Early subsidence of shape-closed hip arthroplasty stems is associated with late revision

A systematic review and meta-analysis of 24 RSA studies and 56 survival studies

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Background and purpose — Few studies have addressed the association between early migration of femoral stems and late aseptic revision in total hip arthroplasty. We performed a meta-regression analysis on 2 parallel systematic reviews and meta-analyses to determine the association between early migration and late aseptic revision of femoral stems.

Patients and methods — Of the 2 reviews, one covered early migration data obtained from radiostereometric analysis (RSA) studies and the other covered long-term aseptic revision rates obtained from survival studies with endpoint revision for aseptic loosening. Stems were stratified according to the design concept: cemented shape-closed, cemented force-closed, and uncemented. A weighted regression model was used to assess the association between early migration and late aseptic revision, and to correct for confounders. Thresholds for acceptable and unacceptable migration were determined in accordance with the national joint registries (≤ 5% revision at 10 years) and the NICE criteria (≤ 10% revision at 10 years).

Results — 24 studies (731 stems) were included in the RSA review and 56 studies (20,599 stems) were included in the survival analysis review. Combining both reviews for the 3 design concepts showed that for every 0.1-mm increase in 2-year subsidence, as measured with RSA, there was a 4% increase in revision rate for the shape-closed stem designs. This association remained after correction for age, sex, diagnosis, hospital type, continent, and study quality. The threshold for acceptable migration of shape-closed designs was defined at 0.15 mm; stems subsiding less than 0.15 mm in 2 years had revision rates of less than 5% at 10 years, while stems exceeding 0.15 mm subsidence had revision rates of more than 5%.

Interpretation — There was a clinically relevant association between early subsidence of shape-closed femoral stems and late revision for aseptic loosening. This association can be used to assess the safety of shape-closed stem designs. The published research is not sufficient to allow us to make any conclusions regarding such an association for the force-closed and uncemented stems.

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Over 1 million total hip arthroplasties (THAs) are performed every year worldwide, and this number is expected to double within the next 2 decades (Pivec et al. 2012). The design and method of fixation of a THA determines the stability of the implant, and these are therefore crucial factors for achievement of long-term survival. However, most of the new THA designs have been introduced onto the market without demonstrating good performance (Sheth et al. 2009). This has led to several THAs having high failure rates, such as the Charnley Elite Plus (Hauptfleisch et al. 2006). To prevent future disasters with orthopedic implants, several countries have developed guidelines to guarantee patient safety, e.g. the NICE guidelines (NHS). Furthermore, it has become increasingly evident that a phased evidence-based introduction, as is common with pharmaceuticals, is necessary to regulate the introduction of new THA designs to the market (Malchau 2000, McCulloch et al. 2009, Schemitsch et al. 2010). This should include systematic assessment and early detection of aseptic loosening in small groups of patients.

Although it may take as long as 10 years for aseptic loosening of implants to become manifest, it is possible to detect the

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loosening process as early as 1–2 years postoperatively, using radiostereometric analysis (RSA). Since RSA allows in vivo, 3D measurement of the migration of THAs with an accuracy of 0.2 mm for translations and 0.5 degrees for rotations, only a small number of patients is needed to compare a new innovative design to a gold-standard design (Grewal et al. 1992, Karrholm et al. 1994, Ryd et al. 1995, Thanner et al. 1995, Hauptfleisch et al. 2006, Nieuwenhuijse et al. 2012). Thus, only a few patients will have been exposed if that design turns out to be a poor one. RSA could therefore play an important role in phased evidence-based market introduction of new THA designs (Faro and Huiskes 1992, Bulstrode et al. 1993, Malchau 1995, 2000, Nelissen et al. 2011).

Following on from our 2 earlier studies on the association between early migration and late aseptic revision of tibial components and acetabular cups, this systematic review and meta-analysis focused on the femoral stem (Pijls et al. 2012a, b). We hypothesized that early migration, as measured with RSA, is associated with late revision for aseptic loosening. We systematically reviewed the association between early migration and late revision for aseptic loosening of the femoral stem in primary THA. This could eventually lead to clinical guidelines, to be used in a phased introduction of new THA designs.

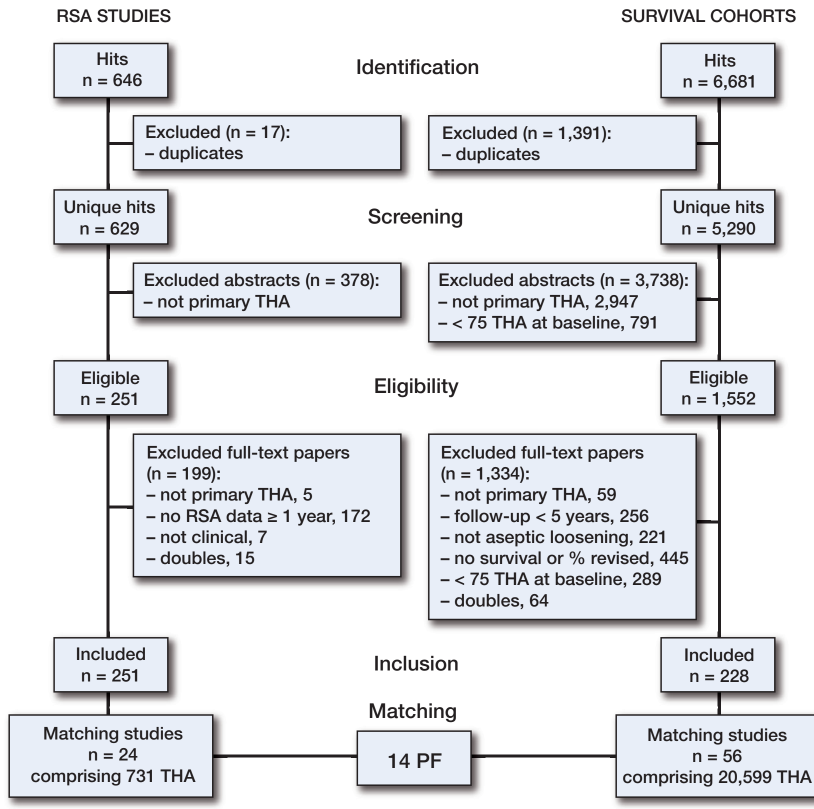

Figure 1. PRISMA flow chart of both reviews. Details of the 14 PF combinations can be found in Table 1.

Material and methods

We performed a meta-regression analysis (international registration number NTR3129; www.trialregister.nl) combining RSA migration data with survival analysis data for each stem design, to assess the association between early migration and late aseptic revision. To this end, 2 parallel systematic reviews (Figure 1) and meta-analyses were performed on studies of patients treated with THA for primary osteoarthritis (OA), secondary osteoarthritis (SA), and fractures of the proximal femur (FF). One review covered early migration data on femoral stems, obtained from RSA studies. The other review covered long-term aseptic revision rates obtained from survival studies, with revision for aseptic loosening of femoral stems as the endpoint. The data were stratified according to the design concept of the femoral stem (i.e. cemented shape-closed, cemented force-closed, and uncemented) (Huiskes et al. 1998). During all phases of the review process, author RN with over 20 years of experience of both RSA and THA, was available for consultation.

Systematic review of RSA studies

Literature search. A literature search was performed in cooperation with a medical librarian (JP), to minimize publication bias (Vochteloo et al. 2010). The search strategy and bibliographies used were the same as in the systematic review and meta-analysis on early migration of acetabular cups in relation to late aseptic revision (Pijls et al. 2012a). Relevant articles were screened for additional references. Then a separate search was conducted in 9 leading orthopedic and biomechanical journals (Acta Orthop, Bone Joint J, Clin Orthop Relat Res, J Arthroplasty, J Bone Joint Surg Am, Knee Surg Sports Traumatol Arthrosc, J Orthop Res, J Biomech, and Clin Biomech). Finally, Google Scholar was used to search for additional relevant studies. 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. More details of the strategy and glossary terms used can be found in the Appendix (see Supplementary data).

Inclusion and exclusion analysis. Initial screening based on the title and abstract of RSA studies was performed by BP to identify studies on patients treated with THA 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 THA, and (2) a minimum RSA follow-up of 1 year, measuring femoral stem migration.

Data extraction. Migration data from RSA studies was independently extracted in duplicate by PV and MN. Since the failure mechanism of femoral stems involves subsidence and retroversion, the data extraction of RSA studies focused on subsidence and retroversion of the femoral stem in the first 2 postoperative years (Karrholm et al. 1994). Data concerning patient demographics and regional influences were extracted to allow for confounder correction (Pijls et al. 2011). The design concept of different femoral stems (i.e. cemented shape-closed, cemented force-closed, or uncemented) was determined by RN.

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

Systematic review of survival studies

Literature search. The search strategy and bibliographies were comparable to those used 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 (Supplementary data) for more details of the strategy and glossary terms.

Inclusion and exclusion analysis. The procedure for screening of the survival studies for eligibility and subsequent inclusion and exclusion analysis was identical to the procedures for the RSA studies with the exception of the inclusion and exclusion criteria. The inclusion criteria for survival studies were (1) primary THA; (2) follow-up time of 5, 10, 15, 20, or 25 years (in the final analysis, only 10 years of follow-up was used); (3) endpoint being revision surgery for aseptic loosening of the femoral stem, or indication for revision surgery when there was poor general health or patient decline; and (4) survival or percentage revised being available for a specific follow-up period (see point 2). Studies with less than 75 THAs at baseline were excluded.

Data extraction. Revision rates for aseptic loosening of the femoral stem at 5-year intervals from survival studies were independently extracted in duplicate by PV and JJ. Data concerning patient demographics and regional influences were also extracted to allow for confounder correction. The design concept of different femoral stems was determined by RN.

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

Analysis

The data were analyzed according to the same methodology as previously used in the systematic review and meta-analysis on early migration of acetabular cups in relation to late aseptic revision (Pijls et al. 2012a). A detailed description of the analysis, methodology, and a worked example are available in the online Appendix (see Supplementary data). The association between early migration and late revision was determined by matching the results from the RSA review to the results of the survival analysis review according to the type of prosthesis and fixation method (e.g. cemented or uncemented), here abbreviated to PF combination. Matching according to PF combination prevents confounding by PF combination, since PF combination is determined by technical factors known to be associated with both migration and a high likelihood of revision for aseptic loosening (AJR 2013, NJR 2012, SHAR 2011). PF combinations were subsequently stratified according to design concept (i.e. cemented shape-closed, cemented force-closed, or uncemented). Depending on the studies available, it is possible that there would be more than 1 combination of matching of RSA and survival studies for a particular PF combination. For instance, if there are 3 RSA studies and 2 survival studies of the same PF combination, then there would be 6 possible combinations (3 × 2). All combinations were considered in the analysis. A meta-analysis for the revision rates 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 was applied to estimate the survival at 10 years and its confidence interval (Fiocco et al. 2009a, b, Putter et al. 2010, Fiocco et al. 2012). Regarding the RSA studies, pooling of migration results at the level of PF combinations was based on weights according to study size (N).

The 10-year results of THA with high revision rates are not likely to be published once 5-year published results show high revision rates. 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 from 5-year results by applying the factor 1.7. This method was validated by comparing the estimated 10-year results with the known 10-year results for the complete cases (AJR 2013, NJR 2012, SHAR 2011).

Adjustment for confounding

Since RSA migration data and survival analysis data were extracted from different studies, it may be possible that differences between study populations might confound the observed association. In order to address this issue, we determined the degree of similarity of the study population between the RSA data and survival analysis data for the same stem design, expressed by a match score, for age, sex, diagnosis, hospital type, and continent. The match score has been constructed according to the results of a Delphi survey among an international group of 37 independent experts and can vary between 0 (poor) and 5 (excellent) (Pijls et al. 2011). This RSA study and the survival study combination scored 1 point for each of the following criteria (up to a maximum of 5 points): (1) the difference in mean age between patients from the 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 the survival study was 10% or less; (3) the difference in percentage of patients diagnosed with primary osteoarthritis between the RSA study and the survival study was 10% or less; (4) the RSA study and the survival study were performed in a similar type of hospital (e.g. both in university medical centers); and (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 the influence of match score, quality of RSA study, quality of survival study, number of THAs in the RSA studies, and number of THAs in the survival studies.

Migration thresholds

According to the principle of "primum non nocere", new implant designs should perform at least as well as the revision standard of national registries with high validity: ≤ 3% revision at 5 years and ≤ 5% revision at 10 years according to the Swedish Hip Arthroplasty Register and the Australian National Joint Replacement Registry (AJR, SHAR). To have a safe margin, these more conservative criteria were chosen over the NICE criteria thresholds (i.e. 5% revision at 5 years and 10% revision at 10 years) (NHS). Based on the revision standard of the national registries, the following 3 categories were constructed for the phased introduction of new THA: "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" 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 (AJR 2013, NJR 2012, SHAR 2011). Accordingly, the PF 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 PF combinations that perform worse than average. For this purpose, the pooled migration per specific combination of prosthesis type and fixation method was sorted according to revision rate and visualized in a dot chart.

Results

RSA studies. The literature search yielded 629 hits for the RSA review, and 24 studies (marked with • in the reference list) were included comprising 731 femoral stems (Figure 1). The mean AQUILA methodological quality score of the RSA studies on a 7-point scale was 5.2 (SD 1.2). Subsidence of the femoral stem was the most frequently reported migration value: 1-year and 2-year subsidence was reported in 22 and 20 out of 27 RSA studies, respectively. Retroversion at 1 year and 2 years was reported in 10 and 13 RSA studies, respectively. Posterior head migration (translation along the z-axis) was reported infrequently and inconsistently, and did not allow a meaningful analysis.

Survival studies. The literature search generated 5,290 hits for the survival analysis review and 56 studies (marked with ○ in the reference list) were included with a total of 20,599 femoral stems (Figure 1). The mean AQUILA methodological quality score of the survival studies on an 11-point scale was 7.0 (SD 2.1).

Early migration and late revision. The matching procedure resulted in 14 different PF combinations (i.e. type of prosthesis and fixation method) and 100 combinations of RSA and survival studies (Table 1). In the entire heterogeneous group of different PF combinations, there was no statistically significant ($p > 0.05$) association between migration, either subsidence or retroversion, and prosthesis survival (Figure 2). Then we divided the PF combinations into more homogenous groups according to design concept: cemented shape-closed, cemented force-closed, and uncemented (Huiskes et al. 1998). For the shape-closed femoral stems, there was an association between subsidence of shape-closed femoral stems and implant survival (Figure 3). For every 0.1-mm increase in 2-year subsidence in shape-closed designs, there was a 4.2% (95% CI: 1.3–7.1; $p < 0.05$) increase in the aseptic revision rate at 10 years. This association remained significant after correction for RSA study quality, survival study quality, number of femoral stems in the RSA study, number of femoral stems in the survival study, and match score (all p-values < 0.05) (Table 2). The force-closed stems, consisting exclusively of the polished Exeter stem in the current meta-analysis, showed excellent long-term survival with no stems exceeding the revision threshold of 5% at 10 years (Figure 2). Further analysis for the force-closed stems was considered inappropriate given the small number of PF combinations and the lack of contrast in revision rates (i.e. no high revision rates (> 5 %)) (Figure 2). For the same reason, no meaningful analyses could be carried out for the uncemented stems since only 1 PF combination (Ribbed uncoated stem) showed a revision rate of more than 5% at 10 years. None of the design concepts

Table 1. Details of prosthesis and fixation (PF) combinations

PF	Prosthesis (stems)	Fixation	Number of RSA studies	Number of survival studies	Number of combinations
1	ABG I	HA-coated	1	8	8
2	Bicontact	Porous-coated	1	4	4
3	Charnley Elite Plus (SC)	Cement (high-viscosity)	2	2	4
4	Charnley Elite Plus (SC)	Cement (low-viscosity)	1	1	1
5	Cementless Spotorno	Uncoated	1	7	7
6	Exeter (FC)	Cement (high-viscosity)	4	8	32
7	Exeter (FC)	Cement (low-viscosity)	3	1	3
8	Honnart Partel-Garches	Uncoated	1	1	1
9	Lubinus SP II (SC)	Cement (high-viscosity)	3	5	15
10	Omnifit	HA-coated	1	5	5
11	Ribbed	Uncoated	1	1	1
12	Scanhip (SC)	Cement (high-viscosity)	1	2	2
13	Spectron EF (SC)	Cement (high-viscosity)	3	4	12
14	Taperloc	Porous-coated	1	5	5
Total			24	54	100

SC: shape-closed; FC: force-closed; HA: hydroxyapatite; ABG: Anatomique Benoist Giraud

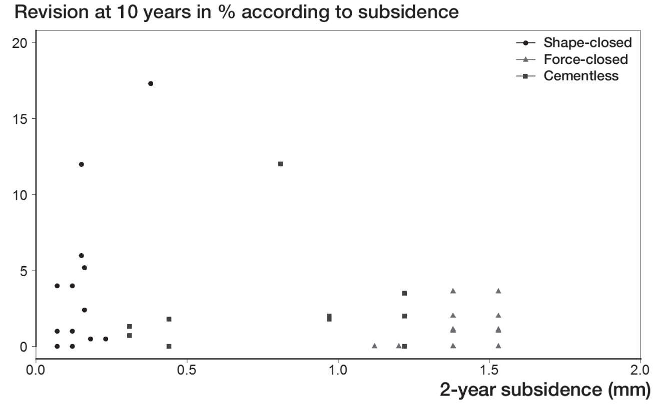

Figure 2. Scatter plot showing the subsidence at 2 years (in mm) and revision rate for aseptic loosening of the femoral stem at 10 years (percentage), categorized according to design concept (i.e. shape-closed, force-closed, uncemented).

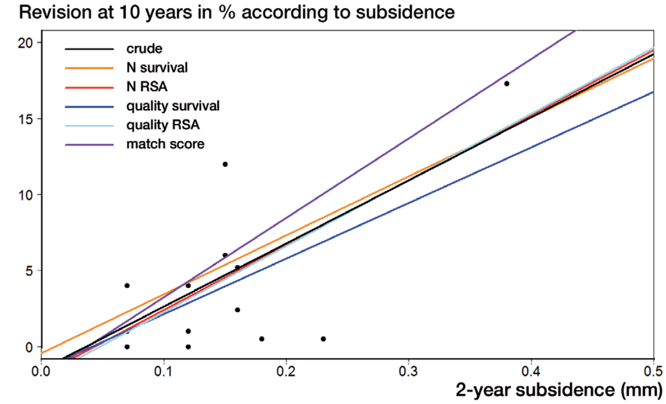

Figure 3. Scatter plot showing the association between 2-year subsidence (in mm) and revision rate for aseptic loosening of the shape-closed femoral stem at 10 years (percentage). The colored lines are derived from weighted regression according to match quality, survival study quality, and RSA quality (the coefficients and 95% CIs are presented in Table 2).

showed an association between retroversion or continuous migration (i.e. 2-year migration minus 1-year migration) and implant survival.

Early migration. The force-closed stems showed the largest amount of early subsidence, with a pooled mean subsidence of 1.0 mm (SE 0.05) and 1.3 mm (SE 0.01) at 1 and 2 years, respectively (Figure 4). The pooled subsidence of the uncemented stems was in-between that of cemented force-closed and shape-closed stems. The uncemented stems showed a pooled mean subsidence of 0.6 mm (SE 0.08) at 1 year and 0.7 mm (SE 0.07) at 2 years. The shape-closed stems showed a pooled mean subsidence of 0.11 mm (SE 0.01) and 0.14 mm (SE 0.01) at 1 and 2 years, respectively.

Migration thresholds. Figure 5 shows the 3 categories of the stems. Subsidence at 2 years was between 0 and 0.15 mm; there was no stem with more than 5% revision for aseptic loosening at 10 years. In the case of 2-year subsidence of more than 0.23 mm, there was no stem with less than 5% revision for aseptic loosening at 10 years. This indicates that accepting 5% revision at 10 years resulted in a threshold of 0.15 mm for acceptable subsidence at 2 years. The threshold for unacceptable subsidence is less distinct, given the lack of data points with an excessive revision rate. However, stems with a subsidence of more than 0.15 mm are at risk of early revision. Adoption of the NICE criteria (10% revision at 10 years) does not alter the threshold of acceptable subsidence of 0.15 mm at 10 years.

Publication bias. The pooled 2-year migration, ranked by the pooled 10-year revision rate for each PF combination, is presented in Figure 6. The PF combinations that migrate less

Table 2. Association between 2-year subsidence of shape-closed femoral stems and revision rate for aseptic loosening at 10 years. Increase in 10-year revision rate (%) for each 0.1-mm increase in subsidence at 2 years. In the crude analysis (unadjusted), 4.2% (95% CI: 1.3–7.1; p < 0.05) was added to the 10-year revision rate for every 0.1-mm increase in subsidence at 2 years

	Increase in revision (%) /0.1-mm subsidence	(95% CI)
Crude	4.2	(1.3–7.1)
Adjusted for [a]:		
N survival [b]	3.9	(0.6–7.2)
N RSA [b]	4.2	(1.2–7.4)
Survival study quality	3.7	(0.6–6.7)
RSA study quality	4.4	(1.8–7.0)
Total match score	5.2	(2.7–7.7)
Range of values	3.7–5.2	(0.6–7.2)

[a] When adjusted for e.g. the number of THAs in survival studies (N survival), 3.9% (95% CI: 0.6–7.2; p > 0.05) was added to the 10-year revision rate for every 0.1-mm increase in subsidence at 2 years. The association between subsidence and revision rate for aseptic loosening remained significant when adjusting for confounders (all p-values < 0.05).
[b] The square root of N was used for the weighted regression, so larger studies weighed more heavily.
N survival: number of THAs in survival studies;
N RSA: number of THAs in RSA studies.

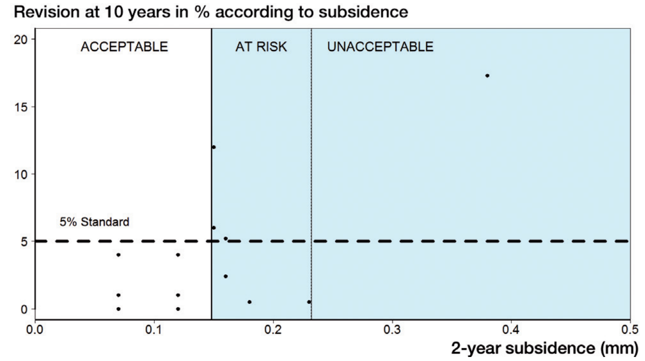

Figure 5. Scatter plot showing the 2-year subsidence and revision rate of shape-closed femoral stems for aseptic loosening at 10 years. The threshold of 0.15 mm for acceptable subsidence is shown. The threshold of 0.23 mm for unacceptable subsidence could be defined less precisely and is also shown. Adoption of the NICE criteria (10% revision at 10 years) did not alter these thresholds.

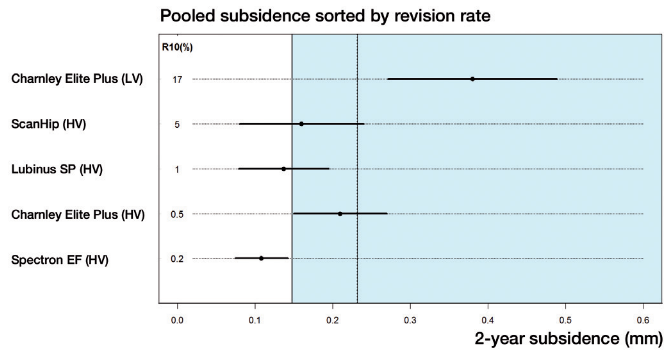

Figure 6. Dot chart showing the pooled 2-year subsidence of shape-closed femoral stems ranked by the pooled 10-year revision rate for each PF combination. The threshold of 0.15 mm for acceptable subsidence is shown and the less precisely definable threshold for unacceptable subsidence (0.23) is also shown.

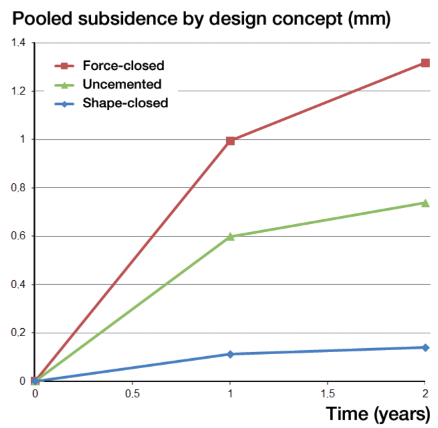

Figure 4. Line chart of the pooled subsidence (in mm) up to 2 years, according to design concept (i.e. shape-closed, force-closed, uncemented). The standard errors were 0.05 mm and 1 mm (force-closed), 0.08 mm and 0.07 mm (uncemented), and 0.01 mm and 0.01 mm (shape-closed) at 1 and 2 years, respectively.

than the acceptable threshold (i.e. Lubinus SP and Spectron EF) have been—according to the Swedish Register—the most and the fourth most commonly used femoral components during the past 10 years, with survival rates of 98% and 97% at 10 years (SHAR). Conversely, the PF combinations that are classified as unacceptable on the basis of their pooled migration (i.e. Charnely Elite Plus) have been abandoned, and are no longer used (Hauptfleisch et al. 2006). These examples show that the possible influence of publication bias on the results is small.

Discussion

The results of this meta-regression analysis, combining data from RSA studies and survival studies, show a clinically relevant association between early subsidence of shape-closed femoral stem designs, as measured with RSA, and clinical failure (i.e. aseptic revision surgery) at 10-year follow-up, corrected for age, sex, diagnosis, type of hospital, region, size of study, and quality of study. For every 0.1-mm increase in subsidence, the 10-year revision rate increases by mean 4% (95% CI: 1.3–7.1). The force-closed stem designs, which in the current meta-analysis consisted of only polished Exeter stems, showed the greatest amount of early subsidence and had excellent long-term survival with none of the stems exceeding the revision threshold of 5% at 10 years. This suggests that subsidence is beneficial for force-closed stems. However, more research with different force-closed stems is necessary to confirm this idea. The subsidence of the uncemented stems varied between that of cemented shape-closed stems and force-closed stems, and there was only 1 PF combination with a revision rate of more than 5% (Ribbed uncoated stem). The available data did not provide a clear pattern for identification of unsafe uncemented designs. Perhaps stabilization of migration is more suitable than the absolute value of migration for identification of unsafe uncemented femoral stems.

The results of our systematic review demonstrate that RSA studies can identify unsafe shape-closed femoral stems as early as 2 years postoperatively. Next to tibial components and acetabular components, our finding is another example of the potential of RSA for early identification of prostheses that perform less optimally (Pijls et al. 2012a, b). Compared to the present policy of introduction of new prostheses, RSA has the potential to prevent widespread use of unsafe prostheses and save numerous patients from revision surgery.

The strengths of our systematic review have been the large number of studies included (78) and the large number of patients (> 20,000), which resulted in 14 different PF combinations. Although no association could be found between early migration and long-term aseptic revision for all PF combinations, the large variation in PF combinations gives us insight in the migration patterns of femoral stems. Since the migration and revision rates were from different studies, the RSA data could not have been used (incorporated) in the decision to perform a revision, so there was no incorporation bias. We considered that the influence of publication bias for the shape-closed femoral stems was small, since the results from the meta-analysis were similar to those from the national joint registries. Confounders only had a small influence on the association between early migration and long-term aseptic revision.

We should also consider some limitations. We were unable to find an association for the complete group of PF combinations and only found an association for the subgroup of shape-closed designs. This was due to the high variation in migration patterns of different PF combinations. The design concept (i.e. shape-closed, force-closed, or uncemented) of a THA determines its migration pattern, and every design concept should therefore be analyzed separately (Huiskes et al. 1998). More research on each design concept is necessary to give a better understanding of acceptable and unacceptable migration for each of the concepts.

Furthermore, the quality of the survival studies and RSA studies showed a large degree of variation. A high methodological quality of all the studies included would have been desirable. Nevertheless, the quality of the survival studies and of the RSA studies showed only small effects on the association between migration and revision rate.

We should also take into account the fact that RSA only evaluates aseptic loosening. Although aseptic loosening is the foremost reason for failure, there are other failure mechanisms (e.g. infection, pain, and instability or pseudotumors in metal-on-metal total hip arthroplasty) which are not evaluated by RSA. RSA studies are therefore only the first step, after preclinical testing, in the phased introduction as proposed by both Faro and Huiskes and Malchau (Faro and Huiskes 1992, Malchau 1995, 2000). Several authors have pleaded for a phased evidence-based market introduction of new prostheses comparable to the introduction of new drugs to the consumer market (Murray et al. 1995, Liow and Murray 1997, Muirhead-Allwood 1998, Malchau 2000). During phase A, multiple single-center RSA studies should be performed to determine the safety of the THA regarding the risk of revision for aseptic loosening and wear. Thresholds for acceptable and unacceptable initial migration can be used for assessment of the new prosthesis (Malchau 1995, 2000). Thus, the observed association in our study between early migration and long-term revision on shape-closed designed femoral stems can be adopted in phased evidence-based market introduction of new THAs. Given that the THA is safe, phase B studies must be conducted to evaluate the clinical performance of the THA regarding pain relief and functioning (clinical scores and patient-reported outcome measures (PROMS)) and to determine the rate of complications within a limited period that is feasible (e.g. severe adverse effects of the implant). Successful completion of phase B would allow introduction to the market and would herald phase C, where the performance of the THA must be monitored by post-marketing surveillance in national joint registries (Schemitsch et al. 2010). This includes both the revision rate and patient evaluations using PROMS.

The Charnley Elite Plus stem is of special interest. This THA was introduced as successor to the well-established Charnley THA. It was assumed that small alterations in the design would enhance survival and patient outcome. However, early clinical studies gave conflicting findings, with some suggesting a similar outcome to that of the conventional Charnley stem, while others suggested a worse outcome (Kalairajah et al. 2004, Makela et al. 2008). Hauptfleisch et al. (2006) found survival of 83% at 10 years, which was in accordance with their earlier predictions of high failure rates based on early RSA evaluation. These authors blamed the design of the Charnley Elite Plus for the poor survival. However, the cement used in that study was low-viscosity cement, and Derbyshire et al. (2006) pointed out that the low-viscosity cement might also have been the reason for the poor survival (Derbyshire et al. 2006). Our results suggest a similar reason: the pooled survival of the Charnley Elite Plus cemented with low-viscosity cement was far worse than the acceptable threshold. The same stem cemented with high-viscosity cement showed better survival, approaching the acceptable threshold. If the threshold of acceptable migration of the prosthesis had been known at the time the Charnley Elite Plus was introduced, it would have been classified as unacceptable after only 2 years of RSA follow-up. This example illustrates the clinical value of migration thresholds for early identification of THAs that have a high likelihood of failure at long-term follow-up. Moreover, this example highlights that not only design but also type of fixation should be taken into account when evaluating femoral stem survival. For the Charnley Elite Plus femoral stem, it was not only the design but also the fixation (low-viscosity or high-viscosity cement) that influenced both early migration and long-term survival. Labeling of femoral stems according to the PF (prosthesis and fixation) combination principle is therefore imperative.

Various authors and regulatory agencies recognize the potential of RSA (Karrholm et al. 1994, Ryd et al. 1995, Malchau 2000, Hauptfleisch et al. 2006). The NICE guidelines of 2003 require adequate long-term clinical data for hip prostheses and regard RSA as a promising technique that may be an early-warning indicator of expected poor long-term revision rates (NHS). Recently, the International Organization for Standardization (ISO) and the European Standards Working Group on Joint Replacement Implants published a standard protocol for early clinical studies that provides requirements for the clinical assessment of migration of orthopedic implants with RSA (ISO 16087:2013). The Dutch Orthopaedic Society now requires a phased introduction with mandatory RSA studies before any new THA is considered for introduction to the Dutch market (Swierstra et al. 2011). In addition, new initiatives for increasing patient safety such as the Beyond Compliance Service not only support the stepwise introduction of new implants to the market, but also acknowledge the importance of training established surgeons how to use a new innovative design (the Beyond Compliance Advisory Group).

In conclusion, 2-year early migration of shape-closed design femoral stems is associated with 10-year revision for aseptic stem loosening. The proposed migration thresholds provide insight into the failure mechanism of shape-closed femoral stems. Too few RSA study and survival study combinations for force-closed and uncemented stem designs were found to give meaningful recommendations on the predictive value of early migration for aseptic revision of these designs. If more RSA migration studies are performed, the value of early migration profiles of these designs will be possible.

Supplementary data

Appendix is available at Acta's website (www.actaorthop.org), identification number 7633.

RGN, BGP, and ERV conceived the study. SM provided methodological input and MF provided statistical input during the conceptual phase of the study. JWP designed the search strategy for the literature search. PV, BGP, MJN, and JJ performed the study selection and matching procedure. PV and JJ appraised the quality of the literature and performed the data extraction. MF and BGP analyzed the data. PV, BGP, ERV, and RGN wrote the initial draft of the manuscript. MF and SM ensured the accuracy of the data and analysis. BGP and MF wrote the Appendix. Critical revision of the manuscript was done by all the authors.

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Statistical code and dataset are available from the corresponding author upon request. R code for the analysis described in the Appendix is available from one of the authors (e-mail m.fiocco@lumc.nl).

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