Chapter 8

Early proximal migration of cups is associated with late revision in THA

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Abstract

We performed 2 parallel systematic reviews and meta-analyses to determine the association between early migration of acetabular cups 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 the national joint registries: 5% revision at 10 years.

Following an elaborate literature search 26 studies (700 cups) were included in the RSA-review and 49 studies (38,013 cups) in the survival-review. The results showed that for every millimeter increase in 2-year proximal migration there was an increase of 10% in revision rate, which remained after correction for age, gender, diagnosis, hospital type, continent and study quality. Consequently, proximal migration up to 0.2mm was considered acceptable, while proximal migration of 1.0mm or more was unacceptable. Cups with proximal migration between 0.2 and 1.0mm were considered at risk for revision rates higher than 5% at 10 years.

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

Introduction

Worldwide several hundred thousand Total Hip Prostheses (THP) are implanted each year and this number is expected to double within the next decades [1,2]. It is crucial to monitor the safety and quality of THP to prevent unneeded harm to patients and costs to society (i.e. reduction of the future revision burden). Most of the new THP designs are on the market without demonstrating safety or effectiveness [3]. This has resulted in the use of several THP with high failure rates, such as the Wagner cup, the Link V cup and the Mecron cup [4-6]. In response to these problems, several countries have developed guidelines to guarantee patient safety e.g. the NICE guidelines [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 THP to the market [8-10]. This should include systematic assessment and early detection of the major cause of THP failure, which is aseptic loosening necessitating revision surgery[11,12]

Although it may take 10 years before the final stages of loosening are visible on conventional radiographs, it is possible to detect loosening early post-operatively with Radiostereometric analysis (RSA). Since, RSA allows in vivo, 3-dimensional measurement of the migration of THP 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 THP [13,14]. RSA could therefore play an important role in the phased evidence-based introduction of new THP.

In this systematic review and meta-analysis we concentrated on the acetabular cup. We hypothesize that early migration of the acetabular cup, measured through RSA, is associated with late revision for aseptic loosening. Therefore, we systematically reviewed the association between early migration and late aseptic revision for the acetabular cup in primary THP. Eventually, this could lead to clinical guidelines to be used in a phased introduction of new THP.

Methods

We performed 2 parallel systematic reviews (international registration number NTR3128; www.trialregister.nl) on studies of patients treated with THP for primary osteoarthritis (OA), secondary osteoarthritis (SA) and fractures of the proximal femur (FF). One review comprises early migration data of acetabular cups from RSA studies. In the other we determined the long term revision rates for aseptic loosening of acetabular cups from survival studies. Figure 8.1 shows the flow of the systematic reviews. During all phases of the review process, a referee – RN – with over 20 years of experience in both RSA and THP was available for consultancy.

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 [15]. 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 Biomech, 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 THP for OA, SA or FF. In cases where the information in the abstract did not suffice or where there was any doubt, studies remained eligible. The full text of eligible studies was independently evaluated in duplicate by 2 reviewers, BP and MN. The inclusion criteria for RSA studies were 1) primary THP and 2) minimal RSA follow-up of 1 year, measuring acetabular cup migration. Non-clinical studies (animal, phantom) were excluded.

Data extraction

BP and MN independently extracted migration data in duplicate from the RSA studies. Since the failure mechanism of acetabular cups consist of increasing proximal migration and increasing inclination the data extraction of RSA studies comprised proximal migration and inclination of the acetabular cup until the second post-operative year [16]. Data concerning patient demographics and regional influences were also extracted to allow for confounder correction [17].

Quality Assessment

The quality of the RSA studies was independently appraised in duplicate by BP and MN at the level of outcome using the AQUILA methodological score [17]. For the RSA studies we modified the AQUILA score by removing items that were not considered relevant for early migration, such as long term follow-up and 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 [18].

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 THP; 2) follow up of 5, 10, 15, 20 or 25 years (in the final analysis only 10 years follow-up was used); 3) endpoint revision surgery for aseptic loosening of the acetabular cup, 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 THP at baseline were excluded.

Data extraction

BP and MN independently determined the revision rates in duplicate for aseptic loosening of the acetabular cups 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 evaluated by BP and MN at the level of outcome using the AQUILA methodological score [17].

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 and Fixation method (e.g. cement or bone ingrowth) here abbreviated to PF. Since PF is determined by technical factors known to be associated with both migration and a high likelihood for revision for aseptic loosening, matching on PF prevents confounding by PF [11,12,19]. Depending on the

available studies, it is possible that there is more than one combination of matching RSA and survival studies for a particular PF. For instance, if there are 3 RSA studies and 2 survival studies of the same PF, then there are 6 possible combinations (3 times 2). All combinations were considered in the analysis. A meta-analysis for the revision rate at 10 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 10 years and its confidence interval [20-23]. Regarding the RSA studies pooling of migration results at the level of PF was based on weights according to study size (N).

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 0 (poor) and 5 (excellent) [17]. 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 of females between the RSA study and survival study was 10% or less.
- the difference in percentage of patients diagnosed with primary osteoarthritis between the RSA study and survival study was 10% or less.
- the RSA study and survival study were performed in the similar type of hospital (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 the association between early migration and late aseptic revision corrected for the influence of match score, RSA study quality, survival study quality, number of THP in the RSA studies and number of THP 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 Hip Arthroplasty Registry and Australian National Joint Replacement Registry [11,12]. Based on this revision standard the following three categories were constructed for the phased introduction of new THP: acceptable, at risk and unacceptable. The category "acceptable" was defined as the level of migration up to which all survival studies have lower revision rates than the standard. The category " unacceptable" 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 [11,12,19]. Accordingly, the PF 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 PF that perform worse than average. For this purpose the migration pooled by PF was sorted according to revision rate pooled by PF and visualized in a dot chart [24].

Results

RSA studies

The literature search yielded 629 hits for the RSA review and 26 studies were included with a total of 700 acetabular cups [5,6,25-42]. Details on study selection and flow of the review are shown in Figure 8.1. The mean AQUILA methodological quality score of the RSA studies was 4.9 (SD 0.8) on a 7-point scale. Proximal migration at 2 year was the most frequently and most consistently reported migration value: 23 out of 26 RSA studies reported it. Change in inclination (rotation around the z-axis) was reported infrequently and inconsistently and did not allow a meaningful analysis. All analyses will therefore focus on proximal migration at 2 year.

Survival studies

After the literature search there were 5,290 hits for the survival review and 49 studies were included with a total of 38,013 acetabular cups, see Figure 8.1 [43-85]. The mean AQUILA methodological quality score of the survival studies was 7.3 (SD 1.1) on an 11-point scale.

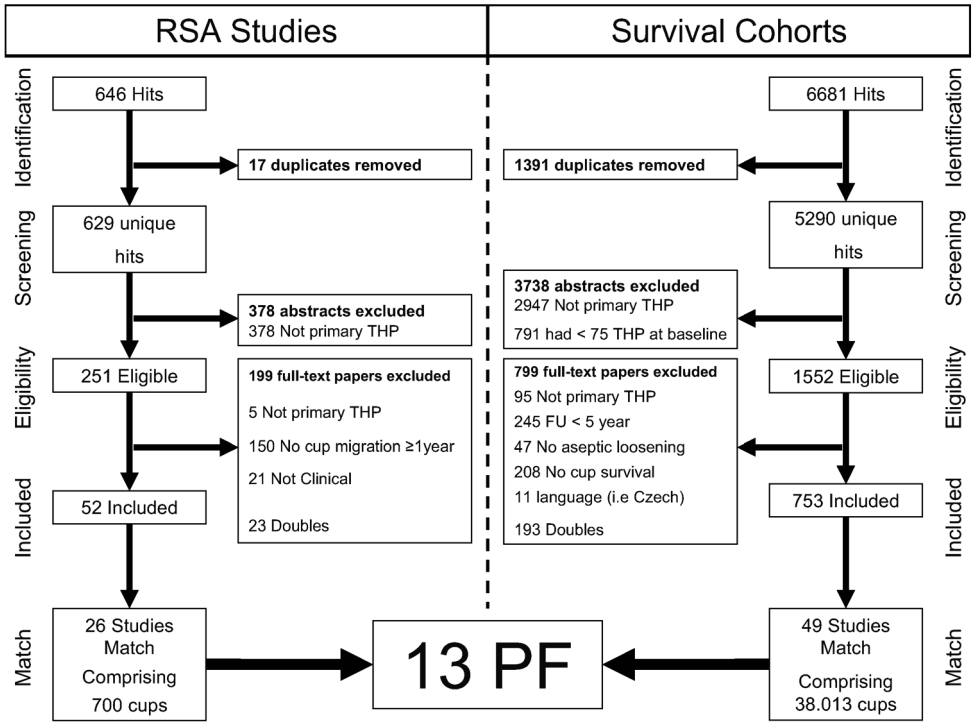

Figure 8.1 PRISMA flowchart of both reviews. Details of the 13 PF can be found in Table 8.1.
RSA = radiostereometric analysis
THP = total hip prosthesis
FU = follow-up
PF = Prosthesis Fixation

Early migration and late revision

The matching procedure resulted in 13 different PF and 94 combinations of RSA and survival studies, see Table 8.1. There was a clear association between 2 year proximal migration and the 10 year revision rate as expressed as prosthesis survival, as shown in Figure 8.2. For every millimeter increase in proximal migration (at 2 years) 10% [95% CI 5.5% to 14.2%], $p < 0.05$, is added to the 10-year revision rate. Although there was some influence on the results of RSA study quality, survival study quality, number of acetabular cups in the RSA study, number of acetabular cups in the survival study and match score, the association remained significant (all p-values <0.05), see Table 8.2.

There was no clear association between proximal migration rate (= 2 year proximal migration minus 1 year proximal migration) and the 10 year revision rate.

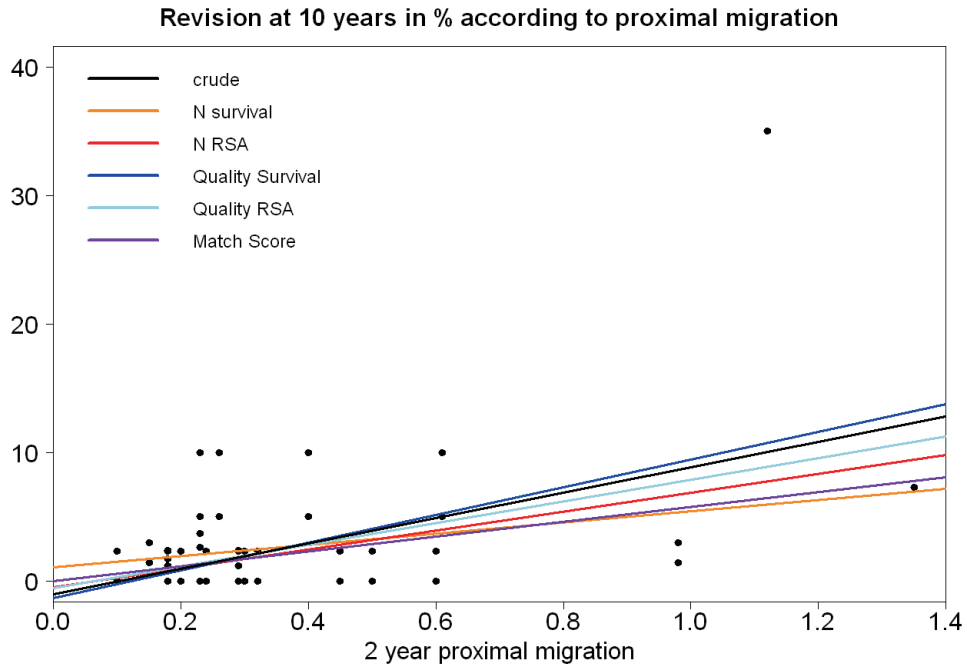

Figure 8.2 Scatterplot showing association between 2 year proximal migration in mm and revision rate for aseptic loosening of the acetabular cup at 10 years in percentages. The colored lines are derived from weighted regression according to match quality, survival study quality and RSA study quality (the coeffcients and 95%CI are presented in Table 8.2).

Table 8.1: Prosthesis and Fixation (PF) characteristics.

PFI	Prosthesis (cups)	Fixation	Number of RSA studies	Number of Survival studies	Number of combinations
1	ABG I	HA coated	1	8	8
2	Birmingham Hip Resurfacing	HA coated	1	4	4
3	Exeter all PE	Cement (high viscosity)	2	3	6
4	Harris Galante I	Porous coated, screws	2	14	28
5	Harris Galante II	Porous coated, screws	1	7	7
6	Link V, threaded	Uncoated	1	1	1
7	Omnifit dual radius	HA coated	2	1	2
8	Scanhip all PE	Cement (high viscosity)	1	3	3
9	Wagner (double) cup	Cement	1	1	1
10	Charnley Ogee	Cement (high viscosity)	8	3	24
11	Spectron all PE	Cement (high viscosity)	1	1	1
12	Lubinus eccentric	Cement (high viscosity)	4	2	8
13	Reflection all PE	Cement (high viscosity)	1	1	1
Total			26	49	94

PE = Poly-Ethylene; HA = Hydroxyapatite; ABG = Anatomique Benoist Giraud

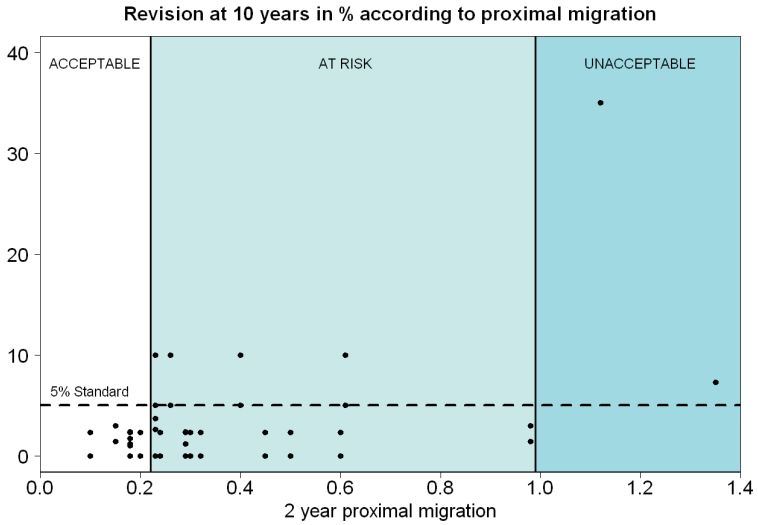

Figure 8.3 Scatter plot showing the relation between 2 year proximal migration and revision of the acetabular cup for aseptic loosening at 10 years. The thresholds of 0.2 and 1.0mm for the three categories – acceptable; at risk; unacceptable - are shown.

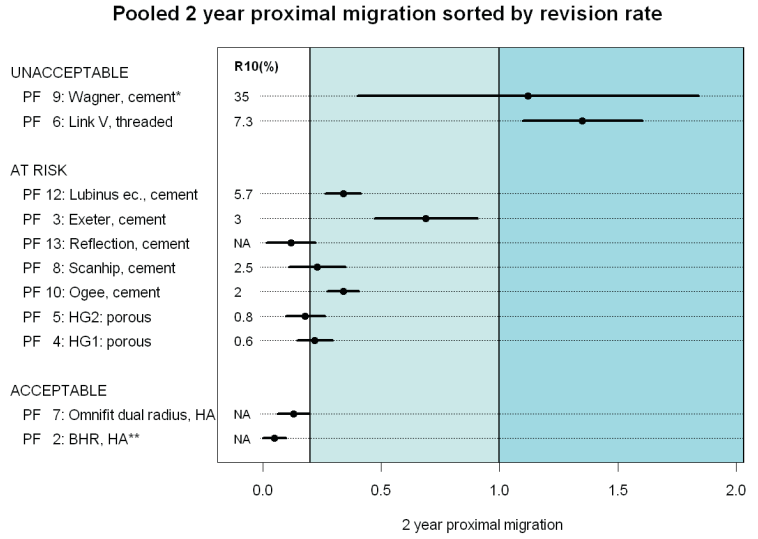

Figure 8.4 Dotchart showing the pooled 2 year proximal migration ranked by the pooled 10 year revision rate for each PF. The unacceptable PF (based on their migration pattern) have been abandoned with the Wagner cup having the worst recorded survival in the Swedish Register [86]. A detailed description for each PF is available in Table 8.1. R10(%) = pooled revision rate at 10 years follow-up in percentage. NA = not available

* This a best-case scenario for the Wagner cup, since the reference scene was not made direct postoperatively. Hence, the actual 2 year proximal migration is more than the observed value presented here.
** The Birmingham Hip Resurface (BHR) prostheses of the RSA study were implanted by the developer, so the migration results (and "acceptable" classification) may not apply to non-developers.

Table 8.2: Association between 2-year proximal migration and revision rate for aseptic loosening at 10 years.

	Increase in revision (%) / mm proximal migration	95% CI
Crude	10	5.5 – 14.2
Adjusted for*:		
N survival**	4.4	1.1 – 7.7
N RSA**	7.4	3.4 – 11.4
Survival study quality	10.8	6.2 – 15.4
RSA study quality	8.4	4.2 – 12.6
Total Match Score	5.8	2.2 – 9.4

Table 8.2 shows the increase in the 10 year revision (%) for each mm increase in 2-year proximal migration. In the crude analysis (unadjusted) 10% [95% CI 5.5% to 14.2%], p <0.05, is added to the 10-year revision rate for every mm increase in 2-year proximal migration.
* When adjusted for e.g. the number of hips in survival studies (N survival) 4.4% [95% CI 1.1% to 7.7%], p <0.05, is added to the 10-year revision rate for every mm increase in 2-year proximal migration.
The associated between 2 year proximal migration 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 cups in survival studies (survival study size).
N RSA = number of cups in RSA studies (RSA study size).

Migration thresholds

Figure 8.3 shows the three categories for the THP. For proximal migration at 2 years between 0 to 0.2mm, there was no cup with more than 5% revision for aseptic loosening at 10 years. In case of 2-year proximal migration of more than 1.0mm, there was no cup with less than 5% revision for aseptic loosening at 10 years. This implies that accepting 5% revision at 10 years resulted in a threshold of 0.2mm for acceptable proximal migration at 2 years and a threshold of 1.0mm for unacceptable migration proximal migration at 2 years.

Publication bias

The pooled 2-year migration ranked by the pooled 10-year revision rate for each PF is presented in Figure 8.4. The Wagner cup and threaded Link V cup were classified as unacceptable based of their pooled migration. These cups have been abandoned and are no longer used in today's orthopaedic practice. Moreover, the Wagner cup, has the worst (overall) survival ever recorded in the history of the Swedish Register: 28% at 10 years [86]. The potential influence of publication bias on the unacceptable threshold is therefore small. The 10-year revision rate for the acceptable PF were lacking (NA), so longer FU of these PF is necessary to investigate if their 10 year revision rate for aseptic loosening of the cup is lower than 5%.

Discussion

Results of this systematic review show a clinically relevant association between early proximal migration of acetabular cups, as measured with RSA, and clinical failure (i,e, revision surgery) at mid term and long term follow-up corrected for, age, gender, diagnosis, type of hospital, region, study size and study quality. Each millimeter proximal migration increases the 10 year revision rate on average by 10%, which is more than twice the standard revision rate of several national joint registries [11,12,19].

We also found that RSA studies can identify unsafe acetabular cups as early as 2 year post-operatively. Early identification of these less optimal performing THP with RSA prevents their widespread use. Compared to the present policy of introduction of new prostheses, such a policy would safeguard numerous patients from potential (extensive) revision surgery with potential postoperative comorbidities.

Strengths of this systematic review are the large number of included studies (75) and patients (>38,000), which resulted in 13 different PF. This large variation in PF, which reflects the diversity in THP designs and fixation methods, ensures wide applicability of the results. Since migration and revision rates are from different studies, the RSA data could not have been used (incorporated) for the decision to perform a revision, this means that there is no incorporation bias.

One limitation is that the migration of the BHR and Omnifit acetabular cups were classified as "acceptable". This means that we expect their 10 year revision rate for aseptic loosening to be lower than 5%. However, since their 10-year revision rate was not available in this review, longer FU of the BHR and Omnifit is required. Regarding the BHR, it should also be noted that the surgery in the RSA study was performed by the developer [27]. Thus, the observed migration (and "acceptable" classification) does not necessarily apply to non-developers. Regarding the Omnifit dual radius cup, it should be noted that although the early migration (primary fixation) is classified "acceptable" the problem is secondary loosening due to excessive wear and osteolysis [34]. A phased introduction should therefore also focus on wear measurements, in which RSA could play an important role.

We are also aware that RSA only evaluates aseptic loosening while other failure mechanisms (e.g. osteolysis and pseudotumors in BHR resurfacing) are not evaluated by RSA. Therefore RSA studies are only the first step in the phased introduction as proposed by Malchau [8,87].

Already more than a decade ago several authors pleaded for a phased evidence-based introduction of new prostheses [8,88-90]. The observed association between early migration and long term revision of acetabular cups translates into practical thresholds values of migration (i.e. RSA) for such a phased evidence-based introduction policy of new THP [8]. During phase A, multiple single

center RSA studies should be performed to determine the safety of the THP with regard to the risk of revision for aseptic loosening and wear. Once the THP is considered safe, phase B studies have to be conducted to evaluate the clinical performance of the THP regarding pain relief and functioning (clinical scores and patient reported outcome measures (PROMS)) and to determine the rate of other complications (e.g. pseudotumors) [87]. After release to the market, phase C starts where the performance of the THP 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).

In this systematic review, RSA studies of 10 to 60 patients followed for only 2 year had the same conclusion as national joint registries where thousands of patients were followed for 10 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 [91].

Of special interest is the Wagner cup, which has the worst survival ever recorded in the history of the Swedish Register: 28% at 10 years [86]. If the threshold of unacceptable migration (1.0 mm) had been known at the time the Wagner cup was introduced, it would have been classified as "unacceptable" after 2 years of RSA follow-up with only eleven patients. The latter would have urged a more close follow-up of this prosthesis. The Link V cup would also have been classified as "unacceptable" after only 2 years of follow-up with RSA. Both examples illustrate the clinical value of the migration thresholds for the early identification of THP with a high likelihood of failure at long-term follow-up.

Various authors and regulatory agencies recognize the potential of RSA [8,13,14,92,93]. 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 early warning indicator of expected poor long term revision rates [7]. 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.

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

Authors' contributions

RGN, BGP and ERV had the idea of the study. SM provided methodological input and MF statistical input during the conceptual phase of the study. JWP designed the search strategy for the literature search. BGP and MJN performed the study selection and matching procedure, appraised the quality of the literature and performed the data extraction. MF and BGP analyzed the data. BGP, MJN, ERV and RGN wrote the initial draft manuscript. MF and SM ensured accuracy of data and analysis. BGP 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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