# Early migration of tibial components is associated with late revision

## A systematic review and meta-analysis of 21,000 knee arthroplasties

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**Purpose**    We performed two parallel systematic reviews and meta-analyses to determine the association between early migration of tibial components and late aseptic revision.

**Methods**    One review comprised early migration data from radiostereometric analysis (RSA) studies, while the other focused on revision rates for aseptic loosening from long-term survival studies. Thresholds for acceptable and unacceptable migration were determined according to that of several national joint registries: < 5% revision at 10 years.

**Results**    Following an elaborate literature search, 50 studies (involving 847 total knee prostheses (TKPs)) were included in the RSA review and 56 studies (20,599 TKPs) were included in the survival review. The results showed that for every mm increase in migration there was an 8% increase in revision rate, which remained after correction for age, sex, diagnosis, hospital type, continent, and study quality. Consequently, migration up to 0.5 mm was considered acceptable during the first postoperative year, while migration of 1.6 mm or more was unacceptable. TKPs with migration of between 0.5 and 1.6 mm were considered to be at risk of having revision rates higher than 5% at 10 years.

**Interpretation**    There was a clinically relevant association between early migration of TKPs and late revision for loosening. The proposed migration thresholds can be implemented in a phased, evidence-based introduction of new types of knee prostheses, since they allow early detection of high-risk TKPs while exposing only a small number of patients.

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Worldwide, several hundred thousand total knee prostheses (TKPs) are implanted each year and this number is expected to increase by a factor of 6 within the next 2 decades (Kurtz et al. 2005, 2007). Most of the new TKP designs have been introduced to the market without being shown to be safe or effective (Sheth et al. 2009). This has resulted in the widespread use of TKPs with failure rates exceeding 10 times the standard of national joint registries (< 5% failures at 10-year follow-up), such as the Accord, St Leger, and Journey-Deuce (Norton et al. 2002, Gilbert et al. 2009, Sheth et al. 2009, Palumbo et al. 2011 (personal communication)). To guarantee patient safety, several countries have developed guidelines, e.g. the NICE guidelines for total hip prostheses (2003). Furthermore, it has become increasingly evident that a phased, evidence-based introduction, as is common for pharmaceuticals, is needed to regulate the introduction of new TKPs to the market (Malchau 2000, McCulloch et al. 2009, Schemitsch et al. 2010). This should include systematic assessment and early detection of the major cause of TKP failure, which is aseptic loosening of the tibial component necessitating revision surgery (2003, AJR 2010).

Although it can take 10 years before loosening causes symptoms, it is possible to detect loosening early postoperatively using radiostereometric analysis (RSA) (Selvik 1989, Grewal et al. 1992, Karrholm et al. 1994, Ryd et al. 1995). Since RSA allows in vivo, 3D measurement of the migration of TKPs with an accuracy of 0.2 mm for translations and 0.5 degrees for rotations, only a small number of patients need be exposed to potentially unsafe TKPs (Grewal et al. 1992, Ryd et al. 1995, Nelissen et al. 1998). RSA could therefore play an important role in the phased, evidence-based introduction of new TKPs (Selvik 1989, Karrholm et al. 1994, Ryd et al. 1995). However, the evidence for the relationship between early migration and TKP revision for aseptic loosening is limited to a few studies from the 1990s (Grewal et al. 1992, Ryd et al. 1995).

Furthermore, the applicability of these studies is restricted, because surgical technique, fixation methods, implant design, and polyethylene have evolved since their publication.

We hypothesized that early migration of the tibial component, measured through RSA, is associated with late revision for aseptic loosening of TKPs. We therefore systematically reviewed the association between early migration and late aseptic revision for the tibial component in TKPs. This could ultimately lead to clinical guidelines to be used in a phased introduction of new TKPs.

## Material and methods

We performed two parallel systematic reviews (international registration number NTR2417; www.trialregister.nl) of studies of patients who received TKPs for end-stage osteoarthritis (OA) or rheumatoid arthritis (RA). One
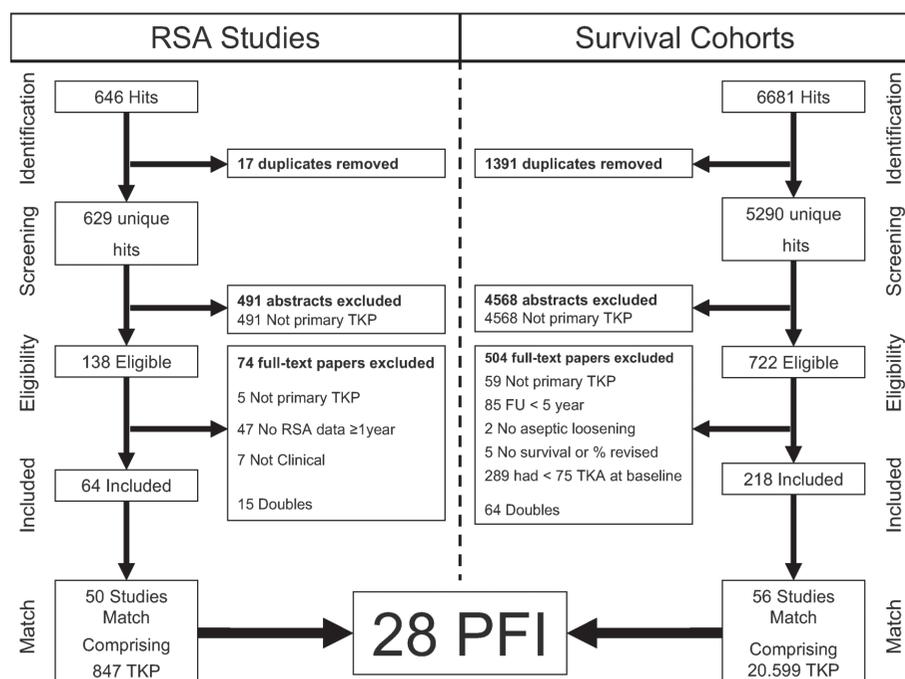


Figure 1. PRISMA flow chart of both reviews. Details of the 28 PFI combinations are given in Table 1. RSA: radiostereometric analysis; TKP: total knee prosthesis; FU: follow-up; PFI: prosthesis-fixation-insert combination.

review comprised data on early migration of TKPs from RSA studies. From the other, we determined the long-term revision rates for aseptic loosening of TKPs from survival studies (Figure 1). During all stages of the review process, a referee (RN) with over 20 years of experience in both RSA and TKR was available for consultation.

### Systematic review of RSA studies

*Literature search.* A thorough literature search was performed together with a medical librarian (JP), to reduce bias by increasing the likelihood of retrieving all relevant studies (Vochteloo et al. 2010). The following bibliographies were searched up to 2009: PubMed, Embase, Web-of-Science, and the Cochrane Library. Relevant articles were screened for additional references. Additionally, a separate search was conducted in 9 leading orthopedic and biomechanical journals (Acta Orthop, Clin Orthop Relat Res, J Arthroplasty, J Bone Joint Surg (Am and Br), Knee Surg Sports Traumatol Arthrosc, J Orthop Res, J Biomech, and Clin Biomech). Finally, Google Scholar was used. Articles in English, French, Italian, Spanish, Dutch, and German were considered. The search strategy consisted of the following components, each defined by a combination of controlled vocabulary and free text terms: (1) RSA, and (2) joint replacement. See Appendix (Supplementary data) for more details on the strategy and terms.

*Inclusion and exclusion analysis.* Initial screening on the basis of title and abstract of RSA studies was performed by BP to identify studies on patients treated with TKPs for OA

or RA. When the information in the abstract did not suffice or where there was any doubt, the studies remained eligible. The full text of eligible studies was independently evaluated in duplicate by 2 reviewers (BP and EV). The inclusion criteria for RSA studies were: (1) primary TKP, and (2) minimal RSA follow-up of 1 year, measuring tibial component migration. Non-clinical studies (animal, phantom) were excluded.

*Data extraction.* BP and KN independently extracted migration data in duplicate from the RSA studies. Migration data comprised translations, rotations, and maximal total point motion (MTPM) of the tibial component in the first postoperative year. MTPM is the unit of measurement for the largest 3D migration of any point on the prosthesis surface (Ryd et al. 1995). Data concerning patient demographics and regional influences were also extracted to allow for confounder correction.

*Quality assessment.* The quality of the RSA studies was independently appraised in duplicate by BP and KN at the level of outcome using the AQUILA methodological score (Pijls et al. 2011). For the RSA studies, we modified the AQUILA by removing items not considered relevant for early migration: long-term follow-up and the revision assessment.

### Systematic review of survival studies

*Literature search.* The search strategy and bibliographies were the same as those in the RSA review, with the exception of the components of the search strategy. The search strategy for the survival studies consisted of the following components, each

defined by a combination of controlled vocabulary and free text terms: (1) joint replacement, (2) implant failure, and (3) survival analysis. See Appendix for more details of the strategy and terms. In the search strategy, no distinction was made between total knee prostheses and total hip prostheses (THPs), because some studies reported on both TKPs and THPs (Ryd 1992).

*Inclusion and exclusion analysis.* The procedure of screening the survival studies for eligibility, and subsequent inclusion and exclusion analysis, was identical to the procedures for the RSA studies, with the exception of inclusion and exclusion criteria. The inclusion criteria for survival studies were (1) primary TKP; (2) follow-up of 5, 10, 15, 20, or 25 years; (3) endpoint revision surgery for aseptic loosening of the tibial component, or indication for revision surgery in patients with poor general health or decline; and (4) survival or percentage revised to be available for specific follow-up (see point 2). Studies with less than 75 TKPs at baseline were excluded.

*Data extraction.* From the survival studies, BP and KN independently determined the revision rates for aseptic loosening of the tibial component at 5-year intervals. Data concerning patient demographics and regional influences were extracted to allow for confounder correction.

*Quality assessment.* The quality of the survival studies was independently appraised in duplicate by BP and KN at the level of outcome using the AQUILA methodological score (Pijls et al. 2011).

### Analysis

A detailed description of the analysis, methodology, and a worked example are available in the online Appendix (see Supplementary data). To determine the association between early migration and late revision, we matched the results from the RSA review to the results of the survival review on type of prosthesis, fixation method (e.g. cement or bone ingrowth), and articulating insert (e.g. modular or non-modular). The combination was termed PFI. Since PFI involves technical factors known to be associated with both migration and the likelihood of revision for aseptic loosening, matching on PFI prevents confounding by PFI (DKAR 2009, NJR 2009, AJR 2010, SKAR 2010). Depending on the studies available, it was possible that there would be more than 1 combination of matching RSA and survival studies for a particular PFI. For instance, if there are 3 RSA studies and 2 survival studies for the same PFI, then there are 6 possible combinations (3 times 2). All combinations were considered in the analysis. A meta-analysis for the revision rate at 5 years was performed. A model for the censoring mechanism was employed to reconstruct the data and then a generalized linear mixed model with study as a random effect was applied to estimate the survival at 5 years and its 95% confidence interval (CI) (Fiocco et al. 2009, 2011, Putter et al. 2009). Regarding the RSA studies, pooling of migration results at the level of PFI was based on weights according to study size (N).

The 10-year results for TKPs with high revision rates may not be published once the 5-year results have been published. Since 10-year revision rates in the registries are on average 1.7 times higher than 5-year revision rates, any missing 10-year results were estimated on 5-year results by applying a factor of 1.7. This method was validated by comparing the estimated 10-year results with the known 10-year results, for the complete cases (DKAR 2009, NJR 2009, AJR 2010, SKAR 2010).

### Adjustment for confounding

Since migration data and revision rate data were extracted from different studies, differences between study populations might confound the observed association. In order to address this issue, we determined the degree of similarity of the population from RSA and survival study combinations, expressed by a match score, for age, sex, diagnosis, hospital type, and continent. The match score was constructed according to the results of a recent Delphi survey among an international group of 37 independent experts, and can vary between 5 (excellent) and 0 (poor) (Pijls et al. 2011). The RSA study and survival study combination scored 1 point for each of the following 5 criteria (up to a maximum of 5 points): (1) the difference in mean age between the patients from RSA study and those from the survival study was 5 years or less; (2) the difference in percentage of females between the RSA study and survival study was 10% or less; (3) the difference in percentage of patients diagnosed with osteoarthritis between the RSA study and the survival study was 10% or less; (4) the RSA study and the survival study were performed in similar types of hospital (e.g. both university medical centers); (5) the RSA study and the survival study were performed on the same continent. All other cases scored zero points.

We used a weighted regression model to assess the association between early migration and late aseptic revision corrected for match score, RSA study quality, survival study quality, number of TKP in the RSA studies, and number of TKP in the survival studies.

### Migration thresholds

According to the principle of "primum non nocere" (first do no harm), new implant designs should perform at least as well as the revision standard of national registries: < 3% revision at 5 years and < 5% revision at 10 years (DKAR 2009, NJR 2009, AJR 2010, SKAR 2010). Based on this revision standard, the following 3 categories were constructed for the phased introduction of new TKPs: "acceptable", "at risk", and "unacceptable". The "acceptable" category was defined as the level of migration up to which all survival studies have lower revision rates than the standard. The "unacceptable" category was defined as the level of migration from which all revision rates are higher than the standard. The category "at risk" was defined as the migration interval between the "acceptable" and "unacceptable" thresholds, in which studies with revision rates lower and higher than the standard were observed.

### Appraisal of publication bias

We assessed the potential effect of publication bias by comparing the results from the meta-analysis to the results from national joint registries, since they do not suffer from publication bias (DKAR 2009, NJR 2009, AJR 2010, SKAR 2010). Accordingly, the PFI combinations that perform better than average in the meta-analysis should also perform better than average in the national joint registries. The same principle also applies to PFI combinations that perform worse than average. For this purpose, the migration pooled according to the specific combination of prosthesis type, fixation method and articulating insert (PFI) and visualized in a dot chart (Jacoby 2006).

## Results

### RSA studies

The literature search yielded 629 hits for the RSA review and 50 studies were included, covering a total of 847 patients (Ryd et al. 1986, 1987, 1988, 1990, 1993, Albrektsson et al. 1990, 1992, Nilsson et al. 1991, 1993, 1998, 2006, Hilding et al. 1995, 2006, 2007, Nielsen et al. 1995, Nelissen et al. 1998, Onsten et al. 1998, Toksvig-Larsen et al. 1998, Adalberth et al. 1999, 2000, 2001, 2002, Østgaard et al. 1999, Li et al. 2000, Toksvig-Larsen et al. 2000, Uvehammer et al. 2001, Hildebrand et al. 2003, Catani et al. 2004, Kienapfel et al. 2004, Norgren et al. 2004, Dalen et al. 2005, Hyldahl et al. 2005a, b, Henricson et al. 2006, Muller et al. 2006, van der Linde et al. 2006a,b, Uvehammer et al. 2007, Wilson et al. 2007, Hansson et al. 2008, Henricson et al. 2008, Therbo et al. 2008, von Schewelov et al. 2008). Details of the study selection and flow of the review are given in Figure 1. The mean quality score of the RSA studies was 3.8 (SD 1.7) on a 7-point scale. MTPM at 1 year was the most frequently and most consistently reported migration value: 44 out of 50 RSA studies reported it. Translations and rotations of the tibial component were reported infrequently and inconsistently, and did not allow a meaningful analysis. Thus, all analyses focused on MTPM at 1 year.

### Survival studies

The literature search resulted in 5,290 hits for the survival review and 56 studies were included, with a total of 20.599 patients; see Figure 1 (Goldberg et al. 1988, Laskin 1990, Samuelson et al. 1990, Wright et al. 1990, Moran et al. 1991, Grewal et al. 1992, Ranawat et al. 1993, 1994, Rinonapoli et al. 1994, Weir et al. 1996, Knight et al. 1997, Scott 1997, Ansari et al. 1998, Hsu et al. 1998, Ewald et al. 1999, Mont et al. 1999, Buehler et al. 2000, Emerson et al. 2000, Robertsson et al. 2000, Stukenborg-Colsman et al. 2000, Berger et al. 2001a,b Faraj et al. 2001, Gill et al. 2001, Khaw et al. 2001, Schroder et al. 2001, Sextro et al. 2001, Fetzer et al. 2002, Forster et al. 2002, Khaw et al. 2002, Worland et al. 2002, Mayman et al. 2003, Goldberg et al. 2004, Arora et al. 2005,

Bozic et al. 2005, Campbell et al. 2006, Clayton et al. 2006, Gioe et al. 2006, Lachiewicz et al. 2006, Vessely et al. 2006, Bertin 2007, Kim et al. 2007, Rodricks et al. 2007, Zaki et al. 2007, Anderson et al. 2008, Chana et al. 2008, Dalury et al. 2008, Parsch et al. 2008, Ritter et al. 2008, Santini et al. 2008, Smith et al. 2008). The mean quality score of the survival studies was 6.0 (SD 1.8) on an 11-point scale.

### Early migration and late revision

The matching procedure resulted in 28 different PFI combinations and 89 combinations of RSA and survival studies (Table 1). There was a clear association between early migration, expressed as MTPM at 1 year, and the 5-year revision rate as expressed as prosthesis survival (Figure 2). For every mm of increase in migration, 7.6% (CI: 5.7–9.5) was added to the 5-year revision rate (p < 0.001). The influence of RSA study quality, survival study quality, number of TKPs in the RSA study, number of TKPs in the survival study, and match score were small relative to the overall effect of migration on revision rate (Table 2).

For TKPs that rely on primary fixation (cemented and uncemented with screws), 7.1% (CI: 4.7–9.5) was added to the 5-year revision rate for every 1 mm increase in MTPM (p <0.001). For TKPs that rely on secondary fixation (uncemented without screws), 10% (CI: 2.7–17) was added to the 5-year revision rate for every 1 mm increase in MTPM (p = 0.018).

### Migration thresholds

Figure 3 shows the 3 categories for the migration of TKP. For MTPM at 1 year of between 0 mm and 0.54 mm, there was no tibial component with more than 3% revision for aseptic loosening at 5 years. With 1-year MTPM of more than 1.6 mm, no tibial components had less than 3% revision for aseptic loosening at 5 years. This indicates that acceptance of 3% revision at 5 years resulted in a threshold of 0.54 mm or acceptable MTPM at 1 year, and a threshold of 1.6 mm for unacceptable MTPM at 1 year. For the 10-year revision rates, the thresholds for acceptable and unacceptable migration were 0.45 mm and 1.6 mm, respectively (Figure 4).

The mean difference between the estimated 10-year revision rate and the known 10-year revision rate was 0.17% (SD 2.1), indicating that there was no systematic error. The 5-year revision rates for the studies with missing 10-year revision rates were already higher than the 10-year revision rate of 5% that is considered to be acceptable. Thus, the 10-year thresholds were not influenced by any missing values.

### Publication bias

The pooled MTPM ranked by the pooled revision rate for each PFI combination is presented in Figure 5. The PFI combinations that migrated statistically significantly less than the acceptable threshold—classified as acceptable—have had excellent track records and low revision rates in several national joint regis-

Table 1. Prosthesis, Fixation and Insert (PFI) characteristics.

| PFI | 89 Prosthesis | Fixation | Insert | Number of RSA studies | Number of survival studies | Number of combi-nations |
|---|---|---|---|---|---|---|
| 1 | Anatomic Modular Knee, CR, MB | Cement | Fixed, Modular | 2 | 2 | 4 |
| 2 | Tricon M, PE pegs, MB | Porous coated, no stem, no screws | Fixed | 3 | 1 | 3 |
| 3 | Duracon, CR, MB | Cement | Fixed, Modular | 1 | 1 | 1 |
| 4 | Total Condylar, no CR | Cement | All PE | 1 | 5 | 5 |
| 5 | Freeman-Samuelson | Uncoated | All PE (HDP) | 2 | 2 | 4 |
| 6 | Freeman-Samuelson, PE pegs, MB | Uncoated | Fixed | 1 | 2 | 2 |
| 7 | Anatomic Graduated Component 2000, CR, MB | Porous coated | Fixed, Non-modular | 1 | 1 | 1 |
| 8 | Miller-Galante I, 4 pegs, CR, MB | Cement | Fixed, Modular | 2 | 1 | 2 |
| 9 | Miller-Galante II, 4pegs, CR, MB | Cement | Fixed, Modular | 2 | 1 | 2 |
| 10 | Optetrak, PS, MB, finned stem | Cement | Fixed | 1 | 1 | 1 |
| 11 | Kinemax Plus, no PS | Cement | All PE | 1 | 1 | 1 |
| 12 | Profix, stemmed, CR, MB | Cement | Fixed, Modular | 1 | 3 | 3 |
| 13 | Porous Coated Anatomic, cruciform stem, CR, MB | Cement | Fixed, Modular | 1 | 1 | 1 |
| 14 | Kinematic Condylar, CR, MB | Cement | Fixed, Non-modular | 6 | 1 | 6 |
| 15 | Miller-Galante I, 4 pegs, CR, MB | Porous coated, 4 screws | Fixed, Modular | 2 | 2 | 4 |
| 16 | Anatomic Graduated Component, CR, MB | Cement | Fixed, Non-Modular | 3 | 3 | 9 |
| 17 | Press Fit Condylar, CR, MB | Porous coated | Fixed, Modular | 1 | 1 | 1 |
| 18 | Duracon, CR, MB | HA/PA coated | Fixed, Modular | 1 | 5 | 5 |
| 19 | Press Fit Condylar, CR, MB | Cement | Fixed, Modular | 9 | 1 | 9 |
| 20 | Press Fit Condylar Sigma, CR, MB | Cement | Fixed, Modular | 3 | 2 | 6 |
| 21 | NexGen Legacy, PS, MB | Cement | Fixed, Modular | 2 | 2 | 4 |
| 22 | Freeman-Samuelson, PE pegs, MB | Cement | Fixed | 2 | 1 | 2 |
| 23 | Freeman-Samuelson, metal pegs, MB | Cement | Fixed, Modular | 2 | 2 | 4 |
| 24 | NexGen, CR, MB, stem | Cement | Fixed, Modular | 1 | 2 | 2 |
| 25 | NexGen, 4 pegs, CR, MB | Cement | Fixed, Modular | 1 | 2 | 2 |
| 26 | Miller-Galante II, 4 pegs, CR, MB | Porous coated, 4 screws | Fixed, Modular | 1 | 2 | 2 |
| 27 | Porous Coated Anatomic, no PS, MB, no stem | Porous coated, 1 screw | Fixed | 1 | 2 | 2 |
| 28 | Interax, CR, MB | Uncoated | Fixed, two halfbearings | 2 | 1 | 2 |
| Total | | | | 50 | 56 | 89 |

CR = cruciate retaining
HA/PA = Hydroxyapatite/periapatite
HDP = high density poly-ethylene
MB = metal backed
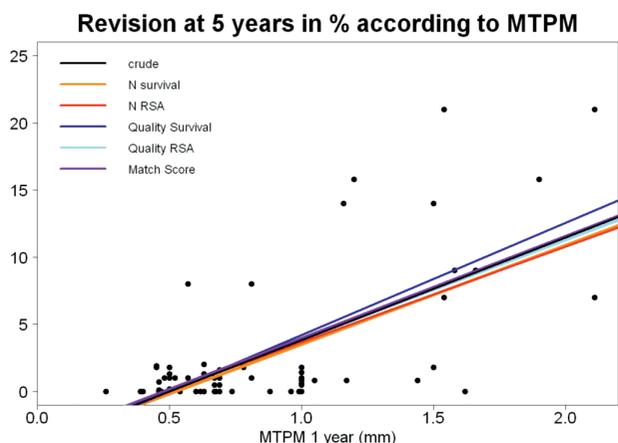PE = poly-ethylene
PS = posterior stabilized



Figure 2. Scatter plot showing association between migration in the first postoperative year expressed as maximal total point motion (MTPM) in mm and revision rate for aseptic loosening of the tibial component at 5 years, as a percentage. The colored lines are derived from weighted regression according to match quality, survival study quality, and RSA study quality (the coefficients and 95% CI are given in Table 2).
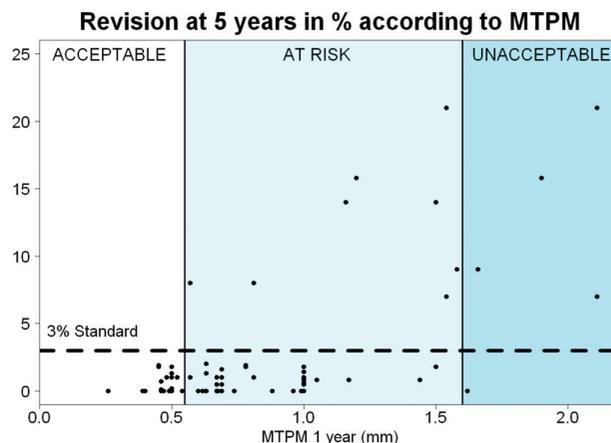


Figure 3. Scatter plot showing the relation between MTPM at 1 year and revision of the tibial component for aseptic loosening at 5 years. The thresholds of 0.54 mm and 1.6 mm for the three categories (acceptable, at risk, and unacceptable) are shown.

Table 2. Association between MTPM at 1 year and revision rate for aseptic loosening at 5 years

|  | Increase in revision (%) / mm MTPM | 95% CI |
|---|---|---|
| Crude | 7.6 | 5.7–9.5 |
| Adjusted for [a]: | | |
|   N survival [b] | 7.4 | 5.6–9.2 |
|   N RSA [b] | 7.1 | 5.4–8.8 |
| Survival study quality | 8.4 | 6.5–10.3 |
| RSA study quality | 7.4 | 5.4–9.4 |
| Total Match Score | 7.6 | 5.6–9.4 |
| Range of values: | 7.1–8.4 | 5.4–10.3 |

Table 2 shows the increase in the 5-year revision (%) for each mm increase in MTPM at 1 year. In the crude analysis (unadjusted) 7.6% [95%CI 5.7–9.5], p<0.001, is added to the 5-year revision rate for every mm increase in MTPM at 1 year.
[a] When adjusted for e.g. the number of TKP in survival studies (N survival) 7.4% [95%CI 5.6–9.2], p<0.001, is added to the 5-year revision rate for every mm increase in MTPM at 1 year.
The association between MTPM1 and revision rate for aseptic loosening remains significant, when adjusting for confounders (all p-values <0.001).
[b] The square rote of N was used for the weighted regression, so larger studies weigh heavier.
N survival = number of TKP in survival studies
N RSA = number of TKP in RSA studies
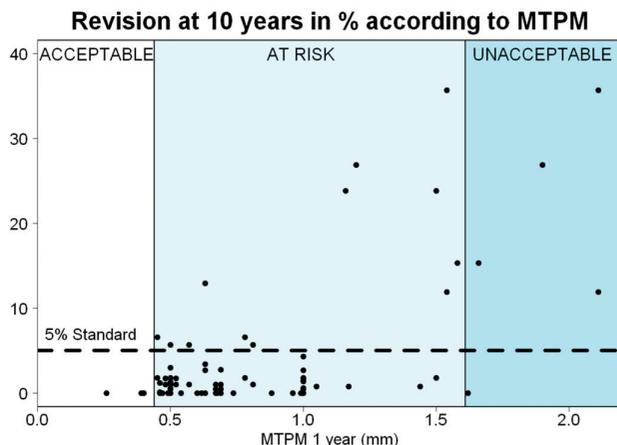


**Revision at 10 years in % according to MTPM**

Figure 4. Scatter plot showing the relation between MTPM at 1 year and revision of the tibial component for aseptic loosening at 10 years. The thresholds of 0.45 mm and 1.6 mm for the three categories (acceptable, at risk, and unacceptable) are shown.

tries (DKAR 2009, NJR 2009, AJR 2010, SKAR 2010). Conversely, the PFI combinations that were classified as unacceptable on basis of their pooled migration have been abandoned and are no longer used. The possible influence of publication bias on the results was therefore small.

## Discussion

The results of this systematic review show a clinically relevant association between early migration, as measured with RSA, and long-term clinical failure resulting in revision for aseptic loosening. Each mm of migration was associated with an increase in 5-year revision rate of 8%, which remained after correction for age, sex, diagnosis, hospital type, continent, and study quality. This is more than twice the standard revision rate of several national joint registries (DKAR 2009, NJR 2009, AJR 2010, SKAR 2010). The results of this systematic review show that RSA studies can identify unsafe TKPs (in

terms of aseptic loosening) as early as 1 year postoperatively. Early identification of unsafe TKPs with RSA should prevent their widespread use and save numerous patients from extensive revision surgery, possibly with postoperative complications.

Some strengths of this systematic review are the large numbers of studies included (> 100) and of patients included



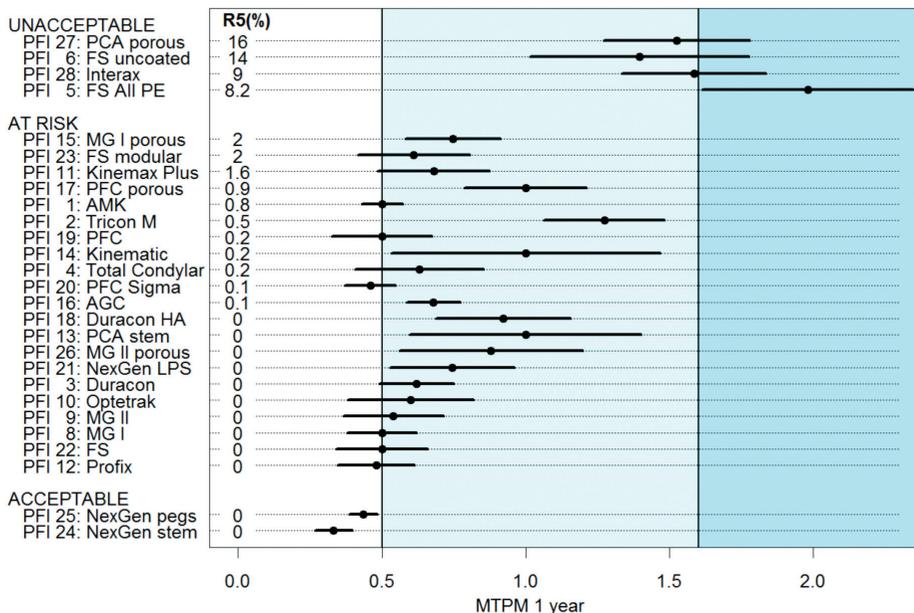**Pooled MTPM sorted by revision rate**

Figure 5. Dot chart showing the pooled MTPM ranked by the pooled revision rate for each PFI combination. The acceptable PFI combinations (based on migration) had excellent track records and low revision rates in several national registries, whereas the unacceptable PFI combinations (based on migration) have been abandoned. Thus, the potential influence of publication bias on the results is small. A detailed description of each PFI combination is given in Table 1. R5(%): pooled revision rate at 5-year follow-up, as a percentage.
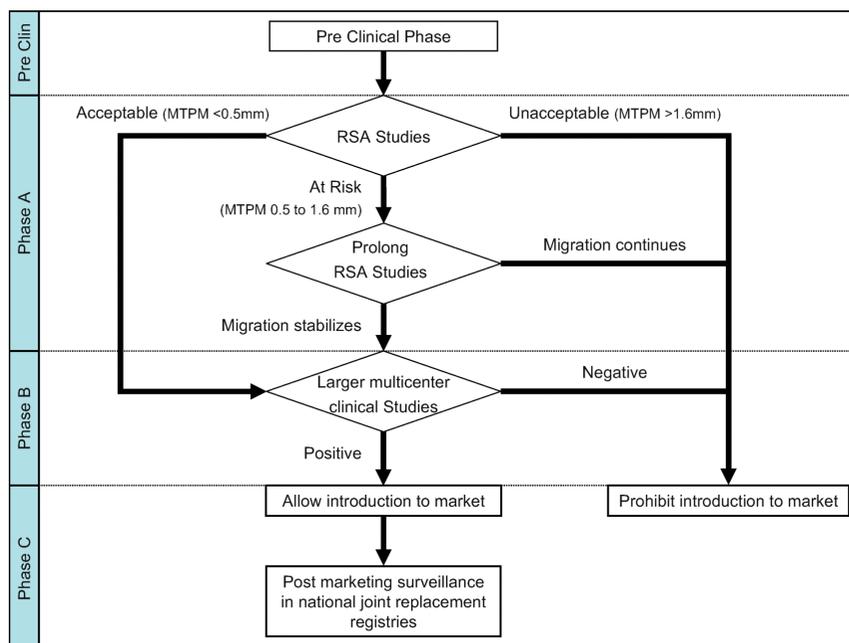
Figure 6. Flow chart showing the role of RSA studies in the phased evidence-based introduction of new TKPs, modified according the Malchau proposal. Stabilization is defined as migration of less than 0.2 mm in the second postoperative year (MTPM from year 1 to year 2) as described by Ryd et al. (1995). See discussion for details of each phase.

(> 27,000), which resulted in 28 different PFI combinations. This large variation, which reflects the diversity of TKP designs and fixation methods, ensures wide generalizability of the results. Since the migration and revision rates were from different studies, there were no migration data available in the survival studies to be incorporated into the decision to perform a revision. Thus, there is no incorporation bias in our results. We consider the risk of publication bias in this systematic review to be small, since the results from the meta-analysis are similar to those from the national joint registries, which do not suffer from publication bias. Confounders had only a small influence on the association between early migration and long-term aseptic revision.

We should also consider some limitations. The quality of the survival and RSA studies showed large variation. High methodological quality of all the studies included would have been desirable. Nevertheless, the quality of the survival studies and the RSA studies showed only very small effects on the association between migration and revision rates.

We focused on MTPM at 1 year postoperatively, but other migration parameters and follow-up beyond 1 year would also be of interest (Ryd et al. 1995). Unfortunately, these parameters were reported too infrequently and inconsistently to permit a meaningful analysis. Future RSA studies could therefore benefit from further standardization, particularly regarding the reporting of the results (Valstar et al. 2005).

We also recognize that RSA only evaluates aseptic loosening while other failure mechanisms (e.g. infection, pain, and instability or pseudotumors in metal-on-metal total arthroplasty) cannot be evaluated by RSA. As a consequence, RSA studies are only the first step in the phased, evidence-based introduction of TKPs—as proposed by Malchau (2000); see Figure 6. During phase A, several single-center RSA studies should be performed to determine the safety of the TKP with regard to the risk of revision for aseptic loosening. If the TKP is considered safe, phase B studies should be conducted to evaluate the clinical performance of the TKP regarding pain relief and functioning (clinical scores and patient-reported outcome measures (PROMS)) and to determine the rate of expected or unexpected complications. Since RSA studies have already evaluated the risk of aseptic loosening, follow-up of 2 years instead of 10 years would be sufficient. This reduces the follow-up needed for a successful phased introduction by almost a decade compared to traditional cohort studies. After release on the market (phase C), the performance of the TKP must be monitored by post-marketing surveillance in national joint replacement registries (Schemitsch et al. 2010). This includes both the revision rate and patient evaluations using PROMS.

In this systematic review, RSA studies of 20–60 patients followed for 1 year led to the same conclusion as national joint registries with thousands of patients followed for 5–10 years. A recent publication has shown a 22–35% reduction in the number of revisions of RSA-tested total knee replacements as compared to non-RSA-tested total knee replacements in the national joint registries (Nelissen et al. 2011). Because inferior designs can already be detected early postoperatively, exposing only a small group of patients to potentially unsafe TKPs, RSA provides the necessary efficiency to make possible phased, evidence-based introduction. Now the observed association between early migration and long-term revision translates into practical thresholds that can lead to clinical guidelines for phased, evidence-based introduction of new TKPs.

Various authors and regulatory agencies recognize the potential of RSA (Grewal et al. 1992, Bulstrode et al. 1993, Karrholm et al. 1994, Ryd et al. 1995, Malchau 2000, Hauptfleisch et al. 2006). The NICE guidelines of 2003 (UK) require adequate long-term clinical data for hip prostheses and indicate that RSA is an alternative to long-term follow-up studies. The Dutch Orthopaedic Society now requires a phased introduction with mandatory RSA studies before any new hip prosthesis is considered for introduction to the Dutch market (2011). Official guidelines for knee prostheses are expected to follow.

In light of the recent disasters with introduction of new orthopedic implants to the market, a phased, clinical introduction for new TKPs is mandatory to prevent patients from receiving potentially unsafe TKPs when standard TKPs with excellent long-term track records are available.

In conclusion, we found a clinically relevant association between early migration of TKPs and late revision for loosening. The proposed migration thresholds can be implemented in a phased, evidence-based introduction, since they allow early detection of TKPs with a high risk of aseptic loosening while exposing only a small number of patients.

## *Data sharing*

The statistical code and dataset are available upon request from the corresponding author at b.g.c.w.pijls@lumc.nl. R code for the analysis described in the Appendix is available from one of the authors (m.fiocco@lumc.nl).

## *Supplementary data*

Appendix is available at our website (www.actaorthop.org), identification number 5477.

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