We compared the performance of uncemented trabecular metal tibial components in total knee replacement with that of cemented tibial components in patients younger than 60 years over two years using radiostereophotogrammetric analysis (RSA). A total of 22 consecutive patients (mean age 53 years, 33 to 59, 26 knees) received an uncemented NexGen trabecular metal cruciate-retaining monobloc tibial component and 19 (mean 53 years, 44 to 59, 21 knees) a cemented NexGen Option cruciate-retaining modular tibial component.

All the trabecular metal components migrated during the initial three months and then stabilised. The exception was external rotation, which did not stabilise until 12 months. Unlike conventional metal-backed implants which displayed a tilting migration comprising subsidence and lift-off from the tibial tray, most of the trabecular metal components showed subsidence only, probably due to the elasticity of the implant.

This pattern of subsidence is regarded as being beneficial for uncemented fixation. In total knee replacement (TKR) studies using radiostereophotogrammetric analysis (RSA) have shown continuous migration cemented tibial implants1-6 which could be interpreted as a sign of continuous bone resorption at the cement-bone interface.7 Uncemented fixation is improved by coating implants with hydroxyapatite (HA).3,5,8,9 We have shown that HA-coated tibial implants migrate for up to three months, then stabilise.8 Early stabilisation and rigid fixation to bone are crucial for bony ingrowth. However, a continuous lift-off for up to 24 months was noticed even for the HA-coated implants. This is of concern because of the potential for exposure of the interface to joint fluid. Overall, clinical results for TKR are very good, but higher revision rates have been reported in patients younger than 60 to 65 years10-12 mainly because of aseptic loosening. This suggests that a more active lifestyle has a higher risk of loosening of the implant.

Trabecular metal is a new material which has recently been introduced for TKR. It has a porosity and modulus of elasticity similar to those of trabecular bone and a high coefficient of friction which may have theoretical advantages for uncemented fixation.13 Experimental studies have shown that trabecular metal gives a high proportion of bony ingrowth and efficient biological fixation.14 Trabecular metal acetabular components have been reported to give excellent results in short- and mid-term follow-up studies.15,16 There are no published clinical studies on TKR using trabecular metal. Our aim therefore was to evaluate the migration pattern of uncemented trabecular metal tibial implants in younger patients with osteoarthritis in order to assess if there were any clinical differences compared with cemented implants and to detect any potential design-specific complications.

Patients and Methods

The study was originally designed as a randomised comparison between an uncemented monobloc trabecular metal cruciate retaining tibial implant and a cemented NexGen cruciate-retaining modular tibial implant (both Zimmer, Warsaw, Indiana). Randomisation was intended to be by the surgeon, one using the trabecular metal cruciate retaining implant at one hospital and the other using the NexGen cruciate retaining implant at a different hospital. Several months after the study began, it was clear that for logistical reasons, the surgeon allocated to the NexGen cruciate retaining implant could not recruit any patients. Therefore the design of the study was changed with all operations being performed at the first Hospital (Falun General Hospital) by one of the authors (AH). All the consecutive trabecular metal cruciate retaining implant operations
were done first followed by the NexGen cruciate retaining operations. This study, approved by the Ethics Committee of Umeå University, is therefore a comparison of two consecutive series of patients operated on by the same surgeon between May 2003 and February 2005.

The inclusion criteria were primary or secondary osteoarthritis, age below 60 years and body-weight less than 120 kg. The exclusion criteria were ongoing or previous infection and malignant disease. All consecutive eligible patients on the waiting list at Falu General Hospital agreed to participate. There were 41 patients (23 women, 18 men; 47 knees) with a mean age of 53 years (33 to 59).

There were 22 patients (26 knees) who received the uncemented trabecular metal cruciate retaining monobloc tibial implant and 19 (21 knees) the cemented NexGen cruciate retaining modular tibial implant. Six patients underwent simultaneous bilateral TKR, four with a trabecular metal cruciate retaining implant and two with a NexGen cruciate retaining implant. The femoral component was either a cemented or uncemented NexGen implant according to a randomisation protocol which is the subject of another study. The femoral components were identical in both groups, having a titanium fibre mesh non-articular surface. The clinical details are given in Table I. Most knees in both groups had a varus deformity (trabecular metal 20 of 26; NexGen 11 of 21).

The trabecular metal tibia is a monobloc component with the polyethylene attached to the metal base plate by a direct compression moulding process which infuses the polyethylene directly into the metal, thereby achieving a uniform penetration of approximately 1.5 mm. The trabecular metal is made of tantalum using a vapour deposition technique forming a metal strut configuration. This has similar properties to those of cancellous bone, with a porosity of 75% to 80% and an elastic modulus close to that of subchondral bone (Fig. 1). It also has a high coefficient of friction to bone, which may increase initial implant-bone stability. The base plate has two hex-shaped pegs (also of trabecular metal) which are press-fitted into the tibial surface. The NexGen cruciate retaining tibial tray for cemented use is made of 3 mm titanium alloy and has a 50 mm central stem with small flanges projecting posterolaterally. The undersurface is slightly grit-blasted and has a peripheral lip to increase penetration of cement by decreasing escape of cement at the margins on impaction. The polyethylene insert is held to the base plate by a peripheral capture mechanism.

The posterior cruciate ligament was retained in all cases but balanced 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°. In the knees in which the tibial component was to be cemented, the proximal tibia was irrigated by high-pressure lavage and dried before application of the cement (vacuum-mixed Palacos with Gentamicin; Schering-Plough, Labo, Belgium). This was applied to the undersurface of the tibial base plate but not around the stem and the component was kept under pressure while the cement was setting. In the uncemented trabecular metal cruciate retaining implants the resected proximal tibia was covered with a thin layer of morcellised autograft before the implant was inserted. A patellar component was used when the patella had substantial osteoarthrits and was eroded producing a concave articular surface. Three patients in each group received this component.

Table I. Pre-operative details of the patients in the two groups

<table>
<thead>
<tr>
<th></th>
<th>Trabecular metal cruciate retaining (uncemented)</th>
<th>NexGen cruciate retaining (cemented)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of knees</td>
<td>26</td>
<td>21</td>
<td>0.77‡</td>
</tr>
<tr>
<td>Median knee society score (range)</td>
<td>36 (10 to 69)</td>
<td>46 (26 to 94)</td>
<td>0.05†</td>
</tr>
<tr>
<td>Median knee score pain score (range)</td>
<td>10 (0 to 20)</td>
<td>20 (0 to 30)</td>
<td>0.20‡</td>
</tr>
<tr>
<td>Median movement in degrees (range)</td>
<td>100 (55 to 125)</td>
<td>100 (65 to 135)</td>
<td></td>
</tr>
<tr>
<td>Median HKA angle in degrees (range)</td>
<td>174 (160 to 187)</td>
<td>175 (163 to 187)</td>
<td>0.13†</td>
</tr>
</tbody>
</table>

* HKA, hip-knee-ankle  
† Fisher’s exact test  
‡ Mann-Whitney U test

![Fig. 1](image-url)  
Photograph showing the under surface of the trabecular metal tibial implant. The trabecular metal is made of tantalum using a vapour deposition technique forming a metal strut configuration. The construct has properties similar to those of cancellous bone with a porosity of 75% to 80%.
For RSA, six markers (three of each diameter 0.8 and 1.0 mm) were inserted at operation into the polyethylene of the trabecular metal cruciate retaining implant. Since the NexGen option cruciate-retaining tibial component was not monobloc but modular, tantalum markers could not be inserted into the polyethylene because of the risk that potential movement between the polyethylene and the tibial tray could distort the RSA evaluation. Therefore the tibial tray was equipped by the supplier with four 1.0 mm diameter tantalum markers encased in titanium rods attached on the undersurface of the tray and one at the tip of the stem. Finally, nine markers of 1.0 mm diameter were spread out into the proximal tibial metaphysis.

Post-operatively, the patients were allowed immediate full weight-bearing, but with the assistance of two crutches for the first six weeks.

Clinical evaluation was carried out pre-operatively and at six weeks and three, 12, and 24 months post-operatively using the Knee Society knee and pain scores. All the clinical examinations were performed by one of the authors (AH). The alignment of the knee was measured before and after surgery as the hip-knee-ankle angle. The alignment of the tibial component in relation to the tibia was measured as described by Nilsson et al. The presence and size of radiolucent lines were analysed on the RSA radiographs as described by the Knee Society. Even if not obtained with the aid of a fluoroscope these stereoradiographs were taken under controlled circumstances and were repeated until the beam was shown to be tangential to the interface.

The initial RSA examination (reference examination) was performed at a mean of four days (two to seven) after the operation. Subsequent examinations were at six weeks and three, 12, and 24 months post-operatively with the patient supine and 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.

The RSA using UmRSA software (RSA Biomedical) was performed using the technique described earlier. 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), set at 0.30, was 0.16 (95% confidence interval (CI), 0.12 to 0.20) for the markers in the tibia and 0.09 (95% CI 0.06 to 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 was the better was the dispersion. The maximum tolerable condition number was set at 100 and the mean was 33 (95% CI 29 to 38) for the tibia and 24 (95% CI 22 to 26) for the implant.

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 (x-axis, anteroposterior (AP) rotation), longitudinal (y-axis, internal-external rotation) and sagittal (z-axis, varus-valgus rotation) axes of the knee. In order to ensure that there were identical points of measurements for the translations, standardised positions on the tibial tray were defined as described previously. Translations were expressed as the maximum total point movement, subsidence and lift-off. In each implant, maximum subsidence and lift-off were defined as the largest distal and proximal translation, respectively. Based on its proposed prognostic importance regarding aseptic loosening the implants were classified as stable or migrating continuously, as described by Ryd et al. An implant displaying an increase in the maximum total point movement of more than 0.2 mm between 12 and 24 months was considered to be continuously migrating.

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

Not all knees could be analysed by RSA at all times. In one trabecular metal knee replacement post-operative RSA radiographs were not obtained and hence no further analyses were possible. In one NexGen cruciate retaining knee the RSA radiographs at 12 months were too poor for analysis. Finally, another trabecular metal cruciate retaining knee was revised at 19 months post-operatively and therefore could not be analysed at 24 months (Table II). This latter

<table>
<thead>
<tr>
<th>Time</th>
<th>Trabecular metal cruciate retaining (uncemented)</th>
<th>NexGen cruciate retaining (cemented)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of knees</td>
<td>26</td>
<td>21</td>
</tr>
<tr>
<td>Analysed by RSA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-operative</td>
<td>25</td>
<td>21</td>
</tr>
<tr>
<td>6 wks</td>
<td>25</td>
<td>21</td>
</tr>
<tr>
<td>3 mths</td>
<td>25</td>
<td>21</td>
</tr>
<tr>
<td>12 mths</td>
<td>25</td>
<td>20</td>
</tr>
<tr>
<td>24 mths</td>
<td>24</td>
<td>21</td>
</tr>
</tbody>
</table>
implant was subjected to microscopic analysis. The implant was recovered by cutting through the tibia a few millimetres beneath the metal surface. The pegs were divided at the same level, then trephined out. The undecalcified implant-bone specimens were fixed \textit{en bloc} in formaldehyde, processed and embedded in methylmethacrylate. Four serial coronal sections through the implant were made on an EXAKT saw-cutting machine (Exakt Apparatenbau AG, Norderstedt, Germany) at approximately 100 \( \mu \)m. The pegs were treated identically and ground to a thickness of less than 50 \( \mu \)m. The surface was stained with Toluidine Blue-basic fuchsin.

Statistical analysis. This was by SPSS version 15 (SPSS Inc., Chicago, Illinois). The recorded movements of an individual implant can have a positive or a negative value. Calculated means and medians would be close to 0 if signed values had been used. Since our interest was only in the size and pattern of migration we used absolute values. Analysis in both groups showed that the RSA data were not normally distributed. Therefore the group data were presented as the median and interquartile range in the tables. Graphically the median, interquartile range and the 10th and 90th percentiles are shown in Figures 2 and 3. The Mann-Whitney U test was used to compare the results at six weeks, three, 12 and 24 months. For comparison of changes of migration over time in the two groups, the Wilcoxon signed-rank test was used. Comparison of clinical data between the groups was by the Mann-Whitney U test. When comparing the number of stable implants in each group Fisher’s exact test was used. The level of statistical significance was set at \( p \leq 0.05 \).

Results
The cemented and uncemented components were equally distributed between the groups (Fisher’s exact test, \( p = 0.77 \)) (Table I).

Size of migration. The trabecular metal cruciate retaining implants had rotated a median 0.3° to 0.5° around the axes of the knee by six weeks, with rotations around the transverse axis being larger than those around the sagittal axis. The corresponding values for the NexGen cruciate retaining implants were below 0.1°, a highly statistically significant difference (Mann-Whitney U test, \( p = 0.0001 \)). Most of the trabecular metal implants (60% to 70%) showed sizes of rotation larger than the precision of the RSA method. Conversely, in most of the NexGen implants (75% to 90%), the rotations were below the precision limit. From six weeks to 24 months the difference in size of rotation between the groups was constant.

In both groups the number of knees showing anterior or posterior rotation and varus or valgus rotation respectively was about evenly distributed, whereas external rotation was more common than internal rotation in both groups (trabecular metal, 21 external, 3 internal; NexGen cruciate retaining, 16 external, 5 internal).
Maximum subsidence and lift-off are shown in Figures 2 and 3. The trabecular metal implants subsided a median 0.8 mm within the first six weeks whereas the median subsidence for the NexGen implants was significantly less (< 0.1 mm) (Mann-Whitney U test, p = 0.0001). Median lift-off for the trabecular metal implants was approximately zero and varied between 0.08 and 0.16 mm in the NexGen group during follow-up. All the trabecular metal implants showed subsidence greater than the precision of RSA compared with only 25% of the NexGen group. In 16 of the knees (75%) in the trabecular metal group, the rotations of the tibial components around the transverse (x) and sagittal (z) axes consisted of a tilting subsidence of the entire component into the resected tibia, with minimal or no lift-off from its surface. The location for maximum subsidence was evenly distributed among the five standardised points of measurement at the edge of the implant. In a few knees with trabecular metal implants, subsidence of one part of the implant was associated with lift-off of the contralateral part. This migration occurred primarily during the initial six weeks and thereafter seemed to stabilise. Median lift-off in these knees was 0.22 mm at six weeks, 0.26 mm at 12 months and 0.29 mm at 24 months. The median subsidence was 0.11 mm at six weeks, 0.17 mm at 12 months and 0.15 mm at 24 months. In the NexGen group, the tilting rotations around the x and z axes consisted of a small median subsidence at or below the precision of the RSA method and an equal or larger median lift-off.

Pattern of migration. In both groups, the pattern of migration was similar, although of different size. Both showed most of the migration within the first six weeks to three months. The implants thereafter seemed to stabilise as there was no further significant migration. The only notable exception was internal-external rotation in the trabecular metal group which did not reach a steady state until 12 months post-operatively. Also, the maximum total point motion was significantly larger in the trabecular metal group (Mann-Whitney test, p = 0.0001), and after three months it stabilised in both (Fig. 4). According to the criteria of Ryd et al23 most of the implants were classified as stable. Only two trabecular metal implants and three NexGen implants showed a change in the implants total joint movement of > 0.2 mm between 12 and 24 months.

Radiological findings. Thin (< 1 mm) radiolucent lines were seen in nine trabecular metal knees on the post-operative radiographs. In seven knees the radiolucent lines were located at the most anterior, posterior, lateral or medial centimetre of the tibial tray and in two knees they were found centrally between the pegs. In all but one knee they disappeared during follow-up. The radiolucent line persisting at 24 months was at the anterior centimetre of the tray and had not progressed.

In the NexGen group, four knees had thin (< 1 mm) radiolucent lines on the post-operative radiographs located under the most peripheral centimetre of the tibial tray. Another six knees developed similar lines by 24 months. In no knee were these lines progressive, and there were no radiolucent lines around the stem. Thus, at two years one knee with a trabecular metal implant and ten with a NexGen implant had thin non-progressive radiolucent lines.

Clinical findings. The clinical results measured as Knee Society knee and pain scores improved in both groups up to 24 months after operation (Table III). The improvement in the median knee score was 51 points in the trabecular metal group and 46 points in the NexGen group. However, the latter showed a significantly higher knee score pre-operatively (p < 0.05) and at 12 (p < 0.007) and 24 months (p < 0.05), mainly due to a better range of movement, since the pain score did not differ. The alignment of the tibial component in relation to the tibia did not differ in the groups and approached the desired 90° in the frontal plane with about 5° of posterior tilt in the sagittal plane. The median post-operative hip-knee-ankle angle did not differ significantly between the groups and most knees in both groups were aligned within 2° of varus to 3° of valgus (Table III).

Complications. Three patients received a secondary patellar component during the follow-up because of persisting anterior knee pain. One in the NexGen group had this operation at nine months and one in the trabecular metal group at 12 months. The latter improved dramatically whereas the former did not improve at all.

One patient with a trabecular metal tibia and an uncemented femoral component complained of continuous pain and stiffness starting shortly after the operation. He weighed 114 kg and had primary osteoarthritis. The
The hip-knee-ankle angle was 177° pre-operatively and 179° post-operatively. The alignment of the tibial component was 90° in the frontal plane with a posterior tilt of 5° in the sagittal plane. A diagnostic arthroscopy at 12 months suggested patellofemoral arthritis and a patellar component was inserted 14 months after the initial operation. RSA showed a greater migration of the tibial component than the median for its group. At 12 months, rotation was 2.11° (posterior) about the x axis, 0.42° (external) about the y axis and 0.53° (varus) about the z axis, resulting in a subsidence of 2.11 mm of the posterior part and a lift-off of 0.28 mm of the anterior part. Rotation about the x axis showed a continuous increase during the first post-operative year, whereas the y and z axes did not change after three months. The migration of the femoral component was similar to that of all uncemented implants. Because insertion of the patellar component was unsuccessful it was thought that the pain was caused by loosening of one or both components and a revision was performed after 19 months. At revision, however, the femoral and tibial components were found to be firmly fixed to bone and no intra-operative cultures or Gram stains were obtained. A NexGen LCCK (Zimmer) revision implant was inserted. One month after the revision he developed infection with coagulase-negative staphylococci and a two-stage further revision had to be performed.

The revised primary trabecular metal tibial implant was examined microscopically. Because of the thickness of the sections no cellular detail was possible. The base showed no bony attachment, but a continuous layer of dense fibrous tissue, 300 μm to 400 μm thick and occasionally up to 1 mm (Fig. 5). The fibres were criss-crossed from the bone surface well into the porous-coating as had been demonstrated by Engh et al25 for stable PCA acetabular components (porous-coated anatomic, Stryker, Kalamazoo, Michigan). There were no birefringent particles. The pegs showed close bone apposition and in small areas there was bony ingrowth to a depth of one or a maximum of two pores (Fig. 6). There was no sign of deep penetration of bone.

Two patients in the trabecular metal group had neurological complications. One with a previous proximal valgus tibial osteotomy had peroneal neuralgia but no paresis. The symptoms were relieved after release of the peroneal nerve. The other had pain and paraesthesia along the peroneal and tibial nerves. The symptoms decreased to some extent during follow-up, but were still present at 24 months.

**Discussion**

The demand for knee replacements in patients aged younger than 60 years is increasing because of the increasing prevalence of osteoarthritis26-28 and their longer life expectancy and greater physical activity. The results of TKR in such patients have hitherto been generally inferior to those in the elderly.10-12 Robust designs and firm fixation to bone are therefore crucial to ensure a survival of 30 years or more. The most common reason for revision, apart from polyethylene wear is aseptic loosening, especially of the

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**Table III. Post-operative clinical and radiological findings in the two groups**

<table>
<thead>
<tr>
<th>Clinical parameter*</th>
<th>Follow-up time</th>
<th>Trabecular metal cruciate retaining (uncemented)</th>
<th>Nexgen cruciate retaining (cemented)</th>
<th>p-value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median (range) KS knee score</td>
<td>6 wks</td>
<td>68 (37 to 93)</td>
<td>70 (41 to 89)</td>
<td>0.36</td>
</tr>
<tr>
<td></td>
<td>3 mths</td>
<td>74 (44 to 95)</td>
<td>82 (53 to 93)</td>
<td>0.48</td>
</tr>
<tr>
<td></td>
<td>12 mths</td>
<td>80 (49 to 96)</td>
<td>92 (64 to 99)</td>
<td>0.007</td>
</tr>
<tr>
<td></td>
<td>24 mths</td>
<td>87 (55 to 95)</td>
<td>92 (65 to 100)</td>
<td>0.049</td>
</tr>
<tr>
<td>Median (range) KS pain score</td>
<td>6 wks</td>
<td>35 (10 to 50)</td>
<td>45 (20 to 50)</td>
<td>0.97</td>
</tr>
<tr>
<td></td>
<td>3 mths</td>
<td>45 (20 to 50)</td>
<td>45 (10 to 50)</td>
<td>0.58</td>
</tr>
<tr>
<td></td>
<td>12 mths</td>
<td>45 (10 to 50)</td>
<td>45 (20 to 50)</td>
<td>0.45</td>
</tr>
<tr>
<td></td>
<td>24 mths</td>
<td>50 (30 to 50)</td>
<td>50 (20 to 50)</td>
<td>0.47</td>
</tr>
<tr>
<td>Median range of motion in degrees (range)</td>
<td>6 wks</td>
<td>80 (20 to 115)</td>
<td>85 (60 to 115)</td>
<td>0.83</td>
</tr>
<tr>
<td></td>
<td>3 mths</td>
<td>100 (55 to 125)</td>
<td>100 (65 to 120)</td>
<td>0.85</td>
</tr>
<tr>
<td></td>
<td>12 mths</td>
<td>105 (70 to 130)</td>
<td>110 (95 to 125)</td>
<td>0.04</td>
</tr>
<tr>
<td></td>
<td>24 mths</td>
<td>110 (75 to 130)</td>
<td>115 (100 to 125)</td>
<td>0.08</td>
</tr>
<tr>
<td>Median (range) HKA angle in degrees</td>
<td>Post-operative</td>
<td>179 (172 to 185)</td>
<td>180 (175 to 187)</td>
<td>0.08</td>
</tr>
<tr>
<td>Median (range) thickness of the tibial component</td>
<td>Post-operative</td>
<td>14 (12 to 17)</td>
<td>14 (12 to 17)</td>
<td>0.74</td>
</tr>
</tbody>
</table>

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* KS, knee society; HKA, hip-knee-ankle; 95% CI, 95% confidence interval
† Mann-Whitney U test
‡ Student’s t-test
tibial component.\textsuperscript{10,12,29} The high rates of loosening during the 1980s and 1990s stimulated the use of uncemented fixation, but the results were disappointing and led to a return to cemented concepts. However, RSA studies have shown continuous migration of cemented implants, indicating bone resorption at the cement-bone interface\textsuperscript{1-6} which could eventually lead to loosening of the components. This may not be of importance in older patients, but could give problems in younger patients. There has therefore been a renewed interest in uncemented implants.

There are so far no published studies which describe the use of trabecular metal in TKR using RSA. However, a similar study by Dunbar et al\textsuperscript{30} was presented at the annual meeting of the American Academy of Orthopaedic Surgeons. Our trabecular metal implants showed considerable migration during the initial three months and thereafter stabilised, except for rotations around the vertical axis. This pattern of early migration and stabilisation is common in uncemented fixation\textsuperscript{1-6} and in HA-coated implants in younger patients.\textsuperscript{6} It is probably because the cut surface of the tibia is not the best surface for receiving an uncemented implant. It has an irregularity of up to 1.4 mm\textsuperscript{31} and the cutting process also generates heat necrosis.\textsuperscript{32} Uncemented implants do not have the filling property of cement and therefore subside until the bone is strong and wide enough to support the implant, whereupon osseo-integration can proceed. Since early stabilisation is crucial for bony ingrowth or ongrowth, the somewhat later stabilisation (internal-external rotation) of the trabecular metal implants in our study could imply fibrous fixation rather than osseo-integration. However, Bellemans\textsuperscript{33} showed that fibrous integration of the implant leads to continuous migration. Since the trabecular implants in this study stabilised the possibility of bone ingrowth or ongrowth remains. In order to confirm this, studies with a follow-up for up to five years may be required.

In most of the trabecular metal implants the migration consisted of tilting and subsidence of the entire implant. This is uncommon in metal-backed implants which usually subside in one area and show a lift-off contralaterally,\textsuperscript{2,6,34} but is occasionally seen with all-polyethylene components.\textsuperscript{35,36} The stiffness of the metal tray in a conventional metal-backed implant is probably the reason. Lift-off has the potential of exposing the interface. This could result in the entrance of joint fluid containing wear particles, which can activate macrophages leading to bone resorption and eventually a higher risk of loosening. The absence of lift-off in most of the trabecular metal implants may be due to the higher elasticity of trabecular metal\textsuperscript{37} and may be regarded as beneficial. The early subsidence in the trabecular implants is presumably the cause of the disappearance of the post-operative radiolucent lines, rather than a sealing effect which is often seen in HA-coated implants as shown by Rahbek et al.\textsuperscript{38}

In some trabecular metal implants, however, lift-off was seen. Its location was erratic and it mostly occurred within...
six weeks and thereafter ceased. It is unclear what factors contributed to lift-off in these cases which did not differ from the rest of the series with regards to pre- and post-operative alignment, weight, age or the presence of radiolucent lines. However, subsidence of the implant was much less than for those implants which showed subsidence of the entire component. It may be that when the bone is strong enough to withstand the initial subsidence, the kinematics of the knee during gait induces lift-off even in a less stiff component. A longer follow-up is needed to evaluate the potential consequences of this.

It is unclear why rotation about the longitudinal axis did not stabilise until after one year. It is possible that the current design with only two pegs may resist the external rotation forces less efficiently than another design. Also, rotation was greater around the transverse than the sagittal axis. This may have been due to the location of the pegs which were in line with the transverse axis of the knee and were therefore less efficient in reducing the forces of flexion or extension. Since an HA coating may enhance early stabilisation and excellent clinical results have been reported in younger patients with HA-coated implants, it would be interesting to evaluate whether HA coating would be of benefit for trabecular metal implants.

In the trabecular metal implant which was revised because of pain and decreased movement, the cause of the pain was unclear. The migration of the tibial component was larger than the median for all trabecular metal implants, and rotation about the x axis increased continuously up to the last RSA at 12 months, thereby indicating possible loosening. However, at revision, the component was not loose and could be removed only after the bone under the implant had been cut. Pain and decreased movement might indicate infection. Unfortunately, no intra-operative cultures were obtained, but the infection occurring early after the revision may indicate that it might have been present at revision. Histological analysis of the revised implant therefore is not straightforward and it is unclear how the findings are representative of trabecular metal implants in general. The orientation of the connective tissue fibres adjacent to the trabecular metal tray in the revised knee was similar to that found for other porous surfaces and may be compatible with long lasting function. It seems unlikely that such dense, well-organised tissue would form in the presence of infection. The bone reaction around the pegs could be described as bony ongrowth rather than ingrowth. There was no indication that there was a stimulus for bone to grow deep into, or through, the trabecular metal, as has been seen in some animal experiments. Therefore it seems that tantalum, like titanium, is biologically inert in the clinical setting. This finding calls for more systematic histological studies of trabecular metal implants possibly in other anatomical locations.

The cemented NexGen tibial components in our study showed a different pattern of migration compared with that found previously for cemented implants which was of continuously increasing migration. The NexGen implants stabilised after six weeks. Moreover, the size of the migration was smaller than that of other designs examined by RSA. There is no obvious explanation for this. It may be that NexGen cruciate retaining prostheses have a better design than other cruciate-retaining TKRs. Bertin et al showed that the kinematic behaviour of this implant was closer to that of the normal knee than other implants and it is possible that this could decrease stresses at the fixation interface. Moreover, the design of the non-articular undersurface with a peripheral lip to increase penetration of cement may be of importance. The very low migration and early stabilisation of the NexGen implants in our study are compatible with other clinical reports on excellent clinical results with cemented NexGen implants. Bertin found a survival at seven years of 100% and in the Swedish Knee Arthroplasty Register the cemented NexGen cruciate retaining prosthesis was the best performing design, with a survival at eight years above 97% in 6304 replacements.

Our study has limitations. It was originally intended to be randomised by surgeon, but had to be changed. We do not believe, however, that this change in design seriously hampered the results.

Another consideration was the different design of the implants in relation to their undersurface, with the trabecular metal implants having two pegs and the NexGen a stem. Albrektsson et al showed that the addition of a stem to the tibial component reduced migration. Conversely, Bertin, in a mid-term study, found no difference in clinical outcome between the cemented and stemmed versus the cemented and pegged retaining version of NexGen cruciate retaining components. Finally, the tibial components could articulate against either a cemented or uncemented femoral component of equal surface design depending on the randomisation protocol. However, because the distribution of the different femoral components was equal in the two groups, we do not believe that this influenced the clinical or RSA results.

In conclusion, our study has shown that trabecular metal tibial components in patients younger than 60 years generally showed sizes and patterns of migration similar to those of other uncemented designs with one exception, namely, that most of the implants displayed pure subsidence with no lift-off from the resected tibia, a finding which we regard as beneficial. Another result was that the cemented tibial components showed only a small amount of early migration followed by stabilisation, which has not previously been seen in RSA studies of cemented TKR. Again we regard such a finding to be beneficial.

We thank research assistant B. Appelblad for measuring all the radiostereometric radiographs.

One or more of the authors have received or will receive benefits for personal or professional use from a commercial party (Zimmer) related directly or indirectly to the subject of this article. In addition, grants were received from Umeå University, Umeå, Sweden.