We studied the quality of fixation of the tibial component using radiostereometric analysis (RSA) in 40 patients who had undergone a cemented Freeman-Samuelson total knee arthroplasty. They were prospectively randomised to either a stemmed metal-backed (MB) or non-stemmed all-polyethylene (AP) tibial component. The articulating geometry of the implants was identical, as was the operative technique and the postoperative regime.

The study showed no complications of fixation using AP tibial components, and the migration was the same as that of their metal-backed counterparts. There was no bony collapse or increased subsidence of any part of the tibial component or increased incidence of radiolucent lines in the knees with AP components. Most AP implants were stable between one and two years after surgery, a finding known to be of positive prognostic significance when predicting future aseptic loosening.

Excellent long-term results with AP components have also been reported,\textsuperscript{7-12} although only with the Total Condylar prosthesis. Ritter\textsuperscript{13} warned against the use of unconstrained AP implants, especially those with a flat-on-flat articulation in the coronal plane, because of increased point contact or edge loading leading to bony collapse and loosening. It is not known if this finding is also valid for other designs which are flat-on-flat in the coronal plane, of which the Freeman-Samuelson prosthesis is an example. To our knowledge, no prospective, randomised studies have been published which compare Freeman-Samuelson AP and MB tibial components with identical articulating geometry.

Our aim was to investigate the fixation of these two tibial components in a prospective, randomised study using radiostereometric analysis (RSA). A follow-up of two years was chosen since RSA allows significant conclusions to be made within this time period.\textsuperscript{14-16}

Patients and Methods

We operated on 40 patients (40 knees) with primary osteoarthritis using a Freeman-Samuelson (Sulzer Orthopaedics AG, Zug, Switzerland) cemented TKA. After giving their informed consent, the patients were randomised to receiving either an AP or a stemmed MB tibial component by the opening of a sealed envelope just before implantation of the components. The inclusion criteria were osteoarthritis of grade III to grade V according to Ahlbäck,\textsuperscript{17} age over 50 years, and a body-weight below 100 kg. We excluded patients who had had previous ipsilateral knee surgery. The study was approved by the Ethics Committee of the University of Uppsala.

We excluded two patients in the MB group from RSA because of the inappropriate marking of the prosthesis or tibial bone. This left 38 patients (7 men, 31 women) with a median age of 69 years (52 to 83) in the study. Table I gives the details of the patients. There were no statistically significant differences between the two groups after randomisation.

The articulating surface of the Freeman-Samuelson TKA is described as ‘roller-in-trough’ and is identical for both the AP and MB versions (Fig. 1). The AP tibial component has two flanged plastic (‘magic’) pegs, but is not available...
with a stem. The metal base-plate of the MB version is 2.5 mm thick and has two small titanium pegs and a 50 mm stem on its undersurface. The polyethylene is attached to the base-plate by a snap-fit mechanism. The polyethylene (Sulene-PE) of both types of component was machined from compression-moulded plates (resin GUR 1020), gamma irradiated in inert gas and vacuum packed. All patellae were resurfaced with a cemented all-polyethylene component.

The operations were performed by or under the supervision of two surgeons (GA, JM) with considerable experience in total knee surgery. The proximal tibia was cut perpendicular to the long axis of the bone in the frontal plane, and a posterior slope of 3 to 5° in the sagittal plane. The knees were carefully balanced including recession or sacrifice of the posterior cruciate ligament if necessary. Vacuum-mixed (Optivac; Scandimed Int AB, Sjöbo, Sweden) bone cement (Palacos with gentamicin; Schering-Plough, Labo, Belgium) was applied to the undersurface of the implants, care being taken to avoid applying cement to the holes for the stem and pegs. The postoperative regime consisted of early mobilisation with immediate, full weight-bearing and physiotherapy.

**RSA analysis.** During the operation we inserted tantalum markers (RSA Biomedical Innovations, Umeå, Sweden) into the proximal tibial metaphysis and into the polyethylene of the tibial component. We undertook the reference RSA seven to ten days after the operation and further examinations at 4, 12 and 24 months using UmRSA software (RSA Biomedical Innovations). Rotations and translations of the tibial component in relation to the tibia were recorded. The maximum subsidence was defined as the greatest distal migration recorded for each implant, maximum lift-off as the greatest proximal migration, and maximum migration (MTPM) as the greatest three-dimensional translation of the part of the tibial tray which moved the most.

The accuracy of the method has been previously determined. The critical levels for significant rotations were >0.15° (transverse axis), >0.20° (longitudinal axis) and >0.10° (sagittal axis), respectively. The corresponding value for subsidence and lift-off was >0.10 mm.

Based on the ability to predict the development of aseptic loosening, we classified the tibial components into non-migrating (‘stable’) or continuously migrating (‘unstable’) as described by Ryd et al. The possible deformation of the polyethylene of the tibial component with time was also determined using the method previously detailed by Ryd et al.

**Measurements on conventional radiographs.** We measured alignment of the knee in the frontal plane as the tibiofemoral angle and the alignment of the tibial component in relation to the long axis of the tibia as described by Nilsson et al. The presence and size of radiolucent lines at the interface of the tibial component were determined as described by the Knee Society.

**Clinical investigation.** We used the Knee Society scoring system for clinical evaluation before and at 4, 12 and 24 months after operation.

**Statistical analysis.** We performed statistical analysis using SPSS for Windows 9.0 (SPSS Inc, Chicago, Illinois). Non-parametric statistical methods were used since the data were not always normally distributed. We constructed graphs as box-plots to display the median, the interquartile range and minimum and maximum values.

**Results**

**RSA analysis.** The results for migration of the tibial component in the two groups are summarised in Figures 2 to 7.
Fig. 2
Box plots showing absolute rotations about the transverse axis (anteroposterior rotation) in the MB and AP groups. The boxes show the median and the interquartile range, and the whiskers the minimum and maximum values.

Fig. 3
Box plots showing absolute rotations about the vertical axis (internal-external rotation) in the MB and AP groups. The boxes show the median and the interquartile range, and the whiskers the minimum and maximum values.

Fig. 4
Box plots showing absolute rotations about the sagittal axis (varus-valgus rotation) in the MB and AP groups. The boxes show the median and the interquartile range, and the whiskers the minimum and maximum values.
Fig. 5
Box plots showing maximum subsidence of the tibial component in the MB and AP groups. The boxes show the median and the interquartile range, and the whiskers the minimum and maximum values.

Fig. 6
Box plots showing maximum lift-off of the tibial component in the MB and AP groups. The boxes show the median and the interquartile range, and the whiskers the minimum and maximum values.

Fig. 7
Box plots showing maximum migration of the tibial component in the MB and AP groups. The boxes show the median and the interquartile range, and the whiskers the minimum and maximum values.
Dispersion of the data was greater for the MB group. The median migration in the AP group was seldom larger than that of the MB group. The direction of rotation of the tibial component about the transverse, vertical, and sagittal axes did not differ between the groups. The site of maximum subsidence and lift-off varied between the implants in each group but did not differ between the groups.

Most of the AP components were classified as stable according to the criteria of Ryd et al., whereas about half of the MB components showed continuous migration between one and two years. Measurements of the inter-marker distances in the polyethylene showed no deformation of the material at two years.

Radiological. After the operation the alignment of the knee was restored to normal (Table II). In both groups the tibial components were placed at 90° to the long axis of the tibia in the frontal plane. In the sagittal plane the AP components were positioned with a slight posterior tilt (Table II).

No implant had associated radiolucent lines on the postoperative radiograph although they developed in both groups during the course of the investigation, in 12 of 18 of the MB group and in 6 of 20 of the AP group (Fisher’s exact test, p = 0.05).

In the MB group lines had usually appeared within four months of surgery. They were progressive in thickness or extent in seven knees and non-progressive in five. The most common location was under the medial or anterior part of the tibial component. No line was thicker than 2 mm. There was no difference in the migration at 24 months between the MB implants with or without radiolucent lines (Mann-Whitney U test, p = 0.19 to 1.00). In one knee a radiolucent line 1 to 2 mm thick was identified beneath the entire component at 12 months. The thickness of this line did not progress during the following year. The migration for this component was equal to the median migration for all AP implants.

Clinical. The median Knee Society knee and function scores increased significantly after surgery for up to 12 months in both groups (Wilcoxon signed-rank test, p < 0.001), whereas only minor improvement was seen between 12 and 24 months (Table III). The range of movement improved slightly up to 24 months in both groups (Table IV). There was no statistically significant difference between the groups with regard to the knee score or range of movement (Tables III and IV).

Complications. There were four complications in the MB group and one in the AP group. In the MB group one woman developed a deep-vein thrombosis. Another underwent surgery for a fracture of the femoral neck four months after TKA, and had a low Knee Society function score as a result. Following a car accident three months after TKA another woman required surgery for a severe ipsilateral patellar fracture, and later developed anterior knee pain and a low function score. The migration of her tibial component was less than the median migration for the MB group. One man required manipulation under anaesthesia one month after operation to increase knee flexion. In the AP group one patient had a deep-vein thrombosis.
Discussion

In spite of perceived advantages, MB designs also have disadvantages. For a given thickness of tibial component, the metal backing will reduce the thickness of polyethylene by 2 to 5 mm with a potential for increased wear. In order to increase the thickness of the polyethylene used in an MB component, increased bone resection is necessary. In modular MB designs an additional interface is created which may serve as an extra source of wear debris. Increased tensile stresses have been observed at the prosthesis-bone interface during eccentric loading of the MB tibial plateau leading to the so-called ‘teeter-totter’ effect. Finally, the addition of metal backing increases the cost of contemporary TKAs by approximately 30%. Consequently, in recent years renewed interest in AP implants has emerged, mainly because of a desire to reduce costs. The optimum design for an AP tibial component is still unclear.

Non-randomised clinical and RSA studies have shown no significant difference between AP and MB implants, but these favourable results have been obtained with highly conforming prostheses. It has been suggested that equally good results would not be obtained with less constrained implants. The Freeman-Samuelson TKA, although conforming in the sagittal plane, is flat-on-flat in the coronal plane. In our study the AP tibial components showed patterns and magnitudes of migration equivalent to their MB counterparts. Moreover, there was a tendency, although not statistically significant, for the median migration to be somewhat lower in the AP group. This was especially pronounced for maximum lift-off. Similarly, more MB than AP implants showed continuous migration between one and two years, a finding known to be indicative of future aseptic loosening. It is also interesting to note that cemented MB acetabular cups have performed worse than AP cups despite the theoretical advantage of a more even distribution of stresses at the interface. Studies have shown that TKAs with flat-on-flat articulation in the coronal plane resist the normal varus-valgus movements, leading to eccentric loads which create compressive and distractive forces at the interface. A stiffer MB implant may be more vulnerable to these stresses than an AP implant. The higher incidence of radiolucent lines in the MB group could be a reflection of this mechanism.

Clinical and in vitro studies have indicated that a stem improves fixation of the tibial component, particularly if it is longer than 80 mm. Our MB implants had a stem, but they did not perform better than the AP components without a stem. Perhaps the stem should be longer than the 50 mm used in our study to be effective.

Analysis of the failures ascribed to AP components have shown that they are usually related to technical errors in alignment at surgery rather than the absence of metal backing. Today, modern instrumentation for TKA allows better alignment, as shown in our study. This could also explain the good performance of the AP implants.

In our study the pegs and the stem were not cemented. The reason for not doing so was that previous in vitro and RSA examinations have shown low rates of migration when only proximal cementation was used. This technique may theoretically result in a less rigid construct than if the pegs and stem were cemented. Cementing in this way, however, would have improved the fixation of both AP and MB implants similarly, and does not explain the similar performance of both types of implant.

Cold flow of the polyethylene has been considered to be a cause of loosening, and can theoretically be reduced or averted by either metal backing or by increasing the thickness of polyethylene. Cold flow has not previously been seen in AP implants of the Total Condylar or Freeman-Samuelson designs, and this was confirmed in our study.

We conclude that there is little evidence to support the possible advantages of metal backing over an AP cemented tibial component. Migration of AP implants was equivalent to that of MB implants, which suggests a good long-term prognosis.

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