Evidence based introduction of orthopaedic implants : RSA, implant quality and patient safety

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Chapter 7

Early migration of tibial components is associated with late revision

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Abstract

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

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.

Following an elaborate literature search 50 studies (847 Total Knee Prostheses(TKP)) were included in the RSA-review and 56 studies (20,599 TKP) 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 post-operative year, while migration of 1.6 mm or more was unacceptable. TKP with migration between 0.5 and 1.6 mm were considered at risk for revision rates higher than 5% at 10 years.

There was a clinically relevant association between early migration of TKP 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 TKP while exposing only a small number of patients.

Introduction

Worldwide several hundred thousand Total Knee Prostheses (TKP) are implanted each year and this number is expected to increase by a factor 6 within the next 2 decades [1,2]. Most of the new TKP designs have been introduced on the market without demonstrating safety or effectiveness [3]. This has resulted in the widespread use of TKP with failure rates exceeding 10 times the standard of national joint registries (5% failures at 10 years follow-up), such as the Accord, St Leger and Journey-Deuce [3-6]. As a response several countries have developed guidelines to guarantee patient safety e.g. the NICE guidelines for total hip prostheses [7]. 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 TKP to the market [8-10]. 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 [7,11].

Although it may take 10 years before loosening may cause symptoms, it is possible to detect loosening early post-operatively with Radiostereometric analysis (RSA) [12-15]. Since, RSA allows in vivo, three-dimensional measurement of the migration of TKP with an accuracy of 0.2mm for translations and 0.5 degrees for rotations, only a small number of patients have to be exposed to potentially unsafe TKP [13,14,16]. RSA could therefore play an important role in the phased evidence-based introduction of new TKP [12,13,15]. However, the evidence for the relation between early migration and TKP revision for aseptic loosening is limited to a few studies from the 1990s [13,14]. Furthermore, the applicability of these studies is restricted, because both surgical technique, fixation methods, implant design and polyethylene have evolved since their publication.

We hypothesize that early migration of the tibial component, measured through RSA, is associated with late revision for aseptic loosening in TKP. Therefore, we set out to systematically review the association between early migration and late aseptic revision for the tibial component in TKP. Ultimately, this could lead to clinical guidelines to be used in a phased introduction of new TKP.

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Methods

We performed two parallel systematic reviews (international registration number NTR2417; www.trialregister.nl) on studies of patients treated with TKP for end stage osteoarthritis (OA) and rheumatoid arthritis (RA). One review comprises early migration data of TKP from RSA studies. In the other we determined the long term revision rates for aseptic loosening of TKP from survival studies. Figure 7.1 shows the flow of the systematic reviews. During all phases of the review, a referee – RN – with over 20 years of experience in both RSA and TKP 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 [17]. 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 within nine leading orthopaedic and biomechanical journals (Acta Orthop, Clin Orthop Rel Res, J Arthroplasty, J Bone Joint Surg (Am and Br) Knee Surg Sports Traumatol Arthrosc, J Orthop Res, J Biomec 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.

Inclusion and exclusion analysis

Initial screening on title and abstract of RSA studies was performed by BP to identify studies on patients treated with TKP for end stage OA or RA. In case the information in the abstract did not suffice or in case of any doubt, the studies remained eligible. The full text of eligible studies was independently evaluated in duplicate by two 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 1st post-operative year. MTPM is the unit of measurement for the largest 3D-migration of any point on the prosthesis' surface [13]. 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 [18]. 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 are the same as those in the RSA review with the exception of the components of the search strategy. The search strategy of 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. In the search strategy no distinction was made between total knee and total hip prostheses (THP), because some studies report on TKP as well as THP [19].

Inclusion and exclusion analysis

The procedure of screening the survival studies for eligibility and subsequent inclusion and exclusion analysis was identical to the procedures of 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 case of poor general health or patient decline; and 4) survival or percentage revised must be available for specific follow-up (see point 2). Studies with less than 75 TKP at baseline were excluded.

Data extraction

BP and KN independently determined the revision rates in duplicate for aseptic loosening of the tibial component at 5 year intervals from the survival studies. 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 [18].

Analysis

A detailed description of the analysis, methodology and a worked example is available in Chapter 9. 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 are technical factors known to be associated with both migration and the likelihood of revision for aseptic loosening, matching on PFI prevents confounding by PFI.[11,20-22] Depending on the available studies, it is possible that there is more than one combination of matching RSA and survival studies for a particular PFI. For instance, if there are 3 RSA studies and 2 survival studies of 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 has been applied to estimate the survival at 5 years and its confidence interval [23-25]. 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 of TKP 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 [11,20-22].

Adjustment for confounding

Since migration data and revision rate data were extracted from different studies, it is possible that differences between study populations may 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, gender, diagnosis, hospital type, and continent. The match score is constructed according to the results of a recent Delphi among an international group of 37 independent experts and can vary between 5 (excellent) and 0 (poor) [18]. The RSA study and survival study combination score 1 point for each of the following criteria (up to a maximum of 5 points):

- the difference in the mean age between the patients from RSA study and those from the survival study was 5 years or less.
- the difference in percentage females between the RSA study and survival study was 10% or less.
- the difference in percentage patients diagnosed with osteoarthritis between the RSA study and survival study was 10% or less.
- the RSA study and survival study were performed in the similar hospital type (e.g. both university medical centers).
- the RSA study and survival study were performed on the same continent.

All other cases score zero points.

We used a weighted regression model to assess on 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 according to the Swedish Knee Arthroplasty Registry [20]. Based on this revision standard the following three categories were constructed for the phased introduction of new TKP: 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 is 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 [11,20-22]. Accordingly, the PFI 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 that perform worse than average. For this purpose the migration pooled by PFI was sorted according to revision rate pooled by PFI and visualized in a dot chart [26].

Results

RSA studies

The literature search yielded 629 hits for the RSA review and 50 studies were included with a total of 847 patients [16,27-68]. Details on study selection and flow of the review are shown in Figure 7.1. 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. All analyses will therefore focus on MTPM at 1 year.

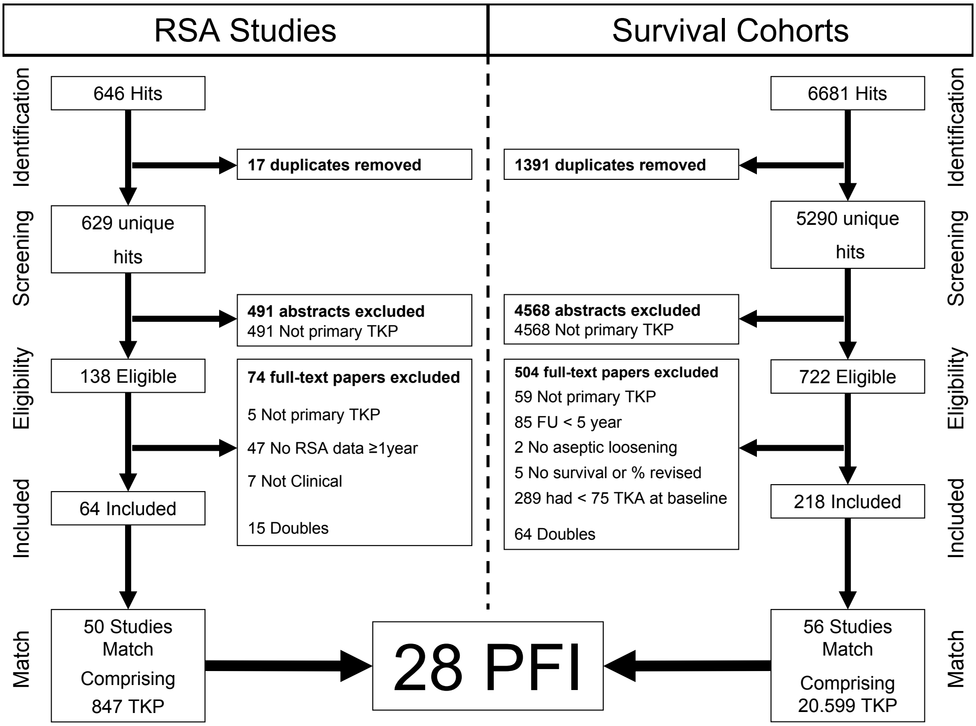

Figure 7.1: PRISMA flowchart of both reviews. Details of the 28 PFI can be found in Table 7.1.
RSA = radiostereometric analysis; TKP = total knee prosthesis; FU = follow-up; PFI = Prosthesis Fixation Insert

Survival studies

After the literature search there were 5,290 hits for the survival review and 56 studies were included with a total of 20.599 patients, see Figure 7.1 [14,69-118]. 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 and 89 combinations of RSA and survival studies, see Table 7.1. 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, as shown in Figure 7.2. For every millimeter increase in migration 7.6% [95% CI 5.7% to 9.5%], $p<0.05$, was added to the 5 year revision rate. The influences of RSA study quality, survival study quality, number of TKP in the RSA study, number of TKP in the survival study and match score were small relative to the overall effect of migration on revision rate, see Table 7.2. For TKP that rely on primary fixation (cemented and uncemented with screws) 7.1% [95%CI 4.7 to 9.5], $p<0.001$ was added to the

5 year revision rate for every 1mm increase in MTPM. For TKP that rely on secondary fixation (uncemented without screws) 10.1% [95%CI 2.7 to 17.4], p=0.018, was added to the 5 year revision rate for every 1mm increase in MTPM.

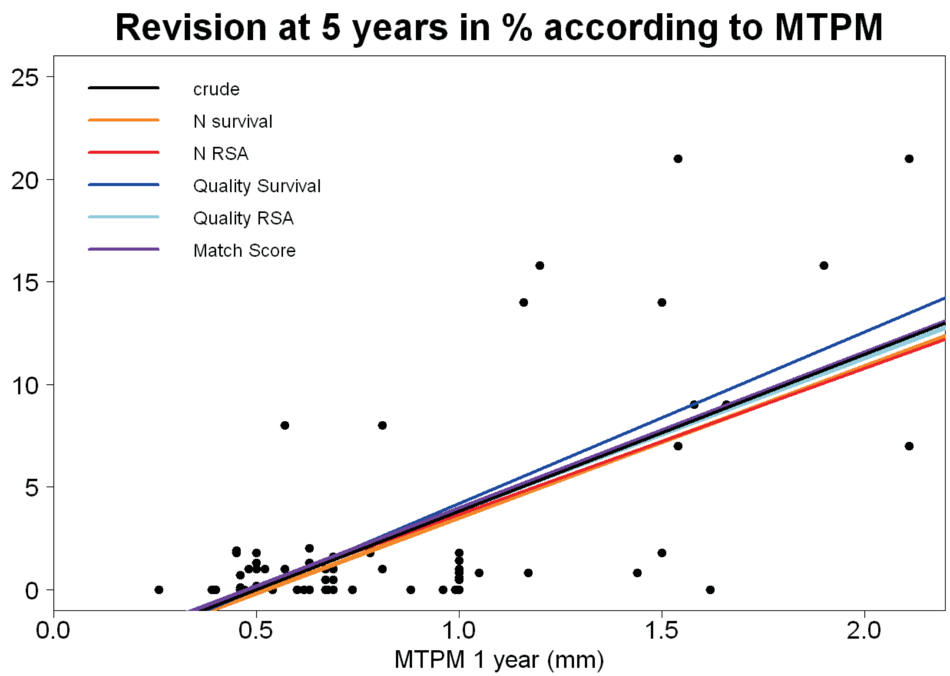

Figure 7.2 Scatterplot showing association between migration in the 1st post-operative year expressed as Maximal Total Point Motion (MTPM) in mm and revision rate for aseptic loosening of the tibial component at 5 years in percentages. The dotted lines are derived from weighted regression according to match quality, survival study quality and RSA study quality (the coeffcients and 95%CI are presented in Table 7.2).

Table 7.1: Prosthesis, Fixation and Insert (PFI) characteristics.

PFI	Prosthesis	Fixation	Insert	Number of RSA studies	Number of Survival studies	Number of combinations
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

CR = cruciate retaining — HDP = High Density Poly-Ethylene
PS = posterior stabilized — PE = Poly-Ethylene
MB = metal backed — HA/PA = Hydroxyapatite/Periapatite

Table 7.2: 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*:		
N survival**	7.4	5.6 – 9.2
N RSA**	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 7.2 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% to 9.5%], $p<0.05$, is added to the 5-year revision rate for every mm increase in MTPM at 1 year.
* When adjusted for e.g. the number of TKP in survival studies (N survival) 7.4% [95%CI 5.6% to 9.2%], $p>0.05$, 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 <0.05).
** 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

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Migration thresholds

Figure 7.3 shows the three categories for the TKP migration. For MTPM at 1 year between 0 and 0.54mm there was no tibial component with more than 3% revision for aseptic loosening at 5 years. In case of 1 year MTPM of more than 1.6mm there was no tibial component with less than 3% revision for aseptic loosening at 5 years. This implies that accepting 3% revision at 5 year resulted in a threshold of 0.54mm or acceptable MTPM at 1 year and a threshold of 1.6mm for unacceptable MTPM at 1 year. For the 10 year revision rates, the thresholds for acceptable and unacceptable migration were 0·45 mm and 1·6mm respectively, see Figure 7.4.

The mean difference between the estimated 10 year revision rate and known 10 year revision rate is 0.17% (SD 2.1%) indicating absence of any systematic error. The 5 year revision rates of the studies with missing 10 year revision rates were already higher than the 5% ten-year revision rate that is considered to be acceptable. Therefore, the 10 years thresholds are not influenced by any missing values.

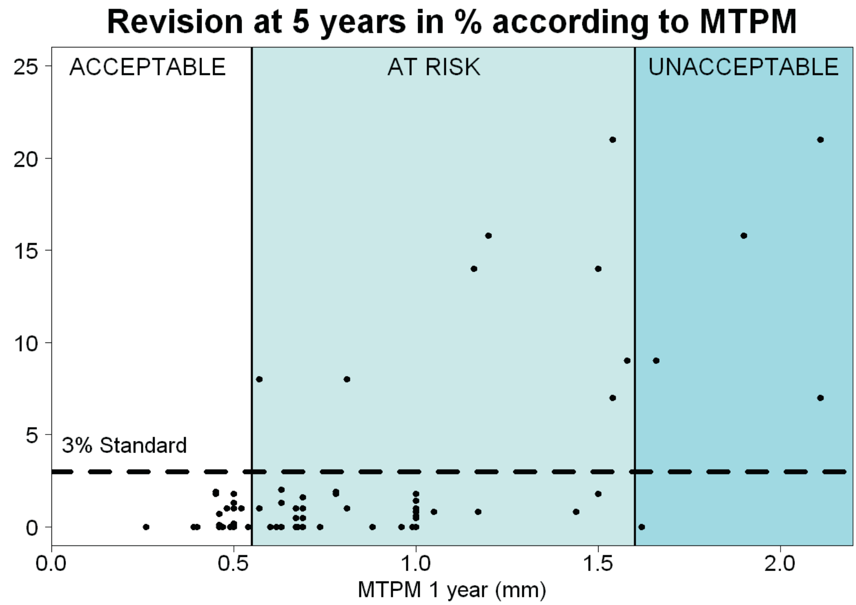

Figure 7.3. Scatter plot showing the relation between MTPM at 1 year and revision of the tibial component for aseptic loosening at 5 years. The thresholds of 0.54 and 1.6mm for the three categories – acceptable; at risk; unacceptable - are shown. MTPM = Maximal Total Point Motion

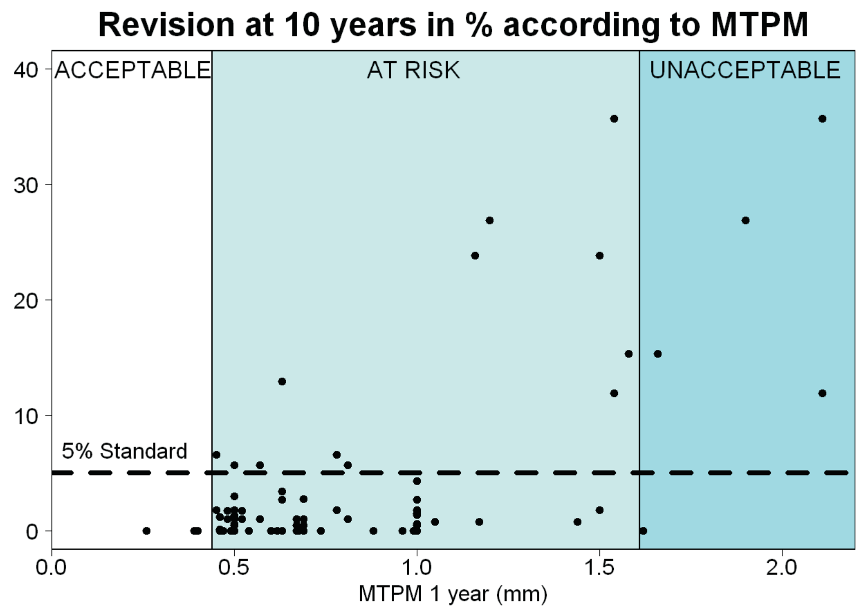

Figure 7.4. Scatter plot showing the relation between MTPM at 1 year and revision of the tibial component for aseptic loosening at 10 years. The thresholds of 0.45 and 1.6mm for the three categories – acceptable; at risk; unacceptable - are shown. MTPM = Maximal Total Point Motion

Publication bias

The pooled MTPM ranked by the pooled revision rate for each PFI is presented in Figure 7.5. The PFI that migrate significantly less than the acceptable threshold -classified as acceptable - have excellent track records and low revision rates in several national joint registries [11,20-22]. Conversely, the PFI that are classified as unacceptable on basis of their pooled migration have been abandoned and are no longer used. The potential influence of publication bias on the results is small.

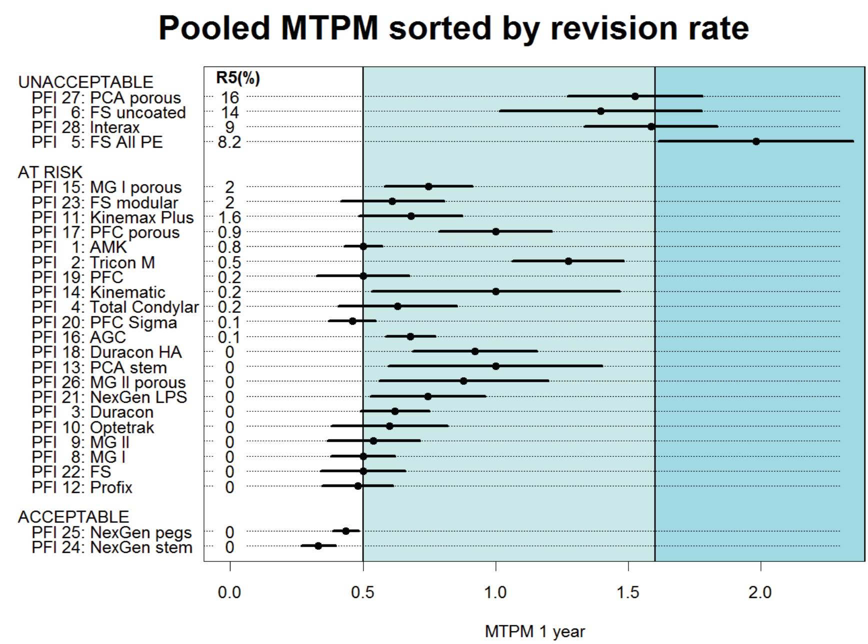

Figure 7.5: Dotchart showing the pooled MTPM ranked by the pooled revision rate for each PFI. The acceptable PFI (based on migration) have excellent track records and low revision rates in several national registries, whereas the unacceptable PFI (based on migration) have been abandoned. Therefore the potential influence of publication bias on the results is small. A detailed description for each PFI is available in Table 1. R5(%) = pooled revision rate at 5 years follow-up in percentage.

Discussion

Results of this systematic review demonstrate a clinically relevant association between early migration, as measured with RSA, and long term clinical failure resulting in revision for aseptic loosening. Each millimeter migration increases the 5 year revision rate by 8%, which remained after correction for age, gender, diagnosis, hospital type, continent and study quality. This is more than twice the standard revision rate of several national joint registries [11,20-22]. The results of this systematic review show that RSA studies can identify unsafe TKP (in terms of aseptic loosening) as early as 1 year post-operatively. Early identification of unsafe TKP with RSA prevents their widespread use. Compared to the present system this safeguards numerous patients from extensive revision surgery with potential postoperative complications.

Some strengths of this systematic review are the large number of included studies (>100) and patients (>27,000) which resulted in 28 different PFI. This large variation in PFI, which reflects the diversity in TKP designs and fixation methods, ensures wide applicability of the results. Since migration and revision rates are from different studies, there is no migration data available in survival studies to be incorporated into the decision to perform a revision. Consequently there is no incorporation bias in our results. The risk of publication bias in this systematic review was considered 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 included studies is desirable. Nevertheless survival study quality and RSA study quality showed only very small effects on the association between migration and revision rates.

We focused on MTPM at 1 year post-operatively, while other migration parameters and follow-up beyond 1 year are also of interest [13]. Unfortunately, these parameters were reported too infrequently and inconsistently to allow a meaningful analysis. Future RSA studies could therefore benefit from further standardization particularly regarding the reporting of the results [119].

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) are not evaluated by RSA. As a consequence RSA studies are only the first step in the phased evidence-based introduction as proposed by Malchau, see Figure 7.6 [8].

During phase A, multiple 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 have to 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 will be sufficient. This reduces the follow-up needed for a successful phased introduction with almost a decade compared to traditional cohort studies. It therefore becomes possible to safely introduce new TKP to the market before their patent has expired. After release to the market, phase C, the performance of the TKP has to be monitored by post-marketing surveillance in national joint replacement registries [10]. This includes both the revision rate and patient evaluations using patient reported outcome measures (PROMS).

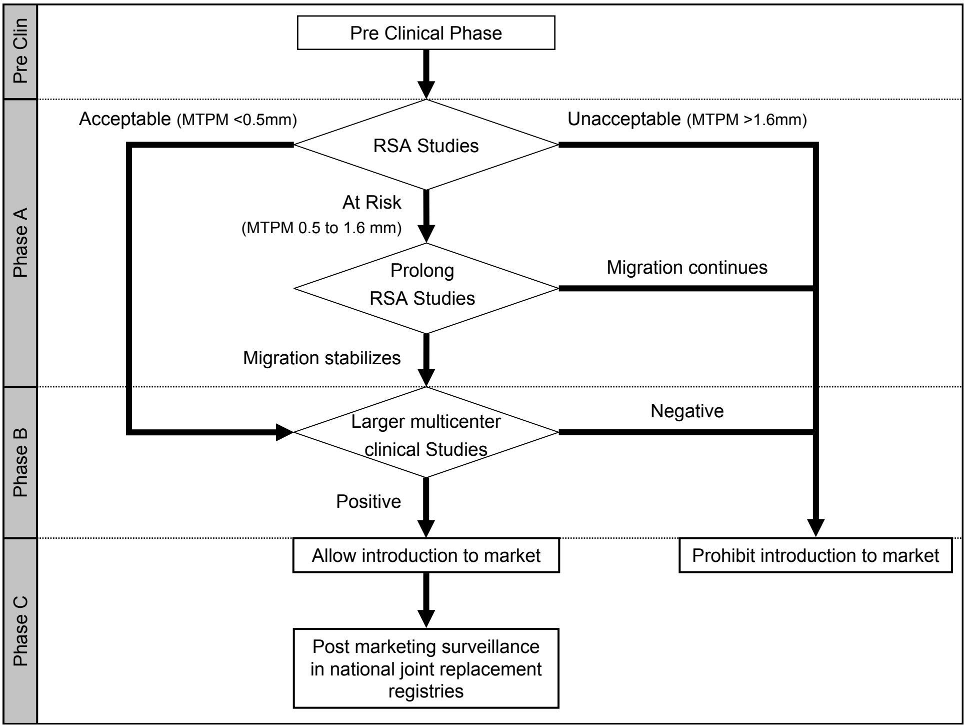

Figure 7.6 Flowchart showing the role of RSA studies in the phased evidence-based introduction of new TKP modified according the Malchau proposal. Stabilization is defined as migration of less than 0.2mm in the second post-operative year (MTPM from year 1 to year 2) as described by Ryd et al (1995) See discussion for details on each phase.

In this systematic review, RSA studies of 20 to 60 patients followed for 1 year led to the same conclusion as national joint registries with thousands of patients followed for 5 to10 years. A recent publication has shown a 22% to 35% reduction in the number of revisions of RSA-tested total knee replacements as compared with non-RSA-tested total knee replacements in the national joint registries [120]. Because inferior designs can already be detected early post-operatively exposing only a small group of patients to potentially unsafe TKP, RSA provides the necessary efficiency to effectuate phased evidence-based introduction. Already more than a decade ago several authors placed a call for phased evidence-based evaluation and clinical introduction of new prostheses [8,121-123]. 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 TKP.

Various authors and regulatory agencies recognize the potential of RSA [8,13-15,124,125]. The NICE guidelines of 2003 (United Kingdom) require adequate long-term clinical data for hip prostheses and indicate RSA as a promising technique that may be an alternative for 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. Official guidelines for knee prosthesis are expected to follow.

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

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

Authors' contributions

RN, BP and EV had the idea of the study. SM provided methodological input and MF statistical input during the conceptual phase of the study. JP designed the search strategy for the literature search. BP and EV performed the study selection and matching procedure. KN and BP appraised the quality of the literature and performed the data extraction. MF and BP analyzed the data. BP, KN, EV and RN wrote the initial draft manuscript. MF and SM ensured accuracy of data and analysis. BP and MF wrote the appendix. Critical revision of the manuscript was performed by all authors. All authors read and approved the final manuscript.

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Data sharing

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 author: m.fiocco@lumc.nl

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