Migration of a novel 3D-printed cementless versus a cemented total knee arthroplasty: two-year results of a randomized controlled trial using radiostereometric analysis

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Aims
Although bone cement is the primary mode of fixation in total knee arthroplasty (TKA), cementless fixation is gaining interest as it has the potential of achieving lasting biological fixation. By 3D printing an implant, highly porous structures can be manufactured, promoting osseointegration into the implant to prevent aseptic loosening. This study compares the migration of cementless, 3D-printed TKA to cemented TKA of a similar design up to two years of follow-up using radiostereometric analysis (RSA) known for its ability to predict aseptic loosening.

Methods
A total of 72 patients were randomized to either cementless 3D-printed or a cemented cruciate retaining TKA. RSA and clinical scores were evaluated at baseline and postoperatively at three, 12, and 24 months. A mixed model was used to analyze the repeated measurements.

Results
The mean maximum total point motion (MTPM) at three, 12, and 24 months was 0.33 mm (95% confidence interval (CI) 0.25 to 0.42), 0.42 mm (95% CI 0.33 to 0.51), and 0.47 mm (95% CI 0.38 to 0.57) respectively in the cemented group, versus 0.52 mm (95% CI 0.43 to 0.63), 0.62 mm (95% CI 0.52 to 0.73), and 0.64 mm (95% CI 0.53 to 0.75) in the cementless group ($p = 0.003$). However, using three months as baseline, no difference in mean migration between groups was found ($p = 0.497$). Three implants in the cemented group showed a > 0.2 mm increase in MTPM between one and two years of follow-up. In the cementless group, one implant was revised due to pain and progressive migration, and one patient had a liner-exchange due to a deep infection.

Conclusion
The cementless TKA migrated more than the cemented TKA in the first two-year period. This difference was mainly due to a higher initial migration of the cementless TKA in the first three postoperative months after which stabilization was observed in all but one malaligned and early revised TKA. Whether the biological fixation of the cementless implants will result in an increased long-term survivorship requires a longer follow-up.

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Introduction
Although total knee arthroplasty (TKA) has a history of approximately 50 years, no consensus has been reached regarding the optimal fixation method. Cement fixation is the most common method, as reflected in national registries.[1-3] However, cementless fixation is gaining interest as it preserves bone stock, avoids cement debris, and has the potential of achieving lasting biological fixation of the prosthesis to the bone.[4] Early cementless implants had poor survival and high revision rates but these results were mainly due to design flaws.[5] In the last decade, new designs, coatings, and porous metals have been developed in an effort to overcome these problems and to facilitate bone ingrowth into the prosthesis.[4]

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Another method to facilitate bone ingrowth is the application of 3D printing techniques[6] which allows the manufacturing of highly porous implants which could mimic the stiffness and elasticity of bone.[7]

Several meta-analyses reported comparable survival and clinical outcomes of cementless and cemented TKA.[8-10] One meta-analysis found superior survival of cemented TKA, but this difference was diminished when only randomized controlled trials (RCT) were included in the analysis.[11] In addition, cementless TKA have shown promising results in studies using radiostereometric analysis (RSA).[12-14] RSA has the ability to measure micromotion of an implant and predict mechanical loosening as early as two years postoperatively.[15-17] High initial migration and continuous migration is associated with early loosening of the implant, making RSA an effective tool for the evaluation of new implants.[15-17] RSA studies reported that cementless implants typically show early migration in the first postoperative year (settling phase), after which stabilization is achieved[13,18,19] which remains evident ten years postoperatively.[14,20,21] By 3D printing a prosthesis with highly porous metal, cementless fixation might be enhanced due to the ingrowth of bone into the prosthesis and initial migration could be reduced to a level comparable to cemented TKA. To date, no RCT using RSA has evaluated the migration of a novel cementless TKA with a 3D-printed highly porous metal called Tritanium (Stryker, Allendale, New Jersey, USA).

The aim of this RCT is to compare the cementless, 3D-printed Tritanium TKA with its cemented counterpart using RSA and clinical outcomes. The hypothesis is that the cementless TKA will be as stable as the cemented TKA during the two-year follow-up.

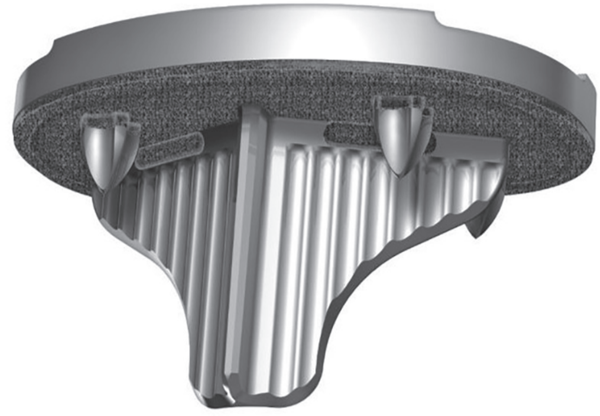


Fig. 1

Illustration of the 3D-printed, cementless tibial baseplate (Tritanium, Stryker, Mahwah, New Jersey, USA).

Methods

This RCT was conducted in the Hässleholm Hospital (Sweden) between October 2015 and October 2016. A total of 72 patients were randomized to either cementless Tritanium Triathlon Cruciate Retaining TKA or cemented Triathlon Cruciate Retaining TKA (Stryker, Warsaw, Indiana, USA). Inclusion criteria were osteoarthritis Ahlbäck[22] stages II to IV, and males or non-pregnant females aged between 40 and 75 years, who had given informed consent. Exclusion criteria were a body mass index (BMI) > 38 kg/m², a bilateral operation, or a neuromuscular/neurosensory deficiency. Randomization was done by means of a computer-generated list using a blocked randomization scheme in a 1:1 ratio. To ensure concealment of treatment allocation, envelopes with randomization were opened just before surgery. Patients remained blinded to the treatment allocation during the study.

The prostheses were identical in geometrical shape except for the addition of 3D-printed in-growth foam, and four pegs onto the under-surface of the tibial baseplate in the cementless group to provide additional stability (Figure 1).[23] The femoral component was press-fit and periapatite coated in the cementless group. Smartset GHV bone cement (DePuy CMW; DePuy Synthes, Blackpool, UK) was used in the cemented group, leaving the tibial keel cementless in all cases. Both groups showed similar tibial preparation and the same jig was used. Patellae were reshaped but not resurfaced, and no tourniquet was used during surgery in both groups. The operation was performed according to the device-specific surgical protocol by a single experienced orthopaedic knee surgeon (STL). Both groups had identical postoperative treatments and follow-up.

The primary outcome measure was migration over the first two years measured by RSA. Migration was expressed as the Maximum Total Point Motion (MTPM), which estimates the length of the translational vector with the greatest migration along or about the transverse, longitudinal, or sagittal axis.[24] Secondary outcome measures were migration from three months onwards, the Knee Society Score[25] (KSS), the Knee Injury and Osteoarthritis Outcome Score[26] (KOOS), and the Forgotten Joint Score[27] (FJS). These scores were collected preoperatively and at three months, one year, and two years postoperatively. All scores ranged from 0 to 100 with higher scores indicating better outcomes.

Eight spherical tantalum beads (ø 0.8 mm; RSA Biomedical, Umeå, Sweden) were inserted into the tibia, and five beads were implanted in the polyethylene of the tibial insert in fixed positions to facilitate the RSA measurements. RSA radiographs were taken with a biplanar technique in a 90° angle (Cage 10, RSA Biomedical, Umeå, Sweden) with the patient supine. These radiographs were taken within two days postoperatively, and after three months, one year, and two years. Double examinations were made at one-year follow-up to determine the precision of the RSA measurements, which is expressed as the SD of the migration of these two subsequent RSA radiographs.[24] Long-leg standing anteroposterior radiographs were taken preoperatively and one-year postoperatively. The hip-knee-ankle angle was measured by a single observer (SH) using a standardized protocol.[28]

The RSA radiographs were analyzed using Model-Based RSA (RSAcore, Leiden, Netherlands) following the RSA guidelines.[24] All measurements were corrected to the right side.[29] Implants with > 0.2 mm MTPM between one- and two-year postoperatively were classified as 'continuously migrating' and considered at greater risk for aseptic loosening.[17] A marker

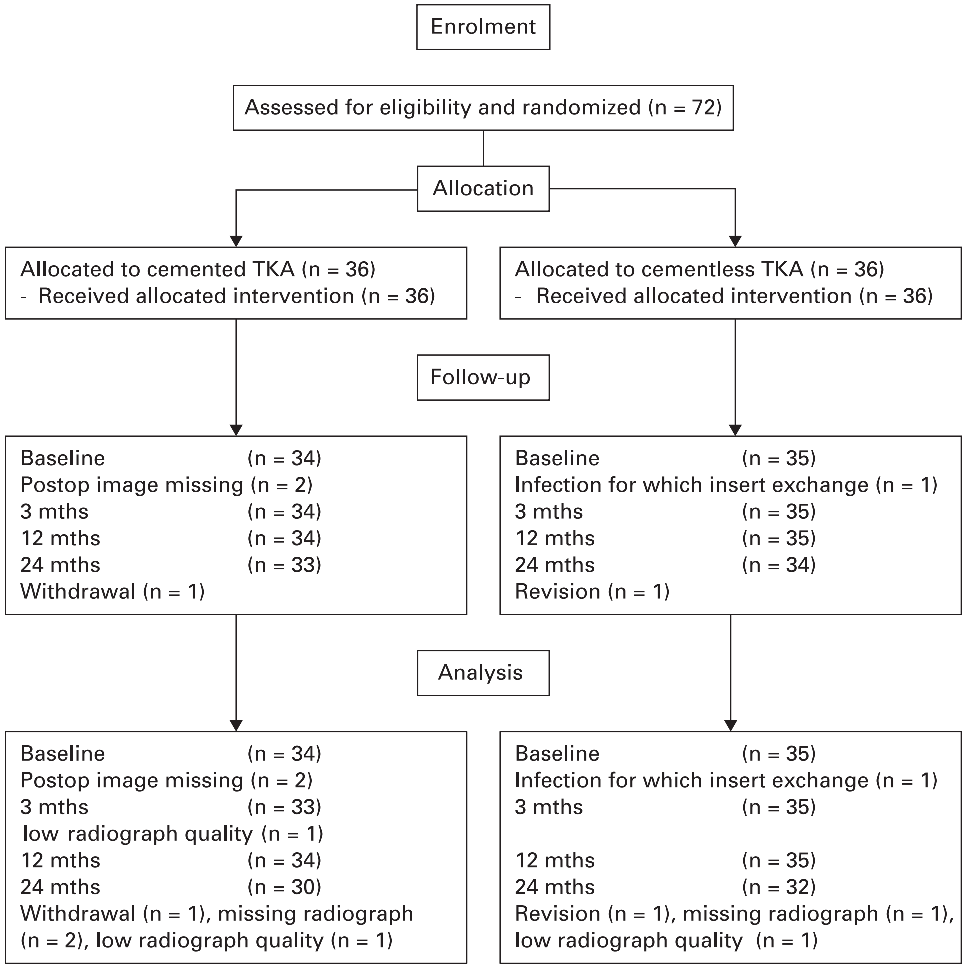


Fig. 2

Consort flowchart. TKA, total knee arthroplasty.

configuration model was constructed in case markers were occluded by the metal implants.[30]

Statistical analysis. In a noninferiority study set-up, 23 subjects are needed for each group assuming a mean MTPM of 0.62 mm with SD 0.15 mm, and study power 80%.[31] The two-sided 95% confidence interval (CI) will then exclude a difference beyond the 0.13 mm measurement error of the RSA-setup in MTPM.[31,32] To compensate for patients with inadequate marking and for loss to follow-up, 36 patients were recruited per study group. Migration and clinical scores were compared between groups using a linear mixed-model. This model deals effectively with missing data and takes the within-subject correlation into account.[33,34] The model consisted of a group variable, a time variable, and an interaction term between the time and group variable with a random intercept. MTPM was transformed using a logarithmic transformation to obtain a Gaussian distribution. The presented values were back-transformed to the original scale. The same analysis was repeated using the three-month measurements as baseline, to assess whether groups differed in migration after the settling phase. A post-hoc analysis was conducted to include any patient characteristics unevenly distributed by chance. A p-value < 0.05 was considered statistically significant. Analyses were performed using SPSS v. 25 (IBM, Armonk, New York, USA).

This study was approved by the Regional Ethical Review Board in Lund (entry no. 2015/8), was registered at clinicaltrials.gov (NCT02578446), and was conducted according to the CONSORT statement.[35] All patients provided informed consent. This study was funded by Stryker but they had no part in the design, conduct, analysis, and interpretations stated in this paper.

Results

Of the 72 patients, two patients had missing baseline radiographs in the cemented group and could not be included in the analyses. In addition, the insert of one patient in the cementless group was exchanged to treat an infection three weeks postoperatively. As the markers were inserted in the polyethylene insert, no marker-based analysis could be performed for this patient after removal of the insert. As a result, 34 patients in the cemented and 35 patients in the cementless group were available for analysis (Figure 2). During follow-up, one patient

Table I. Baseline characteristics.

Characteristic	Cemented (n = 34)	Cementless (n = 35)
Mean age, yrs (SD)	66 (6.3)	65 (5.7)
Male sex, n (%)	18 (53)	18 (51)
BMI, kg/m² (SD)	30 (3.1)	28 (3.1)
Right, n (%)	15 (44)	19 (54)
Mean surgery duration, mins (SD)	45 (4.6)	43 (6.0)
HKA angle preoperative, n (%)		
Neutral*	1 (3)	4 (11)
Varus†	30 (88)	23 (66)
Valgus‡	3 (9)	8 (23)
HKA angle postoperative, n (%)		
Neutral*	23 (68)	20 (57)
Varus†	6 (18)	9 (26)
Valgus‡	5 (15)	6 (17)
ASA classification, n (%)		
I	4 (12)	13 (37)
II	26 (77)	21 (60)
III	4 (12)	1 (3)
Ahlbäck grade, n (%)		
I	1 (3)	0 (0)
II	7 (21)	8 (23)
III	25 (74)	27 (77)
IV	1 (3)	0 (0)
Mean KSS-Knee score, points (SD)	30 (8.9)	33 (9.2)
Mean KSS-Function score, points (SD)	61 (4.4)	61 (5.9)

*Neutral = -3°to 3°.
†Varus < -3°.
‡Valgus > 3°.
ASA, American Society of Anesthesiologists; BMI, body mass index; HKA, hip-ankle-knee; KSS, Knee Society Score

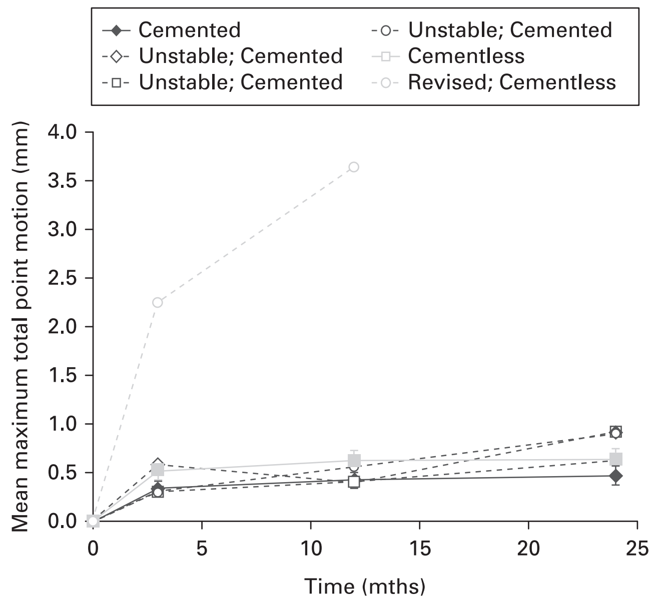


Fig. 3

Graph showing mean maximum total point motion with 95% confidence intervals (error bars) of both groups over time. The solid line represents the mean MTPM of the group including all implants. The interrupted line represents the three unstable implants in the cemented group and the revised TKA in the cementless group.

withdrew in the cemented group, four RSA examinations in the cemented group and two RSA examinations in the cementless group could not be analyzed due to technical issues or missing radiographs (Figure 2). BMI was slightly higher in the cemented group and there were more patients with lower ASA in the cementless group, but other characteristics were similar for both groups (Table I).

The precision of the translations and rotations was 0.1 mm and 0.1°, respectively. The mean error of rigid body fitting was 0.1 mm (0.02 to 0.30) and 0.1 mm (0.02 to 0.33) for the prosthesis and the tibial bone, respectively. The mean condition number was 35 (21 to 103) and 38 (24 to 93) for the prosthesis and the tibial bone, respectively.

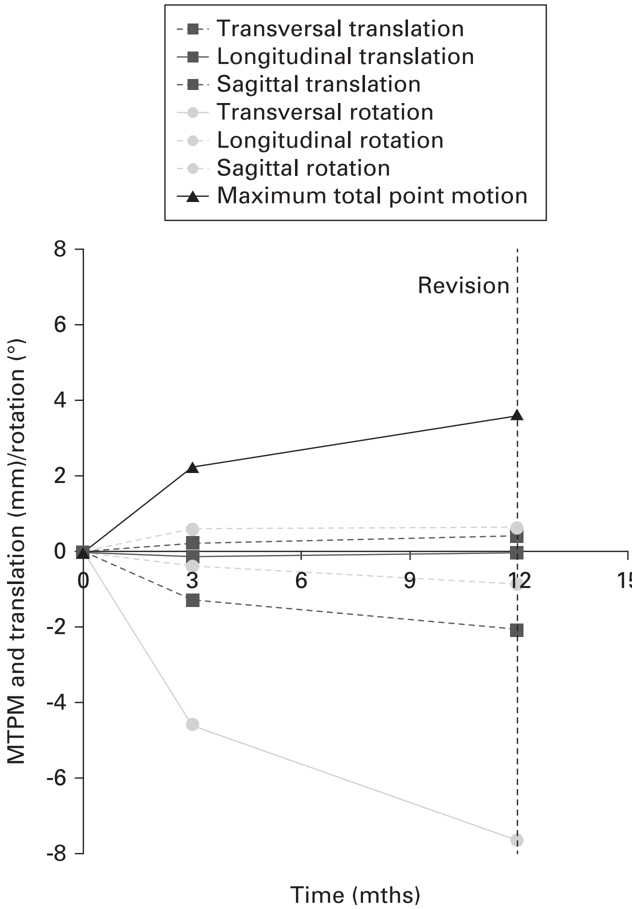
MTPM differed between groups during the two-year follow-up period (p = 0.003, linear mixed model). The MTPM at three months, one-year, and two-year follow-up was 0.33 mm (95% CI 0.25 to 0.42; 0.09 to 0.93), 0.42 mm (95% CI 0.33 to 0.51; 0.19 to 1.34), and 0.47 mm (95% CI 0.38 to 0.57; 0.14 to 1.07) in the cemented group, versus 0.52 mm (95% CI 0.43 to 0.63; 0.10 to 2.24), 0.62 mm (95% CI 0.52 to 0.73; 0.13 to 3.63) and 0.64 mm (95% CI 0.53 to 0.75; 0.18 to 2.03) in the cementless group, respectively (Figure 3). Using three months as reference, the between-group difference in increase of the MTPM up to two years of follow-up was 0.01 mm (95% CI 0.01 to 0.03; p = 0.497, linear mixed model).

One patient in the cementless group had a revision 20 months postoperatively due to progressive pain and migration of the tibial component. This patient was a 71-year-old female with a BMI of 30 kg/m² and was classified as ASA 2. The pre- and postoperative hip-knee-ankle (HKA) angle was 10° (i.e. valgus) and -11° (i.e. varus), respectively. The Medial Proximal Tibial Angle was 3° (i.e. valgus) preoperatively, and was -5° (i.e. varus) postoperatively. Main mode of failure was posterior tilting of the tibial component (Figure 4). Three cemented tibial components showed continuous migration (Figure 3). Apart from the revised implant, none of the cementless implants was considered unstable. The initial migration observed in the cementless group primarily consisted of tibial component subsidence (Figure 5). There were no differences in translations or rotations in any other direction (Supplementary Figures a to e).

The KSS-Knee (p = 0.117) and -Function (p = 0.459) showed no statistical difference between groups, nor did the KOOS Symptoms (p = 0.806), Pain (p = 0.740), Activities of daily living (p = 0.676), Sports and recreation (p = 0.546), Quality of life (p = 0.725), and the FJS (p = 0.922) at any interval, using a linear mixed model (Figure 6).

Discussion

The present study compared the migration of a novel, cementless, 3D-printed tibial component, and a cemented tibial component of a TKA with a similar design. Over the two-year period, the cementless implants had a higher initial migration. However, as expected, this difference was caused by initial settling of the cementless implants during the first three months



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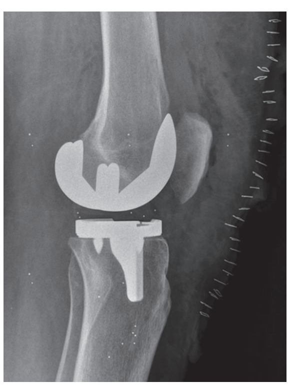

b

c

Fig. 4

a) Graph showing the migration pattern a 71-year-old female patient with the revised cementless TKA. The most prominent mode of failure is the rotation about the transversal axis. b) Immediate postoperative lateral radiograph and c) one-year postoperative lateral knee radiograph showing the backward tilting of the tibial component.

after which stabilization was observed in all but one (revision) implant. These results are in line with previously reported RSA results using the same cementless implant.[12] In comparison, three cemented implants were initially stable but showed continuous migration between one and two years of follow-up.

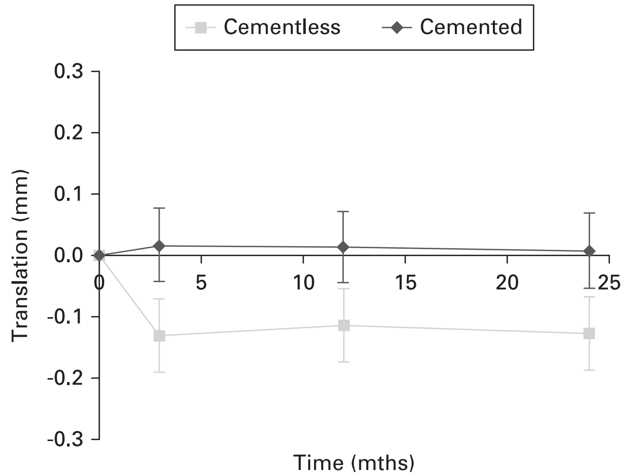

Fig. 5

Graph showing mean translation along the longitudinal axis. Error bars are 95% confidence intervals. Lift-off is represented by a positive value and subsidence is represented by a negative value.

Using recently proposed six-month thresholds (MTPM < 0.5 mm acceptable; 0.5 mm to 1.6 mm at risk; > 1.6 mm unacceptable), the cemented and cementless implants in the present study would be classified as acceptable and at risk, respectively.[16] However, as Laende et al[13] suggested, because these thresholds do not discriminate between fixation methods, different thresholds should be implemented as higher early migration of cementless TKA was not associated with more instability.

When comparing our results for the cementless TKA with those from other studies, the mean MTPM at three months in the present study was lower (0.52 mm, 95% CI 0.43 to 0.63) than previously reported MTPM values ranging between 0.82 mm and 1.52 mm (Figure 7).[12,18,21,36,37] This might be related to the tibial component design as well as material properties for initial optimal bone fixation. The main direction of migration was subsidence in the first three months, which mirrored other RSA studies using cementless implants.[19,20]

The HKA of the patient with the revised implant changed from 10° preoperatively (i.e. valgus) to -11° (i.e. varus) postoperatively, with the tibial component positioned more in varus postoperative. The revised patient had the greatest pre- and postoperative difference in HKA, and the greatest postoperative varus HKA. The influence of pre- and postoperative alignment on implant failure is still unclear, as conflicting results have been published.[38,39] A recent study found that varus aligned TKA resulted in a higher migration than in-range aligned TKA,[40] while another study showed that varus aligned tibial components show more migration.[41] Hence, early failure of the cementless TKA requiring revision might be attributed to malalignment contributing to increased micromotion resulting is failure to obtain bone ongrowth.

This was the first RCT presenting RSA results of this novel 3D-printed, cementless TKA. This relatively new manufacturing technique is becoming more accessible for broader use and the costs of 3D printing decreased substantially between 2001 and 2011.[7] Another benefit of 3D-printed implants, beyond the ability to manufacture highly porous implants to allow

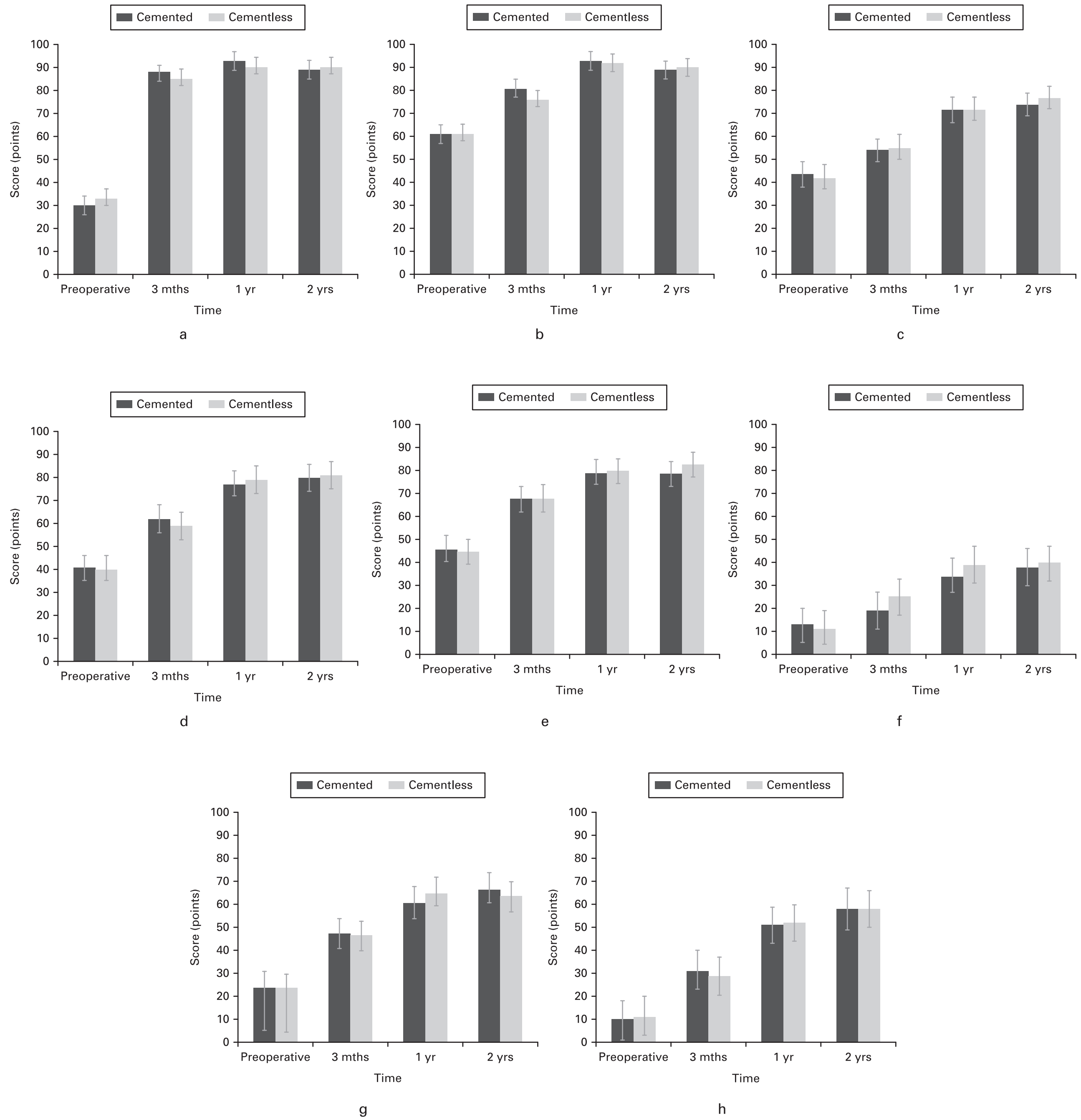

Fig. 6

a) Chart showing the Knee Society Score (KSS)-Knee over time. b) Chart showing the KSS-Function over time. c) Chart showing the Knee Injury and Osteoarthritis Outcome Score (KOOS)-Symptoms over time. d) Chart showing the KOOS-Pain over time. e) Chart showing the KOOS-Activities of daily living over time. f) KOOS-Sports and recreation over time. g) Chart showing the KOOS-Quality of life over time. h) Chart showing the Forgotten Joint Score over time. Error bars are 95% confidence intervals.

osseointegration into the bone, is the ability to match better the elasticity and stiffness of the bone, which could result in less stress-shielding around the implant.[7,42] The 3D-printed, cementless TKA in this study shows promising results as the initial migration seems to be lower than other cementless designs. Likewise, several other studies using a similar implant-reported excellent short-term survival rates and clinical scores.[43-45]

Limitations of this study are that we could not separate the effect of the cementless design from the four additional pegs onto the under-surface of the tibial plateau. Theoretically, these pegs could provide more rotational stability, but this has not been studied before in vivo so that a study comparing a cementless knee implant with and without pegs is needed. Moreover, patients with a BMI of > 38 kg/m^2 were excluded even though in

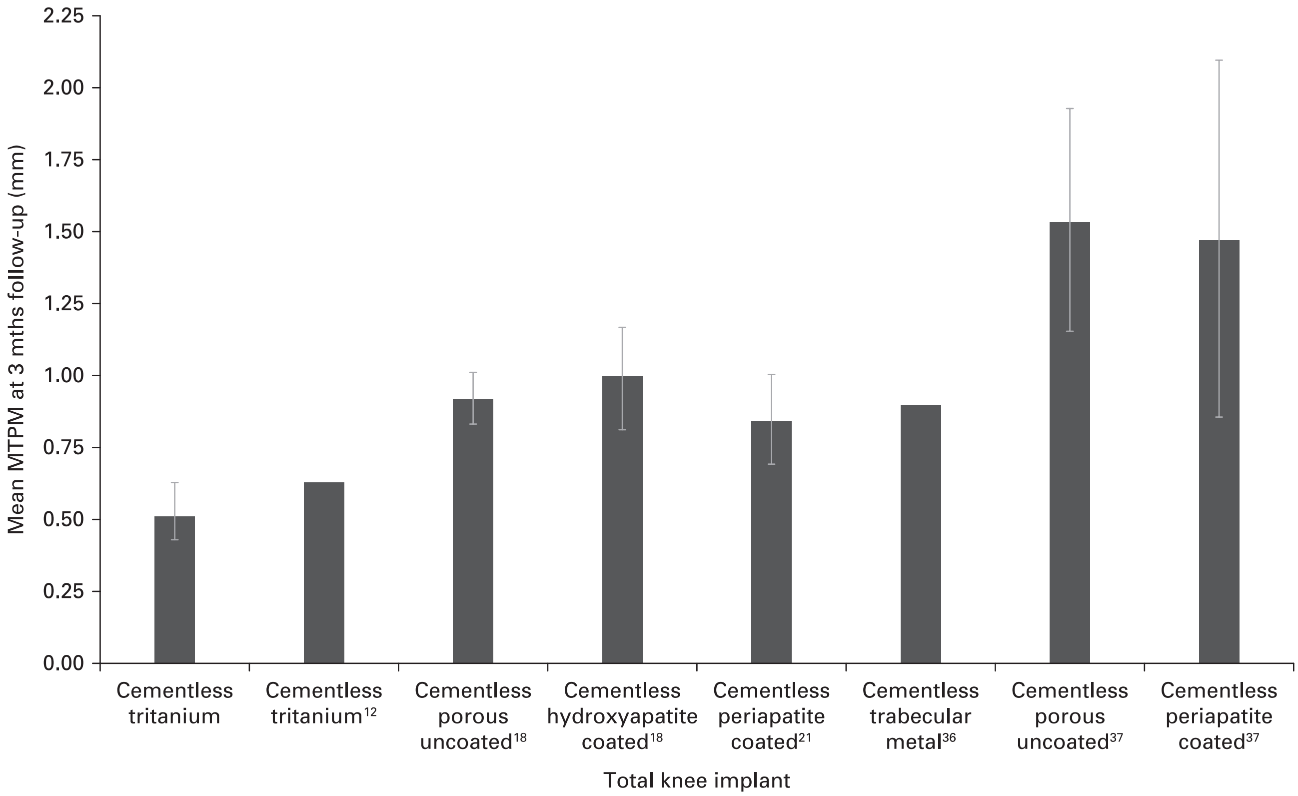

Fig. 7

Chart showing the reported MTPM at three months follow-up of different cementless TKA. The error bars represent the 95% confidence intervals (information not provided in two studies).

a previous study they have been shown to benefit from cementless coated TKA.[46] Future studies should assess the benefits for this specific population. In addition, the cementless implants were slightly more malaligned postoperatively compared with the cemented TKA. It is unclear whether this difference is due to the fixation method or a more demanding surgical technique. As the procedures were performed by a single surgeon (STL), there is a limit to the generalizability of the results, although the observed differences between groups cannot be attributed to a surgeon effect as found in a previous RSA study.[47] In addition, marker-based RSA analysis was used instead of model-based RSA, which may have introduced slight measurement errors due to micromotion at the locking mechanism of the polyethylene. Lastly, this study was single blinded as it was impossible to blind clinicians given the differences in radiological appearance of both implants. However, RSA is an objective method of assessing implant migration and no influence on these results would be expected. The current study underscores the importance of evaluation of new techniques such as 3D printing.[48,49] In conclusion, the cementless TKA migrated more than the cemented TKA in the first two years. This difference was mainly due to a higher initial migration of the cementless TKA in the first three postoperative months after which stabilization was observed in all but one malaligned and early revised TKA. Whether the biological fixation of the cementless implants will result in an increased long-term survival will become clear when longer follow-up results becomes available.

Take home message

- The cementless total knee arthroplasty (TKA) showed more migration compared to the cemented TKA due to higher initial migration the cementless implant. After three months, both the cemented and cementless TKA were stable.
- The most prominent direction of migration for the cementless implants was tibial subsidence.

Supplementary material

The supplementary material includes the mean translation along the transverse and the sagittal axis of the cemented and cementless TKA. In addition, it includes the mean rotation about the transverse, longitudinal and sagittal axis of both groups.

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