



Initial stability of tibial components in primary knee arthroplasty. A cadaver study comparing cemented and cementless fixation techniques

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The purpose of this roentgen stereophotogrammetric analysis (RSA) study was to evaluate the initial stability of cemented and cementless tibial components *in vitro*. Twenty tibia specimens were matched into two groups. In the first group, the tibial trays were cemented superficially and in the second group cementless fixation with stem and screws was performed. An axial load of 2000 N for 1000 and 10,000 cycles was applied onto the specimens and RSA was performed. The experimental results after 1000 cycles showed a higher migration with significant differences for the parameters maximum lift off ($p = 0.011$) and maximum total point motion ($p = 0.002$) in the cementless group. After 10,000 cycles, the migration in the cementless group increased significantly for maximum lift off ($p = 0.043$), maximum subsidence ($p = 0.045$) and maximum total point motion ($p = 0.013$). The higher migration rates in the cementless group demonstrate a lower initial mechanical stability of cementless tibial components which can cause an early component loosening.

Keywords: total knee arthroplasty ; radiostereometry ; cementing technique ; migration ; tibial component loosening.

INTRODUCTION

Total knee arthroplasty (TKA) is a proven and well-established treatment for advanced degenerative joint disease of the knee with survival rates of 90 to 95% at 10 to 15 years (9,24,27,44). In the recent decades, there has been a great debate about cemented versus cementless fixation of

TKA (6,25,13,32). Cemented TKA has generally shown good long-term clinical outcomes. It is commonly understood that cement represents a weak interface (29,15,50). Freeman *et al* (16) demonstrated that cement has weak resistance to tension and shear forces. It has been shown that cement deforms and degrades over the years (19). To improve the long-term survival of the implants and eliminate the disadvantages of cement – especially in younger patients – cementless fixation in TKA has been developed. It was hypothesized that a more physiological and successful integration of the bone and implant would result in enhanced long-term results (31). One of the major problems concerning cementless TKA is the early migration – particularly of the

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tibial component - due to micromovement between the bone and the implant (12). It is known that the longevity of cementless tibial implants depends on the initial fixation stability (7). Several studies showed that relative implant movement of 150 μm or more between the bone and the implant can inhibit bone ingrowth and hence biologic fixation, whereas relative movement of 40 μm or less improves implant stability by encouraging bone ingrowth (40,41,52). Examinations using radiophotostereogrammetric analysis (RSA) found lower migration of cemented compared with cementless tibial components (10,38). Contrary to these findings, Nilsson *et al* (37) did not find any difference in migration between cemented and cementless tibial components.

There are many designs of cementless TKA showing good long-term success, nearly equal to the results of cemented implants. Schroder *et al* (49) investigated the clinical and radiographic outcome of a cementless, porous-coated TKA with a survival rate of 97% at 10 years.

The controversy regarding the fixation of TKA still continues. The critical factor for the bone ingrowth is the initial mechanical stability of the implant. The aim of the present cadaver study was to investigate the hypothesis that the initial stability of cementless tibial components can achieve results comparable to those of superficially cemented fixation of tibial components under axial loading.

MATERIAL AND METHODS

Twenty fresh-frozen tibiae from donors with macroscopic and radiological evident osteoarthritis of the knee were used. The mean age of the donors was 79.6 years (SD \pm 9.4). The specimens were matched into two groups according to gender, age and tibia dimension, 10 specimens per group. To exclude osseous abnormalities and lesions, an initial radiograph was taken. No abnormalities of the tibia specimens used were evident. Afterwards, the implantation technique was randomized to each group. Prior to osseous preparation of the proximal tibia, all soft tissues and the fibula were removed. The original cemented and cementless tibial tray design of the Genesis II total knee arthroplasty system (Smith&Nephew, Schenefeld, Germany) was used. Tibia specimens were prepared according to standard manu-

facturer's guidelines with the original Genesis II instruments for cemented and cementless implants. After assembling the extramedullary tibial alignment guide in correct rotation, the cutting block was positioned using the primary tibial stylus touching the less affected side of the tibia. The depth of the proximal tibial cut amounted to 8 mm with a posterior slope of 3°. In the cemented group the superficially cementing technique was applied (the tray was cemented, the stem was not). After preparation of the osseous bed, the tibiae were cleaned by pulsed jet-lavage (InterPulse Jet Lavage, Stryker, Duisburg, Germany) to open up the cancellous spaces and thus optimize cement penetration into the trabecular bone of the tibial metaphysis. After drying of the implantation surface, the original tibial tray was cemented in standardized technique with the bone cement Palacos R+G (Heraeus, Wehrheim, Germany). For best cement quality and avoidance of cement inconsistency, cooled cement, previously stored at 4°C, was prepared with the vacuum EASYMIX system (Heraeus, Wehrheim, Germany) and a vacuum pump. Subsequently, the cement was applied with an EASYMIX cement gun on the undersurface of the tibial tray with cement coating thickness of approximately 4-6 mm. Finally the original Genesis II tibial tray (Genesis II, Smith&Nephew, Schenefeld, Germany) was impacted into the prepared osseous bed using a mallet and an impactor handle and fixed with a continuous pressure for 15 minutes.

For cementless implantation, the cementless Genesis II tibial tray design was used. This porous-coated component has four pegs, an adapter for a stem as well as four holes for screws. After preparation of the osseous bed, the original cementless tibial component with a compatible keeled cementless stem was inserted and fixed with four 6.5 mm titanium screws in the tibia epiphysis. After the implantation of the cemented and cementless implants, the distal third of the tibiae was osteotomized and discarded.

Testing Apparatus and Radiophotostereogrammetry

To perform the radiostereogrammetric analysis, a minimum of eight spherical tantalum markers (diameter: 1.0 mm) were spirally and randomly inserted into the proximal tibia using a special applicator. Furthermore the polyethylene insert was marked with seven tantalum markers using a defined technique and arrangement. To avoid marker dislocation in the polyethylene inlay the inserting channel was closed with heated polyethylene. Finally, the polyethylene inlay was inserted on the tibial tray using the manufacturer's inserter.

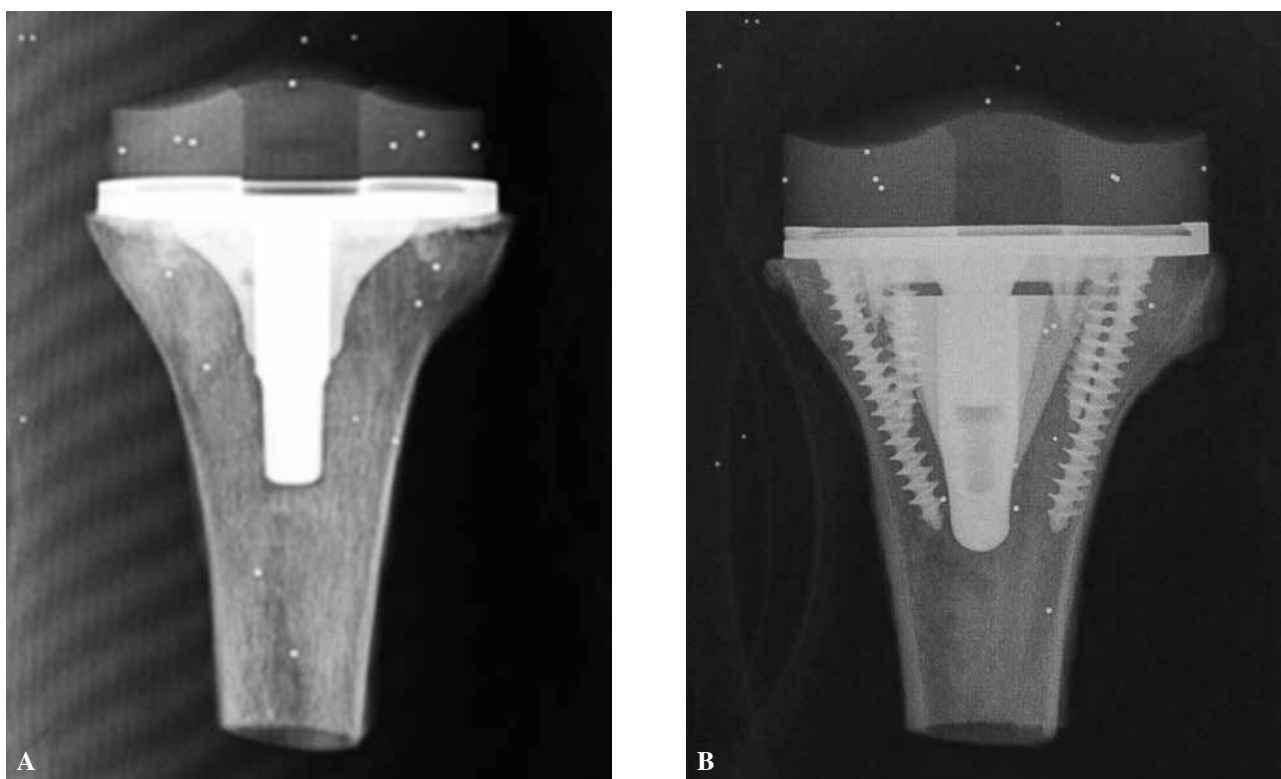


Fig. 1. — A : Standard anteroposterior postoperative radiograph of surface cemented tibia specimen with a polyethylene inlay in RSA technique ; B : Standard anteroposterior postoperative radiograph of cementless tibia specimen with a polyethylene inlay in RSA technique.

Initial RSA radiographs were taken before the specimens were exposed to cyclic load (Fig. 1). Afterwards, the polyethylene inlay was removed and the tibial specimen was mounted in a special bowl, which could be fixed in a computer-controlled universal testing machine (81806-EDC-100, Frank, Weinheim, Germany). All specimens were tested with an axial load of 2000 N, which represents approximately three times body weight of a 70-kg patient, i.e. the approximate peak load during normal walking (34). No rotation or angular stress was applied to the tibial component.

The tibial specimen was exposed to 1000 and 10.000 load cycles with a load frequency of 1 Hz. RSA analysis was performed before loading, to establish the baseline position, after 1000 and 10.000 load cycles. The load transfer was carried out on the main weight bearing zone on the tibial tray using a dedicated tool, which could be adjusted to the dimension of the tibial tray. During the whole testing procedure, the test specimens were moistened with 0.9% sodium chloride solution.

Radiostereogrammetric analysis

Radiographs were taken in a standardised way in neutral position in two planes. For the radiographs and analyses the tibia specimen was mounted in a Plexiglass-Cage (RSA BioMedical, Umeå, Sweden) with incorporated tantalum markers at defined positions. Radiographs were acquired simultaneously with two x-ray tubes arranged in orthogonal position (Multix Up, resp. Vertex, Siemens AG, Forchheim, Germany). X-ray images were digitized with an AGFA ADC Compact (Agfa HealthCare, Cologne, Germany) and exported for further evaluation to the RSA software (RSA-CMS, Medis, Leiden, Netherlands).

The values examined for radiostereogrammetric analysis were maximum total point motion (MTPM), maximum subsidence (MaxSub), maximum lift off (MaxLiftOff), maximum translation (Transl) and maximum rotation (Rot) along the x-, y- and z-axes. Negative translation along the y-axis corresponds to subsidence

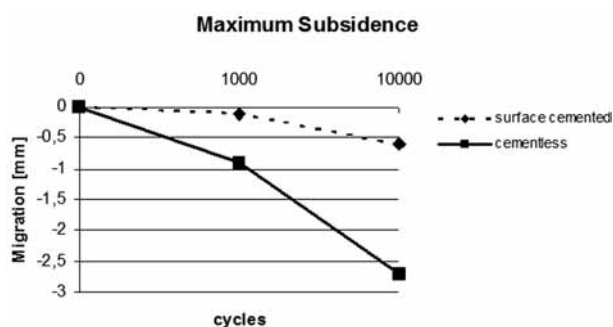


Fig. 2. — Migration of cementless and superficially cemented tibia component representing Maximum Subsidence (MaxSub).

and positive translation along the y-axis to lift off (34,36) described by Adalberth *et al*(1). The accuracy of the RSA method is 0.1 mm for subsidence and lift off, and 0.1° for rotations along the axes. A motion of the tibial tray of more than 2 mm was defined as failure.

Statistical analysis

All data collected were analyzed using a commercially available software package (SPSS for Windows, 11.0, SPSS Inc., Chicago, IL, USA). The nonparametric Wilcoxon signed-rank test was used for the comparison of migration. The results are expressed as medians and 25% and 75% percentiles. Significance was determined at p-values of 0.05. Comparison of failures was made with the Fisher's exact test.

RESULTS

Ten tibial specimens per group of cemented and cementless tibial component fixation were tested. All tested specimens could be used for final radiostereogrammetric analysis. In the cementless group the median maximum subsidence after 1000 cycles was -0.5 mm (25% percentile : -1.7 ; 75% percentile : -0.2) and increased to -2.5 mm (25% percentile : -4.5 ; 75% percentile : -1.0) after 10,000 cycles. Median maximum lift off was 0.9 mm (25% percentile : 0.4 ; 75% percentile : 1.1) after 1000 cycles and increased to 1.3 mm (25% percentile : 0.1 ; 75% percentile : 2.1) after 10,000 cycles. Maximum total point motion increased from 2.8 mm (25% percentile : 1.2 ; 75%

percentile : 4.0) at 1000 cycles to 5.9 mm (25% percentile : 0.8 ; 75% percentile : 8.6) at 10,000 cycles. In the comparison of all parameters after 1000 and 10,000 cycles, there were no significant differences. In the superficially cemented group, the median maximum subsidence after 1000 cycles was 0.0 mm (25% percentile : -0.3 ; 75% percentile : 0.0) and decreased to -0.1 mm (25% percentile : -1.2 ; 75% percentile : 0.1) after 10,000 cycles. Median maximum lift off was 0.0 mm (25% percentile : 0.0 ; 75% percentile : 0.2) after 1000 and 10,000 cycles. Maximum total point motion increased from 0.2 mm (25% percentile : 0.1 ; 75% percentile : 0.5) at 1000 cycles to 1.3 mm (25% percentile : 0.2 ; 75% percentile : 0.0) at 10,000 cycles. The statistical analysis for this group also did not show significant differences between the migration parameters. Comparing cemented versus cementless tibial fixation after 1000 cycles, the cementless group showed higher migration with significant differences for the parameters maximum lift off ($p = 0.011$) and maximum total point motion ($p = 0.002$). After 10,000 cycles, the cementless group revealed an increased migration and the statistical analysis detected significant differences for the parameters maximum lift off ($p = 0.043$), maximum subsidence ($p = 0.045$) and maximum total point motion ($p = 0.013$) (Table I, Fig. 2, 3 & 4).

Evaluation of motion of the tibial tray revealed that a motion of more than 2 mm (defined as failure) occurred in the group with superficially cementing technique in two cases. In the cementless group failure was observed in eight cases. Statistical evaluation with chi-square test according to Pearson showed a significant difference between the two groups ($p = 0.007$).

DISCUSSION

The finding of the present study was that cementless fixation of the tibial component in TKA showed a significantly inferior initial stability compared to the superficially cemented tibial component *in vitro*.

As a result of excellent long-term survival rates, cemented TKA seems to be the gold standard (5,42,43,45,54). The tibia is the critical compo-

Table I. — RSA results of tibial component migration for cementless and superficially cementing technique tested with an axial load of 2000 N after 1000 and 10,000 cycles for the following parameters : MTPM : maximum Total Point Motion, MaxSub : Maximal Subsidence, MaxLiftOff : maximum Lift Off, Transl : Translation along the labeled axes x-y-z in mm, Rot : Rotation along the labeled axes x-y-z in degree

	Cementless				Surface cementing				p-value 1.000	p-value 10.000
	1000 cycles		10,000 cycles		1000 cycles		10,000 cycles			
	median	percentile 25/75	median	percentile 25/75	median	percentile 25/75	median	percentile 25/75		
MTPM [mm]	2.8	1.2/4.0	5.9	0.8/8.6	0.2	0.1/0.5	0.5	0.1/0.9	0.002	0.013
MaxSub [mm]	-0.5	-1.7/-0.2	-2.5	-4.5/-1.0	0.0	-0.3/0.0	-0.1	-1.2/-0.1	0.055	0.045
MaxLiftOff [mm]	0.9	0.4/1.1	1.3	0.1/2.1	0.0	0.0/0.2	0.0	0.0/0.2	0.011	0.043
Transl_x [mm]	0.3	0.0/1.3	-1.1	-2.7/0.7	0.1	0.0/0.2	0.0	0.0/0.3	0.328	0.369
Transl_y [mm]	-0.2	-0.5/0.7	-0.7	-3.2/0.8	0.0	0.0/0.0	0.1	0.0/0.3	0.328	0.141
Transl_z [mm]	0.0	-0.4/0.5	-0.4	-5.0/1.6	0.0	0.0/0.0	0.0	0.0/0.2	0.722	0.141
Rot_x [°]	0.7	0.0/0.9	-0.1	-2.5/3.0	0.0	0.0/1.1	0.4	0.1/1.6	0.657	0.288
Rot_y [°]	0.8	0.0/2.3	-0.6	-12.0/3.0	0.1	0.0/0.2	0.1	0.0/0.5	0.155	0.624
Rot_z [°]	-0.3	-1.5/0.4	0.7	-0.6/4.4	0.0	0.0/0.1	0.1	0.0/0.5	0.076	1.000

RSA results of tibial component migration for cementless and superficial cementing technique tested with axial load of 2000 N, after 1000 and 10,000 cycles for the following parameters : MTPM : maximum total point motion, MaxSub : maximal subsidence, MaxLiftOff : maximum Lift Off, Transl : Translation along the labeled axes x-y-z in mm, Rot : Rotation along the labeled axes x-y-z in degree.

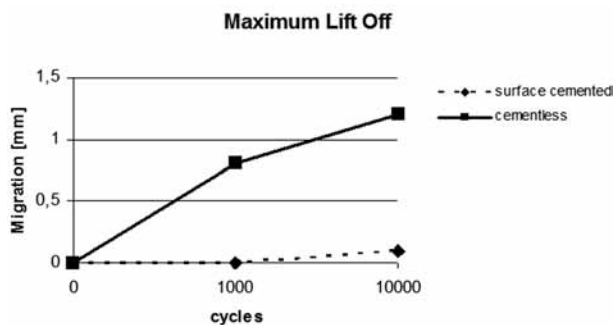


Fig. 3. — Migration of cementless and superficially cemented tibial component representing Maximum Lift Off (MaxLiftOff).

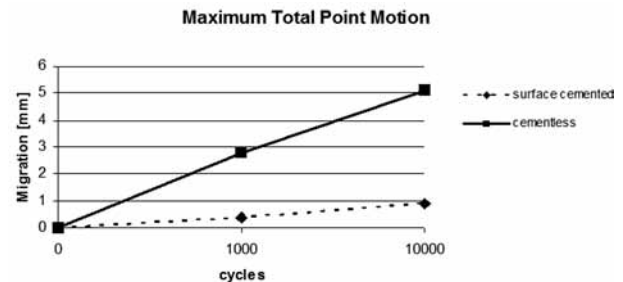


Fig. 4. — Migration of cementless and superficially cemented tibia component representing Maximum Total Point Motion (MTPM).

ment to any total knee arthroplasty and loosening of the tibial component is the major problem in TKA (18,51). The debate about cemented versus cementless fixation of the tibial component still continues. Cementless fixation of the implant was introduced in the 1980s for younger patients. Postulated advantages of this fixation technique were minimizing operation time, avoidance of “cement disease” and of cement removal at time of

TKA revision. However, cementless fixation in TKA has shown inadequate results in the past. Loosening rates of cementless implants were reported up to 8-15% excluding revisions caused by patellar complications (13,5,39). Freeman *et al* (17) reported 1.6% tibial failure rate with the Freeman-Samuelson design in the first four years. The reason for the failure of the first-generation cementless TKA was insufficient initial mechanical stability

with a limited osseointegration which caused increased lift-off and subsidence of the implant (32).

To achieve a more stable cementless fixation and increase the osseointegration of the tibial tray, stems, keels, pegs and posts combined with screws were introduced (12,23,28). Kraemer *et al* (26) showed in a cadaver study a reduced micromotion of Genesis tibial trays using stems and screws. The aim of this fixation was to achieve a micromotion lower than 150 μm , because larger micromotion interferes with bone ingrowth. However, the results of these modifications did not reveal the expected success of an increased stability of the tibial component. In several studies particularly the loosening of the tibial component caused increased postoperative problems and early revisions (17,4,30,55,56). Berger *et al* (5) investigated a series of 102 patients with 131 cementless Miller-Galante-I total knee arthroplasties with screw augmentation and documented an 8% aseptic loosening rate of the tibial component.

Ryd *et al* (47) could demonstrate in an RSA investigation with two years follow-up a twofold higher migration for cementless tibial components compared to the cemented implants. These findings on early implant migration could be confirmed in further RSA studies (56). Fukuoka *et al* (18) noted in an RSA study that cementless implants showed continuous migration of the tibial component during the first three to six months and then became stable.

However, in the literature there are some cementless TKA designs reaching results comparable to cemented fixation (9,21,22,49). Baker *et al* (3) could not demonstrate a significant difference between the cementless versus cemented fixation technique in total knee replacement. One reason for their results may be caused by the modification of the contact surface between bone and implant especially due to highly porous metal and hydroxyapatite coated implants which should improve an osseous ingrowth. Soballe *et al* (53) compared in a RSA study cementless implants coated with hydroxyapatite versus titanium alloy without hydroxyapatite. They noted that implants coated with hydroxyapatite showed significantly less migration after 12 months. Gejo *et al* (20) compared cementless titanium-porous coated TKA fixed with additional

screw fixation and hydroxyapatite-tricalcium phosphate coated components with screwless fixation. They documented that implants coated with hydroxyapatite promote osseointegration. Epinette and Manley (14) demonstrated a 99.2% survival rate of hydroxyapatite-coated cementless TKA components at a mean of 11.2 years. Contrary to these findings, Moran *et al* (33) noted failure of the tibial component using a cementless porous-coated total knee replacement in 19%.

A reason for the increased migration of the cementless tibial components seems to be the initial load causing an insufficient osseous ingrowth of the implant, thus generating soft tissue at the bone-implant interface. To prevent motion of the implant in its bony bed in the initial phase and enhance osseous ingrowth, patients with a cementless implant should avoid full weight bearing in the first six weeks. However, Branson *et al* (8) demonstrated that motion between the bone and the implant can already be noted by load occurring during knee movement without weight-bearing.

These results could be confirmed by the present study. The cementless group showed considerable migration for MTPM, maximum subsidence and maximum lift off after 1000 cycles. After 10,000 cycles the tibial fixation showed a progressive migration which can be assessed as reflecting persistent unstable fixation. The migration of the tibial components in this study is comparable to the available investigations. Albrektsson *et al* (2) investigated in a randomized study the tibial component fixation of Freeman-Samuelson prostheses and demonstrated that cement augmentation significantly reduced the migration one year after operation for the maximum total point-motion of 1.5 to 0.5 mm, and also significantly reduced subsidence. Similar findings were reported by Ryd *et al* (48). They studied the migration of porous coated anatomic TKA's in 20 cases and noted that the use of cement significantly reduced the migration one year after operation for maximum total point-motion from 1.9 to 0.8 mm. Carlsson *et al* (11) have noted maximum rotation around the x- und y-axis, in contrast to maximum rotation around the y-axis in our findings. An explanation for this better stability could be the osseointegration of the implant

which could not be simulated under *in vitro* conditions in the present study. In our study, eight cementless tibial components and two cemented components showed migration of more than 2 mm which was defined as failure. This increased migration could be caused by the exclusively metaphyseal fixation. Stern *et al* (54) reported that implants with longer stems were associated with increased micromotion. Even though Yoshii *et al* (57) noted that long stems could reduce subsidence and lift-off in cementless TKA, further investigations concerning an advantage of metaphyseal fixation techniques of cementless implants were needed.

A limitation of the present study is a reduced sensitivity of RSA for movements less than 0.2 mm (46). In contrast to other *in vitro* studies that used more sensitive measuring devices, this experimental set-up allows comparisons to available clinical studies as well as planning of further clinical investigation to evaluate this topic. A second critical aspect is the age and bone density of the specimens used. To minimize the bias of bone quality the specimens were matched into two groups according to gender, age and tibia dimension. Furthermore, an initial radiograph of the tibia specimen excluded abnormalities and osseous lesions of the bone or an evident osteopenia. This procedure enhanced the consistency of the groups. At last we randomised the fixation technique to both groups to prevent a systemic bias. However, considering the aging population and the increasing numbers of TKA's performed, it is realistic to perform TKA in elderly patients as was done in this investigation. The usage of cadaveric bone for this investigation may be a further critical aspect.

The aim of the present study was to compare the initial stability of cementless versus superficially cemented tibial components using the RSA technique. We noted that cementless fixation shows higher mean maximum lift off, mean maximum subsidence and maximum total point motion as well. In the cementless group, the number of cases defined as unstable showing a migration of the tibial tray greater than 2 mm was also higher. The findings of the present study cannot support the hypothesis that the initial stability under axial loading achieved with cementless fixation can give

results comparable to those of cemented fixation. Nevertheless, recently developed biomaterials seem to improve the initial stability of cementless fixation. Therefore, further clinical studies with long term follow-up as well as comparing cementation of the tibial tray only with cementation of the tray and the stem are required to determine the best fixation technique.

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