thereby protect the interface from the ingress of joint fluid containing particles that may potentiate bone resorption (Rahbek et al. 2000, 2005). Thus, even the pattern of the initial migration of trabecular metal components suggests a positive effect on long-term fixation.

The reason for why the rotation about the longitudinal axis did not stabilize until after 1 year is unclear. One explanation

may be that the design, with only 2 pegs, may resist the external rotation forces less efficiently than other designs.

2 other RSA studies of TM tibial implants have been published, both showing similar findings to those in the present study, namely early migration and then stabilization lasting up to 2–5 years. Stilling et al. (2011) compared cruciate-retaining monoblock TM tibias with pegged and screw-fixed uncemented titanium fiber-mesh tibias. The median age of the patients (61 and 64 years, respectively) was about 10 years higher than in the present study. The TM tibias stabilized within 3 months whereas the titanium components stabilized first after 1 year. The other study, by Wilson et al. (2012), compared TM tibias with cemented stemmed NexGen tibias. In contrast to our study, the implants were posterior-stabilized and the mean age was slightly higher. RSA examinations were done 0.5, 1, 2, and 5 years postoperatively. The authors found that the TM tibias showed a large degree of migration between the postoperative examination and that at 6 months. It then stabilized, as in our study.

In conclusion, the present study shows that the TM tibia has a high degree of initial migration followed by stabilization lasting up to 5 years—a pattern of migration which, according to current knowledge, suggests good long-term performance regarding fixation. However, the patients should be followed for much longer before this can be confirmed. Another important result was the early and enduring stabilization of the cemented NexGen CR prosthesis, a phenomenon that has not been reported previously for cemented tibial implants.

Supplementary data

Tables 5 and 6 are available at Acta's website (www.actaorthop.org), identification number 5693.

AH performed the surgery, performed the follow-ups, analyzed the data, and wrote the manuscript. DR analyzed the radiographs. KGN initiated the study, analyzed data, and also wrote the manuscript. All authors critically reviewed drafts and contributed to the final paper.

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