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Tibial Component Undersizing Is Related to High Degrees of Implant Migration Following Cementless Total Knee Arthroplasty

A Study of Radiostereometric Analysis Data for 111 Patients with 2-Year Follow-up

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Background: Radiostereometric analysis (RSA) studies have shown that the continuous migration of tibial components is predictive of aseptic loosening following total knee arthroplasty (TKA). In the present study, we investigated whether accurate sizing and placement of tibial components are related to the degree of implant migration as measured with use of RSA.

Methods: A total of 111 patients who underwent TKA surgery with a cementless tibial component were followed for a period of 2 years postoperatively, during which implant migration was assessed with use of RSA. RSA was performed within 7 days postoperatively and after 3, 6, 12, and 24 months. Postoperative radiographs were evaluated for component size and placement in the tibia. The evaluations were performed by experienced knee surgeons who were blinded to the migration data and clinical outcomes. A multivariable linear regression analysis was conducted.

Results: Continuous implant migration (i.e., migration occurring between 12 and 24 months postoperatively) had a negative association with tibial component size (coefficient [B], −0.2; 95% confidence interval [CI], −0.33 to −0.08). Subsidence was associated with the absence of posterior cortical bone support (B, −0.7; 95% CI, −1.09 to −0.28), the absence of lateral cortical bone support (B, 0.8; 95% CI, 0.29 to 1.37), frontal-plane varus malalignment (B, 0.6; 95% CI, 0.12 to 1.16), and component undersizing (B, −0.4; 95% CI, −0.06 to −0.68). Posterior tilt was associated only with undersizing (B, 0.6; 95% CI, 0.27 to 1.11).

Conclusions: Undersized cementless tibial components are at a higher risk for poor fixation with continuous migration following TKA. Therefore, a higher risk of aseptic loosening should be expected.

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

Cementation of tibial components remains the gold standard in total knee arthroplasty (TKA); however, the use of cementless TKA is increasing. Meta-analyses and literature reviews comparing newer cementless TKA implant designs with cemented implants have found similar or equivalent functional outcomes and survivorship between the 2 implant types[1-5]. The advantages of cementless fixation are the elimination of aseptic loosening as a result of bone resorption at the bone-cement interface and enhanced fixation as a result of bone ingrowth[6]. Cementless fixation is often chosen in young patients with high physical demands and good bone quality, and newer cementless designs have been shown to be durable and reliable at long-term follow-up[7,8].

Radiostereometric analysis (RSA) has proven to be the best available method for predicting future aseptic loosening and late revision following TKA[9,10]. RSA provides detailed information regarding the migration of inserted arthroplasty components in relation to the surrounding bone. For cementless tibial components, the degree of continuous migration is arguably more relevant than the degree of initial migration[11-13]. For both cementless and cemented tibial components, the dominant directions of migration are subsidence and posterior rotation in the tibial host bone[11,14,15] (Fig. 1). The RSA technique is typically utilized in randomized trials comparing new component designs with an established gold-standard component that has low levels of migration, and the technique has been

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJSOA/A548).

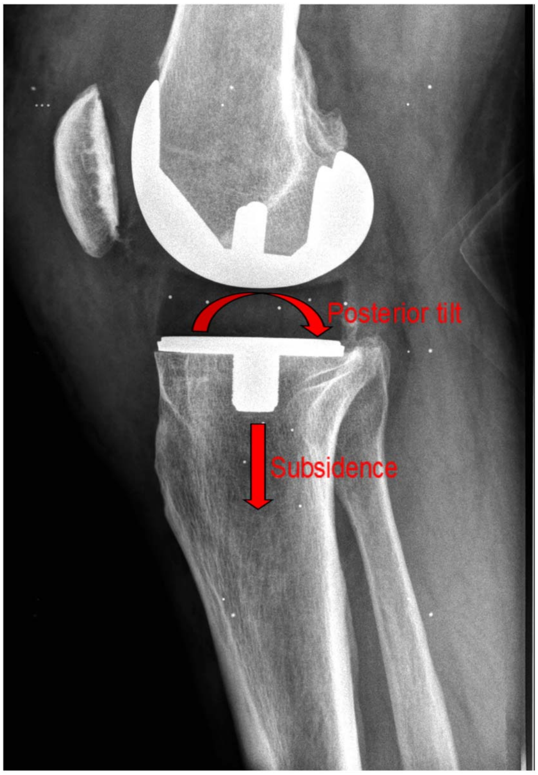

Fig. 1
A radiograph showing implant migration following cementless TKA. The arrows indicate the predominant migration directions of the cementless tibial component. Curved arrow = posterior tilt, straight arrow = subsidence.

recommended as an important part of the early evaluation of new orthopaedic prostheses[16].

In this exploratory study, we aimed to investigate the relationship between the migration of cementless tibial components and factors related to surgical technique, such as the sizing of the tibial component; the placement of the tibial component, including a lack of cortical bone support (i.e., the bone-shell in the epiphysis) on either side of the tibial component; and varus or valgus angulation. We hypothesized that tibial component undersizing and a lack of cortical bone support on either side of the tibial component would be related to higher degrees of migration and, specifically, to subsidence of the tibial component. We reasoned that undersizing of the cementless tibial component would result in a decreased and altered area of weight transfer in the trabecular bone of the proximal tibia.

Materials and Methods

We included 111 patients who underwent cementless TKA for primary osteoarthritis and who had completed 2-year follow-up with RSA data. All patients included had taken part in 1 of 2 prospective randomized clinical trials; the flowcharts for each trial have been presented in previous publications[11,17]. Patients received either the Vanguard Porous Plasma Spray (Zimmer Biomet), the Vanguard Regenerex (Zimmer Biomet), or the monoblock or modular version of the NexGen Cruciate Retaining Trabecular Metal Technology (Zimmer Biomet) cementless tibial component. All patients received a cruciate-retaining cementless femoral component and underwent patellar resurfacing with a cemented all-polyethylene patellar component. All operations were performed by experienced knee surgeons at the Clinic for Knee and Hip Replacement, Department of Orthopedics, Herlev-Gentofte Hospital, or at the Hørsholm Knee Clinic. All patients were <70 years old at the time of surgery and had no bone-related diseases other than osteoarthritis. All inclusion and exclusion criteria for the 2 randomized clinical trials were identical.

Postoperative radiographs were assessed by 2 experienced knee surgeons at different institutions who were blinded to the identity of the patient, the operating surgeon, the migration data, and the clinical outcome. The assessors were asked to judge the radiographs according to the following factors: tibial component size (undersized, fitted, or oversized), presence of cortical bone support (anterior, lateral, medial, and posterior support), frontal-plane alignment (varus, neutral, or valgus), and sagittal-plane alignment (less than, equal to, or greater than the planned posterior slope). A lack of cortical bone support was defined as the presence of a gap from the tibial component to the edge of the epiphyseal bone in the proximal tibia and the placement of the tibial component on the cut tibial surface.

Horizontal-plane alignment was not possible to evaluate from the radiographs. Varus and valgus angulation were assessed in relation to the tibial axis with use of anteroposterior radiographs. Sagittal alignment was assessed with use of lateral radiographs with reference to the planned posterior slope, which was 7° for all of the investigated components. Full-length lower-extremity radiographs were not available, and thus hip-knee-ankle angles could not be measured accurately.

RSA

The RSA was performed with use of marker-based software (UmRSA version 6.0; RSA Biomedical). We inserted 0.8-mm tantalum markers into the tibial host bone and 1-mm markers into the polyethylene. Markers were inserted using the same technique in similar grids in all patients. RSA radiographs were made at the Rigshospitalet Department of Radiology within 7 days postoperatively and after 3, 6, 12, and 24 months. Patients were positioned in a standardized supine position with the operative knee placed in a plexiglass biplane calibration cage (Calibration Cage 21; Tilly Medical Products). The same physician positioned the patients at each examination. Ceiling-mounted, portable x-ray tubes were positioned perpendicular in the anterior-posterior and medial-lateral planes at a distance of 100 cm from the films, which were placed in portable cassettes. The x-ray settings were 50 kV and 25 mAs for all examinations. All radiographs were approved by the same physician to ensure sufficient quality. The radiographs were digital, with 9 pixels per millimeter. The radiographs were imported into the UmRSA software with use of DICOM Link (version 3.0; RSA Biomedical) with a resolution of 254 dots per inch. To ensure the reliability of the migration results, the condition number cutoff was set at 130 and the mean error cutoff was set at 0.300 mm in accordance with general RSA guidelines[18].

Ethics

The prior studies were approved by the Scientific Ethical Committee of Copenhagen (H-1-2012-033 and H-3-2009-007). After written and oral information were provided, informed consent was obtained from all participants prior to their inclusion in the study. The present study was approved by the Danish Data Protection Agency (ID 01766, GEH-2012-027, 2009-41-3737).

Statistical Analysis

We investigated the relationship between surgical technique factors, such as the sizing and placement of the component, and tibial component migration by performing a multivariable linear regression analysis with maximum total point motion (MTPM), subsidence (negative y-axis translation), or posterior tilt (negative x-axis rotation) as the dependent variable and tibial component size; lateral, medial, anterior, and posterior cortical bone support; and malalignment as the independent variables. We refrained from excluding any variables from the statistical analysis in order to achieve the best-fitting model. The 4 included types of cementless tibial components were not differentiated in the statistical analysis. The unstandardized coefficient of regression (B), p value, coefficient of determination (R^2), and 95% confidence interval (CI) were calculated. Significance was set at $p < 0.05$.

Two experienced knee surgeons who were blinded to migration data and clinical outcomes assessed the size of the component and its placement in the tibia. One primary blinded assessment was utilized for the statistical analysis, and 1 secondary blinded assessment was utilized as a control to assess reproducibility. Interobserver agreement regarding the blinded assessments of the postoperative radiographs was evaluated by calculating the kappa value for each of the factors that the observers were asked to assess.

Source of Funding

No external funding was received for this study.

Results

Over the course of the 24-month follow-up period, the migration pattern of the cementless tibial component for all patients followed the expected migration pattern, with a relatively high initial migration (mean total MTPM after 3 months, 1.07 mm; standard deviation [SD], 0.57 mm). From 6 to 12 months postoperatively, the components stabilized, with an increase in the MTPM from a mean of 1.13 mm (SD, 0.56 mm) to a mean of 1.15 mm (SD, 0.58 mm). There was similarly little migration from 12 to 24 months postoperatively, with a mean MTPM of 1.21 mm (SD, 0.56 mm) after 24 months (Fig. 2-A). The predominant directions of migration were subsidence and posterior tilt, with most of the migration occurring during the first 3 postoperative months (Figs. 2-B and 2-C).

The results of the blinded radiographic assessments, including the number of patients assigned to each category by

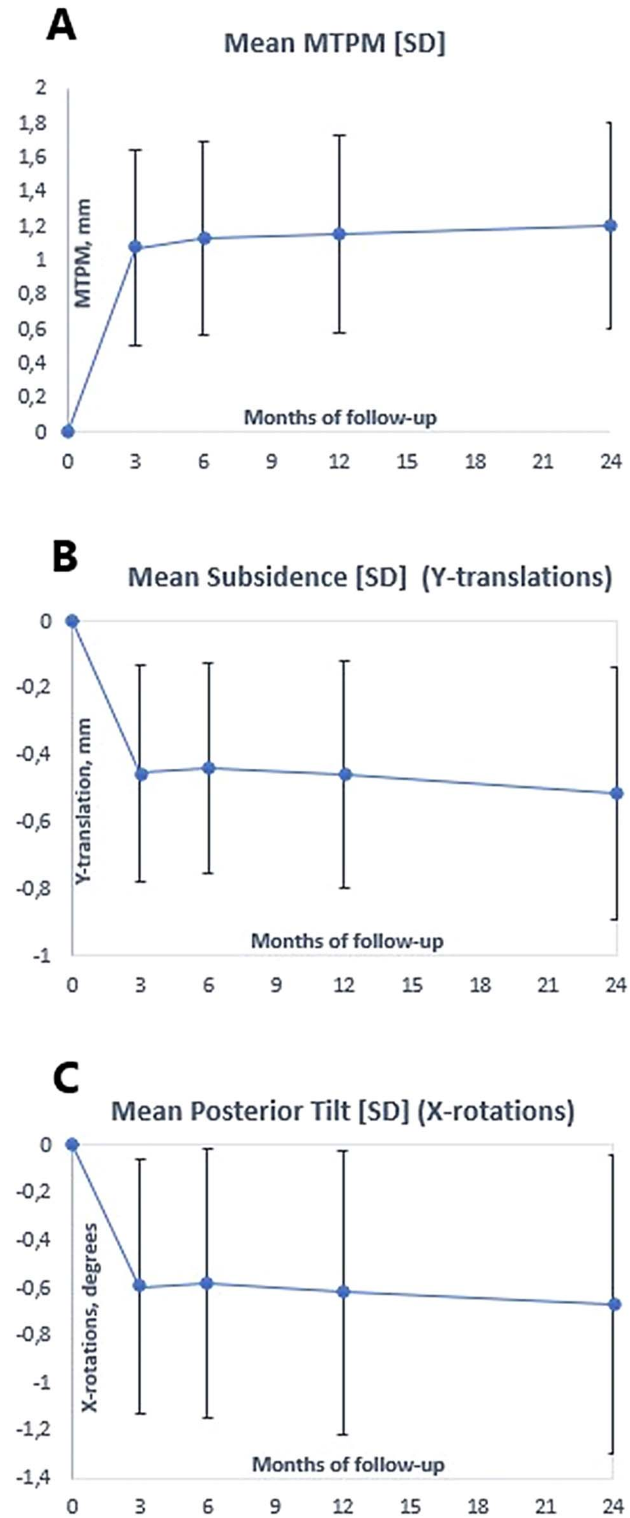

Fig. 2

Fig. 2-A The mean MTPM and standard deviation for the entire cohort during the 24-month follow-up period. **Fig. 2-B** The mean subsidence (negative y-axis translation) and standard deviation for the entire cohort during the 24-month follow-up period. **Fig. 2-C** The mean posterior tilt (negative x-axis rotation) and standard deviation for the entire cohort during the 24-month follow-up period.

TABLE I Interobserver Agreement and the Number of Patients Assigned to Each Category

Factor Assessed	No. of Cases: Primary Assessor	No. of Cases: Secondary Assessor	Kappa
Tibial component size			0.79
Undersized	31	35	
Fitted	69	69	
Oversized	11	7	
Posterior cortical bone support			0.52
Yes	83	67	
No	28	44	
Anterior cortical bone support			0.76
Yes	75	69	
No	36	42	
Lateral cortical bone support			0.69
Yes	100	100	
No	11	11	
Medial cortical bone support			0.63
Yes	93	81	
No	18	30	
Frontal malalignment			0.60
Varus	8	8	
Neutral	103	103	
Valgus	0	0	
Sagittal malalignment*			0.40
Posterior slope	13	22	
Correct slope	74	80	
Anterior slope	24	9	

*Posterior and anterior slopes were relative to the intended 7° of the postoperative posterior slope.

each assessor and the kappa value showing the amount of interrater variation for each factor, are presented in Table I. The kappa values for all assessed factors averaged 0.63 (range, 0.40 to 0.79), with the lowest kappa values found for sagittal malalignment and posterior cortical bone support of the tibial component and the highest kappa values found for tibial component size and anterior cortical bone support.

The results of the multivariable linear regression analysis of the relationship of each of the surgical technique factors to total migration (i.e., the MTPM from 0 to 24 months postoperatively) and continuous migration (i.e., the MTPM from 12 to 24 months postoperatively) are presented in Table II. Tibial component size was negatively associated with both total migration and continuous migration; that is, a smaller size of the tibial component relative to the host bone was associated with a higher degree of total and continuous migration (Table II).

Subsidence (negative y-axis translation) was significantly associated with tibial component size, posterior and lateral cortical bone support, and frontal-plane varus malalignment of the component (Table II). Continuous subsidence (negative y-axis translation from 12 to 24 months postoperatively) was not significantly associated with any variable.

Posterior tilt (negative x-axis rotation) was significantly associated only with tibial component size (Table II). Continuous posterior tilt (negative x-axis rotation from 12 to 24 months postoperatively) was not significantly associated with any variable.

None of the included patients underwent a revision TKA procedure during the 24-month follow-up period.

Discussion

The expected migration pattern for cementless components is an initial migration within the first 6 months that is relatively high compared with that of cemented tibial components followed by a stabilization period similar to that of cemented components[11,12,14]. Implants that do not achieve stabilization are considered at risk for aseptic loosening[10].

The findings of this study indicate that undersizing of the cementless tibial component results in poorer fixation, a higher degree of continuous migration, and increased subsidence and posterior tilt. Although this study was exploratory in nature, these findings could be of clinical importance. This cohort of 111 patients (111 cementless components) with 2 years of RSA follow-up represents a high-quality data set for investigating the relationship between surgical technique factors and implant migration, which could not have been done ethically and practically in a randomized setting.

In our experience, surgeons tend to undersize the tibial component in cases in which a perfect fit is not possible. This pattern was also evident in our study cohort, in which the 2 blinded observers assessed a total of 31 and 35 of 111 components as having been undersized and a total of 11 and 7 components as having been oversized (Table I). Undersizing the tibial component necessitates placing that component without sufficient cortical bone support on either or all sides of the component. In the cut surface of the tibia, compressive strength is highest in the lateral and medial periphery of the trabecular bone and is lowest in the central part of the trabecular bone. Therefore, in addition to reducing the area of weight distribution, undersizing also moves a greater part of the weight transfer to the weaker central bone[19,20]. The tendency for surgeons to undersize tibial components may be the result of several previous studies showing that tibial component oversizing and medial overhang are associated with postoperative pain and poor functional outcomes[21-23]. However, other studies have indicated that overhang is not associated with pain and poor function[24,25]. Undersizing may be especially undesirable in cementless TKA if the tibia is cut distal to the metaphyseal bone in order to compensate for erosion of the medial or lateral condyle of the tibia, as trabecular bone strength decreases substantially at ≥5 mm below the surface of the joint[20]. Bone strength is linearly correlated with bone mineral density, and a relationship between low tibial bone mineral density and high degrees of migration was demonstrated in a previous study of ours[26]. However, further research is needed to

TABLE II Results of the Multivariable Stepwise Regression Best-Fitting Model

	B	95% CI	P Value	R^2
Total migration ($MTPM_{0\text{-}24\ months}$), in mm				67%
Tibial component size	−0.72	−1.19 to −0.24	0.003	
Posterior cortical bone support	1.33	0.70 to 1.95	<0.001	
Anterior cortical bone support	0.18	−0.27 to 0.63	0.428	
Lateral cortical bone support	−1.49	−2.31 to 0.67	<0.001	
Medial cortical bone support	−0.51	−1.14 to 0.13	0.115	
Frontal malalignment	−0.57	−1.40 to 0.27	0.178	
Sagittal malalignment	0.13	−0.27 to 0.53	0.514	
Continuous migration ($MTPM_{12\text{-}24\ months}$), in mm				44%
Tibial component size	−0.21	−0.33 to −0.08	<0.001	
Posterior cortical bone support	0.05	−0.13 to 0.22	0.602	
Anterior cortical bone support	0.06	−0.06 to 0.18	0.350	
Lateral cortical bone support	−0.15	−0.37 to 0.07	0.172	
Medial cortical bone support	−0.11	−0.28 to 0.06	0.216	
Frontal malalignment	0.01	−0.21 to 0.23	0.961	
Sagittal malalignment	0.00	−0.10 to 0.11	0.949	
Total subsidence (negative y-axis translation), in mm				62%
Tibial component size	−0.37	−0.06 to −0.68	0.021	
Posterior cortical bone support	−0.69	−1.09 to −0.28	<0.001	
Anterior cortical bone support	−0.13	−0.43 to 0.17	0.376	
Lateral cortical bone support	0.83	0.29 to 1.37	0.003	
Medial cortical bone support	0.37	−0.05 to 0.79	0.081	
Frontal malalignment	0.64	0.12 to 1.16	0.017	
Sagittal malalignment	0.02	−0.25 to 0.28	0.912	
Total posterior tilt (negative x-axis rotation), in degrees				36%
Tibial component size	0.57	0.27 to 1.11	0.007	
Posterior cortical bone support	−0.36	−1.16 to 0.44	0.376	
Anterior cortical bone support	−0.29	−0.87 to 0.30	0.339	
Lateral cortical bone support	−0.00	−1.07 to 1.06	0.994	
Medial cortical bone support	0.16	−0.67 to 0.99	0.699	
Frontal malalignment	0.11	−0.92 to 1.14	0.837	
Sagittal malalignment	0.10	−0.43 to 0.62	0.715	

account for the relationship between bone mineral density and body mass index in this patient group.

In our experience, an undersized tibial component or a tibial component that fits in the coronal plane but not in the sagittal plane will most often be placed closer to the anterior cortex than to the posterior cortex because that is surgically easier; however, the supporting cortical bone is strongest in the posterior regions[19,20].

Newer TKA systems provide a wider selection of component sizes and shapes than older systems, which should improve the possibility for exact component sizing. However, when the ideal tibial component size is unavailable, it is important for surgeons to consider that undersizing the tibial component increases the risk of poor fixation, as demonstrated in the present study.

Limitations

This was a retrospective exploratory study performed with use of data from separate randomized clinical trials. The study population was insufficiently sized to detect a relationship between tibial component size and clinical or patient-reported outcomes. As such, larger studies are needed to investigate these potential relationships. ■

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