Humeral stem loosening following reverse shoulder arthroplasty – systematic review and meta-analysis

by

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Declaration

I, Barend Christiaan Grey, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Abstract

Background

Aseptic stem loosening following reverse shoulder arthroplasty (RSA) is an uncommon complication. The majority of literature on RSA consists of case series with short follow-up periods. It remains unknown which factors contribute to aseptic stem loosening in RSA. Our analysis aimed to compare the incidence of aseptic stem loosening, humeral radiolucent lines (RLL) and revision for stem loosening between: 1) cemented and uncemented stems, and 2) different etiological subgroups

Methods

In a systematic review 75 articles were included after assessment of study methodology and a meta-analysis of 1660 cemented and 805 uncemented stems was performed. We compared the incidence of aseptic stem loosening, humeral RLL, and revision for stem loosening between: 1) cemented and uncemented stems from cohorts with short (< 5 years) mean follow-up periods, long (≥ 5 years) mean follow-up periods, and all cohorts combined; and 2) different etiological subgroups.

Results

The overall incidence of aseptic stem loosening was 1%. When comparing cemented to uncemented stems, there was no significant difference in the incidence of aseptic stem loosening or of revision for stem loosening in both the short and long term follow-up groups. Humeral RLL were more common with cemented stems (15.9% versus 9.5%, $p = 0.002$). The highest incidence of aseptic stem loosening occurred in the tumor subgroup (10.81%), followed by RSA as revision for failed arthroplasty (3.66%). No stem loosening was seen in the acute fracture or fracture sequelae groups.

Conclusion

Aseptic stem loosening occurred more commonly in cohorts with long follow-up times (2% vs 0.8%, $p = 0.01$). There was no difference in the incidence of aseptic stem loosening or revision for stem loosening between cemented and uncemented stems. Humeral RLL occurred more frequently when cemented stems were used.

Patients treated with RSA following excision of proximal humerus tumors and RSA as revision for failed arthroplasty were at greater risk of aseptic stem loosening.

Background

Humeral stem loosening is an uncommon complication following reverse shoulder arthroplasty (RSA). A systematic review by Zumstein et al. in 2011 reported an 1.3% incidence of humeral stem loosening.(1) However, at the time of the review, only four of the included studies had follow-up periods longer than five years. The timing at which loosening occurred and the relationship between loosening and cementing, or indication for surgery was not investigated.

Gilot et al. performed a multicenter retrospective radiographic study to investigate aseptic humeral stem loosening following RSA.(2) Radiographs taken at three years' follow-up were analyzed. No loosening occurred in the group with uncemented stems (115 stems) while in the cemented group (177 stems) two stems (1.18%) developed aseptic loosening. However, the difference was not statistically significant ($p = 0.198$).

A multicenter review by Melis et al., with a mean follow-up period of 9.6 years, reported various radiographic changes occurring around cemented and uncemented reverse shoulder arthroplasty stems.(3) Humeral radiolucent lines occurred around 57% of stems. Stem loosening was defined as radiolucent lines $\geq$ 2mm in > 3 zones, and was more common in cemented stems (11.8%) than uncemented stems (5.9%).

Boileau recently reported on complications and revisions in their series of RSA in 825 patients.(4) Surgical reintervention was required in 84 patients. Aseptic stem loosening was responsible for 10% of these reinterventions. He suggested that proximal humeral bone loss, often encountered in patients with fracture sequelae, revision arthroplasty and proximal humeral tumors following excision could contribute to stem loosening. He postulated that this may have been due to increased rotational forces transmitted to the remainder of the distal stem. While literature has shown higher complication and revision rates for RSA performed as a revision procedure for failed hemiarthroplasty and total shoulder arthroplasty(1, 5-8), no studies have proven that aseptic stem loosening is more common in this group. Similarly, stem loosening has not been proven to be more common in patients with

proximal humeral fractures or fracture sequelae.

Our review aimed to: 1) compare the incidence of radiological aseptic stem loosening, humeral radiolucent lines (RLL) and revision for RSA stem loosening between cemented and uncemented stems with short (<5 years) or long (≥5 years) follow-up periods; 2) compare these outcomes between primary RSA and RSA performed as a revision procedure for failed hemiarthroplasty, anatomical total shoulder arthroplasty and failed reverse shoulder arthroplasty.

Methods

We followed the PRISMA guidelines(9) and our review protocol was registered on the PROSPERO database(10), registration number CRD42016037965.

PICOTS statement

Population: Patients treated with reverse shoulder arthroplasty (RSA)

Intervention: Cemented stems

Control: Uncemented stems

Outcomes:

Radiological: Humeral stem loosening, radiolucent lines

Clinical: Revision of RSA due to stem loosening

Time period: < 5 years and ≥ 5 years' follow-up

Study design: Systematic review and meta-analysis

Search strategy

Electronic database searches were performed from 22 to 24 April 2016. We searched four databases (Pubmed, Scopus, Web of Science and Cochrane Library). The search terms used and details of the database search are described in Appendix 1.

Study eligibility

We included all clinical studies on RSA, published in English, regardless of study design, sample size, data of publication or follow-up time, describing radiographic stem loosening, or revision for stem loosening. Exclusion criteria were biomechanical and cadaver studies, case reports, reviews and studies on stem-less RSA. Due to inadequate data on patient demographics, follow-up times and cementing of stems, publications using arthroplasty registry data were excluded. To avoid including stems with possible septic loosening, studies on revision for septic arthroplasty were also excluded. Following removal of duplicates, the 1658 abstracts were independently screened by BG and SR. All articles identified for full text review by either author were then retrieved for evaluation. Inter-observer agreement for study eligibility after abstract screening was tested using kappa statistics.

When follow up publications on the same patient cohort were present, preference was given to the latest publication with the longest follow-up time. Where different publications had overlapping patient cohorts the authors were contacted to separate their data. If this was not possible, preference was first given to papers with the longest follow-up times, followed by papers with the largest patient cohorts. When studies had insufficient data on the use of cement, the authors were contacted via email, up to 3 times when necessary, and then excluded if data were still not supplied.

Assessment of study quality

Case series were assessed for bias using a Quality Appraisal Tool for Case Series developed by the Institute of Health Economics, Alberta, Canada in collaboration with health technology assessment agencies in Spain and Australia using a modified Delphi technique.(11) This is a checklist using twenty questions to evaluate the potential for bias in case series (Appendix 2). Even though this checklist has been validated, no cut off value has been determined to exclude case series from further analysis. Cohort studies were evaluated for bias using the Newcastle Ottawa Scale(12) and prospective randomized control trials were evaluated using the Jadad Scale.(13) For the meta-analysis we only included data from the prospective randomized control trials, cohort studies with NOS score > 5 and case series with a score ≥ 14 to ensure greatest data fidelity.

Data collection

Data were extracted into an Excel spreadsheet under the following headings: principle author, cohort details (dates of series and surgeons responsible), study design, etiology (indication for RSA), primary / revision procedure, RSA brand, use of cement, number of RSA cases, female percentage, average age, follow up time (mean, minimum and range / standard deviation), number of stems with humeral radiolucent lines, number of stems becoming radiologically loose (defined as humeral RLL ≥ 2mm in more than 3 zones),(2, 3, 14) and the number of stems revised for aseptic loosening.

Statistics

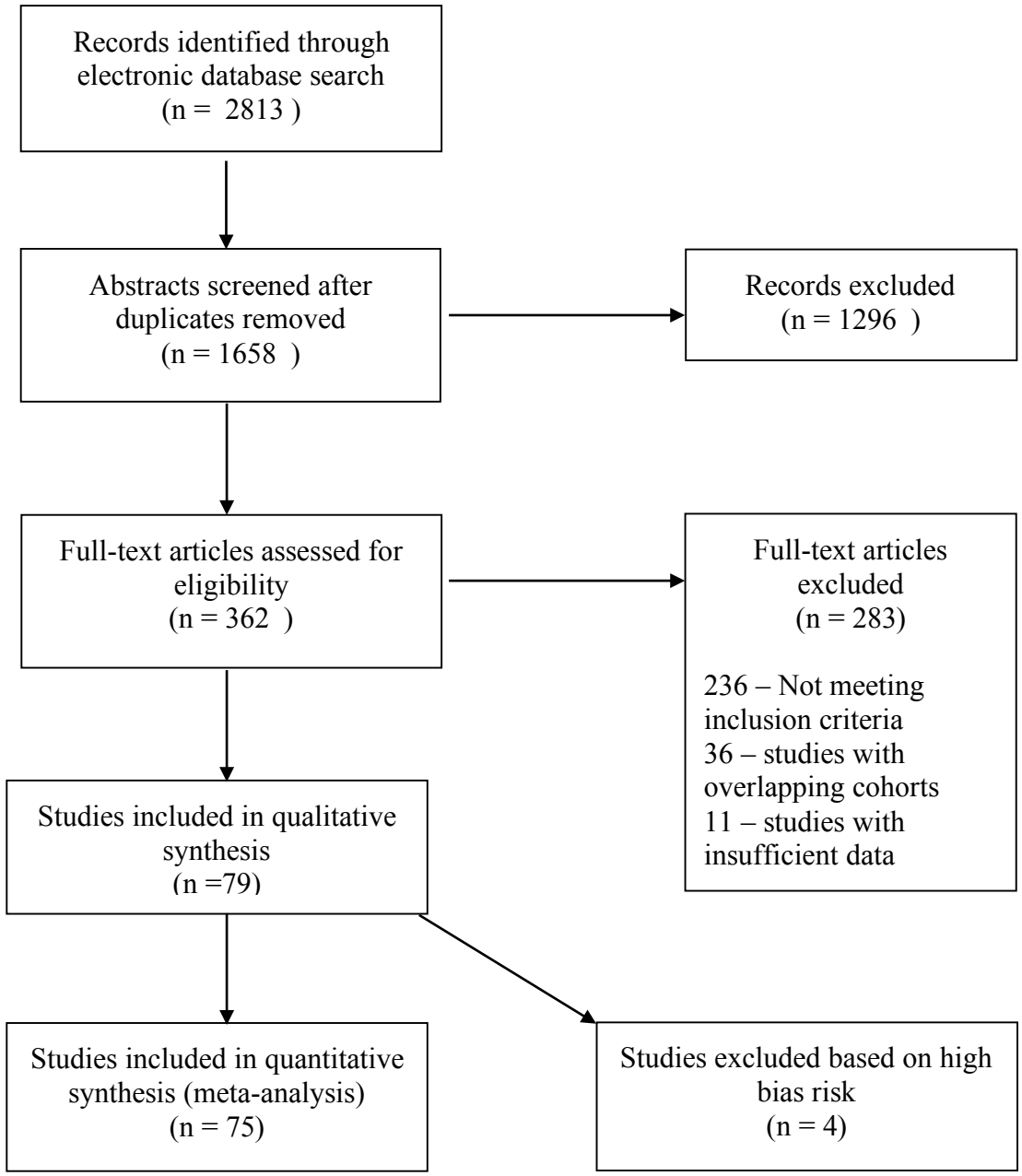
Due to the varying study design and high number of non-events in the eligible studies it was not feasible to conduct a traditional study-level meta-analysis. Rather, results from individual studies were pooled for each study outcome. Chi-square tests were conducted with an alpha of 0.05 using Holm-Bonferroni sequential correction to account for multiple testing.

Firstly, we compared the incidence of radiological stem loosening, humeral radiolucent lines (RLL) and revision for RSA stem loosening between cemented and uncemented stems from cohorts with short (<5 years) or long (≥5 years) follow-up periods. Subsequently, we did a subgroup analysis to compare these same outcomes between RSA performed as primary arthroplasty procedure and RSA performed to revise failed hemiarthroplasty, total shoulder arthroplasty and failed reverse shoulder arthroplasty. To improve the homogeneity of the primary RSA group, we subdivided it into smaller subgroups based on similar pathology. We grouped patients with cuff tear arthritis, irreparable cuff tears and osteoarthritis with rotator cuff insufficiency together into one group. Other subgroups of primary RSA were acute fractures, proximal humeral tumors, rheumatoid arthritis or inflammatory arthritis, and fracture sequelae. The revision RSA group consisted of patients treated with RSA to revise failed hemiarthroplasty, total shoulder arthroplasty or failed reverse shoulder arthroplasty. When cohorts had mixed etiological subgroups and data for each subgroup were not available, these cohorts were not included in the subgroup analysis.

Results

The electronic database search yielded 2813 articles. The subsequent screening process is shown in the PRISMA flow diagram (Figure 1). The inter-observer agreement for study eligibility following abstract screening was moderate (kappa = 0.57).

Figure 1. PRISMA flow diagram.



Seventy-five articles were finally included in the analysis. Sixty-five of these were case series (level IV evidence), eight were cohort studies (7 level III, 1 level II) and two were prospective randomized control trials (level I). Eight studies used uncemented stems exclusively (Table 1). Forty-four studies used cemented stems exclusively (Table 2). Both cemented and uncemented stems were used in 23 studies (Table 3).

All 75 included studies provided data on aseptic stem loosening and revision for aseptic stem loosening. The overall incidence of aseptic stem loosening was 1%, and this was significantly higher in the long follow-up cohorts (2% vs 0.8%, $p = 0.01$). When comparing cemented and uncemented stems, we found no significant difference in the incidence of aseptic stem loosening or revisions for aseptic stem loosening (Tables 4 and 5); this was in cohorts with short and long follow-up periods. Only 38 studies provided data on the incidence of humeral RLL. Overall, humeral RLL were more common when cemented stems were used (Table 6). Interestingly, this was most significant in the cohorts with less than five years' follow up, but not significant in cohorts with more than 5 years' follow up.

Table 1. Studies reporting on the use of uncemented stems exclusively.

Paper	Study type	Score	Nr cases	Female (%)	Mean age	Mean F/U (months)	Etiology	RLL	Loose stems	Revised stems
Al-Hadithy, 2014 (15)	Retrospective case series, level IV	17	41	78.4	79	60	CTA	2	0	0
Bogle, 2013 (16)	Retrospective case series, level IV	15	40	NR	71.6	24	Mixed	4	0	0
Giuseffi, 2014 (17)	Retrospective case series, level IV	15	44	70.7	76	27	Mixed	NR	0	0
Kadum, 2014 (18)	Prospective cohort, level III	NOS 7	15	73.3	72	35	Mixed	1	0	0
Rittmeister, 2001 (19)	Retrospective case series, level IV	15	6	83	60.3	54.3	RA / IA	NR	0	0
Saier,2015 (20)	Prospective case series, level IV	17	28	62.9	72	24	ICT / CTA / OA	0	0	0
Sebastia-Forcada, 2014 (21)	PRCT	Jadad 4	31	87.1	74.7	29.4	Acute fracture	4	0	0
Woodruff, 2003 (22)	Retrospective case series, level IV	16	13	100	64	87	RA / IA	NR	0	0

RLL – Humeral radiolucent lines; NR – Not reported; CTA – cuff tear arthropathy; ICT – irreparable cuff tear; RA – rheumatoid arthritis; IA – inflammatory arthritis; OA – osteoarthritis; PRCT – prospective randomized control trial

Table 2. Studies reporting on the use of cemented stems exclusively

Paper	Study type	Score	Nr cases	Female (%)	Mean age	Mean F/U (months)	Etiology	RLL	Loose stems	Revised stems
Atalar, 2014 (23)	Retrospective case series, level IV	15	14	85.7	74	34	CTA	0	0	0
Athwal, 2016 (24)	Retrospective case series, level IV	17	24	83.3	75	36	CTA	2	0	0
Boileau, 2006 (6)	Retrospective case series, level IV	16	38	80	74.3	40	Mixed	29	1	1
Boileau, 2011 (25)	Prospective case series, level IV	17	42	66.7	72	28	Mixed	NR	0	0
Bonnevialle, 2015 (26)	Retrospective case series, level IV	15	8	70	55	42	Tumor	2	1	0
Bufquin, 2007 (27)	Prospective case series, level IV	18	40	95.3	78	22	Acute fracture	NR	0	0
Castricini, 2013 (28)	Prospective case series, level IV	18	62	73.8	72.5	60	Mixed	5	0	0
Cazeneuve, 2012 (29)	Retrospective case series, level IV	15	37	94.6	75	88	Acute fracture	6	0	0

Cuff, 2012 (30)	Prospective case series, level IV	18	74	67.6	70.4	62	Mixed	2	1	1
Cuff, 2013 (31)	Prospective cohort , level II	NOS 9	24	58.3	74.4	29	Acute fracture	NR	0	0
De Wilde, 2011 (32)	Retrospective case series, level IV	15	9	44.4	45.1	92	Tumor	1	1	1
Ekelund, 2011 (33)	Retrospective case series, level IV	16	23	75.9	68	45	CTA	NR	0	0
Flury, 2011 (34)	Retrospective case series, level IV	15	19	85	67.7	46	Revision	1	0	0
Formaini, 2015 (35)	Retrospective case series, level IV	17	25	68	77	17	Acute fracture	0	0	0
Frankle, 2005 (36)	Retrospective case series, level IV	17	60	68	71	33	Mixed	NR	0	0
Gallinet, 2009 (37)	Retrospective cohort, level III	NOS 8	16	81	74	12.4	Acute fracture	5	0	0
Garofalo, 2015 (38)	Retrospective case series, level IV	15	22	77	77.2	24	Acute fracture	NR	0	0
Garofalo, 2015 (39)	Retrospective case series, level IV	17	87	71.3	76.2	27	Acute fracture	NR	0	0
Giannotti, 2014 (40)	Retrospective case series, level IV	16	36	87.9	75	37	CTA	NR	0	0

Grassi, 2014 (41)	Retrospective case series, level IV	14	15	100	75	22	Acute fracture	0	0	0
Greiner, 2014 (42)	Retrospective case series, level IV	16	50	77.6	69	34	Fracture sequelae	NR	0	0
Greiner, 2015 (43)	PRCT, level I	Jadad 4	31	64.7	75.4	22	CTA	NR	0	0
Guven, 2016 (44)	Retrospective case series, level IV	15	10	50	49.4	18.2	Tumor	NR	0	0
Iannotti, 2012 (45)	Retrospective case series, level IV	15	4	25	65.5	38.5	Revision	NR	0	0
Jacobs, 2001 (46)	Retrospective case series, level IV	14	7	100	72	26	CTA	NR	0	0
John, 2010 (47)	Prospective case series, level IV	16	17	66.7	67.3	24.3	ICT	NR	0	0
Kaa, 2013 (48)	Retrospective case series, level IV	15	10	62.5	41.5	46.4	Tumor	NR	2	2
Kaisidis, 2014 (49)	Prospective case series, level IV	15	29	55.2	81	26	Acute fracture	NR	0	0
Klein, 2008 (50)	Prospective case series, level IV	15	20	70	74.9	33.3	Acute fracture	0	0	0
Lenarz, 2011 (51)	Retrospective case series, level IV	17	30	90	76.7	23	Acute fracture	0	0	0

Levy J, 2007 (52)	Retrospective case series, level IV	16	19	61.1	72	38	Revision	1	1	0
Lollino, 2009 (53)	Retrospective case series, level IV	15	15	86.7	68.4	24	Mixed	NR	0	0
Lopiz, 2016 (54)	Retrospective case series, level IV	17	42	81	81.7	32.6	Acute fracture	0	0	0
Mizuno, 2012 (55)	Prospective case series, level IV	14	47	69.6	74.4	30	Mixed	0	0	0
Muh, 2013 (56)	Retrospective case series, level IV	17	67	56.1	52.2	36.5	Mixed	NR	0	0
Paladini, 2005 (57)	Retrospective case series, level IV	15	7	71.4	68	30	Revision	1	0	0
Raiss, 2014 (58)	Retrospective case series, level IV	17	32	87.5	68	48	Fracture non-union	NR	0	0
Reitman, 2011 (59)	Retrospective case series, level IV	14	13	61.5	70	29	Acute fracture	NR	0	0
Stephens S, 2015 (60)	Retrospective cohort, level III	NOS 9	16	64.7	70.5	51	Revision	NR	3	0
Von Engelhardt, 2015 (61)	Retrospective case series, level IV	16	11	87.7	73.2	17.5	Mixed	NR	0	0
Werner, 2014 (62)	Retrospective case series, level IV	16	21	85.7	71	59	Chronic dislocation	NR	0	0

Willis, 2012 (63)	Retrospective case series, level IV	16	16	75	65	37	Fracture malunion	2	0	0
Young A, 2011 (64)	Retrospective case series, level IV	16	18	87.5	70.1	46	RA / IA	NR	0	0
Zafra, 2014 (65)	Prospective case series, level IV	18	35	80	69	51	Fracture non-union	23	0	0

RLL – Humeral radiolucent lines; NR – Not reported; CTA – cuff tear arthropathy; ICT – irreparable cuff tear; RA – rheumatoid arthritis; IA – inflammatory arthritis; OA – osteoarthritis; PRCT – prospective randomized control trial

Table 3. Studies reporting on the use of both cemented and uncemented stems

Paper	Study type	Score	Cement	Nr cases	Female (%)	Mean age	Mean F/U (months)	Etiology	RLL	Loose stems	Revised stems
Boughebri, 2013 (66)	Retrospective case series, level IV	15	Yes	2	71.4	67.5	33.2	CTA	0	0	0
same series			No	13	71.4	67.5	33.2	CTA	0	0	0
Budge, 2013 (67)	Prospective case series, level IV	19	Yes	13	80	67	34.5	Revision	0	0	0
same series			No	2	80	67	34.5	Revision	NR	0	0
Ek, 2013 (68)	Retrospective case series, level IV	16	Yes	29	41.5	60	93	ICT	NR	0	0
same series			No	11	41.5	60	93	ICT	NR	0	0
Grassi, 2009 (69)	Retrospective case series, level IV	14	Yes	15	92	75	42	Mixed	1	0	0
same series			No	8	92	75	42	Mixed	2	0	0

Hattrup, 2012 (70)	Retrospective case series, level IV	17	No	5	70.6	70	37	RA / IA	0	0	0
same series			Yes	14	70.6	70	37	RA / IA	7	1	0
Hattrup, 2016 (71)	Retrospective case series, level IV	16	Yes	14	76.9	67	37.4	Fracture sequelae	4	0	0
same series			No	6	76.9	67	37.4	Fracture sequelae	0	0	0
Irlenbusch, 2015 (72)	Prospective case series, level IV	15	Yes	37	70.6	71.9	25.5	Mixed	0	0	0
same series			No	18	70.6	71.9	25.5	Mixed	0	0	0
Katz, 2016 (73)	Retrospective case series, level IV	17	Yes	34	74	72	45	ICT / CTA	NR	0	0
same series			No	106	74	72	45	ICT / CTA	NR	3	1
King, 2015 (74)	Retrospective cohort, level III	NOS 8	Yes	25	84	73.6	50.4	ICT / CTA / OA	0	0	0
same series			No	16	31.25	71.6	48	ICT / CTA / OA	1	0	0
Leung, 2012 (75)	Retrospective cohort, level III	NOS 9	Yes	31	63	72	36	CTA	NR	0	0

same series			No	5	63	72	36	CTA	NR	0	0
Martinez, 2012 (76)	Retrospective case series, level IV	15	Yes	20	59.1	77	48	Fracture sequelae	NR	0	0
same series			No	24	59.1	77	48	Fracture sequelae	NR	0	0
Melis, 2011 (3)	Retrospective case series, level IV	15	Yes	34	69.2	69.4	115	Mixed	39	4	0
same series			No	34	69.2	69.4	120	Mixed	NR	2	0
Middleton, 2014 (77)	Retrospective case series, level IV	16	Yes	66	53.9	67	50	Mixed	NR	1	1
same series			No	23	53.9	67	50	Mixed	NR	0	0
Ross, 2015 (78)	Retrospective case series, level IV	16	Yes	14	87	79	54.8	Acute fracture	1	0	0
same series			No	15	87	79	54.8	Acute fracture	1	0	0
Russo, 2015 (79)	Retrospective case series, level IV	15	Yes	3	88	75	60	Acute fracture	0	0	0
same series			No	47	88	75	60	Acute fracture	4	0	0

Sadoghi, 2011 (80)	Prospective cohort, level III	NOS 9	Yes	52	55.9	66	42	ICT	NR	3	3
same series			No	8	55.9	66	42	ICT	NR	0	0
Schneeberger, 2014 (81)	Retrospective case series, level IV	14	Yes	5	68.4	65	54	ICT	1	0	0
same series			No	13	68.4	65	54	ICT	1	0	0
Shi, 2015 (82)	Retrospective case series, level IV	16	Yes	6	100	66.2	43	Fracture sequelae	NR	0	0
same series			No	15	73.3	66.1	44.3	CTA	NR	0	0
Simovitch, 2015 (83)	Retrospective case series, level IV	16	Yes	24	62.5	73	43	Mixed	NR	0	0
same series			No	17	62.5	73	43	Mixed	NR	0	0
Statz, 2016 (84)	Retrospective case series, level IV	15	Yes	17	58.5	68	32.4	Mixed	0	0	0
same series			No	24	58.5	68	32.4	Mixed	1	1	1
Wiater, 2014 (14)	Retrospective cohort, level III	NOS 8	Yes	37	59.5	72	37	ICT / CTA	1	0	0

same series			No	64	68.8	72.5	32.4	ICT / CTA	2	0	0
Wirth, 2016 (85)	Retrospective case series, level IV	16	Yes	4	70	75	24	Mixed	NR	0	0
same series			No	72	70	75	24	Mixed	NR	0	0
Young S, 2009 (86)	Retrospective case series, level IV	14	Yes	8	79.2	78.9	38	Mixed	NR	0	0
same series			No	41	79.2	78.9	38	Mixed	NR	0	0

RLL – Humeral radiolucent lines; NR – Not reported; CTA – cuff tear arthropathy; ICT – irreparable cuff tear; RA – rheumatoid arthritis; IA – inflammatory arthritis; OA – osteoarthritis; PRCT – prospective randomized control trial

Table 4. Pooled incidence of aseptic stem loosening

Study group	Total number of patients	Events	Incidence	P value*
< 5 years				
Uncemented	659	4	0.6%	0.6046
Cemented	1410	13	0.9%	
≥5 years				
Uncemented	146	2	1.4%	0.7157
Cemented	250	6	2.4%	
Combined				
Uncemented	805	6	0.75%	0.4002
Cemented	1660	19	1.16%	
Combined				
< 5 years	2069	17	0.82%	0.01
≥ 5 years	396	8	2.02%	

*P-values corrected using Holm-Bonferroni correction

Table 5. Pooled incidence of revision for aseptic stem loosening

Study group	Total number of patients	Events	Incidence	P value*
< 5 years				
Uncemented	659	2	0.3%	0.7275
Cemented	1410	7	0.5%	
≥ 5 years				
Uncemented	146	0	0%	0.5333
Cemented	250	2	0.8%	
Combined				
Uncemented	805	2	0.25%	0.5202
Cemented	1660	9	0.54%	

*P-values corrected using Holm-Bonferroni correction

Table 6. Pooled incidence of humeral radiolucent lines

Study Group	Total number of patients	Events	Incidence	P value*
< 5 years				
Uncemented	298	17	5.7%	0.0001
Cemented	505	79	15.6%	
≥ 5 years				
Uncemented	122	23	18.9%	0.654
Cemented	219	36	16.4%	
Combined				
Uncemented	420	40	9.5%	0.0023
Cemented	724	115	15.9%	

*P-values corrected using Holm – Bonferroni correction

Subgroup analysis investigating underlying etiology (reason for RSA), revealed the highest incidence of stem loosening and revision for stem loosening in the tumor subgroup, followed by RSA as revision for failed arthroplasty. (Tables 7 and 8) None of the stems in the acute fracture or fracture sequelae groups developed stem loosening. However, 41% of stems in the fracture sequelae group and 7% of stems in the acute fracture groups developed humeral RLL (Table 9).

Table 7. Pooled incidence of aseptic stem loosening amongst etiological subgroups

Subgroups	Total number of patients	Events	Incidence	P value*
CTA / ICT / OA	989	6	0.61%	< 0.001
Acute fractures	497	0	0%	
Tumors	37	4	10.81%	
RA / IA	86	1	1.16%	
Fracture sequelae	220	0	0%	
Revision RSA	164	6	3.66%	
CTA / ICT / OA vs Revision RSA				
CTA / ICT / OA	989	6	0.61%	0.008
Revision RSA	164	6	3.66%	

CTA – cuff tear arthropathy; ICT – irreparable cuff tear; OA – osteoarthritis with cuff insufficiency; RA – rheumatoid arthritis; IA – inflammatory arthritis; *p – values corrected using Holm – Bonferonni correction

Table 8. Pooled incidence of revision amongst etiological subgroups

Subgroups	Total number of patients	Events	Incidence	P value*
CTA / ICT / OA	1002	4	0.4%	< 0.001
Acute fractures	497	0	0%	
Tumors	37	3	8.11%	
RA / IA	86	0	0%	
Fracture sequelae	199	0	0%	
Revision RSA	164	2	1.22%	
CTA / ICT / OA vs Revision RSA				
CTA / ICT / OA	1002	4	0.4%	< 0.001
Revision RSA	164	2	1.22%	

CTA – cuff tear arthropathy; ICT – irreparable cuff tear; OA – osteoarthritis with cuff insufficiency; RA – rheumatoid arthritis; IA – inflammatory arthritis; *p – values corrected using Holm – Bonferonni correction

Table 9. Pooled incidence of humeral RLL amongst etiological subgroups

Subgroups	Total number of patients	Events	Incidence	P Value
CTA / ICT / OA	716	14	1.96%	< 0.001
Acute fractures	295	21	7.12%	
Tumors	17	3	17.65%	
RA / IA	19	7	36.84%	
Fracture sequelae	71	29	40.85%	
Revision RSA	60	3	5%	

CTA – cuff tear arthropathy; ICT – irreparable cuff tear; OA – osteoarthritis with cuff insufficiency; RA – rheumatoid arthritis; IA – inflammatory arthritis; *p – values corrected using Holm – Bonferonni correction

Discussion

Our review confirmed that aseptic stem loosening following RSA is an uncommon complication. In our analysis the overall incidence was 1%. However, the majority of the literature on RSA only has short and mid term follow-up data. Of the 75 studies included in our analysis, only four studies had minimum follow-up times of five years or more(3, 22, 30, 68) and only nine studies had mean follow-up times longer than five years.(3, 15, 22, 28-30, 32, 68, 79) There is an expectation with any form of arthroplasty that the loosening rate of implants will increase with time. This was also shown in our study, with a higher incidence of loosening in the longer follow-up studies (2% vs 0.8%, $p = 0.01$).

Similar to previous studies(2, 14, 74) and a recent meta-analysis(87), we found no difference in the incidence of aseptic stem loosening and revision for stem loosening between cemented and uncemented stems. A multicenter radiographic review of 292 patients treated with RSA (177 cemented stems, 115 uncemented stems), reported two loose cemented stems (1.18%) and no loose uncemented stems, which was not statistically significant. Wiater et al.(14) performed a retrospective cohort study of 101 patients with cuff tear arthropathy or severe rotator cuff insufficiency treated with RSA, comparing 37 cemented stems to 64 uncemented stems. There were no loose stems identified in either group. King et al.(74) reviewed 83 RSA cases (32 cemented stems and 51 uncemented stems) with a mean follow-up period of 3.5 years. They identified one loose stem in each group, which was not significantly different. The systematic review by Phadnis et al.(87) pooled data from 41 clinical studies on RSA and compared 1455 cemented stems to 329 uncemented stems. They also found no significant difference in stem loosening, but a higher incidence of humeral RLL in uncemented stems. The authors mentioned that this was mainly due to the study by Bogle et(16) which reported four RLL distal to the tip of uncemented stems which were all non-progressive.

We found significantly more humeral RLL amongst cemented stems, especially amongst cohorts with shorter mean follow-up periods. In cohorts with long follow-up this difference disappeared. The accuracy of reporting humeral RLL is questionable as stress shielding can also mimic humeral radiolucent lines.(88) This phenomenon is

caused by altered force transfer following stemmed arthroplasty. Stress shielding was first noticed with uncemented total hip arthroplasty stems, especially when larger diameter(89) and extensive porous coated(90) stems were used. Subsequently it has also been reported to occur more commonly around uncemented anatomical(91) and reverse(3) shoulder arthroplasty stems. The tuberosities and cortices surrounding the stem are gradually resorbed because the force transfer occurs through the implant more than the surrounding bone. An uncemented stem that initially borders onto the cortices may appear to develop radiolucent lines when the cortices become thinner. Stress shielding may explain why humeral RLL became more frequent in uncemented stems from cohorts with longer follow-up times.

Subgroup analysis showed that RSA performed for failed hemiarthroplasty (HA), anatomical total shoulder arthroplasty (TSR) and failed RSA had a higher incidence of aseptic stem loosening than primary RSA performed for cuff tear arthropathy, acute fractures or fracture sequelae. A recent paper on the revision of failed RSA's identified 85 failures out of 1418 RSA cases that required revision.(7) Four out of these 85 revisions were for aseptic stem loosening, and all four of these RSA's were originally performed for failed arthroplasty that subsequently developed proximal humeral bone loss.

In the presence of proximal humeral bone loss, torsional forces are concentrated at the remainder of the stem-cement and cement-bone interfaces which theoretically increases the risk of stem loosening. A biomechanical study confirmed significantly higher rotational micro motion of RSA stems cemented in proximal humeral bone loss models compared with intact humeral models when subjected to torsional forces of 5 – 17.5 N-m.(92) Proximal humeral bone loss is also present following wide excision of proximal humeral tumors and in our study this subgroup of patients had the highest loosening rate.

Interestingly, no loose stems were found in the acute fracture or fracture sequelae subgroups. This may be due to the short follow-up times of papers on proximal humeral fractures and fracture sequelae. The only author with long term radiological data on RSA done for acute proximal humeral fractures is Cazeneuve. In his latest follow-up publication(29) with a mean follow-up time of 7.3 years, he reported a

16% incidence of humeral RLL, but no patients with radiological stem loosening or revision for loose stems. Aseptic stem loosening has been reported in RSA performed for acute fractures(88) and patients with fracture sequelae(93), but these studies were not included in our analysis. Hussey et al.(93) reported 2 loose stems requiring revision in their series of 19 patients (11%) treated with RSA for failed internal fixation of proximal humerus fractures. We did not include their study due to inadequate information on the use of cement. Youn et al.(88) also reported two radiologically loose stems in their series of 20 patients (10%) with acute proximal humerus fractures, but these stems were asymptomatic and didn't require revision. Their study was excluded due to overlapping patient cohorts with the study by Young et al.(86)

There are a few limitations to our study. Firstly, the majority of the included studies were case series, level IV evidence. However, by using a validated score we only selected the higher quality studies to minimize bias. Secondly we used a radiological definition to define loose stems. Some of the stems appearing loose were asymptomatic and did not require revision. Therefore, we also investigated the incidence of revision for aseptic stem loosening. We did not include stem subsidence in our definition of stem loosening, as uncemented stems often subside to a limited extent in the early post-operative period(16, 87), but subsequently stabilize and should not be considered loose. Thirdly, due to reasons mentioned before we could not perform a traditional study-level meta-analysis. Therefore, we pooled data from each study to investigate the outcomes of interest.

Finally, we did not compare outcomes between the different brands of cemented and uncemented stems used as it was not the focus of this analysis. This was also impossible to do, as data were inadequate when different brands were used in the same study, and due to the low number of loose stems overall. Further prospective research is required to investigate the influence of RSA design on aseptic stem loosening.

Conclusion

There is no difference in the incidence of aseptic stem loosening or revision for stem loosening between cemented and uncemented RSA stems. It is a rare complication, with a significant increase in longer follow – up studies. We suspect that proximal humeral bone loss increases the risk of stem loosening and we advise that patients treated with RSA following tumor excision or as revision of failed arthroplasty be carefully monitored for aseptic stem loosening.

Appendix 1. Search strategy.

The following electronic databases searches were performed:

1. Pubmed (22 April 2016)
2. Scopus (23 April 2016)
3. Cochrane library (24 April 2016)
4. Web of Science (24 April 2016)

Keywords used:
"reverse shoulder"
OR "reverse total shoulder"
OR "inverse shoulder"
OR "inverse total shoulder"
OR "Grammont prosthesis"

Results of search:
Pubmed: 1049
Scopus: 1149
Cochrane: 20
Web of Science: 595

Total: 2813 records

Appendix 2: Case series quality appraisal checklist(11)

Study objective:

1. Was the hypothesis/aim/objective clearly stated?

Study design

2. Was the study conducted prospectively?
3. Were the cases collected in more than one center?
4. Were patients recruited consecutively?

Study population

5. Were the characteristics of the patients included in the study described?
6. Were the inclusion and exclusion criteria for entry into the study clearly stated?
7. Did patients enter the study at a similar point in the disease? (same indication)

Intervention and co-intervention

8. Was the intervention of interest clearly described?
9. Were additional interventions (co-interventions) clearly described?

Outcome measures

10. Were relevant outcome measures clearly defined in introduction/methods?
11. Were the outcome assessors blinded to intervention received?
12. Were the relevant outcomes measured using appropriate objective and subjective methods?
13. Were the relevant outcomes measured before and after the intervention?

Statistical analysis

14. Were the statistical tests used to assess the relevant outcomes appropriate?

Results and conclusions

15. Was follow-up long enough for important events and outcomes to occur?
16. Were losses to follow-up reported?
17. Does the study provide estimates of the random variability in the data analysis of relevant outcomes?
18. Were the adverse events reported?
19. Were the conclusions supported by results?

Competing interests and sources of support

20. Were both competing interests and sources of support for the study reported?

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