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Safety of orthopedic implants: implant migration analysis a must

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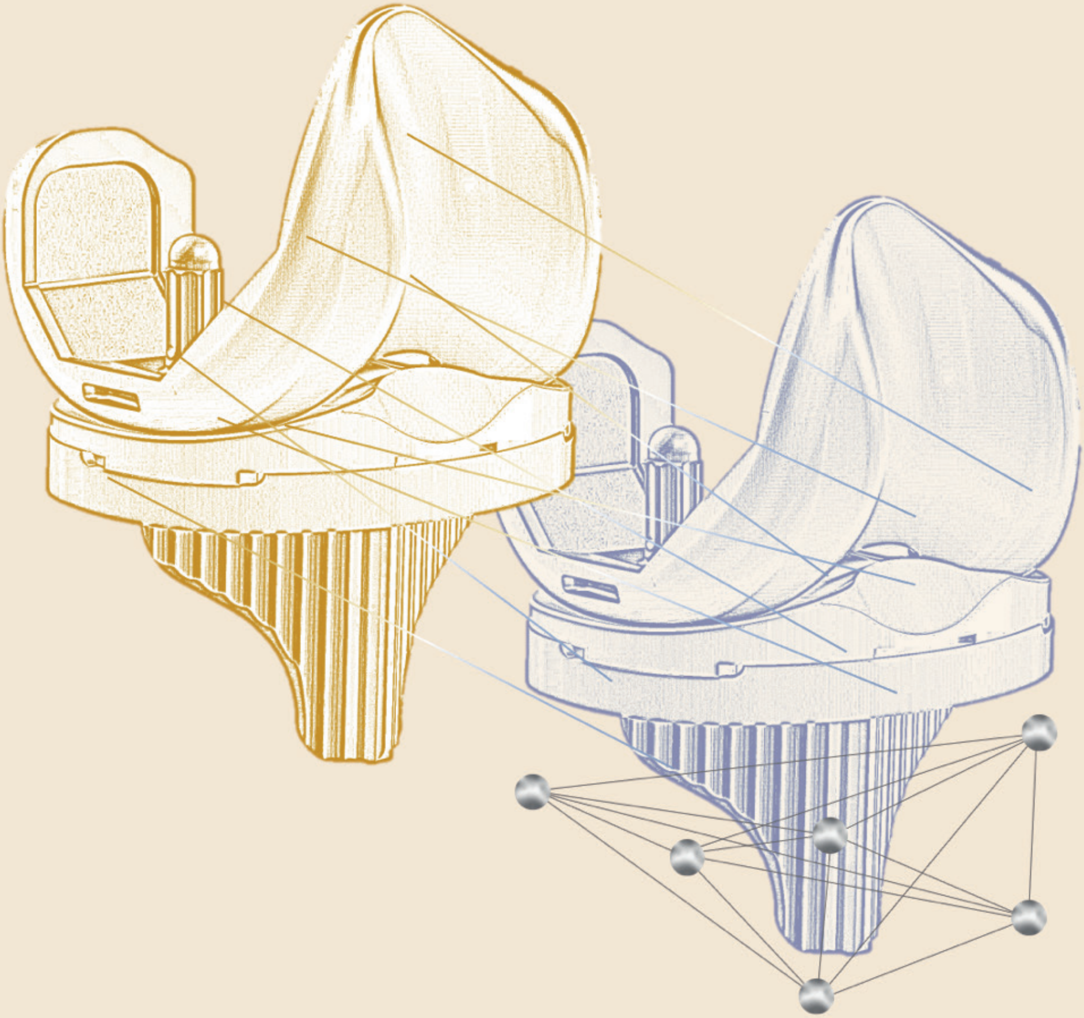

Chapter VII

RSA migration of unicondylar knee arthroplasties is comparable to migration of total knee arthroplasties

A meta-analysis

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Abstract

Importance

Aseptic loosening is a major cause of failure for unicondylar knee arthroplasty (UKA). In total knee arthroplasty (TKA), early migration as measured with radiostereometric analysis (RSA) is a strong predictor of late revision for aseptic loosening of the tibial component. Migration in the first two years provides information on the fixation of an implant. However, the migration pattern of UKAs has not been systematically determined and it is unclear if the migration pattern of UKAs is similar to TKAs Therefore, the present meta-analysis aims to evaluate the migration patterns of tibial components of UKAs.

Evidence review

All RSA studies reporting on migration at two or more postoperative moments of an UKA were included. Pubmed, Web of Science, Cochrane and Embase were searched up to April 2021. The risk of bias was assessed using the methodological score of the Assessment of Quality in Lower Limb Arthroplasty tool. All phases of the review were performed by two reviewers independently. A random effects model was applied to pool the migration data.

Findings

The literature search yielded 3187 hits of which ten studies were included, comprising 13 study groups and 381 UKAs. The majority of the early migration occurred in the first 6 months postoperatively followed by a period of very little migration, similar to what is reported for TKAs. The pooled mean migration expressed as the maximum total point motion of all UKAs at three months, six months, one year, and two years was 0.43 mm (95%CI 0.38-0.48), 0.54 mm (95%CI 0.40-0.67), 0.59 mm (95%CI 0.52-0.66), and 0.61 mm (95%CI 0.55-0.68), respectively. Migration at one- and two-year was higher than migration of TKAs as reported in

previous studies. All-polyethylene UKAs migrated more at one year (0.69 mm; 95%CI 0.58-0.80) than metal-backed UKAs (0.52 mm; 95%CI 0.46-0.58).

Conclusions and Relevance

The migration pattern of UKAs is comparable to the migration pattern of TKAs in the first two years as both show initial migration in the first few months and very little migration thereafter. However, UKAs had higher migration at one- and two-year follow-up.

Level of evidence

Level II

Funding

None

Registration

Not registered

Bullet Points

What is already known?

- Migration profiles of TKA include high initial migration in the first few months and stabilization thereafter
- TKA migrating >0.2 mm maximum total point motion (MTPM) between year one and year two are at risk for failure due to aseptic loosening
- Three other thresholds for migration at one year have been proposed to assess the risk of tibial loosening of total knee arthroplasty (TKA): <0.54 mm MTPM, 0.54–1.6 mm MTPM, and >1.6mm MTPM.
- No migration profiles or thresholds for unicondylar knee arthroplasty (UKA) are reported

What are the new findings?

- The migration pattern of UKA was comparable to TKA with high initial migration followed by a stabilization phase between one- and two-year follow-up
- Migration of the UKA tibial components was higher at one- and two-year follow-up compared to TKA
- Future studies should assess whether TKA thresholds are applicable for UKAs

Introduction

Unicondylar knee arthroplasty (UKA) has the potential to treat medial and lateral knee osteoarthritis without replacement of the entire knee joint.[1] Although the popularity of UKA is increasing, isolated medial or lateral osteoarthritis of the knee is mostly treated with total knee arthroplasty (TKA). This is reflected in arthroplasty registries where 90147 TKA and 11916 UKA surgeries were registered in the National Joint Registry (NJR; England, Wales, Northern Ireland) in 2019.[2] UKA has several advantages over TKA such as shorter operation time, shorter length of stay, decreased risk of early complications (e.g., deep infection, myocardial infarction), greater range of motion, and higher patient reported outcome scores.[3] However, one of the major disadvantages is a higher mean revision rate of UKAs with reported rates between 8.3-11.0% for UKA compared to a mean TKA revision rate of 3.4-4.2%.[2] The main reason for revision of an UKA is aseptic loosening followed by dislocation or subluxation, and pain.[2]

In TKA, early migration (i.e., one to two years) has been associated with late (i.e., five to ten years) revision for aseptic loosening.[4] Additionally, continuous migration after the first post-operative year has been associated with early onset of aseptic loosening.[5] Moreover, three thresholds for migration at one year have been proposed to assess the risk of tibial loosening of TKA and to classify in TKAs in an acceptable group (i.e., <0.54 mm maximum total point motion (MTPM)), at-risk group (i.e., 0.54–1.6 mm MTPM), and an unacceptable group (i.e., >1.6mm MTPM).[4] Therefore, the migration pattern provides important information on implant safety. The migration pattern can be measured very accurately with radiostereometric analysis (RSA), which has an accuracy of 0.2mm.[5] While the migration pattern has been established for TKA it is unknown for UKAs and it is unclear how the UKA migration pattern compares to the TKA migration pattern. Therefore, the present meta-analysis aimed to evaluate the migration patterns of tibial components of UKAs. The question was whether the postoperative migration pattern and magnitudes of migration of UKAs were the same as earlier reported for TKAs. The hypothesis that

UKAs had a comparable migration pattern as well as comparable magnitude of migration up to two years as TKAs was tested.

Methods

This study is a meta-analysis and was performed in concordance with the PRISMA statement.[6] The systematic review comprised migration patterns from RSA studies. The methodology of the review is the same as previously described for TKAs.[7] The present review was not registered.

Literature Search

The literature search was conducted with a medical librarian (JP). RSA studies were searched up to October 2019 and was updated for studies up to April 2021 using Pubmed, Web of Science, Cochrane and Embase. The search included a combination of the terms defining 'RSA' and 'Joint Replacement' (Appendix A). It was decided to conduct a broad search including all joint replacements instead of focusing on UKA to minimize the possibility of missing studies. Studies in English, Dutch, German, French, Spanish and Italian were considered.

Inclusion and exclusion analysis

All RSA studies reporting migration patterns of an UKA were identified. A migration pattern was defined as the reporting of migration at two or more postoperative follow-up moments within the first two years of follow-up using the maximum total point motion (MTPM).[7] The MTPM is defined as the point on the implant with the highest migration relative to the bone and is the most frequently reported outcome measure in RSA studies to report migration.[4, 5] Titles and abstracts were screened by two reviewers (SH, LD) independently. If the reviewers disagreed, the study remained eligible, and the full-text was screened. The eligible full-texts were screened by the same two reviewers independently, and any disagreements were resolved by discussion or after consulting a third reviewer (BP). Inclusion criteria for the RSA studies were: (1) primary UKA and (2) MTPM measured with RSA. Studies with less than five UKA or non-clinical studies (e.g., phantom or animal studies) were excluded. If the same cohort was reported in multiple publications, the publication with the longest follow-up was formally included, while the other publications were used for additional data if required.

Data extraction

SH and LD independently extracted the data using a predefined SPSS database (IBM SPSS Statistics 26.0; IBM Corp, Armonk, NY, USA). Data extracted were first author, journal, year of publication, implant design, fixation method (i.e., cemented, uncemented), anatomical compartment (i.e., medial, lateral, both), insert (i.e., fixed, mobile), material (i.e., metal-backed, all-polyethylene), follow-up in years, and RSA technique (i.e., marker-based, model-based). Marker-based RSA is a technique which relies on movements between markers attached to or inserted into the prosthesis and markers positioned in the surrounding bone. In contrast to marker-based RSA, model-based RSA measures migration by comparing movements between a prosthesis model and markers positioned in the surrounding bone. Although these techniques have obvious differences, calculated MTPM from these different techniques do not show significant differences and can be pooled.[8] The number of patients at baseline and during follow-up was extracted as well as the age, sex, RSA results comprising of the MTPM at time intervals up to and including three months, four months, six months, one year, and two years. For the purpose of pooling data, MTPM at 3 and 4 months were combined as a single time point. The standard deviation or standard error was extracted. Some studies reported the MTPM graphically. In these studies, the MTPM was measured in the graphs by both reviewers and the average of both measurements was taken.

Quality assessment

Risk of bias was assessed using the methodological score of the Assessment of Quality in Lower Limb Arthroplasty (AQUILA) tool.[4, 9] The AQUILA is a tool which was designed to assess the quality of observational studies in lower limb arthroplasty. SH and LD assessed the risk of bias individually and any discrepancy was resolved by discussion.

Data analysis

Migration patterns of included UKAs were plotted up to 2 years. A pooled mean was calculated using a random-effects model, weighting means according to their standard error (se).[10] If se was missing, this was calculated by subtracting the lower limit of the 95% confidence interval from the upper limit of the 95% confidence interval, and by dividing this difference by 3.92 (2*1.96). If the standard deviation was missing, this was calculated by dividing the standard error by the square root of the number of included patients.[11] To assess the migration pattern of UKAs, MTPM of UKAs were pooled at each time point (i.e., three-four months, six months, one year, two years). Secondary, migration of metal-backed tibial (MBT) and all-polyethylene tibial (APT) components were separately analyzed and compared. In a post-hoc analysis, mean migration at one year was plotted against publication year in order to assess the influence of time on migration of UKAs. The Metafor Package in R Statistics (version 3.6.1; R Foundation for Statistical Computing, Vienna, Austria) was used for the analysis.[10]

Figure VII.I PRISMA flowcharts of the selection and inclusion process of the review. UKA: unicondylar knee arthroplasty; TKA: total knee arthroplasty; RSA: radiostereometric analysis; MTPM: maximum total point motion

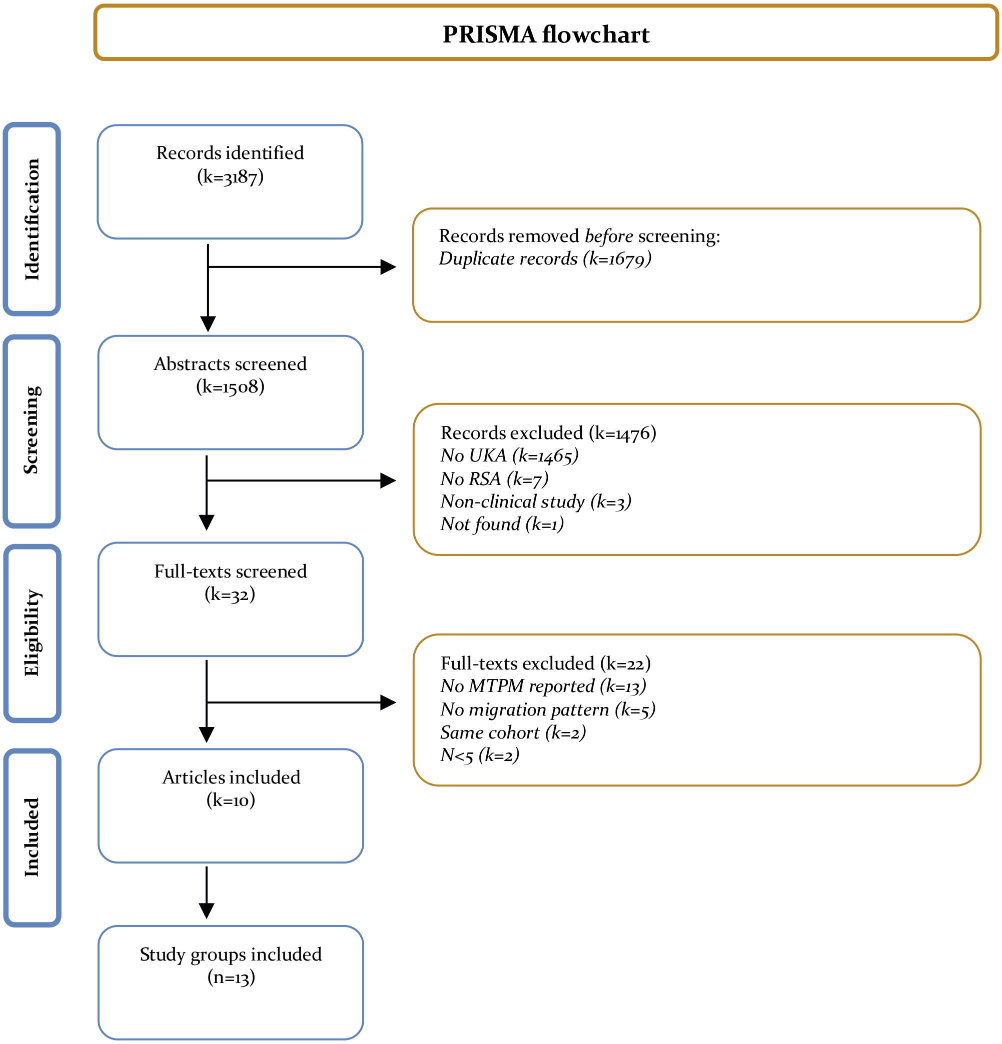


Table VII.I Study characteristics of RSA studies. RSA: radiostereometric analysis; MTPM: maximum total point motion; se: standard error; NR: not reported

Author (Year)	**Unicondylar knee arthroplasty**	**Patients** Total, N	**Age** Mean, years	**MTPM 3-4 months** Mean, millimeters (se)	**MTPM 6 months** Mean, millimeters (se)	**MTPM 1 year** Mean, millimeters (se)	**MTPM 2 years** Mean, millimeters (se)
Linde (2019)[17]	Oxford Phase III cemented medial mobile-bearing metal-backed tibial component	53	65			0.47 (0.04)	0.54 (0.05)
Koppens (2019)[16]	Oxford Phase III cemented medial mobile-bearing metal-backed tibial component	33	64	0.42 (0.06)		0.54 (0.07)	0.55 (0.06)
	Sigma cemented medial fixed-bearing metal-backed tibial component	32	61	0.44 (0.06)		0.51 (0.08)	0.50 (0.06)
Koppens (2018)[15]	Sigma High-Performance cemented medial fixed-bearing metal-backed tibial component	45	64	0.47 (0.08)		0.53 (0.09)	0.65 (0.09)
Bruni (2015)[13]	Duracon cemented medial/lateral (unclear) (fixed) bearing all-polyethylene tibial component	36	71			1.12 (0.27)	1.35 (0.39)
Ensini (2013)[21]	Optetrak cemented medial (fixed) bearing all-polyethylene tibial component	23	69	0.46 (0.08)	0.67 (0.08)	0.70 (0.14)	0.77 (0.17)
Bragonzoni (2005)[12]	Duracon cemented medial+lateral all-polyethylene tibial component	16	NR	0.47 (0.09)	0.55 (0.08)	0.61 (0.16)	0.67 (0.18)
Soavi (2002)[20]	Duracon cemented medial all-polyethylene tibial component	20	72			0.60 (0.15)	0.60 (0.17)
Hyldahl (2001)[14]	Miller-Galante cemented medial metal-backed tibial component	18	NR			0.61 (0.10)	0.96 (0.20)
	Miller-Galante cemented medial all-polyethylene tibial component	20	NR			0.78 (0.14)	0.78 (0.14)
Lindstrand (2000)[18]	Duracon cemented medial+lateral all-polyethylene tibial component	49	72	0.39 (0.04)	0.41 (0.03)	0.65 (0.10)	0.61 (0.07)
Ryd (1992)[19]	Marmor cemented medial+lateral metal-backed tibial component	24	NR		0.76 (0.12)	0.95 (0.23)	1.09 (0.24)
	Lund tibial component cemented medial+lateral metal-backed tibial component	12	NR		0.39 (0.08)	0.77 (0.23)	0.80 (0.26)

Results

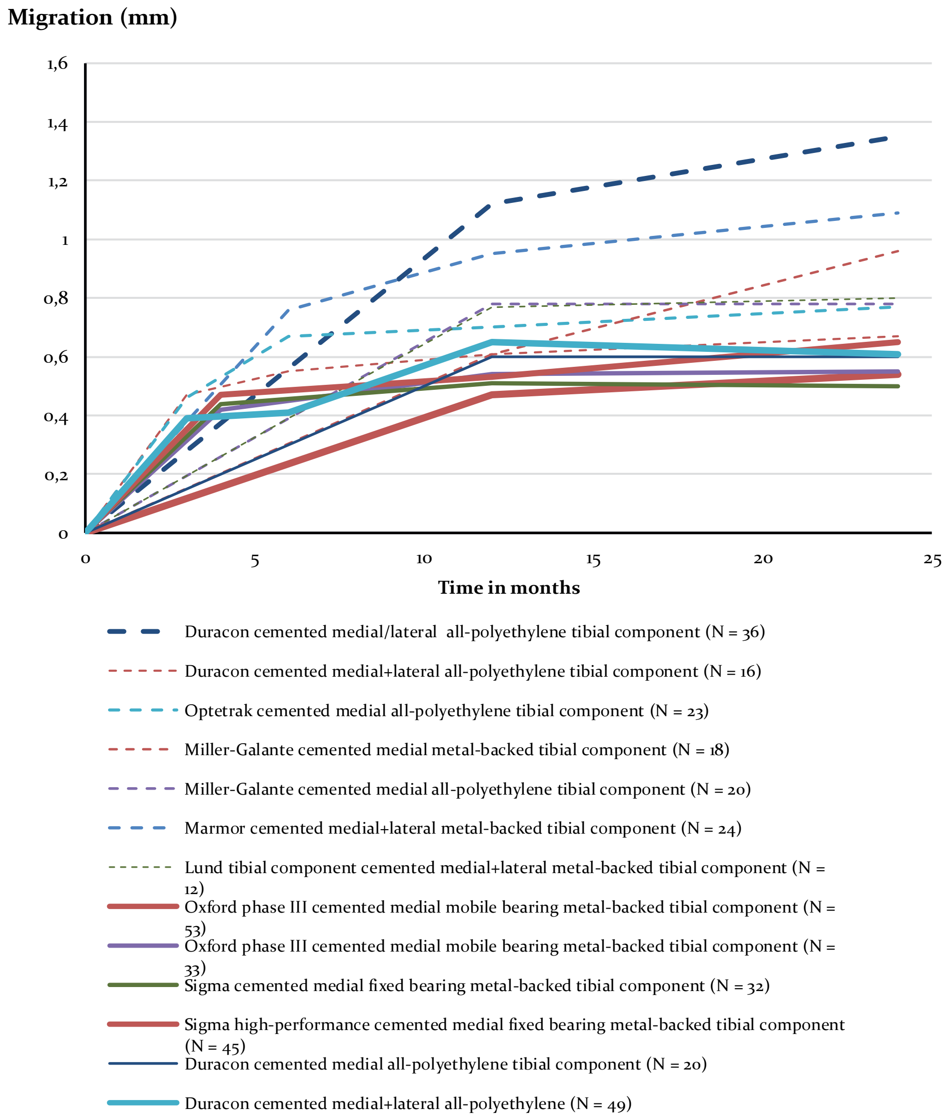
Inclusion of RSA studies

A total of 3187 records were found in the initial search of which 1679 duplicates leaving 1508 records to be screened based on title and abstract. Another 1476 records were excluded due to not involving an UKA (k=1465), not being an RSA study (k=7), not being a clinical study (k=3) and one full-text could not be found (k=1). The full-texts of 32 records were screened for eligibility, and 22 records were excluded as 13 records did not report the MTPM, 5 records did not report a migration pattern, 2 records used the same cohort, and 2 records included less than 5 UKAs, leaving ten records to be included [Fig. VII.I, Table VII.I]. Risk of bias of included studies is included in Appendix B. Follow-up was predefined in all studies and almost all studies (k=9) included more than 20 UKA. None of the studies were excluded based on the risk of bias.

Migration results

Ten studies comprising thirteen study groups were included [Table VII.I].[12-21] The number of UKAs per study group ranged between 12 and 53 with a median of 24. All implants in the studies were cemented. The pooled mean migration of all UKAs at three-four months, six months, one year, and two years was 0.43 mm (95% CI 0.38 to 0.48), 0.54 mm (95% CI 0.40 to 0.67), 0.59 mm (95% CI 0.52 to 0.66), and 0.61 mm (95% CI 0.55 to 0.68), respectively [Fig. VII.II-VII.III]. UKAs migrated predominately in the first three-four months. Migration of UKAs at one year and two years was higher than migration of TKAs at these time points [Fig. VII.III].[7] The increase in migration between six months and one year was 0.17 mm (95% CI 0.03 to 0.32) based on five study groups.

Figure VII.II The mean maximum total point motion (MTPM) of the included UKA by group over a 2-year period. The thickness of the lines are relative to the number of patients included with larger studies having thicker lines and smallers studied having thinner lines. Number of included patients, mean age, and mean MTPM with standard errors are reported in table 1. UKA: unicondylar knee arthroplasty



After one year there was little migration: pooled increase in MTPM migration between one year and two years was 0.05 mm (95% CI -0.03 to 0.12) based on 13 study groups. This increase was comparable to the increase of TKAs between one year and two years: 0.04 mm (95% CI 0.02-0.06).[7] Secondary, migration of MBT and APT were compared. MBT and APT UKAs showed a comparable migration pattern up to 6 months follow-up, but APT had a statistically significant higher MTPM at one year (p=0.007), while this difference was less prominent at two years (p=0.09; Fig. VII.IV). The influence of publication year on migration was plotted post-hoc. This figure suggests that migration of metal-backed UKAs have decreased over time in contrast to migration of all-polyethylene UKAs [Fig. VII.V].

Figure VII.III Mean migration expressed as the maximum total point motion in millimetres. The blue bold line represents the pooled mean of all UKA and the black lines represent the 10th, 25th (interrupted line), 50th (bold line), 75th (interrupted line) and 90th percentiles. The yellow line represents the mean migration of cemented TKA as previously reported.[7] UKA: unicondylar knee arthroplasty; TKA: total knee arthroplasty

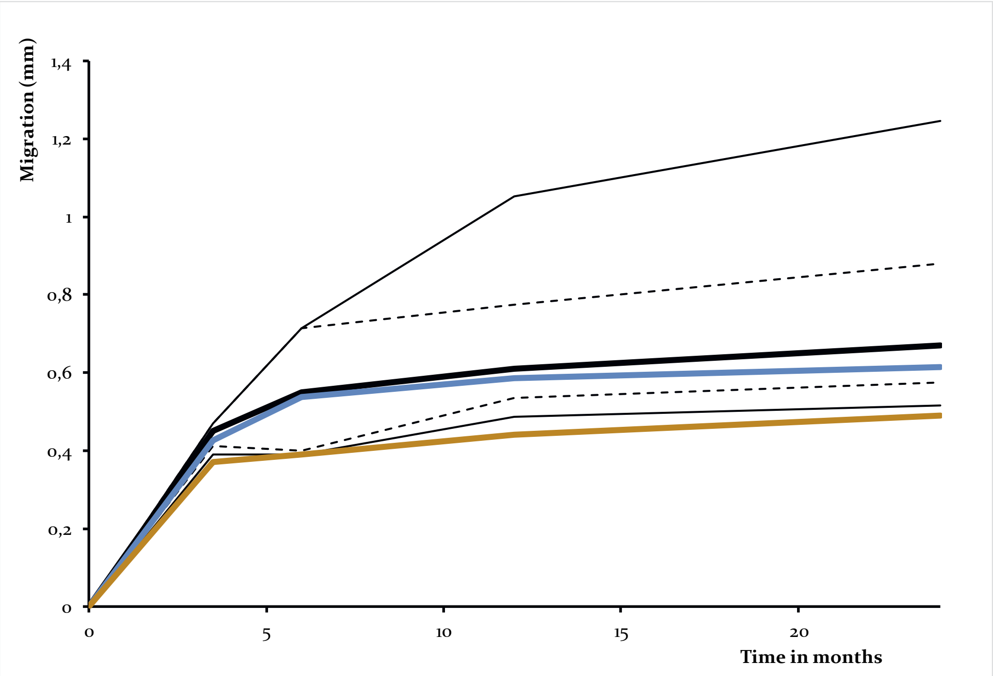


Figure VII.IV Mean migration with 95% confidence intervals (vertical error bars) expressed as the maximum total point motion in millimetres (mm) of all-polyethylene and metal-backed UKA over a 2-year period. The red, interrupted line represents the all-polyethylene UKAs, and the blue, continuous line represents the metal-backed UKAs. The yellow, interrupted line represents the mean migration of cemented all-polyethylene TKAs, and the yellow, solid line represents the mean migration of cemented metal-backed TKAs as previously reported.[7]

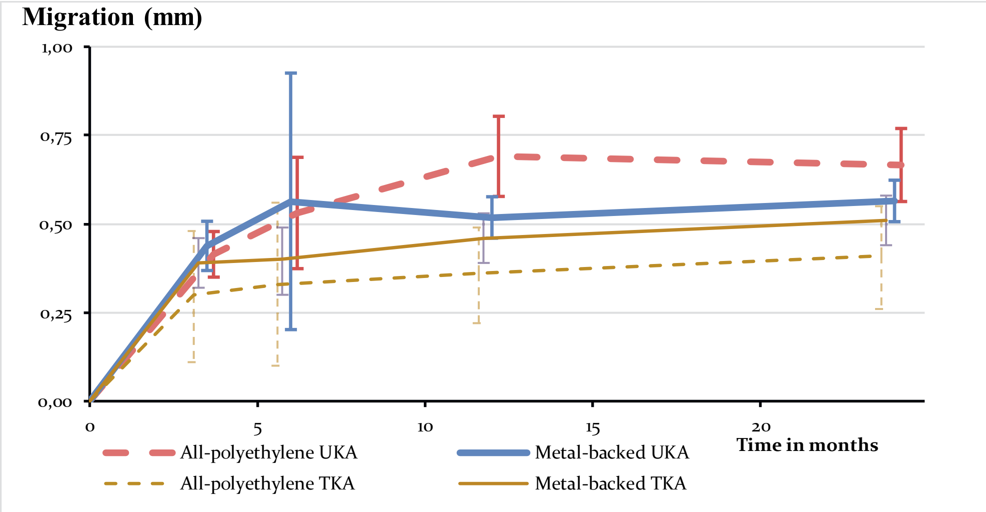
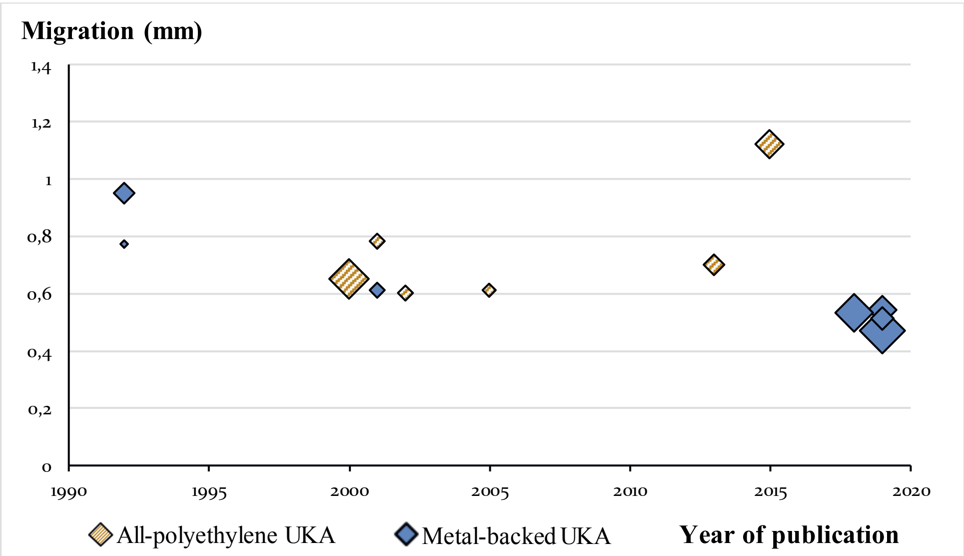


Figure VII.V Mean migration expressed as the maximum total point motion at one year in millimetres (mm) presented over time by publication year. Diamond size corresponds to the number of included patients with larger diamonds having more patients than smaller diamonds. Red, line-filled diamonds represent all-polyethylene UKAs, and the blue, solid-filled diamonds represent metal-backed UKAs. UKA: unicondylar knee arthroplasty



Discussion

The present review aimed to assess the migration profile of UKAs and found that these were comparable with the migration profile of TKAs with high initial migration and little migration between one year and two years. However, UKAs had a higher initial migration at one-year and two-year compared with TKAs. In addition, APT UKAs migrated more than MBT UKAs. Last, a trend towards a decrease of migration of MBT UKAs over the past three decades was found.

These findings suggest that the threshold used to identify implants at risk for early loosening (i.e., >0.2 MTPM from the first to the second postoperative year) could be used for UKAs as has been done by several UKA RSA studies.[13, 15-17, 21] Beside this threshold, Pijls et al. (2012) proposed a classification of TKAs into three groups based on one-year MTPM and long-term survival of TKAs: <0.54 mm one-year MTPM (i.e., acceptable), 0.54 – 1.6 mm one-year MTPM (i.e., at risk), and >1.6mm one-year MTPM (i.e., unacceptable).[7] If this classification was to be used to classify the included UKAs of the present meta-analysis, three UKAs would have been classified as acceptable, ten as at risk, and none as unacceptable. However, the one-year MTPM was higher for UKAs compared to TKAs which would naturally result in a higher number of UKAs classified as at risk or unacceptable. Whether it is justified to use this classification for UKAs remains unclear and long-term RSA UKA studies are needed to address this question. Moreover, the clinical relevance of the found difference in migration between UKAs and TKAs is unclear and should be studied further.

Our review did not include any migration studies comprising uncemented UKAs. There was one RSA study comparing uncemented and cemented UKAs, but this study did not report MTPM and was therefore not included.[22] This study found a comparable migration of uncemented and cemented UKAs.[22] Kerens et al. (2017) found no difference in revision or clinical scores, but found less radiolucent lines and a shorter operative time for uncemented UKAs,[23] while two recent registry studies found a lower revision rate for uncemented UKAs compared to cemented UKAs using 14814 and 8733 UKAs.[24, 25] The popularity of uncemented UKAs is increasing: in the Dutch arthroplasty register, 3% of UKA was uncemented in 2010 while 54% was uncemented in 2019.[26] RSA studies assessing the migration of uncemented UKAs are thus required, especially for new UKAs or UKAs without long-term follow-up either in registries or published studies.

The results of our review showed that APT UKAs migrated more than MBT UKAs at one year and two years follow-up. This finding is in line with the results from a recent meta-analysis which found a 2.13 higher risk of all-cause revision and a 1.66 higher risk for revision due to aseptic loosening for APT compared to MBT.[27]

There are several UKA designs available and only some of these UKA designs have been evaluated with RSA and were included in this systematic review. The five-year all-cause revision rates of these UKAs varies between 3.3% and 16.8%.[2, 26] Considering this variation of revision rate, a phased introduction is especially needed for UKAs to ensure patient safety. It is, therefore, highly recommended to test novel UKA designs with RSA in addition to cohort studies for mid- and long-term survival.[28-30]

Some limitations of this review should be considered. First, the number of included RSA studies was small compared to a previous review on TKAs. Ten RSA studies compared to 50 RSA studies for TKAs were included.[4, 7] In order to obtain a better understanding of the migration profiles of different implant designs, studies including novel UKA designs are needed. Moreover, some studies used medial and lateral UKAs or did not specify whether medial or lateral UKAs were included without further specifying outcomes for the medial or lateral UKAs separately. It would be helpful if future studies clearly specify the design, fixation method, insert and the anatomical compartment of UKAs to allow comparison between studies and facilitate future systematic reviews. Last, the present review did not assess the influence of specific patient characteristics or surgical technique on migration nor was the influence of publication year statistically analysed as the number of groups was limited and further subgroup analysis was deemed inappropriate. Future studies should pool individual patient data to assess the influence of patient characteristics on UKA migration.

Conclusion

The migration pattern of UKAs is comparable to the migration pattern of TKAs in the first two years as both show initial migration in the first few months and limited migration hereafter. However, UKAs had higher migration at one- at two-year.

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Chapter VII