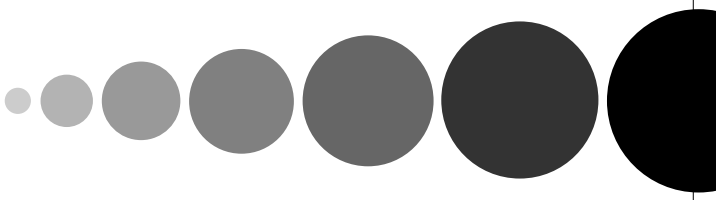
# Objective clinical performance outcome of total knee prostheses. A study of mobile bearing knees using fluoroscopy, electromyography and roentgenstereophotogrammetry

Garling, E.H.

# Chapter 8



# The effect of periapatite on the micromotion of total knee arthroplasty tibial components in osteoarthritis

## A controlled prospective, randomized RSA study in 90 patients

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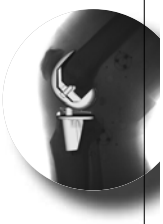
## Abstract

Both cemented and cementless total knee designs produce excellent clinical results. However, for specific patient groups, the cementless knees could have advantages. The way of bonding of the prosthesis to the adjacent bone remains a topic in total knee arthroplasty (TKA), especially in the younger patient population. Furthermore, the question of the value of adding a calciumphosphate coating to the prosthesis surface remains.

A controlled randomized prospective study was performed on 90 Duracon TKA, to evaluate the effect of a Periapatite (PA) coating on the fixation of the tibial tray using micromotion (as measured with roentgen stereophotogrammetric analysis) as evaluation method. Twenty-five cemented components were included as the control group.

The coated and the non-coated groups matched perfectly well for sex, age, weight, length, BMI and Insall score. Stage of osteoarthritis according to Ahlback, preoperative and postoperative femorotibial angle (FTA) and the mechanical leg axis showed no statistical differences. The non-coated tibial components showed more subsidence at two years 0.5 ± 0.63 mm (range, -0.50 to 2.07 mm), than the PA coated tibial components: 0.1 ± 0.60 mm (range, -0.34 to 2.75 mm); ($p = 0.047$). Also the medial-lateral motion of the non-coated group was significantly larger ($p = 0.003$). Translation and rotation migration data for the other axes were not significantly different. As expected the control group – cemented components – showed no subsidence after two-years follow-up: -0.1 ± 0.17 (range, -0.44 to 0.22 mm).

This study shows that periapatite augmentation improves the fixation of the Duracon total knee prosthesis, thus preventing mechanical loosening and subsequent long-term revision.



## 8.1 Introduction

Nowadays, total knee arthroplasty is considered a routine procedure for degenerative changes of the knee joint. Cemented fixation of the components is still the most frequently used way of fixation. The advantages of a cemented design are the immediate implant stability, and the fact that the cement will act as a barrier for wear particles migration into the bone-prosthesis interface. Advantages of cementless designs are that more bone is preserved, which is of special importance to younger patients (Hofmann et al., 2002), and that peri-prosthetic fracture treatment can be performed more easily, which is important to the elderly patients.

However, studies on the long-term results of cementless designs (Akizuki et al., 2003; Gejo et al., 1988; Nilsson et al., 1999) show the same – and sometimes even better – favorable clinical results as with cemented designs (Buechel, 2002; Whiteside, 2001). The addition of a calcium phosphate coating might even augment the bone-prosthesis fixation and may also act as a barrier for ingress of wear-particles by sealing of the interface through periprosthetic bone ingrowth (Rahbek et al., 2000).

Since these cementless designs have to osteointegrate for enduring fixation, this process of bonding between bone and prosthesis is the crucial issue for failure apart from polyethylene failure. Osteointegration is reflected by the absence of progressive micromotion (Nelissen et al., 1998; Ryd et al., 1995), absence of radiolucent lines and bone remodeling next to the prosthesis (Fuiko et al., 2003). The addition of a hydroxyapatite (HA) coating on the tibial tray may reduce micromotion in a cementless design even more (Akizuki et al., 2003; Nelissen, 1995; Onsten et al., 1998; Regnner et al., 2000; Toksvig-Larsen et al., 2000). Early migration as measured with roentgen stereophotogrammetric analysis (RSA) has been shown to be related to long-term implant survival (Grewal et al., 19992; Ryd et al., 1995).

The purpose of this study was to examine the amount of three-dimensional micromotion of the tibial component in a prospective randomized RSA study, comparing uncoated tibial components and tibial components coated with periapatite (PA). Cemented tibial components were used as a control group.

## 8.2 Materials and Methods

### 8.2.1 Patients

Ninety consecutive primary total knee arthroplasties (TKA) (eighty-two patients) were included in this prospective, randomized RSA study. During surgery, a randomization scheme selected the patients for either the PA coated group or the uncoated group (Duracon: Stryker Howmedica Osteonics). Subsequently twenty-five cemented TKA's of the same design were included as a control group to validate the measurements. All patients had osteoarthritis. The PA group consisted of 44 knees and the uncoated group of 46 knees. The institution's ethics committee approved the study, and the patients gave informed consent.

***Tibial components***

The Duracon prosthetic design consists of a posterior cruciate retaining, non-constrained system. All tibial baseplates had a cruciform keel for rotational stability and the same porous coated multiple layer beads ingrowth surface. In general, HA coating is applied with a plasma spraying process (Nelissen et al., 1998; Onsten et al., 1998), but this technique is not appropriate to coat the deeper layers of a porous surfaced prosthesis. The Duracon porous coated surface consists of a multiple layer beads (diameter 0.4 mm) with a porosity of 35%, a mean pore size of 425 micrometer and a thickness of 1.5 mm. During the PA coating technique, the prosthesis is submerged in a watery bath of calcium and phosphate at regulated pH (7.4) and temperature (80°). As result of this process nucleation of the calcium phosphate as calcium deficient HA (similar to the process of bone mineralization) on the metal surface will take place. The PA technique reveals a pure single crystallized precipitated HA coating with a thickness of 20 micrometer in all layers of the porous surfaced prosthesis. No other calcium phosphate phases are present with this type of coating technique.

In all knee replacements a PA porous coated femoral component and a full polyethylene cemented patellar prosthesis was used. The femorotibial design is a biconcave polyaxial radiated design with elongated posterior condyles and is medial-lateral stabilized with two pegs. The anatomically shaped patella component

articulates in a proximal elongated trochlear groove. The exchangeable UHMW polyethylene insert, minimal thickness 11 mm, is fixed with an anterior and posterior lipping mechanism on the tibial tray (Figure 1).

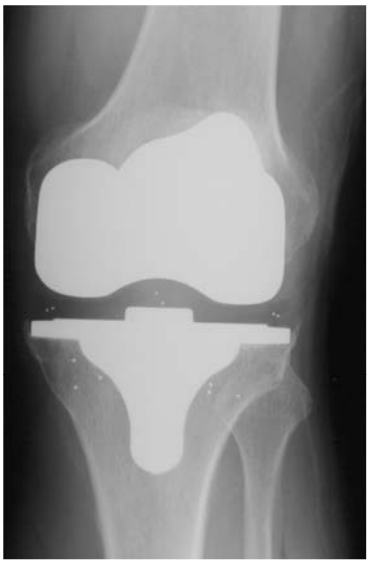


**Figure 1.** Radiograph of Duracon total knee prosthesis. Six tantalum markers are visible in the polyethylene inlay and in the tibia bone.

***Operative technique and after-treatment***

In all knee replacements, the same standard surgical procedure under tourniquet control was used. After a straight midline incision the knee was opened with a medial Payer approach. The tibial cutting surface was extramedullary aligned (classical prosthetic alignment perpendicular to the talocrural joint) and the distal femoral cut intra medullary aligned and was adjusted to the femoral anatomy both based on long standing X-rays. Soft tissue releases were performed when necessary. In the implants were bone cement (Genta Palacos, Biomet-Merck, Sjöbo, Sweden) was used, the bone surfaces were cleaned with a pulse lavage system.

During operation three to eight tantalum beads (1 millimeter diameter) were inserted in preselected places in the metaphysial bone of the tibia. The insert of the tibial tray was manufactured with six tantalum balls (Howmedica Inc., Rutherford, USA). The locking mechanism between the insert and the tibial tray was pre-tested and showed no movement between the two parts.

After one day of bed rest patients were mobilized with two crutches and partial weight bearing during 6 weeks. Anti-trombotic profylaxis was performed using acenocoumarol (6 weeks), peri operatively patients received three doses of Cefamandol intravenously for infection prevention.

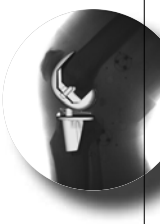
### 8.2.2 Radiographs and RSA

The patients were evaluated preoperatively, and at one week before mobilization, three months, six months, one year, and two years postoperatively. At each evaluation the clinical status was assessed and radiographs for RSA were made. Immediately after the operation, at the one-year, and at the two-year follow-up, standard anterior/posterior (AP) were taken with the patient standing. Lateral radiographs as well as axial radiographs of the patella were made supine. The femorotibial angle, the lateral and AP position of the tibial and femoral component were measured as well as the leg axis (Ewald, 1989).

The RSA set-up consisted of two synchronized roentgen tubes positioned approximately 1.5 meter above a roentgen cassette (35x43 cm) at a 20° angle to the vertical. Both roentgen tubes simultaneously exposed the roentgen film. A calibration box made of Perspex™ was used to define the three-dimensional (laboratory) coordinate system. For this purpose 38 tantalum 1-mm markers were positioned in the lower plane of the box (fiducial markers). In order to calculate the focus position, 20 1-mm tantalum markers were positioned in the upper plane of the box (control markers).

With a Vidar VXR-12 scanner (Vidar, Lund, Sweden), the radiographs were scanned at 150 dots per inch resolution and eight-bit gray scale resolution. The measurement of marker coordinates in the digitized radiographs, the three-dimensional reconstruction of the marker positions, and the micromotion analysis was done with RSA-CMS (Medis, Leiden, The Netherlands), a software package that performs the RSA procedure automatically in digitized or digital radiographs (Valstar, 2001; Vrooman et al., 1998).

In order to assess the micromotion of the implant with a high accuracy, the bone markers need to be well fixated in the bone. Bone markers were defined unstable when they moved more than 0.3 mm with respect to the other bone markers. Unstable markers were excluded from analysis.



The first RSA examination served as the reference baseline. All subsequent evaluations of micromotion were related to the relative position of the prosthesis with respect to the bone at that the time of the evaluation. In 30 knees (16 PA and 14 uncoated) the first RSA radiograph was not made within 5 days after operation but at six weeks. As a consequence this radiograph was used as the reference baseline. Micromotion of the components was expressed as translation of the center of gravity of the prosthesis makers and rotation of the rigid body defined by the prosthesis markers about this center of gravity. Positive directions for translations along the orthogonal axes were: transverse (medial-lateral), longitudinal (caudal-cranial), and sagittal (posterior-anterior). Positive directions for rotations about the coordinate axes were anterior tilt (transverse axis), internal rotation (longitudinal axis), and varus (sagittal axis).

When an integrated bone-prosthesis interface exists, the implant should be stable and a stable implant would not be at risk for aseptic loosening. In an RSA study of Ryd et al. (1995), a micromotion rate of 0.2 mm or more during the second postoperative year was identified to be a predictor for loosening of total knee implants at ten-year follow-up with a predictive power of about 85%. In this study, implants were defined to be at risk for aseptic loosening when the translation rate during the second postoperative year was larger than 0.5 mm along one or more coordinate axes (Ryd et al., 1995) and/or the rotation rate was larger than one degree about one or more coordinate axes.

The reproducibility of the RSA measurements was determined by means of double examination of twenty patients (Table 1). Double examination consists of two RSA examinations of the same patient exposed within a time interval of about ten minutes. Because of the short time-interval between these two radiographs, the assumption is made that the implant did not migrate between these two exposures relative to the surrounding bone. By comparing these two radiographs, the accuracy of the micromotion parameters can be assessed (Ranstam et al., 2000).

In some cases problems occurred with respect to the marking of the tibia. In six cases, the bone was either marked with less than three markers, or the markers were positioned so that they were occluded by the component. These cases were excluded from the analysis.

**Table 1.** Accuracy of the RSA measurements based on double examinations. Presented numbers are the upper limits of the 95%-confidence interval (N = 20).

| | **Translation (mm)** | | | **Rotation (°)** | | |
|---|---|---|---|---|---|---|
| | Trans | Long | Sag | Trans | Long | Sag |
| Stem | 0.25 | 0.15 | 0.44 | 0.48 | 0.41 | 0.26 |

### 8.2.3 Statistical methods

Mean values and standard deviations were calculated for all variables. For comparison of the mean values of the two groups, a Kruskall-Wallis test was used. In order to explore the effects of the two types of fixation on the amount of micromotion after two-years a linear regression was used with migration at the two years follow-up as the dependent variable and the fixation type and the base-line examination (directly postoperative or 6 weeks post operative) as co-variables. Levene's test for homogeneity of variance was used to determine the differences of the group variances in the micromotion data. For all analyses, significance was determined by a p-value of less than 0.05.

## 8.3 Results

### 8.3.1 Clinical results

The two groups and the cemented control group matched perfectly well for sex, age, weight, length, BMI and Insall score. Stage of osteoarthritis according to Ahlback, preoperative and postoperative femorotibial angle (FTA) and the mechanical leg axis showed no statistical differences (Table 2). The average operating time was 79 minutes (SD 18) for the uncemented knees and 81 minutes (SD 15) for cemented knees.

During follow-up 5 PA coated, 3 uncoated and 1 cemented knee (9 patients) were lost to follow-up (not knee related). In the PA group 3 patients died, all after one year follow-up, one other patient had a cerebrovascular accident within two weeks after operation and the fifth patient moved abroad after 6 month follow-up. Based on the RSA results at the last follow-up, these knees were judged as stable.

In the uncoated group one patient died and one moved after one year follow-up. Both knees were stable based on RSA examination. The third patient underwent an upper limb amputation because of vascular problems in another hospital. For this patient, RSA follow-up was too short for defining stability, which was the same for the patient in the cemented group who died after 6 month follow-up. Otherwise there was no evidence of clinical or radiographic failure in any of these patients.

Clinical results by means of Insall score, active knee flexion and active extension lag showed no statistical difference among the two groups and the cemented control group during follow-up (Table 3).

**Table 2.** Preoperative patient data (mean and standard deviations).

| | **PA coated** | **Uncoated** | **Cemented** |
|---|---|---|---|
| Sex F/M | 33/10 | 31/12 | 14/11 |
| Age | 71 (± 7.8) | 71 (± 7.27) | 72 (± 6.6) |
| Weight (kg) | 78 (± 13.3) | 79 (± 12.57) | 79 (± 11.4) |
| Length (cm) | 165 (± 8.6) | 166 (± 8.53) | 168 (± 7.8) |
| BMI | 29 (± 4.7) | 30 (± 4.9) | 29 (± 4.9) |
| Insall | 53 (± 14.9) | 49 (± 14.6) | 60 (± 13.8) |
| Ahlbäck 1-5 (N) | 6/18/10/6/2 | 9/13/13/5/3 | 4/15/4/2 |
| FTA | 184 (± 8.9) | 183 (± 8.6) | 181 (± 4.9) |
| Leg axis | 177 (± 8.6) | 177 (± 8.4) | 174 (± 4.5) |

**Table 3.** Clinical results during follow-up (mean and standard deviations).

| | **PA coated** | | **Uncoated** | | **Cemented** | |
|---|---|---|---|---|---|---|
| | **Post** | **2 yrs** | **Post** | **2 yrs** | **Post** | **2 yrs** |
| Insall | 81.8 (± 11.76) | 88.5 (± 8.35) | 83.0 (± 8.80) | 88.5 (± 9.02) | 82.2 (± 13.04) | 90.6 (± 6.98) |
| Flexion | 98.5 (± 13,82) | 102.4 (± 12.67) | 100.1 (± 10.74) | 106.0 (± 12.66) | 97.0 (± 10.10) | 107.1 (± 12.59) |
| Extension | 1.5 (± 3,62) | 0.2 (± 0.93) | 2.5 (± 5.04) | 0.6 (± 2.00) | 2.4 (± 5.42) | 0.6 (± 2.24) |

### 8.3.2 Radiographic results

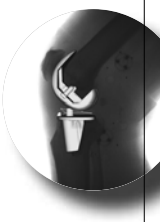
Routine radiographs of the knee revealed no radiolucent lines of two millimeters or more around the tibial, femoral or patellar component in any knees of the three groups at the two-year follow-up evaluation. Sclerotic lines around the keel of the tibia tray were seen in 8 knees, 1 in the PA group and 7 in the uncoated group ($P < 0.05$; Pearson Chi Square test).

**Table 4.** Radiographic results (mean and standard deviations) or number of knees.

| | **PA coated** | | **Uncoated** | | **Cemented** | |
|---|---|---|---|---|---|---|
| | **Post** | **2 yrs** | **Post** | **2 yrs** | **Post** | **2 yrs** |
| FTA | 186.0 (± 4.37) | 185.3 (± 3.98) | 187.5 (± 3.59) | 186.4 (± 3.81) | 187.0 (± 2.85) | 186.3 (± 2.75) |
| Hip-knee-ankle axis | 179.6 (± 4.66) | 178.4 (± 3.77) | 180.8 (± 3.28) | 179.8 (± 3.77) | 180.0 (± 2.58) | 180.0 (± 2.75) |
| Hip-knee-ankle axis <177° (n) | 10 | 12 | 5 | 10 | 2 | 1 |
| Hip-knee-ankle axis >183° (n) | 6 | 6 | 5 | 4 | 6 | 5 |

**Table 5.** Component position on AP and lateral radiographs (mean and standard deviation).

| | **PA coated** | | **Uncoated** | | **Cemented** | |
|---|---|---|---|---|---|---|
| | **Post** | **2 yrs** | **Post** | **2 yrs** | **Post** | **2 yrs** |
| Femur AP (°) | 98 (± 2.6) | 98 (± 2.4) | 99 (± 2.6) | 99 (± 2.7) | 99 (± 2.3) | 98 (± 2.1) |
| Femur lat (°) | 2 (± 2.5) | 1 (± 2.0) | 2 (± 2.4) | 2 (± 2.7) | 10 (± 2.3) | 1.3 (± 2.2) |
| Tibia AP (°) | 88 (± 2.6) | 88 (± 2.5) | 89 (± 2.2) | 89 (± 1.8) | 89 (± 3.2) | 89 (± 2.7) |
| Tibia lat (°) | 87 (± 2.8) | 86 (± 2.9) | 87 (± 2.7) | 86 (± 2.4) | 85 (± 2.5) | 86 (± 2.5) |



The average femoral-tibial angle was not different for the two groups and did not change substantially during follow-up (Table 4). The radiographic results of the components, evaluating the surgical technique for all groups individually by component position on standardized plain radiographs showed no differences between the three groups. In the cemented control group the FTA, legaxis and component positioning did not significantly differ from the other two groups (Table 5).

### 8.3.3 RSA results

The migration of the tibial components in millimeters at the two years follow-up is presented in Table 6. The graphs of the migration data showing the patterns of how the components in the two randomized groups and the control group migrated during the two-year follow-up are presented in Figures 2–7.

At two year follow-up the non-coated tibial components showed more subsidence 0.5 ± 0.63 mm (range, -0.50 to 2.07 mm), than the PA coated tibial components: 0.1 ± 0.60 mm (range, -0.34 to 2.75 mm); (p = 0.047). In the first six weeks after implantation the uncoated implants already subsided 0.3 mm, while the PA coated group subsided only 0.1 mm. Also the medial-lateral motion between the two groups was significantly different (p = 0.003).

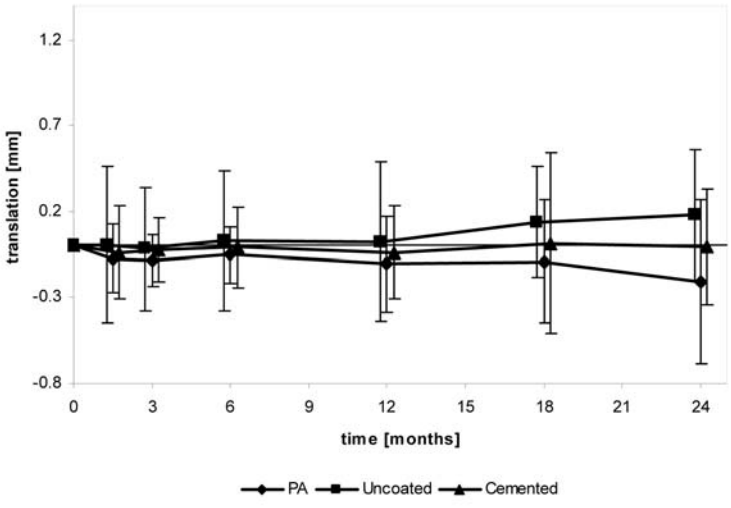



**Figure 2.** Medial-lateral translations of the PA coated, uncoated and cemented tibial components (mean and standard deviation).

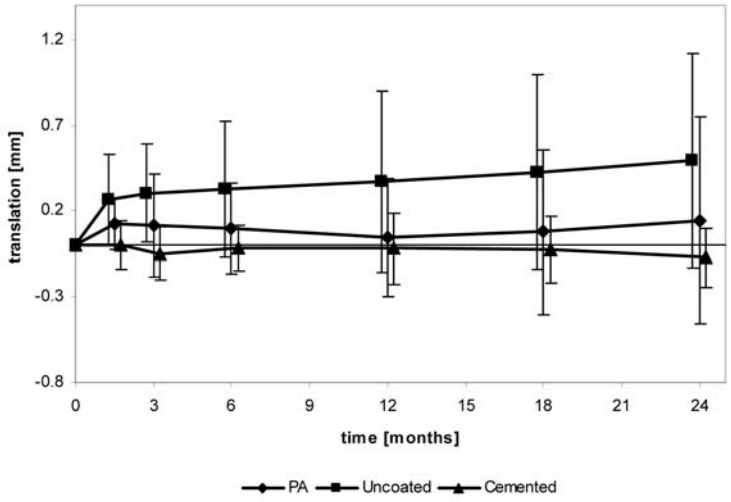



**Figure 3.** Caudal-cranial translations of the PA coated, uncoated and cemented tibial components (mean and standard deviation).

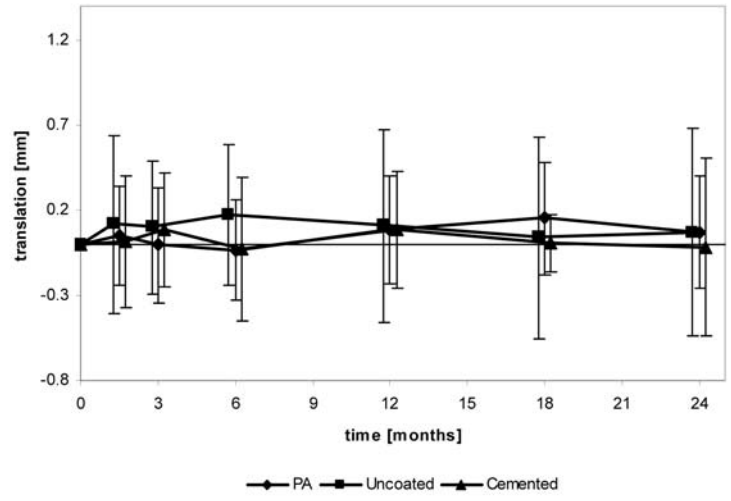



**Figure 4.** Posterior-anterior translations of the PA coated, uncoated and cemented tibial components (mean and standard deviation).

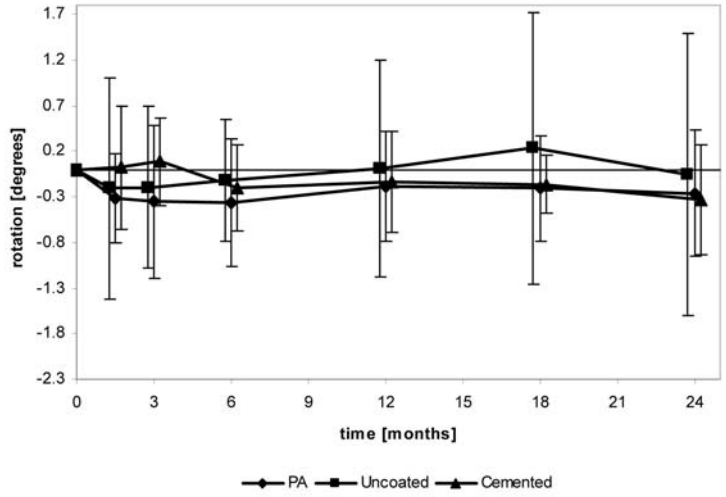



**Figure 5.** Anterior tilt of the PA coated, uncoated and cemented tibial components (mean and standard deviation).

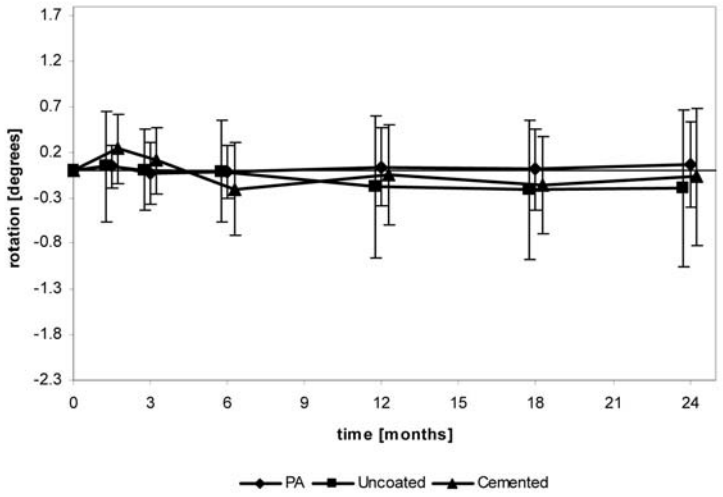



**Figure 6.** Internal rotations of the PA coated, uncoated and cemented tibial components (mean and standard deviation).

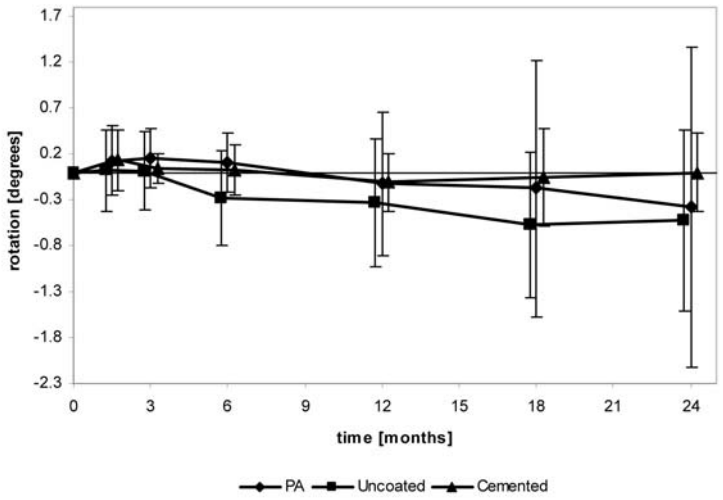



**Figure 7.** Varus rotation of the PA coated, uncoated and cemented tibial components (mean and standard deviation).

Translation along the other 2 axis and rotation around all three axis migration data along the other axes were not significantly different among the groups. The effect of the other co-variable 'base-line examination' was not significant ($p>0.2$) for all directions. This indicates that there was no difference between the delayed base-line examination group on the total amount of micromotion from 6 weeks post operatively up to the two year examination compared with the completely examined group. As in the group with the baseline within 5 days post operatively as in the group with the baseline at six weeks, it was possible to identify the stable tibial trays and the migrating tibial trays at risk for late aseptic loosening.

The two groups showed no differences in the rotational migration data. However, the uncoated group showed a significant higher variance in anterior tilt compared to the PA coated components (Levene's test: $p = 0.01$). The tibial slope was not of influence on the amount of tilting of the components. The PA coated group showed also a high variance in varus rotation. This could be explained by one of the components in that group showing a high varus (7.7 degrees) tilt at the two years follow-up. This varus rotation of that tibial tray was also clearly visible on the plain

radiographs. However, clinically there were no signs of failure of this component at two year follow-up. No relation between the femoral-tibial angle and varus/valgus rotation of the components could be found.

The significant difference in the micromotion data between the two groups in medial-lateral direction can also be explained by the varus/valgus rotations of the components. These rotations are expressed by a medial-lateral motion of the center point of gravity of the markers in the polyethylene. Therefore it is very important to present three-dimensional micromotion data, not limited to in-plane translations that are actually caused by rotations of the components.

As expected the control group showed no subsidence after two-years follow-up: -0.1 ± 0.17 mm (range, -0.44 to 0.22 mm). Only a small posterior tilt of 0.3 degrees was observed. Four of the cemented components showed a posterior tilting of the component and three components an anterior tilt. The results of the control group validated the RSA measurements in this study.

A total of 11 tibial trays from the PA group (26%), and 29 tibial trays from the uncoated group (63%) could be identified as at risk according to the definition given in the Materials and Methods section of this paper.

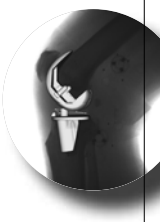
**Table 6.** Migration (mean and standard deviation) of the PA coated, uncoated and cemented tibial components at the 2-year follow-up evaluation.

| | | PA coated | Uncoated | Cemented |
|---|---|---|---|---|
| **Translations** | medial-lateral | -0.21 ± 0.48 | 0.18 ± 0.38 | -0.01 ± 0.34 |
| | caudal-cranial | 0.15 ± 0.60 | 0.49 ± 0.63 | -0.07 ± 0.17 |
| | posterior-anterior | 0.07 ± 0.33 | 0.07 ± 0.61 | -0.02 ± 0.52 |
| **Rotations** | anterior tilt | -0.26 ± 0.69 | -0.05 ± 1.55 | -0.33 ± 0.60 |
| | internal rotation | 0.07 ± 0.47 | -0.19 ± 0.86 | -0.07 ± 0.75 |
| | varus rotation | -0.38 ± 1.75 | -0.53 ± 0.98 | -0.00 ± 0.43 |

## 8.4 Discussion

The loosening process of total knee implants seems to start with the tibial component. Continuous micromotion during the first two years after implantation in one or more directions detected by RSA, a validated tool to measure micromotion *in vivo*, reflects the start of this process (Grewal et al., 1992; Kärrholm et al., 1994; Ryd et al., 1995). General requirements for good fixation are close apposition of bone to the porous surface and a lack of movement at the developing interface between bone and implant. Optimization of the interface between bone and implant is therefore of paramount importance. In a cemented design, suboptimal conditions of both surfaces are corrected by the cement, but in cementless designs, apart from the type of ingrowth surface (calciumphosphate and/or metal pore diameter) the status of the prepared bone surfaces, bone quality and the gap between bone and implant are of high importance. In a comparative study of human cancellous bone remodeling to titanium and hydroxylapatite (HA) coated implants, Hofman showed that HA increases the percentage of the implant surface with ingrowth of bone (Hofmann et al., 1993). Ongrowth or ingrowth of human cancellous bone is possible in gaps smaller than 50 μm while HA had no metabolic influence on bone mineral apposition rate. In another study, Bloebaum showed the same maximum gap healing properties (max 50 μm) of surrounding human cancellous bone in the absence of HA on the titanium implants and found that bone apposition on non coated titanium implants needed a minimal time of 12 weeks (Bloebaum et al., 1971). Taking the assumption that HA coating accelerates bone ingrowth or ongrowth in time, it will create a higher area percentage bone-prosthesis contact. This could be an explanation for the higher level of migration of the uncoated implants observed in our RSA results and the faster stabilisation of the periapatite implants after an initial period of subsidence.

From animal experiment it was already known that a thin lining of bone is present on the implant surface at three weeks, while at 6 weeks the implant is histologically osteointegrated (Geesink et al., 1988). In human, Hardy (Hardy et al., 1991) and Frayssinet (Frayssinet et al., 1993) showed intimate contact between woven bone and the hydroxyapatite coated hip prosthesis before six weeks after implantation. This study is in agreement with an earlier study by Nelissen on RSA measurement



in TKA which also showed favorable results of adding a calcium-phosphate coating to the surface of uncemented tibial trays in TKA. In that study the noncoated components subsided significantly more than the coated and cemented components (Nelissen et al., 1998). In our study and the study by Nelissen the coated implants show stabilization after a short initial period of subsidence projecting the ingrowth phase, where as the uncoated implants show ongoing subsidence. Major difference between that study and the current study is the amount of subsidence observed in the uncoated groups, 0.73 mm vs 0.5 mm respectively at two years follow-up. One explanation for this difference could be the non-homogenous patient selection in the study by Nelissen. They included a mix of patients with rheumatoid arthritis and osteoarthritis. In generally patients with rheumatoid arthritis have more osteoporosis inducted by the use of corticosteroids resulting in a weaker foundation for the tibial tray. Li and Nilsson acknowledged this observation by showing a significant relationship between lower average BMD and more migration of the tibial component in TKA (Li and Nilsson, 2000).

The greater variability in the migration profile of the uncemented tibial trays as found in this study stresses more the individual differences in bone ongrowth to the prosthesis, a factor not only determined by the available bone mass, but also dependent on the distance between bone and prosthesis immediate after implantation as well the intrinsic mechanical stability. Technically optimized instrumentation is necessary especially in uncemented TKA not only for creating correct alignement but also for exact bone cuts to create immediate implant stability without gaps. So, addition of the calcium phosphate PA did enhance initial component stability comparable to cemented TKA. Several other studies also acknowledge the beneficial effect of calcium phosphates (Akizuki et al., 2003; Fuiko et al., 2003; Nelissen et al., 1998; Nilsson et al., 1999; Onsten et al., 1998; Toksvig-Larsen et al., 2000).

Looking at the different migration profiles of the cementless TKA designs described in these studies, the profile of the porous surface of the TKA seems also to be a factor related with migration. The titanium PFC design described by Önsten et al. had a porous surface with a pore diameter of 120-220 micrometer (Onsten et al., 1998), while the vitallium Interax total knee described by Nelissen et al. had a fiber mesh surface with pore diameter of 1690 micrometer. The first mentioned

uncoated design showed a mean subsidence of 0.71 ± 0.56 mm (coated 0.87 ± 0.56), while the components in the latter study subsided 0.73 ± 0.92 mm at the two-year follow-up (coated 0.06 ± 0.17 mm) in a rheumatoid arthritis patient group. In our series with a homogenous osteoarthritic patient group, the uncoated tibial trays, (pore size 425 micrometer) subsided 0.5 mm ± 0.63 mm (range -0.50 to 2.07 mm) while the coated subsided 0.1 mm ± 0.60 mm (range -0.34 to 2.75). One reason for this difference might be their patient selection but another reason may be the quality of the pore size. In experiments with calcium aluminate, Klawitter showed that a minimal pore diameter of 100 μm is necessary for the ingrowth of bone (Klawitter et al., 1971). A minimal pore diameter of 50 μm is needed for ingrowth of osteoid and smaller pore sizes of about 5 μm to 15 μm result in ingrowth of fibrous tissue. If coatings are added to the porous surface more open structures may be required to keep the structure open. The Duracon prosthesis in this study has a porous surface with a pore diameter of 425 μm and after adding the 20 **μ**m periapatite layer a remaining pore size diameter of 385 **μ**m, which should be enough for ingrowth of bone according to the results of Klawitter. The small remaining pore size diameter (120-220 micrometer) in the PFC study by Önsten could be the explanation for the high amount of subsidence in their coated group (0.87mm ± 0.56 mm). It must be emphasized that for all surface gap sizes reported in the literature, the addition of a calciumphosphate coating improved fixation, independent of the initial migration. A randomized RSA study comparing calciumphosphate coated tibial components with different gap sizes should further prove this effect. It is expected that when calciumphosphate coated implants sustain the forces that threaten the fixation in the early period after implantation, a strong and enduring fixation will be obtained. The influence of the local BMD on migration patterns of cemented and non cemented tibial trays is another subject of further analysis.

## 8.5 Conclusion

This study shows that periapatite augmentation improves the fixation of the Duracon total knee prosthesis, thus preventing mechanical loosening and subsequent long-term revision. Uncemented non coated tibial trays in TKA are not advised to use.

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