

Supplementary article data

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

A systematic review and meta-analysis of 26 RSA studies and 49 survival studies

Bart G Pijls¹, Marc J Nieuwenhuijse¹, Marta Fiocco⁴, Josepha WM Plevier³, Saskia Middeldorp^{5,6}, Rob GHH Nelissen¹, and Edward R Valstar^{1,2}

¹Department of Orthopaedics, Bio-Imaging Group, Leiden University Medical Center, Leiden; ²Department of Biomechanical Engineering, Faculty of Mechanical, Maritime and Materials Engineering, TU Delft; ³Walaeus Library and ⁴Department of Medical Statistics and Bioinformatics, Leiden University Medical Center, Leiden; ⁵Academic Medical Center, Department of Vascular Medicine, Amsterdam; ⁶Department of Clinical Epidemiology, Leiden University Medical Center, Leiden, the Netherlands.

Correspondence: b.g.c.w.pijls@lumc.nl

Submitted 12-02-29. Accepted 12-09-03

Appendix

Methodological concept

To determine the association between early migration and late revision it is necessary to match the results from the RSA review to the results of the survival review, because migration data and revision rate data are commonly reported in different studies. In other words, since there are very few studies directly addressing the relation between early migration of cups and late revision, it is only possible to study this relation indirectly.

In medicine, treatment effects can be studied indirectly in so called meta-analyses of indirect comparison by comparing two different treatments against a common control (Song et al. 2003). Results of such meta-analyses are usually, but not always, similar to those of meta-analyses of direct comparison trials. This mostly depends on whether underlying assumptions are met or not. This will be elaborated on further below. The concept of indirect comparison is illustrated in appendix Figure A.1. Suppose we are interested in the comparison of treatment A versus treatment C yet no studies are available that directly compare these two treatments. However, there are studies that directly compare treatment A with treatment B (study 1) and treatment C with treatment B (study 2). Then the estimate of the indirect comparison of treatment A versus C (T_{ac}) is calculated by:

$$T_{ac} = T_{study1} - T_{study2}$$

or

$$T_{ac} = T_{ab} - T_{bc}$$

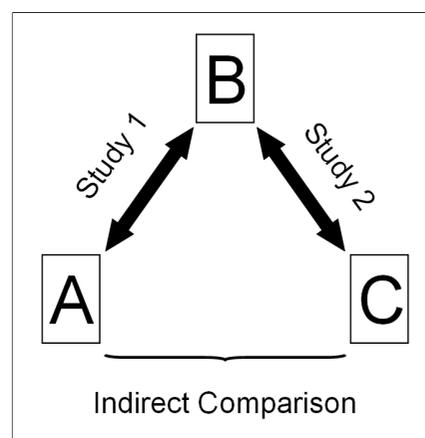


Figure A.1 Indirect comparison of A versus C

Regarding the association between early migration and late revision, the concept is the same as that for indirect meta-analyses. However, since we are dealing with an association rather than a treatment effect, there is no common control group. Instead, we use the type of Prosthesis and Fixation method (e.g. cement or bone ingrowth), PF, to match migration with revision rates, as illustrated in appendix Figure A.2.

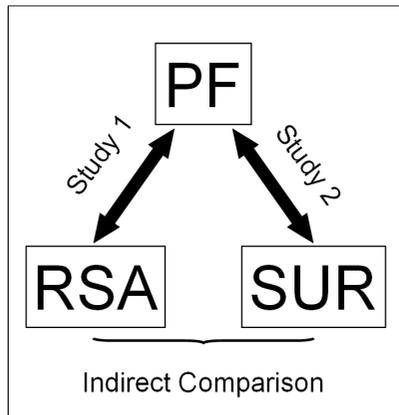


Figure A.2 Indirect comparison of RSA and SUR (survival)

Migration and revision rates are assumed to be a characteristic of a particular type of prosthesis and fixation method. Therefore prosthesis and fixation method (PF) acts similar to the common control group (B) in indirect meta-analyses.

Prosthesis and fixation method (PF) is defined as an uniquely identifiable cup design with uniquely identifiable fixation method. It should be noted that uniquely identifiable cup design is not equal to brand name, as there are multiple cup designs with the same brand name. For instance the uncemented omnifit cup is available in the following different (von Schewelov et al. 2004):

omnifit dual radius, HA-coated
 omnifit dual radius, porous-coated
 omnifit dual geometry, HA-coated
 omnifit dual geometry, porous-coated
 omnifit "screw cup"

Each of the above versions is considered as a separate PF. The omnifit example also clearly illustrates the variation in fixation methods. We distinguished the following fixation methods:

cement: low viscosity
 high viscosity
 Boneloc (was considered separately as a special case)

cementless *: HA-coated
porous-coated
uncoated
(any other type of coating, e.g. HA + tricalcium phosphate (TCP))

Assumption for the indirect method

The validity of the indirect comparison depends on the internal validity (methodological quality) and similarity of the included studies (Song et al. 2003).

Internal validity

Regarding the internal validity we determined the methodological quality of the RSA studies and survival studies according to the AQUILA methodological score (Pijls et al. 2011). This score was used as a weight in a weighted regression model to assess how it influenced the association between early migration and late aseptic revision: studies with higher scores weighed heavier in the analyses.

Table II from the manuscript shows that in the crude analysis the 10 year revision rate increases by 10% for every mm increase in 2-year proximal migration. When survival study quality was used as a weight, the 10% increase/mm 2-year migration of the crude analysis changed to 10.8%. So, with survival study quality as a weight 10.8% is added to the revision rate for every mm increase in 2-year proximal migration. When RSA study quality was used as a weight, the 10% increase/mm in 2-year migration of the crude analysis changed to 8.4%. So, with RSA study quality as a weight 8.4% is added to the revision rate for every mm increase in 2-year proximal migration.

In conclusion internal validity expressed as survival study quality and RSA study quality had a small effect on the association between early migration and late aseptic revision and together with on average good methodological score for the RSA and survival studies, the requirement of adequate internal validity was met.

Similarity

Regarding the similarity (external validity) of the matched RSA and survival studies we determined the match score based on similarity in age, gender, diagnosis, hospital type and continent. These items and cut off values are based on the results of a recent Delphi among an international group of 37 independent experts and were hence determined before the analyses were performed (Pijls et al. 2011). The match score thus resembles similarity between matching RSA and survival studies and varies between 0 and 5 points. A worked example of the calculation of match scores is available further below. A higher score indicates greater similarity of the matched RSA and survival study. The match score is calculated as follows:

Age

When the difference in mean age between matching RSA and survival study is less than 5 years they receive 1 point. When the difference is more than 5 years or unknown (mean age is not reported), they receive 0 points.

Gender

When the difference in percentage females between matching RSA and survival study is less than 10% they receive 1 point. When the difference is more than 10% or unknown (percentage females is not reported), they receive 0 points.

Diagnosis

When the difference in percentage patients with osteoarthritis between matching RSA and survival study is less than 10% they receive 1 point. When the difference is more than 10% or unknown (percentage patients with osteoarthritis is not reported), they receive 0 points.

Hospital type

The following hospital types were considered: Academic, Developer, Special institute, High volume, Public. When the matching RSA and survival study were performed in the same type of hospital they received 1 point. When they were performed in different types of hospital or the type of hospital was unknown, they received 0 points.

Continent

When the matching RSA and survival study were performed on the same continent they received 1 point. When they were performed on different continents or the continent was unknown, they received 0 points.

The match score was used as a weight in a weighted regression model to assess how it influenced the association between early migration and late aseptic revision: studies with higher scores weighed heavier in the analyses.

Table II from the manuscript shows that in the crude analysis the 10 year revision rate increased by 10% for every mm increase in 2-year proximal migration. When match score was used as a weight, the 10% increase/mm 2-year migration of the crude analysis changed to 5.8%. So, with match score as a weight 5.8% is added to the revision rate for every mm increase in 2-wear proximal migration.

In conclusion similarity expressed as match score had some effect on the association between early migration and late aseptic revision, but the association remained clinically and statistically significant. Therefore the requirement of similarity was met.

Pooling migration data and survival data

Pooling of migration data and survival data was performed for the appraisal of publication bias: the pooled results from the literature were compared with those from the national joint registries, since they do not suffer from publication bias.

Pooling migration data

Regarding the RSA studies pooling of migration results at the level of PF was weighed by number of cups in the RSA study based on the following formula:

$$\text{Pooled mean}_{1-x} = (\text{mean}_1 * N_1 + \text{mean}_2 * N_2 + \dots + \text{mean}_x * N_x) / (N_1 + N_2 + \dots + N_x)$$

Where N_i is the size of a single study i ($i=1, \dots, x$). The standard deviation (SD) was pooled according to weighted variation as given below:

$$\text{Pooled SD}_{1-x} = \sqrt{(\text{SD}_1 * \text{SD}_1 * (N_1 - 1) + \text{SD}_2 * \text{SD}_2 * (N_2 - 1) + \dots + \text{SD}_x * \text{SD}_x * (N_x - 1)) / (N_1 + N_2 + \dots + N_x - x)}$$

sqrt = square root of

Pooling survival data

Starting point for the meta-analysis are the revision rates at 10 years reported in each manuscript and the minimum and the maximum follow-up (min_{FUP} , max_{FUP}) of patients.

These quantities may be given directly but most often they will need to be estimated from the manuscript by looking at dates of accrual (if given) and from the date of submission, or perhaps publication of the manuscript. A model for the censoring mechanism based on the minimum and the maximum follow-up is assumed here for computing the number at risk and person years for each time. Let $C(t)$ be the function that models the censoring mechanism. Based on the available information we choose the function $C(t)$ as follows

$$C(t) = \begin{cases} 1 & \text{if } t \leq \min_{\text{FUP}} \\ 1 - \frac{t - \min_{\text{FUP}}}{\max_{\text{FUP}} - \min_{\text{FUP}}} & \text{if } \min_{\text{FUP}} < t < \max_{\text{FUP}} \\ 0 & \text{if } t \geq \max_{\text{FUP}}. \end{cases} \quad (1)$$

This function expresses the proportion of patients at time t that have at least t time units of follow-up. Given the number of eligible patients (n), the effective number at risk, the number of revisions at time j and the number of censored are estimated, respectively, as

$$\tilde{r}_j = nS_jC_j, \quad (2)$$

$$d_j = n(S_{j-1} - S_j) \frac{C_{j-1} + C_j}{2}, \quad (3)$$

and

$$c_j = n(C_{j-1} - C_j) \frac{S_{j-1} + S_j}{2}. \quad (4)$$

S_j : survival at time j

C_j : value of the function $C(t)$ defined in (1) at a specific time j

r_j : number at risk at time j

d_j : number of deaths at time j

c_j : number of censored at time j

This assumes that the censored observations are distributed uniformly over the interval. Under the same assumption, from the number of patients at risk $\sim r_j$, we can define the number of person-years over interval I_j , as $r_j = \Delta_j(\tilde{r}_j - c_j/2)$, where $\Delta_j = t_j - t_{j-1}$ is the length of I_j . Following the methodology described the data for each study involved in the meta-analysis have been reconstructed. A Poisson mixed model with study as random effects has been fitted to the reconstructed data, to estimate the pooled revision probability and the confidence interval at 10 years.

Worked example

For this worked example will use the Harris Galante I porous coated + screws cup.

Matching procedure

2 RSA studies met the inclusion criteria (Onsten et al. 1994, Onsten et al. 1994) both of them report migration of the HG I porous-coated cup with screws.

Regarding the the Harris Galante I porous coated + screws cup, 14 survival studies met the inclusion criteria.

When matching the RSA studies to the survival study we get the following 28 (2 * 14) combinations.

Combi	Survival study	RSA study
1	Bohm 1998 JBJSBr	Önsten 1994 Acta
2	“	Önsten 1994 JBJSAm
3	Callaghan 1999 CORR	Önsten 1994 Acta
4	“	Önsten 1994 JBJSAm
5	Ender 2005 ZCO	Önsten 1994 Acta
6	“	Önsten 1994 JBJSAm
7	Garcia-Rey 2008 IO	Önsten 1994 Acta
8	“	Önsten 1994 JBJSAm
9	Latimer 1996 JBJSAm	Önsten 1994 Acta
10	“	Önsten 1994 JBJSAm
11	Parvizi 2004 JOA	Önsten 1994 Acta
12	“	Önsten 1994 JBJSAm
13	Petersen 1999 JBJSAm	Önsten 1994 Acta
14	“	Önsten 1994 JBJSAm
15	Ricci 2008 JOA	Önsten 1994 Acta
16	“	Önsten 1994 JBJSAm
17	Thanner 1999 AOS	Önsten 1994 Acta
18	“	Önsten 1994 JBJSAm
19	Tomkins 1997 JBJSAm	Önsten 1994 Acta
20	“	Önsten 1994 JBJSAm
21	Ince 2007 CORR	Önsten 1994 Acta
22	“	Önsten 1994 JBJSAm
23	Firestone 2007 JBJSAm	Önsten 1994 Acta
24	“	Önsten 1994 JBJSAm
25	Dlima 1998 CORR	Önsten 1994 Acta
26	“	Önsten 1994 JBJSAm
27	Woolson 1996 JBJS Am	Önsten 1994 Acta
28	“	Önsten 1994 JBJSAm

In order to prevent increasing complexity the remainder of the worked example will only use combinations 1 through 6.

Combi	2 year proximal migration (mm)	10 year revision (%)
1	0.15	0
2	0.24	0
3	0.15	0
4	0.24	0
5	0.15	2.3
6	0.24	2.3

These combination provide the x-coordinate (migration) and y-coordinate (revision) for the figures 2 and 3 of the manuscript.

Match score

Regarding the similarity (external validity) of the matched RSA and survival studies we determined the match score based on similarity in age, gender, diagnosis, hospital type and continent (see above).

For example regarding Onsten 1994 Acta and Bohm 1998 the match score is calculated as follows:

age (1 point), because the difference in mean is less than 5 years
 gender (1 point), because the difference in % females is less than 10 percent
 diagnosis (0 points), because the difference in % OA is more than 10 percent
 hospital (1 point), because patients were operated in similar hospital types
 continent (1 point), both studies are from the same continent

Thus the match score for combi 1 (Bohm et al. 1998, Onsten et al. 1994) is $1+1+0+1+1 = 4$.
 The match scores of combi 1 through 6 are shown below.

Combi	age	gender	Diagnosis	Hospital	Continent	Match score
1	1	1	0	1	1	4
2	0	0	0	1	1	2
3	1	0	0	1	0	2
4	0	0	0	1	0	1
5	1	1	0	1	1	4
6	0	0	0	1	1	2

A higher score indicates greater similarity of the matched RSA and survival study. The match score was used as a weight in a weighted regression model to assess how it influenced the association between early migration and late aseptic revision (see above): therefore in this example combi 1 and 5 weigh the heaviest, while combi 4 has the lowest weight.

Pooling of migration data

We will continue with the HG 1 cup to illustrate the pooling of migration data.

The data for the 2 year proximal migration are:

	mean	SD	N
Onsten 1994 Acta:	0.18	0.16	30
Onsten 1994 JBJSAm	0.29	0.37	14

The pooled mean is calculated according to the following formula:

$$\text{Pooled mean}_{1-x} = (\text{mean}_1 * N_1 + \text{mean}_2 * N_2 + \dots + \text{mean}_x * N_x) / (N_1 + N_2 + \dots + N_x)$$

$$\text{Pooled mean} = (0.18 * 30 + 0.29 * 14) / (30 + 14) = 9.46/44 = 0.22 \text{ mm}$$

The standard deviation (SD) was pooled according to weighted variation according to the following formula:

$$\text{Pooled SD}_{1-x} = \sqrt{(\text{SD}_1 * \text{SD}_1 * (N_1 - 1) + \text{SD}_2 * \text{SD}_2 * (N_2 - 1) + \dots + \text{SD}_x * \text{SD}_x * (N_x - 1)) / (N_1 + N_2 + \dots + N_x - x)}$$

$$\text{Pooled SD} = \sqrt{(0.16 * 0.16 * (30 - 1) + 0.37 * 0.37 * (14 - 1)) / (30 + 14 - 2)} = \sqrt{(0.74 + 1.78) / 42} = \sqrt{0.06005} = 0.24$$

With a pooled mean of 0.22mm a pooled SD of 0.24 and N_{total} of 44 the 95% confidence interval becomes:

0.15mm to 0.29mm

Pooling of survival data

The pooled 10 year revision of the HG1 cup uses all the revision rates from the 14 included studies (see above). The pooled 10 year revision aseptic loosening was 0.6% for the HG1 cup as is shown in figure 4 of the manuscript.

Details of the literature search strategy

RSA studies

PubMed: ("Photogrammetry"[Mesh] OR "roentgen stereophotogrammetric analysis" OR rsa OR radiostereometr* OR stereophotogrammetr* OR "roentgen fluoroscopic")

AND

("Joint Prosthesis"[Mesh] OR hip prosthesis OR knee prosthesis OR TKA OR THA OR THR OR TKR OR "joint replacement" OR Arthroplasty, Replacement[mesh] OR "total knee replacement" OR "total hip replacement")

Survival cohort studies

PubMed: ("Joint Prosthesis"[Mesh] OR hip prosthesis OR knee prosthesis OR TKA OR THA OR THR OR TKR OR "joint replacement" OR Arthroplasty, Replacement[mesh] OR "total knee replacement" OR "total hip replacement")

AND

("Prosthesis Failure"[Mesh] OR "prosthetic loosening" OR "aseptic loosening" OR "implant loosening" OR "implant failure")

AND

("survival analysis"[MeSH Terms] OR ("survival"[All Fields] AND "analysis"[All Fields]) OR "survival analysis"[All Fields] OR cohort studies[mesh] OR "follow up" OR "follow-up" OR experience OR outcome)

These strings were adapted to fit the vocabulary of the other databases mentioned above.

The results were limited to humans.

Reference List

Bohm P, Bosche R. Survival analysis of the Harris-Galante I acetabular cup. *Journal of Bone and Joint Surgery - Series B*. 1998;(3):May.

Onsten I, Carlsson AS. Cemented versus uncemented socket in hip arthroplasty. A radiostereometric study of 60 randomized hips followed for 2 years. *Acta Orthop Scand*. 1994;65(5):517-21.

Onsten I, Carlsson AS, Ohlin A, Nilsson JA. Migration of acetabular components, inserted with and without cement, in one-stage bilateral hip arthroplasty. A controlled, randomized study using roentgenstereophotogrammetric analysis. *JBone Joint Surg Am*. 1994;76(2):185-94.

Pijls BG, Dekkers OM, Middeldorp S, Valstar ER, Van der Heide HJ, Van der Linden-Van der Zwaag HM, et al. AQUILA: Assessment of QUality In Lower limb Arthroplasty: An expert Delphi consensus for total knee and total hip arthroplasty. *BMC Musculoskelet Disord.* 2011;12(1):173.

Song F, Altman DG, Glenny AM, Deeks JJ. Validity of indirect comparison for estimating efficacy of competing interventions: empirical evidence from published meta-analyses. *Bmj.* 2003;326(7387):472.

von Schewelov T, Sanzen L, Onsten I, Carlsson A. Catastrophic failure of an uncemented acetabular component due to high wear and osteolysis - An analysis of 154 Omnifit prostheses with mean 6-year follow-up. *Acta Orthopaedica Scandinavica.* 2004;75(3):283-94.