



Universiteit
Leiden
The Netherlands

Safety of orthopedic implants: implant migration analysis a must

Hasan, S.

Citation

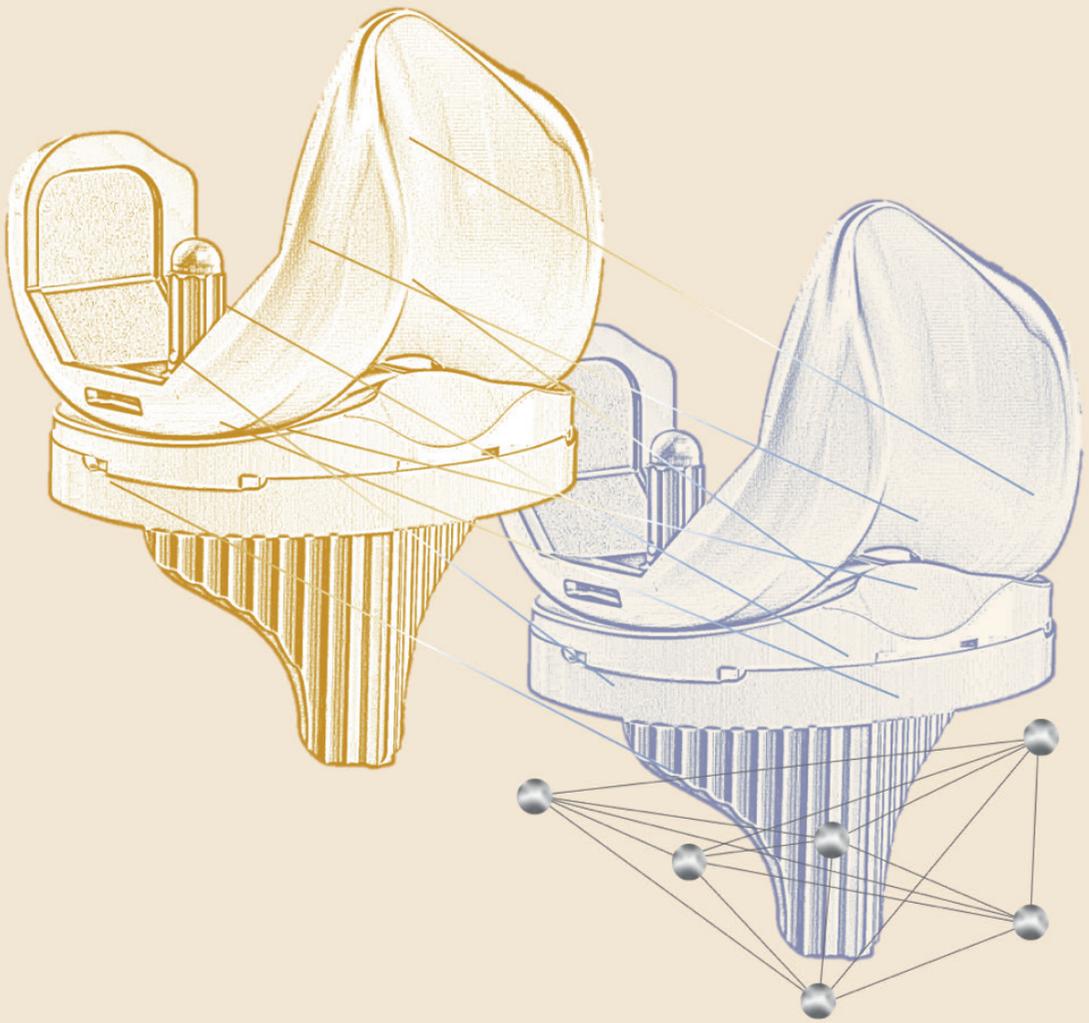
Hasan, S. (2024, June 4). *Safety of orthopedic implants: implant migration analysis a must*. Retrieved from <https://hdl.handle.net/1887/3762018>

Version: Publisher's Version

License: [Licence agreement concerning inclusion of doctoral thesis in the Institutional Repository of the University of Leiden](#)

Downloaded from: <https://hdl.handle.net/1887/3762018>

Note: To cite this publication please use the final published version (if applicable).



Chapter V

Migration of a novel 3D-printed cementless versus a cemented total knee arthroplasty

Two-year results of a randomized trial using radiostereometric analysis

Shaho Hasan¹, Koen T. van Hamersveld¹, Perla J. Marang-van de Mheen², Bart L. Kaptein¹, Rob GHH Nelissen¹, Sören Toksvig-Larsen³

¹Department of Orthopaedics, Leiden University Medical Center, Leiden, The Netherlands

²Department of Biomedical Data Sciences, Leiden University Medical Center, Leiden, The Netherlands

³Department of Orthopaedics, Hässleholm Hospital, Hässleholm, Sweden and Department of Clinical Sciences, Lund University, Lund, Sweden

Bone & Joint Journal. 2020;102-B(8):1016-1024.
Doi 10.1302/0301-620X.102B8.BJJ-2020-0054.R1

Abstract

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.

Keywords

3D printing; Radiostereometric analysis; Total knee arthroplasty.

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 Another method to facilitate bone ingrowth is the application of 3D printing techniques which allows the manufacturing of highly porous implants which could mimic the stiffness and elasticity of bone.^{6, 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 which remains evident ten years postoperatively.^{13, 14, 18-21} 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.

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 stages II to IV, and males or non-pregnant females aged between 40 and 75 years, who had given informed consent.²² 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 V.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

Figure V.1 3D-printed, cementless tibial base plate (Tritanium, Stryker, NJ, USA)



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 (KSS), the Knee Injury and Osteoarthritis Outcome Score (KOOS), and the Forgotten Joint Score (FJS).²⁵⁻²⁷ 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 (\varnothing 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 configuration model was constructed in case markers were occluded by the metal implants.³⁰

Statistical analysis

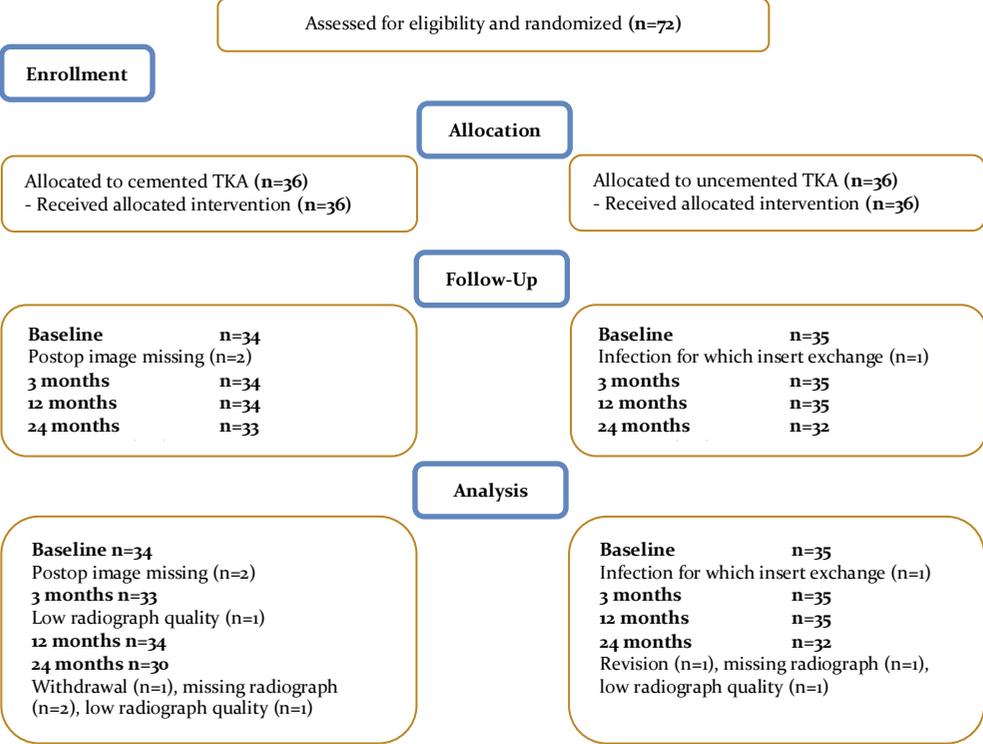
In a noninferiority study set-up, 23 subjects are needed for each group assuming a mean MTPM of 0.62 mm with SD 0.15 mm, and study power 80%.³¹ The two-sided 95% confidence interval (CI) will then exclude a difference beyond the 0.13 mm measurement error of the RSA-setup in MTPM.^{31, 32} To compensate 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 V.II].

Figure V.II Consort Flowchart



During follow-up, one patient 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 V.II]. 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 V.I].

Table V.I Baseline characteristics

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

SD = Standard Deviation. HKA = Hip-Knee-Ankle angle. Neutral = -3° - 3° , varus $<-3^{\circ}$, valgus $>3^{\circ}$. ASA classification = American Society of Anesthesiologists. KSS = Knee Society Score.

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 V.III). 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).

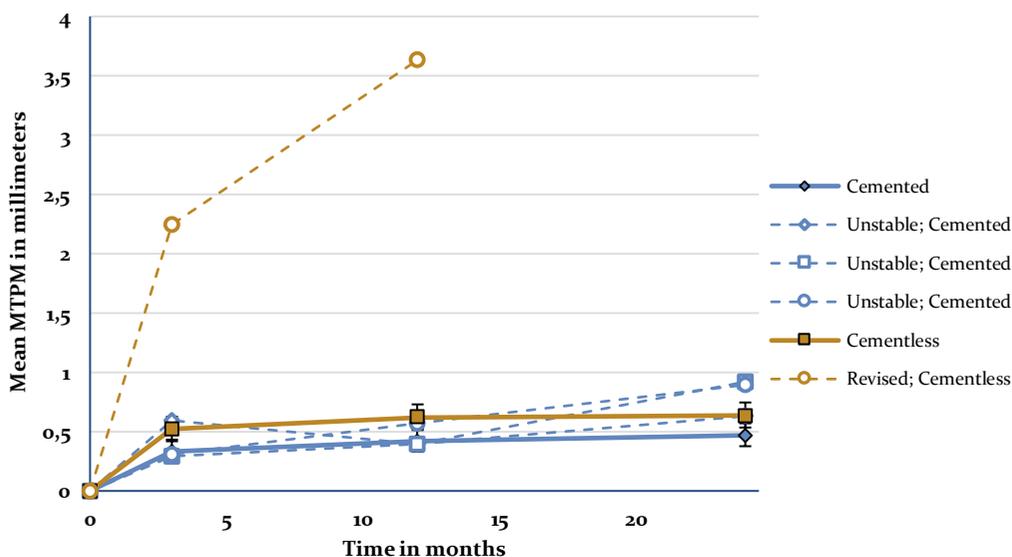


Figure V.III Mean MTPM of the cemented and cementless group with 95% confidence intervals. The MTPM of 3 continuously migrating cemented TKAs and one revised cementless TKA were plotted.

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 V.IV]. Three cemented tibial components showed continuous migration [Figure V.III].

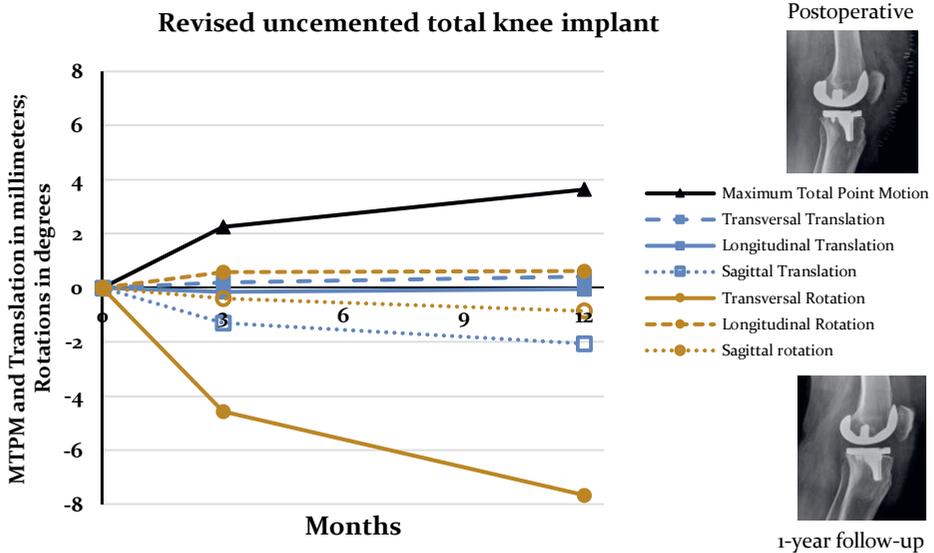


Figure V.IV Migration pattern of the revised cementless total knee implant. Most prominent mode of failure is the rotation about the transverse axis. Backward tilting of the tibial component is also visible on the lateral knee radiograph 1-year postoperative.

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 V.V]. There were no differences in translations or rotations in any other direction [Figure V.VI A-E].

Figure V.V Translation along the longitudinal axis. Error bars represent 95% confidence intervals. Lift-off is represented by a positive value and subsidence by a negative value.

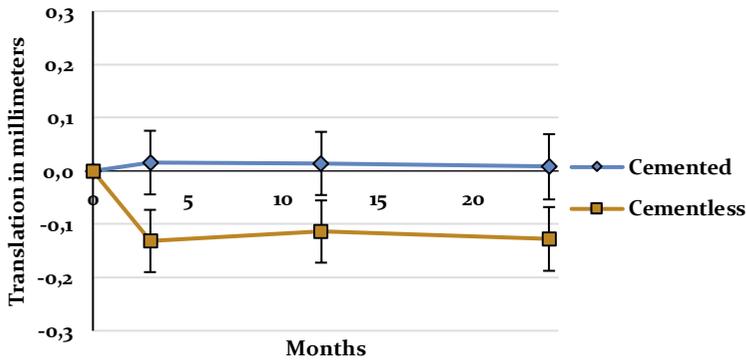
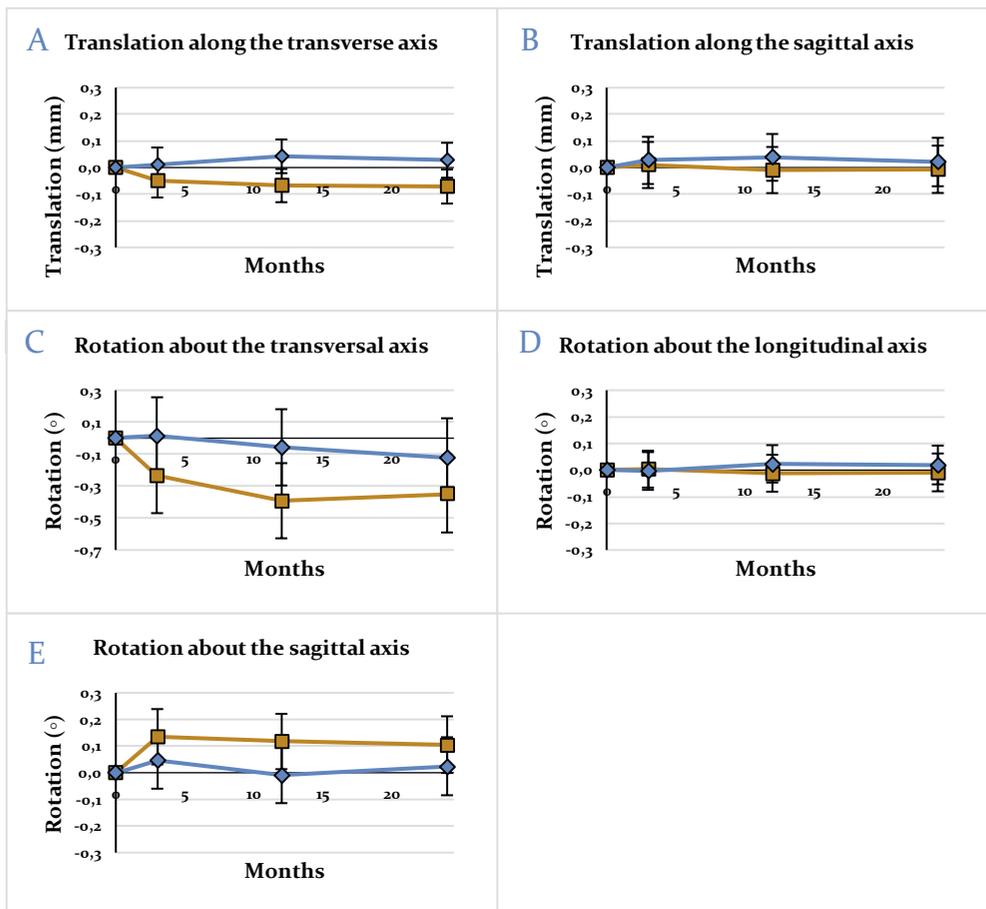
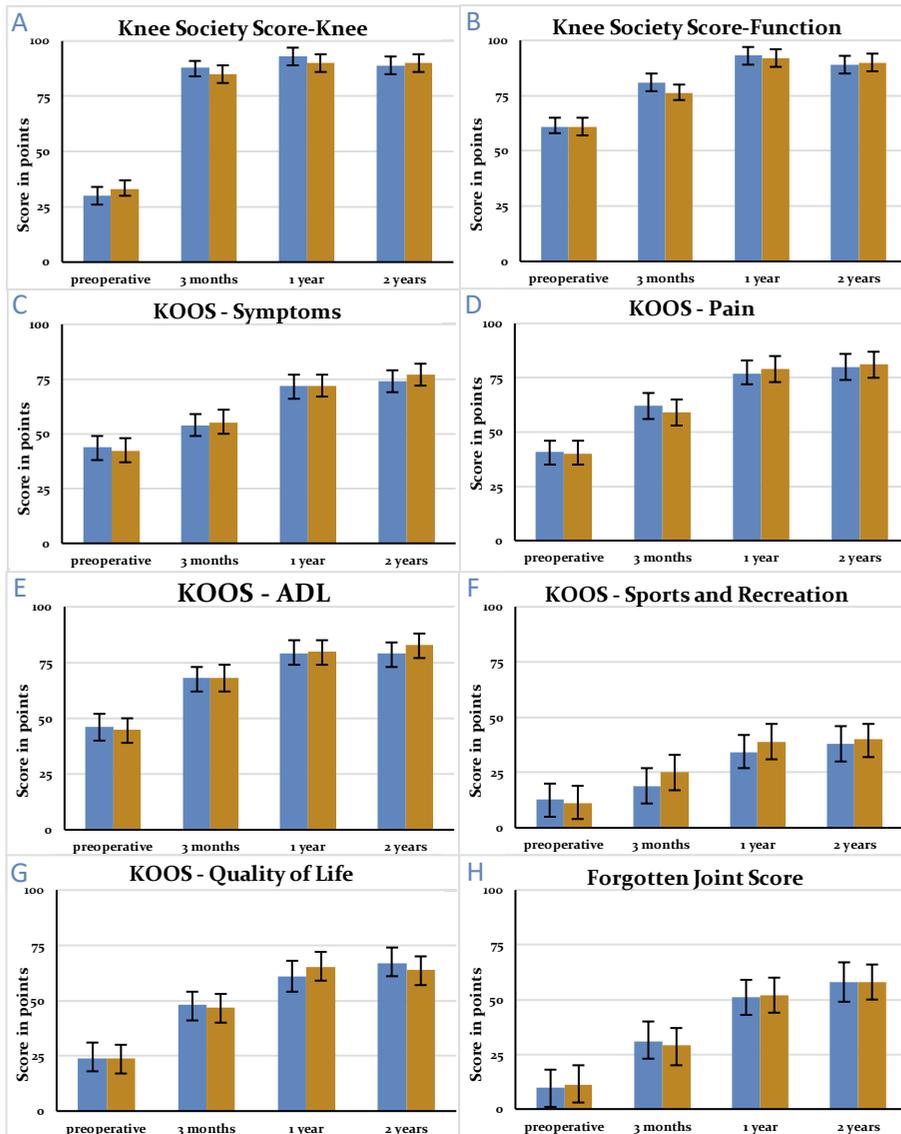


Figure V.VI A-E Translation along the transverse and sagittal axis, and rotation about the transverse, longitudinal and sagittal axis. Means are presented with 95% confidence intervals.



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 V.VII A-H].

Figure V.VII A-H Clinical scores per domain. Error bars are 95% confidence intervals. KOOS = Knee Injury and Osteoarthritis Outcome Score; ADL = Activities Daily Living.

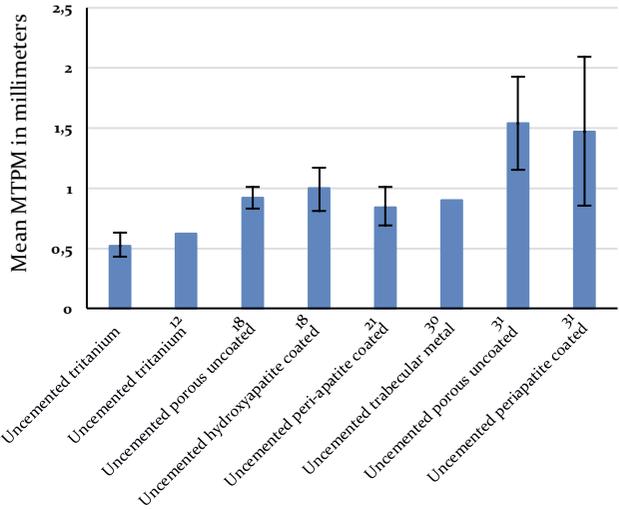


Discussion

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 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. 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. (2019) 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.¹³

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 V.VIII].^{12, 18, 21, 36, 37} This might be related to the tibial component design as well as material properties for initial

Figure V.VIII Mean MTPM at 3 months follow-up of uncemented total knee implants. Error bars represent the 95% confidence interval



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, while another study showed that varus aligned tibial components show more migration.^{40, 41} Hence, early failure of the cementless TKA requiring revision might be attributed to malalignment contributing to increased micromotion resulting in failure to obtain bone ingrowth.

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 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/m² were

excluded even though in 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 become 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.

Funding statement

This study was funded by Stryker but had no part in the design, conduct, analysis, and interpretations stated in this paper. Although none of the authors has received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article, benefits have been or will be received but will be directed solely to a research fund, foundation, educational institution, or other non-profit organization with which one or more of the authors are associated.

ICMJE COI statement

S. Hasan and B. L. Kaptein report an institutional grant, money paid to support travel, and payment for writing or reviewing the manuscript, all from Stryker, related to this study. K. T. van Hamersveld and P. J. Marang-van de Mheen report money paid to their institution from Stryker to support travel, related to this study. R. G. H. H. Nelissen reports an institutional grant and money paid to support travel from Stryker, related to this study. S. Toksvig-Larsen reports an institutional grant from Stryker, related to this study, as well as institutional grants/grants pending from Stryker, and money paid to their institution and personal payments from Stryker, Smith & Nephew, and Johnson & Johnson for consultancy and payment for lectures, all unrelated to this study.

Ethical review statement

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.

Trial registration number

Clinicaltrials.gov NCT02578446.

References

1. Dutch Arthroplasty Register (LROI). Online LROI annual report 2017. Available from: <http://www.lroi-rapportage.nl/media/pdf/PDF%20LROI%20annual%20report%202017.pdf>. Accessed on July 14, 2018.
2. National Joint Registry for England Wales Northern Ireland and the Isle of Man. 14th Annual Report 2017. Available from: <https://reports.njrcentre.org.uk/Portals/0/PDFdownloads/NJR%2014th%20Annual%20Report%202017.pdf>. Accessed on July 20, 2018.
3. Swedish Knee Arthroplasty Register. Annual Report 2017. Available from: http://www.myknee.se/pdf/SVK_2017_Eng_1.0.pdf. Accessed on July 14, 2018.
4. Dalury DF. Cementless total knee arthroplasty: current concepts review. *Bone Joint J.* 2016 98-b(7):867-73 DOI: 10.1302/0301-620x.98b7.37367.
5. Meneghini RM, Hanssen AD. Cementless fixation in total knee arthroplasty: past, present, and future. *J Knee Surg.* 2008 21(4):307-14.
6. Trauner KB. The Emerging Role of 3D Printing in Arthroplasty and Orthopedics. *J Arthroplasty.* 2018 33(8):2352-2354 DOI: 10.1016/j.arth.2018.02.033.
7. Mumith A, Thomas M, Shah Z, Coathup M, Blunn G. Additive manufacturing: current concepts, future trends. *Bone Joint J.* 2018 100-b(4):455-460 DOI: 10.1302/0301-620x.100b4.Bjj-2017-0662.R2.
8. Hu B, Chen Y, Zhu H, Wu H, Yan S. Cementless Porous Tantalum Monoblock Tibia vs Cemented Modular Tibia in Primary Total Knee Arthroplasty: A Meta-Analysis. *J Arthroplasty.* 2017 32(2):666-674 DOI: 10.1016/j.arth.2016.09.011.
9. Mont MA, Pivec R, Issa K, Kapadia BH, Maheshwari A, Harwin SF. Long-term implant survivorship of cementless total knee arthroplasty: a systematic review of the literature and meta-analysis. *J Knee Surg.* 2014 27(5):369-76 DOI: 10.1055/s-0033-1361952.
10. Zhou K, Yu H, Li J, Wang H, Zhou Z, Pei F. No difference in implant survivorship and clinical outcomes between full-cementless and full-cemented fixation in primary total knee arthroplasty: A systematic review and meta-analysis. *Int J Surg.* 2018 53:312-319 DOI: 10.1016/j.ijvsu.2018.04.015.
11. Gandhi R, Tsvetkov D, Davey JR, Mahomed NN. Survival and clinical function of cemented and uncemented prostheses in total knee replacement: a meta-analysis. *J Bone Joint Surg Br.* 2009 91(7):889-95 DOI: 10.1302/0301-620x.91b7.21702.
12. Sporer S, MacLean L, Burger A, Moric M. Evaluation of a 3D-printed total knee arthroplasty using radiostereometric analysis: assessment of highly porous biological fixation of the tibial baseplate and metal-backed patellar component. *Bone Joint J.* 2019 101-b(7_Supple_C):40-47 DOI: 10.1302/0301-620x.101b7.Bjj-2018-1466.R1.
13. Laende EK, Astephen Wilson JL, Mills Flemming J, Valstar ER, Richardson CG, Dunbar MJ. Equivalent 2-year stabilization of uncemented tibial component migration despite higher early migration compared with cemented fixation: an RSA study on 360 total knee arthroplasties. *Acta Orthop.* 2019 90(2):172-178 DOI: 10.1080/17453674.2018.1562633.
14. Laende EK, Richardson CG, Dunbar MJ. Predictive value of short-term migration in determining long-term stable fixation in cemented and cementless total knee arthroplasties. *Bone Joint J.* 2019 101-b(7_Supple_C):55-60 DOI: 10.1302/0301-620x.101b7.Bjj-2018-1493.R1.
15. Pijls BG, Valstar ER, Nouta KA, Plevier JW, Fiocco M, Middeldorp S, et al. Early migration of tibial components is associated with late revision: a systematic review and meta-analysis of 21,000 knee arthroplasties. *Acta Orthop.* 2012 83(6):614-24 DOI: 10.3109/17453674.2012.747052.
16. Pijls BG, Plevier JWM, Nelissen R. RSA migration of total knee replacements. *Acta Orthop.* 2018:1-9 DOI: 10.1080/17453674.2018.1443635.
17. Ryd L, Albrektsson BE, Carlsson L, Dansgard F, Herberts P, Lindstrand A, et

- al. Roentgen stereophotogrammetric analysis as a predictor of mechanical loosening of knee prostheses. *J Bone Joint Surg Br.* 1995 77(3):377-83.
18. Carlsson A, Bjorkman A, Besjakov J, Onsten I. Cemented tibial component fixation performs better than cementless fixation: a randomized radiostereometric study comparing porous-coated, hydroxyapatite-coated and cemented tibial components over 5 years. *Acta Orthop.* 2005 76(3):362-9.
19. Dunbar MJ, Wilson DA, Hennigar AW, Amirault JD, Gross M, Reardon GP. Fixation of a trabecular metal knee arthroplasty component. A prospective randomized study. *J Bone Joint Surg Am.* 2009 91(7):1578-86 DOI: 10.2106/JBJS.H.00282.
20. Pijls BG, Valstar ER, Kaptein BL, Fiocco M, Nelissen RG. The beneficial effect of hydroxyapatite lasts: a randomized radiostereometric trial comparing hydroxyapatite-coated, uncoated, and cemented tibial components for up to 16 years. *Acta Orthop.* 2012 83(2):135-41 DOI: 10.3109/17453674.2012.665330.
21. Van Hamersveld KT, Marang-Van De Mheen PJ, Nelissen R, Toksvig-Larsen S. Peri-apatite coating decreases uncemented tibial component migration: long-term RSA results of a randomized controlled trial and limitations of short-term results. *Acta Orthop.* 2018:1-6 DOI: 10.1080/17453674.2018.1469223.
22. Ahlbäck S. Osteoarthritis of the knee. A radiographic investigation. *Acta Radiol Diagn (Stockh).* 1968:Suppl 277:7-72.
23. Muth J, Poggie M, Kulesha G, Michael Meneghini R. Novel Highly Porous Metal Technology in Artificial Hip and Knee Replacement: Processing Methodologies and Clinical Applications. *JOM.* 2013 65(2):318-325 DOI: 10.1007/s11837-012-0528-5.
24. ISO16087:2013(E). *Implants for surgery: Roentgen stereophotogrammetric analysis for the assessment of migration of orthopaedic implants.* Geneva, Switzerland: International Organization for Standardization. 2013.
25. Insall JN, Dorr LD, Scott RD, Scott WN. Rationale of the Knee Society clinical rating system. *Clin Orthop Relat Res.* 1989(248):13-4.
26. Roos EM, Lohmander LS. The Knee injury and Osteoarthritis Outcome Score (KOOS): from joint injury to osteoarthritis. *Health Qual Life Outcomes.* 2003 1:64 DOI: 10.1186/1477-7525-1-64.
27. Behrend H, Giesinger K, Giesinger JM, Kuster MS. The "forgotten joint" as the ultimate goal in joint arthroplasty: validation of a new patient-reported outcome measure. *J Arthroplasty.* 2012 27(3):430-436.e1 DOI: 10.1016/j.arth.2011.06.035.
28. Cooke TD, Sled EA, Scudamore RA. Frontal plane knee alignment: a call for standardized measurement. *J Rheumatol.* 2007 34(9):1796-801.
29. Valstar ER, Gill R, Ryd L, Flivik G, Borlin N, Karrholm J. Guidelines for standardization of radiostereometry (RSA) of implants. *Acta Orthop.* 2005 76(4):563-72 DOI: 10.1080/17453670510041574.
30. Kaptein BL, Valstar ER, Stoel BC, Rozing PM, Reiber JH. A new type of model-based Roentgen stereophotogrammetric analysis for solving the occluded marker problem. *J Biomech.* 2005 38(11):2330-4 DOI: 10.1016/j.jbiomech.2004.09.018.
31. Molt M, Toksvig-Larsen S. Similar early migration when comparing CR and PS in Triathlon TKA: A prospective randomised RSA trial. *Knee.* 2014 21(5):949-54 DOI: 10.1016/j.knee.2014.05.012.
32. No authors listed. Power (sample size) calculators. Sealed envelope. Available from: <https://www.sealedenvelope.com/power/continuous-noninferior/>.
33. Krueger C, Tian L. A comparison of the general linear mixed model and repeated measures ANOVA using a dataset with multiple missing data points. *Biol Res Nurs.* 2004 6(2):151-7 DOI: 10.1177/1099800404267682.
34. Ranstam J, Turkiewicz A, Boonen S, Van Meirhaeghe J, Bastian L, Wardlaw D. Alternative analyses for handling incomplete follow-up in the intention-to-treat analysis: the randomized controlled trial of balloon kyphoplasty versus non-surgical care for vertebral compression fracture (FREE). *BMC Med Res Methodol.* 2012 12:35 DOI: 10.1186/1471-2288-12-35.
35. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated

- guidelines for reporting parallel group randomised trials. *Bmj*. 2010 340:c332 DOI: 10.1136/bmj.c332.
36. Henricson A, Linder L, Nilsson KG. A trabecular metal tibial component in total knee replacement in patients younger than 60 years: a two-year radiostereophotogrammetric analysis. *J Bone Joint Surg Br*. 2008 90(12):1585-93 DOI: 10.1302/0301-620x.90b12.20797.
37. Hansson U, Ryd L, Toksvig-Larsen S. A randomised RSA study of Peri-Apatite HA coating of a total knee prosthesis. *Knee*. 2008 15(3):211-6 DOI: 10.1016/j.knee.2008.01.013.
38. Fang DM, Ritter MA, Davis KE. Coronal alignment in total knee arthroplasty: just how important is it? *J Arthroplasty*. 2009 24(6 Suppl):39-43 DOI: 10.1016/j.arth.2009.04.034.
39. Mandelin J, Liljestrom M, Li TF, Ainola M, Hukkanen M, Salo J, et al. Pseudosynovial fluid from loosened total hip prosthesis induces osteoclast formation. *J Biomed Mater Res B Appl Biomater*. 2005 74(1):582-8 DOI: 10.1002/jbm.b.30244.
40. van Hamersveld KT, Marang-van de Mheen PJ, Nelissen R. The Effect of Coronal Alignment on Tibial Component Migration Following Total Knee Arthroplasty: A Cohort Study with Long-Term Radiostereometric Analysis Results. *J Bone Joint Surg Am*. 2019 101(13):1203-1212 DOI: 10.2106/jbjs.18.00691.
41. Teeter MG, Naudie DD, McCalden RW, Yuan X, Holdsworth DW, MacDonald SJ, et al. Varus tibial alignment is associated with greater tibial baseplate migration at 10 years following total knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc*. 2018 26(6):1610-1617 DOI: 10.1007/s00167-017-4765-6.
42. Arabnejad S, Johnston B, Tanzer M, Pasini D. Fully porous 3D printed titanium femoral stem to reduce stress-shielding following total hip arthroplasty. *J Orthop Res*. 2017 35(8):1774-1783 DOI: 10.1002/jor.23445.
43. Miller AJ, Stimac JD, Smith LS, Feher AW, Yakkanti MR, Malkani AL. Results of Cemented vs Cementless Primary Total Knee Arthroplasty Using the Same Implant Design. *J Arthroplasty*. 2018 33(4):1089-1093 DOI: 10.1016/j.arth.2017.11.048.
44. Nam D, Lawrie CM, Salih R, Nahhas CR, Barrack RL, Nunley RM. Cemented Versus Cementless Total Knee Arthroplasty of the Same Modern Design: A Prospective, Randomized Trial. *J Bone Joint Surg Am*. 2019 101(13):1185-1192 DOI: 10.2106/jbjs.18.0162.
45. Sultan AA, Mahmood B, Samuel LT, Stearns KL, Molloy RM, Moskal JT, et al. Cementless 3D Printed Highly Porous Titanium-Coated Baseplate Total Knee Arthroplasty: Survivorship and Outcomes at 2-Year Minimum Follow-Up. *J Knee Surg*. 2019 DOI: 10.1055/s-0039-1677842.
46. Sinicrope BJ, Feher AW, Bhimani SJ, Smith LS, Harwin SF, Yakkanti MR, et al. Increased Survivorship of Cementless versus Cemented TKA in the Morbidly Obese. A Minimum 5-Year Follow-Up. *J Arthroplasty*. 2019 34(2):309-314 DOI: 10.1016/j.arth.2018.10.016.
47. Van Hamersveld KT, Marang-Van De Mheen PJ, Nelissen R, Toksvig-Larsen S. Migration of all-polyethylene compared with metal-backed tibial components in cemented total knee arthroplasty. *Acta Orthop*. 2018:1-6 DOI: 10.1080/17453674.2018.1464317.
48. Nelissen RG, Pijls BG, Karrholm J, Malchau H, Nieuwenhuijse MJ, Valstar ER. RSA and registries: the quest for phased introduction of new implants. *J Bone Joint Surg Am*. 2011 93:62-5 DOI: 10.2106/jbjs.k.00907.
49. Nieuwenhuijse MJ, Nelissen RG, Schoones JW, Sedrakyan A. Appraisal of evidence base for introduction of new implants in hip and knee replacement: a systematic review of five widely used device technologies. *Bmj*. 2014 349:g5133 DOI: 10.1136/bmj.g5133.