The minimum follow-up required for radial head arthroplasty

A META-ANALYSIS

P. Laumonerie,
N. Reina,
P. Kerezoudis,
S. Declaux,
M. E. Tibbo,
N. Bonnevialle,
P. Mansat

From Hôpital Pierre-Paul Riquet, Toulouse, France

Aims

The primary aim of this study was to define the standard minimum follow-up required to produce a reliable estimate of the rate of re-operation after radial head arthroplasty (RHA). The secondary objective was to define the leading reasons for re-operation.

Materials and Methods

Four electronic databases, between January 2000 and March 2017 were searched. Articles reporting reasons for re-operation (Group I) and results (Group II) after RHA were included. In Group I, a meta-analysis was performed to obtain the standard minimum follow-up, the mean time to re-operation and the reason for failure. In Group II, the minimum follow-up for each study was compared with the standard minimum follow-up.

Results

A total of 40 studies were analysed: three were Group I and included 80 implants and 37 were Group II and included 1192 implants. In Group I, the mean time to re-operation was 1.37 years (0 to 11.25), the standard minimum follow-up was 3.25 years; painful loosening was the main indication for re-operation. In Group II, 33 Group II articles (89.2%) reported a minimum follow-up of < 3.25 years.

Conclusion

The literature does not provide a reliable estimate of the rate of re-operation after RHA. The reproducibility of results would be improved by using a minimum follow-up of three years combined with a consensus of the definition of the reasons for failure after RHA.

■ P. Laumonerie, MD, Orthopaedic Surgeon
■ N. Reina, MD, PhD, Orthopaedic Surgeon
■ S. Declaux, MD, Orthopaedic Surgeon
■ N. Bonnevialle, MD, PhD, Orthopaedic Surgeon
■ P. Mansat, MD, PhD, Orthopaedic Surgeon
Institut Locomoteur, Hôpital Pierre-Paul Riquet, Place du Dr Baylac, TSA 40 031, Toulouse 31059, France.

■ P. Kerezoudis, MD, Neurosurgeon
■ M. E. Tibbo, MD, Orthopaedic Surgeon
Mayo C inic, 1216 2nd Street SW, Rochester, Minnesota 55905, USA.

Correspondence should be sent to P. Laumonerie; email: laumonerie.pierre@hotmail.fr

One-third of fractures involving the elbow joint affect the radial head[1,2] and the treatment of Mason III fractures remains controversial.[3-10] Open reduction and internal fixation is the standard treatment for comminuted fractures of the proximal radius,[3-7] whilst arthroplasty or simple resection of the radial head are alternatives.[3,4,6,8-15] Resection of the radial head yields satisfactory long-term results.[12-17] The alteration of the kinematics of the elbow and forearm and self-perpetuating cycle of degenerative changes can result from other factors (increasing pression on the ulna for example) than progressive valgus instability, radial ascent and secondary ulnocarpal injury.[16-20] In the presence of associated ligamentous injury, radial head arthroplasty (RHA) can give better results.[9,18-24] Reconstruction of the lateral column through RHA permits the maintenance of the normal axis of the elbow and reduces the risk of degenerative arthritis in both the elbow and wrist joints.[10,25] RHA is therefore an alternative choice for the treatment of acute and chronic proximal radial fractures.[4-6,11,26] Heijink et al[27] in a systematic review, reported that the medium- and long-term functional results after RHA were good to excellent in 85% of patients using the Mayo Elbow performance score. Recently, variable complication rates have been reported, including rates of re-operation ranging from 0% to 29% after RHA.[27-30] However, the indications for further surgery have rarely been described.[27] Van Riet et al[30] stated that painful loosening was the main reason for failure of RHA. The low numbers in the studies, the lack of a standardised classification of the reason for failure and the plurality of methodologies used have prevented reproducible studies of RHA.

The primary objective of this study was to define the minimum follow-up required to analyse the complications of RHA. The hypothesis was that the minimum follow-up in the published series was inadequate. The secondary objective was to establish clear definitions for

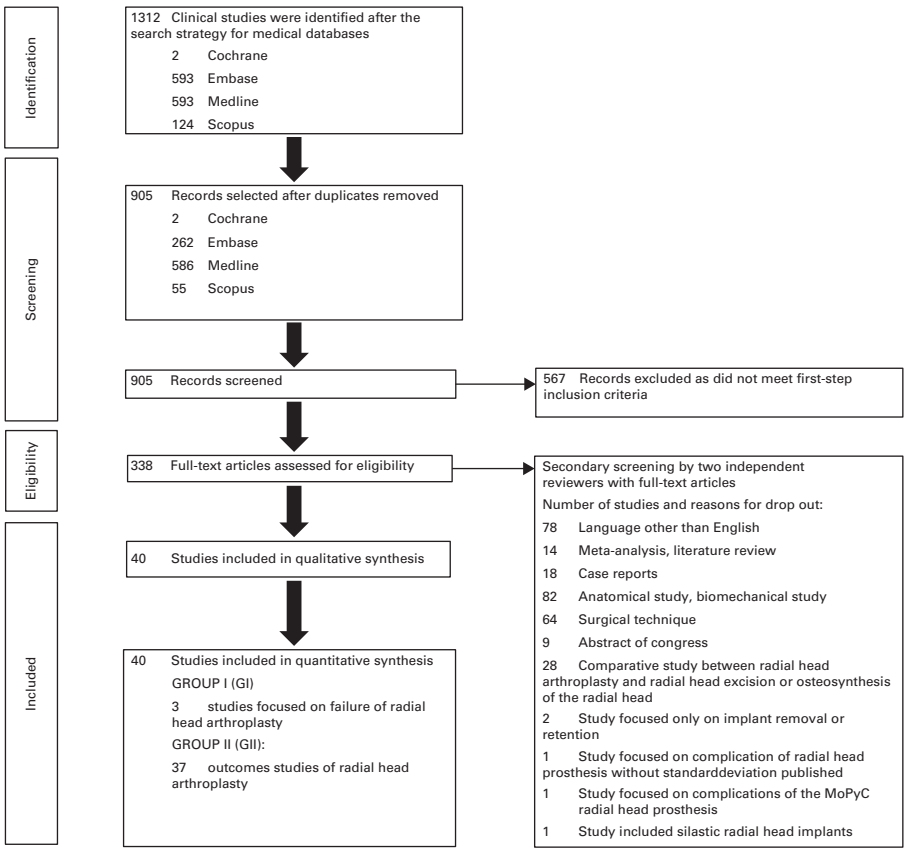

Fig. 1

Summary of search strategy (Preferred Reporting Items for Systematic Reviews and Meta-Analyses flowchart) for relevant studies on minimum follow-up of radial head arthroplasty and the indications for re-operation.

the reasons for failure of RHA with the hypothesis that painful loosening was the main reason for re-operation.

Materials and Methods

A literature search was performed using Ovid Medline, Ovid Embase, Scopus and Cochrane Library and the Medical Subject Headings vocabulary. The search was limited to English language literature. The following terms were combined with 'AND' and 'OR': 'radial head'; 'arthroplasty'; 'prosthesis'; 'radial head prosthesis'; and 'radial head arthroplasty'. The references in each study were reviewed to identify additional articles corresponding to the research criteria. Inclusion criteria involved studies that addressed failure of RHA and described the reasons for removal of the implant and those reporting the clinical and radiographical outcomes of RHA, published between January 2000 and March 2017.

Exclusion criteria were; biomechanical and anatomical studies, meta-analyses and systematic reviews, case reports, abstracts and studies comparing RHA and other forms of treatment. Studies which did not report the mean time between the initial surgery and re-intervention were excluded as were those that focused on implant-specific complications or those that included silastic radial head implants (Silastic Swanson Radial Head Implant; Dow Corning Corporation, Midland, Michigan). Data were extracted from manuscripts, tables and figures. Two investigators (PL, NR) independently reviewed the text of all eligible articles, disagreement being resolved with discussion and consensus. When information was incomplete, the corresponding authors of the articles were contacted.

Articles were divided into those related only to the reasons for removal of the implant (complete exchange, exchange of the acetabular component alone or conversion to a radio-capitellar prosthesis) and re-operation with retention of the implant (Group I). Gathering comprehensive data from each study for all patients in this group allowed for meta-analysis of the cohorts as a single group. These data were: age, gender, removal, re-operation with (or without) removal of the implant, failure, follow-up to re-operation and reasons for failure. Group II articles included those reporting the clinical and radiographic outcomes of RHA. A description of the results from Groups I and II comprised the total number of RHAs, re-operations with removal or retention of the implant. The design of the implant (bipolar or monopolar) and the timing of the re-operation (acute or delayed) were also reported for both groups. The double standard deviation of the mean time to

Table I. Patient characteristics of articles reporting re-operations for failed radial head arthroplasty (Group I)

	Duckworth et al[37]	Kachooei et al[38]	Laumonerie et al[39]	Overall
Country of principal institution	United Kingdom	United States	France	N/A
Date of inclusion	1994 to 2010	2000 to 2014	2002 to 2015	1994 to 2015
Year of publication	2014	2016	2016	N/A
Study design	Retrospective, single-centre	Retrospective, single-centre	Retrospective, single-centre	N/A
Patients (n)	29	22	29	80
Male (n)	12	11	22	45
Female (n)	17	11	7	35
Mean age (yrs, range)	44.4 (16 to 93)	49.6 (23 to 64)	50.4 (20 to 73)	48.1 (16 to 93)
Acute application (n)	29	22	18	69
Delayed application (n)	0	0	11	11
Associated lesions (n)				
Terrible triad	2	10	13	25
Essex-Lopresti	1	0	1	2
Monteggia or olecranon fractures	9	11	10	30
Ligamentous injury (medial or lateral collateral ligament)	5	13	11	29
None	11	4	10	25
Radial head implant (n)	29	22	29	80
Monopolar design	29	22	0	51
Bipolar design	0	0	29	29
Tight-fitting implant anchorage, overall	29	5	29	63
Tight-fitting implant anchorage, cemented	29	0	29	58
Tight-fitting implant anchorage, press-fit	0	5	0	5
Loose-fitting implant anchorage	0	17	0	17
Causes of re-operation with removal of the implant (n)	**26**	**18**	**18**	**62**
Painful loosening	5	3	13	21
Persistent stiffness	12	6	0	18
Humero-radial conflict	0	5	4	9
Isolated diffuse pain	6	0	0	6
Deep infection	1	2	0	3
Clinical instability	0	1	1	2
Synovitis	2	0	0	2
Painful heterotopic ossification (normal ROM)	0	1	0	1
Indication for re-operation with retention of the implant (n)	**5**	**4**	**11**	**20**
Clinical instability	0	1	6	7
Persistent stiffness	0	2	1	3
Subluxation of the radial head	3	0	0	3
Ulnar nerve palsy	2	0	3	5
Painful loosening	0	1	0	1
Humero-radial conflict	0	0	1	1

N/A, not applicable; ROM, range of movement

re-operation in Group I (2SDGI) was used as the reference minimum follow-up for the analysis of complications. Comparison of the 2SDGI with the minimum follow-up in each article in Group II was performed to test the primary hypothesis. The reasons for re-operation and the mean time to re-operation with removal or retention of the implant in Group I were analysed to validate the secondary hypothesis.

Statistical analysis. We used independent *t*-tests or Wilcoxon-Rank Sum tests and chi-squared or Fisher's Exact tests to compare continuous and categorical variables respectively, in correlation with the type of implant (bipolar or monopolar). We calculated the weighted proportions for the following pre-and post-operative variables: inclusion of acute injuries, percentage inclusion of delayed injuries, rates of removal, rates of revision and re-operation. In order to account for anticipated heterogeneity in the studies, we used a random effects DerSimonian-Laird model.[31,32] Heterogeneity was evaluated using Cochran Q and I^2 test. Confidence intervals (CI) were fixed at 95%. Publication bias regarding the rate of re-operation following RHA was assessed after constructing a funnel plot of the Logit of the rate of re-operation against its standard error. Asymmetry at the bottom of the plot, i.e. higher concentration of studies on one side of the mean rate of re-operation than on the other, is suggestive of publication bias.[33] Statistical significance was set at $p < 0.05$. For the purposes of the statistical analysis as well as the design of the figures, two commercially available softwares were used: JMP (JMP Version 11, SAS Institute Inc., Cary, North Carolina) and Comprehensive Meta-analysis (Biostat, Englewood, New Jersey).

Results

A total of 1312 studies were initially identified. After exclusion of duplicates and irrelevant articles, 339 eligible

Table II. Patient characteristics of articles reporting follow-up of radial head arthroplasty (Group II)

Authors	Year of publication	Type of study	Acute cases, n (%)	Delayed cases, n (%)	Re-operations, n (%)
Tarallo et al[43]	2017	Monopolar	31 (*100*)	0 (*0*)	0 (*0*)
Gauci et al[44]	2016	Bipolar	26 (*60.46*)	17 (*39.53*)	8 (*18.60*)
Moghaddam et al[45]	2016	Monopolar	75 (*100*)	0 (*0*)	5 (*6.67*)
Marsh et al[42]	2016	Monopolar	55 (*100*)	0 (*0*)	0 (*0*)
Levy et al[46]	2016	Monopolar	15 (*100*)	0 (*0*)	4 (*26.67*)
Kodde et al[47]	2016	Bipolar	5 (*18.52*)	22 (*81 48*)	8 (*29.63*)
Heijink et al[48]	2016	Bipolar	8 (*33.33*)	16 (*66.67*)	2 (*8.33*)
Abdulla et al[49]	2015	Bipolar	21 (*100*)	0 (*0*)	0 (*0*)
Laun et al[50]	2015	Bipolar	12 (*100*)	0 (*0*)	0 (*0*)
Mou et al[51]	2015	Monopolar	12 (*100*)	0 (*0*)	0 (*0*)
Allavena et al[52]	2014	Bipolar	16 (*72.72*)	6 (*27.27*)	10 (*45.00*)
Berschback et al[53]	2013	Bi-monopolar	27 (*100*)	0 (*0*)	2 (*7.40*)
El Sallakh[54]	2013	Monopolar	12 (*100*)	0 (*0*)	0 (*0*)
Sarris et al[55]	2013	Bipolar	30 (*93.75*)	2 (*6 25*)	2 (*6.25*)
Ricón et al[56]	2012	Bipolar	28 (*100*)	0 (*0*)	5 (*17.85*)
Zunkiewicz et al[57]	2012	Bipolar	23 (*76.67*)	7 (*23.30*)	2 (*6.67*)
Katthagen et al[58]	2012	Monopolar	16 (*51.51*)	15 (*48.39*)	6 (*19.35*)
Rotini et al[59]	2012	Bipolar	11 (*35.48*)	20 (*64.51*)	2 (*6.45*)
Ha et al[60]	2012	Bi-monopolar	243 (*94.18*)	15 (*5.81*)	62 (*24.02*)
Muhm et al[61]	2011	Monopolar	25 (100)	0 (*0*)	0 (*0*)
Maghen et al[62]	2011	Monopolar	21 (91.30)	2 (*8.87*)	6 (*26.09*)
Lamas et al[63]	2010	Bipolar	47 (100)	0 (*0*)	3 (*6.38*)
Celli et al[64]	2010	Bipolar	16 (100)	0 (*0*)	0 (*0*)
Burkhart et al[41]	2010	Bipolar	9 (52.94)	8 (*47.06*)	1 (*5.88*)
Fehringer et al[65]	2009	Monopolar	17 (100)	0 (*0*)	0 (*0*)
Shore et al[66]	2008	Monopolar	0 (0)	32 (*100*)	0 (*0*)
Lim and Chan[67]	2008	Bipolar	6 (100)	0 (*0*)	0 (*0*)
Doornberg et al[68]	2007	Monopolar	27 (100)	0 (*0*)	7 (*25.92*)
Popovic et al[40]	2007	Bipolar	51 (*100*)	0 (*0*)	1 (*1.96*)
Wretenberg et al[69]	2006	Monopolar	22 (*100*)	0 (*0*)	5 (*22.73*)
Dotzis et al[70]	2006	Bipolar	12 (*85.71*)	2 (*14.29*)	1 (*7.14*)
Chapman et al[71]	2006	Monopolar	8 (*50.00*)	8 (*50.00*)	0 (*0*)
Grewal et al[72]	2006	Monopolar	26 (*100*)	0 (*0*)	1 (*3.84*)
Brinkman et al[73]	2005	Bipolar	0 (*0*)	11 (*100*)	2 (*18.18*)
Harrington et al[74]	2001	Monopolar	20 (*100*)	0 (*0*)	4 (*20.00*)
Moro et al[10]	2001	Monopolar	25 (*100*)	0 (*0*)	0 (*0*)
Popovic et al[75]	2000	Bipolar	11 (*100*)	0 (*0*)	0 (*0*)

articles were identified. After detailed evaluation of the articles, 40 observational studies were included in the analysis and divided into two groups. Group I comprised three observational studies assessing failures of RHA requiring re-operation with removal or retention of the implant. Four single-centre retrospective studies dedicated exclusively to complications after RHA were excluded. Two of these did not include patients who underwent re-operation with retention of the implant.[30,34] One did not publish the standard deviation of their data[35] and one only discussed the complications associated with the MoPyC pyrocarbon radial head implant (Bioprofile-Tornier, Cedex, France).[36] Group II comprised of 37 observational studies reporting the clinical and radiographic outcomes of RHA (Fig. 1).

Group I included 80 patients (45 men and 35 women, mean age 48 years (18 to 73)) requiring re-operation; 63 implants were removed and 17 were retained. Two patients from Duckworth et al's[37] series required re-operation because of an ulnar nerve palsy and pain which were treated by revision of the implant and ulnar neurolysis (Table I).[37-39]

Group II included 1174 patients (635 men and 539 women) with a mean age of 48.72 years (26 to 61). Out of 1192 implants, 696 were monopolar and 496 were bipolar. A total of 1009 RHAs were performed for acute injuries (90% (0% to 100%)) and 183 for chronic lesions or post-traumatic sequelae (10% (0% to 100%)) (Table II).[10,40-75] The mean rate of re-operation was 9.7% (0% to 45%) (Fig. 2); the mean rates of removal and retention of the implant were 3.8% (0% to 22.7%) and 6.13% (0% to 27.3%), respectively. The rates of acute injury ranged from 0% to 100% (pooled proportion (PP) 0.90, 95% CI 0.78 to 0.93, I^2 = 54.80%). The rates of chronic injury ranged from 0% to 100% (PP 0.10, 95% CI 0.07 to 0.21, I^2 = 54.8%). The rates of re-operation ranged from 0% to 45% (PP 0.10, 95% CI 0.09 to 0.16, I^2 = 9.46%). The rates of removal of the implant ranged from 0% to 27.3% (PP 0.04, 95% CI 0.05 to 0.10; I^2 = 54.5%) and the rates of retention of the

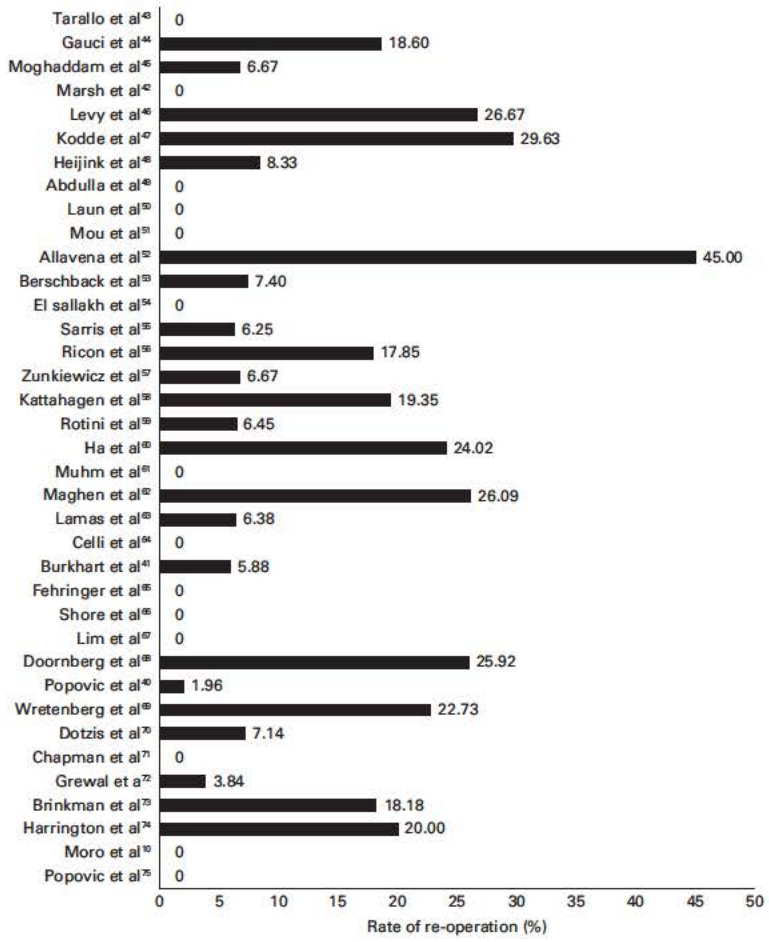

Fig. 2

Rate of re-operation in 37 articles (Group II) describing the outcomes of radial head arthroplasty published between January 2000 and March 2017.

implant ranged from 0% to 22.7% (PP 0.06, 95% CI 0.06 to 0.11, I^2 = 51.1%) respectively. Based on the I^2 value there was moderate heterogeneity between the included studies.

The mean time to re-operation for the patients in Group I was 1.37 years (0 to 11.2). The reference minimum follow-up (2SDGI) in these studies was 3.25 years. The mean time to removal was significantly greater than the mean time to re-operation with retention of the implant: 1.7 years (0 to 11.2) *versus* 0.3 years (0.02 to 1.08), respectively (95% CI 0.84 to 1.79, p = 0.001).

A total of 33 Group II articles (89.2%) included patients with < 3.25 years of minimum follow-up (Fig. 3). The mean minimum follow-up was 1.74 years (0.08 to 6.5). The minimum follow-up for each Group II article is shown in Figure 3. The mean follow-up for Group II articles was 3.9 years (1.0 to 12.1).

The three main reasons for re-operation in Group I articles were painful loosening (22), persistent stiffness (21) and humero-radial conflict (ten). The primary reasons for removal and revision were painful loosening (21) and instability (seven) (Table I; Fig. 4). Diagnostic criteria for the four most common complications are shown in Table III and form the basis of a new classification.

Publication bias. The funnel plot is shown in Figure 5. There was significant asymmetry at the bottom right side of the plot, meaning a lack of smaller studies with higher rates of re-operation, suggesting potential publication bias.

Discussion

Following our review of the literature from the 01 January 2000, we found that the outcomes of RHA have generally been reported with a minimum follow-up of < 3.25 months (89.2% of patients in 33 of 37 studies). In order to obtain reproducible results it is important to have a minimum follow-up period and to establish clear definitions of the reasons for failure of RHA.[76] According to the Meta-analysis of the Observational Studies in Epidemiology group, six key points define the methodological qualities of observational studies: 1) clear definition of outcomes; 2) clear definition of the assessment of outcome; 3) an independent assessment of the parameters of outcome; 4) sufficient follow-up; 5) no selective loss during follow-up; and

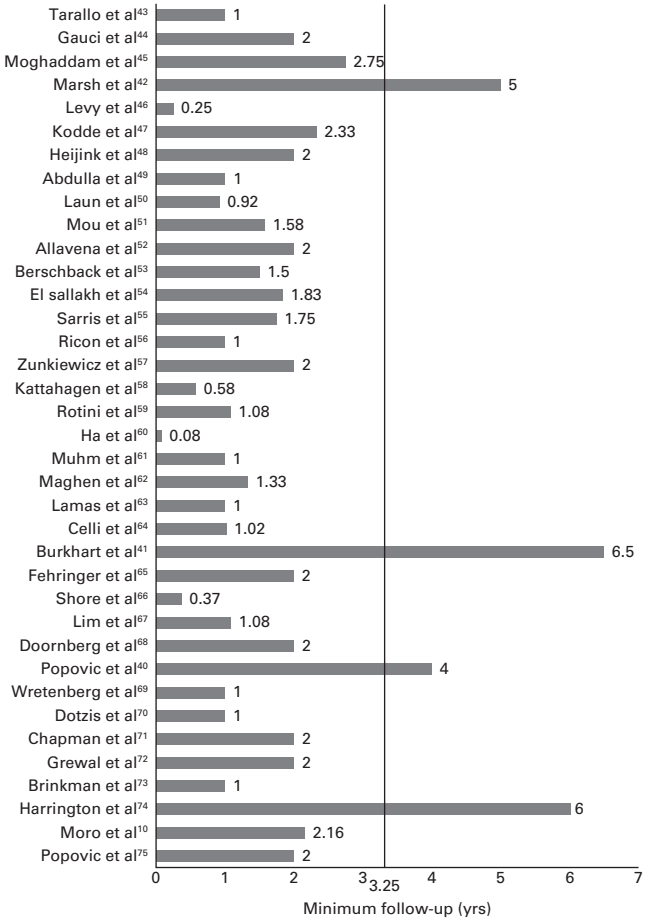

Fig. 3

Minimum follow-up in 37 articles (Group II) describing the outcomes of radial head arthroplasty published between January 2000 and November 2016.

6) the identification of important confounders and prognostic factors.[76]

The current literature underestimates the rate of failure of RHA and smaller studies with higher rates of re-operation are less likely to be published. The heterogeneity of mean and minimum follow-up times in the studies could compromise the reproducibility of the outcomes. We therefore propose a minimum follow-up of 39 months following RHA. Of the four studies with a minimum follow-up of > 39 months,[40-42,74] one reported the reasons for failure of RHA (two minor and one major capitellar wear) beyond the minimum follow-up time.[39] Neuhaus et al[34] in a case series of 14 patients reported that 50% of those that required removal of the implant occurred during the first post-operative year with a mean time of 1.92 years (0.04 to 12). The mean time to re-operation with retention of the implant in our review was 0.28 years (0.02 to 1.08), which was consistent with the literature.[26,27] The time to re-operation with retention of the implant was significantly lower than the time to removal of the implant. The distribution of the reasons for failure was also skewed when patients with too short of a follow-up were included.

Based on the 80 patients in Group I who underwent re-operation, we have devised a new classification system which includes four main modes of failure of an RHA: painful loosening; stiffness; humero-radial conflict and instability. The other reasons for failure were isolated or diffuse pain in the elbow, deep infection, subluxation, synovitis and painful heterotopic ossification with a normal range of movement. We suggest that this new classification will be reproducible.

We were able to confirm that painful loosening is the main indication for re-operation after RHA[29,30,77] which is in agreement with the findings of van Riet et al,[30] although Neuhaus et al[34] were unable to find a significant link between radiographic loosening and persistent pain. We found that the definition of painful loosening described by O'Driscoll and Herald[77] was clear and reproducible. According to biomechanical studies,[78,79] there is an increased risk of painful loosening when using narrow or short stems. The method of anchorage (tight or loose fit, etc.) is also a risk factor. The increased rate of loosening in short-stemmed designs in Group I constituted a confounding bias for the analysis of painful loosening.[39] Laumonerie et al[39]

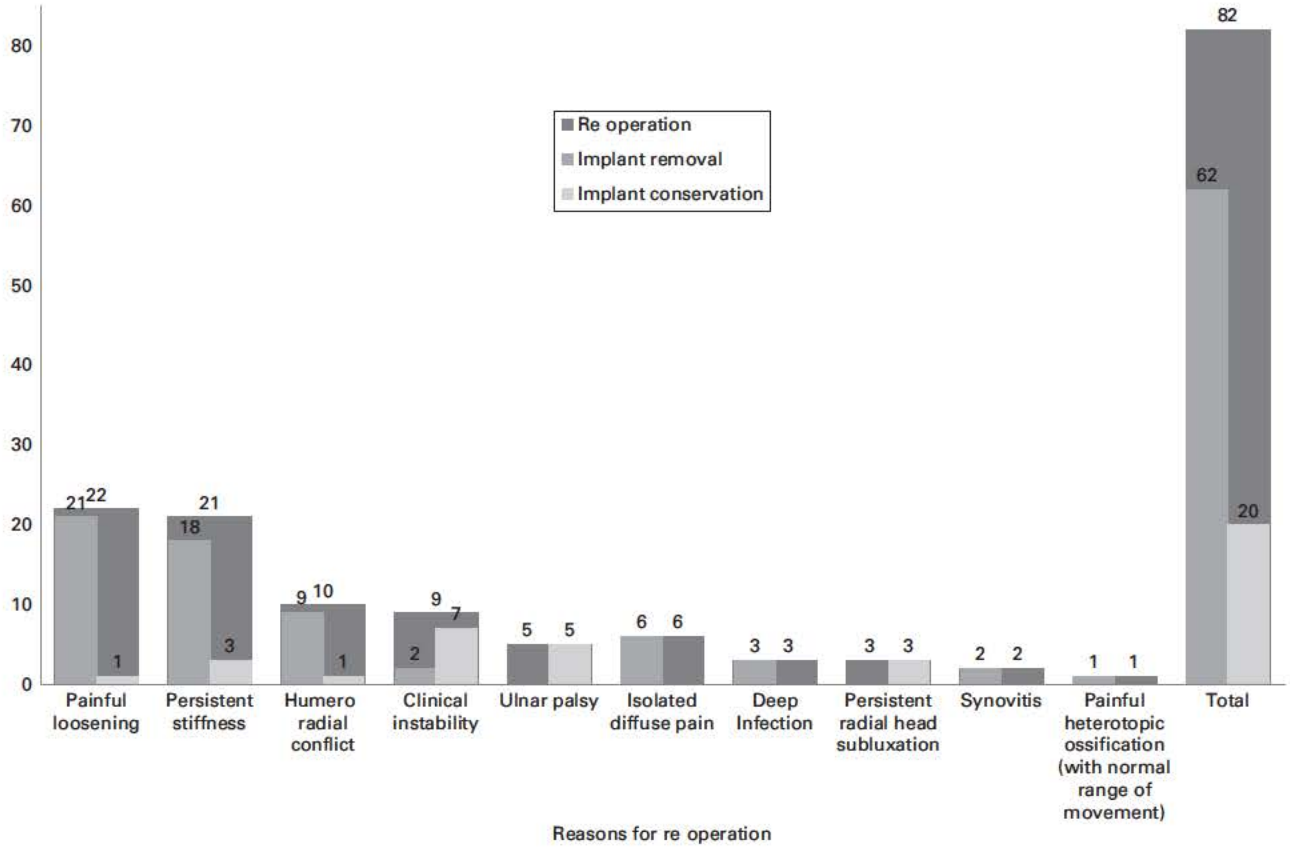

Fig. 4

Indications for re-operation with removal or retention of the implant (Group I).

Table III. Revised nomenclature for failure of radial head implants

	Cause	Rate of re-operation (%)	Definition
I	Painful loosening	*27.5*	New type of pain characterised by insidious pain in the proximal radial aspect of the forearm, exacerbated by loading the radiocapitellar joint and relieved by rest; radiographic signs of loosening are not needed
II	Persistent stiffness	*26.25*	Active and passive range of movement limited after radial head arthroplasty
III	Humero-radial conflict	*12.5*	Persistent pain in the proximal radial aspect of the forearm associated with capitellar osteopenia, capitellar erosion or prosthesis overstuffing
IV	Persistent clinical instability	*11.25*	Clinical instability confirmed by the posterolateral rotatory apprehension test

speculated that difficulties in obtaining satisfactory stability when using short stemmed bipolar implants (rHead RECON prosthesis; Stryker-Small Bone Innovation, Morrisville, Pennsylvania) may predispose the surgeon to favour stability over the positioning of the implant.

In our review, instability was the main reason for re-operation with retention of the implant. Biomechanical studies have shown a significantly higher rate of instability in bipolar implants, which has been confirmed in clinical studies although without statistical evidence.[80-82] Moon et al[82] argued that the superior radiocapitellar stability of monopolar devices can be explained by the increased concave compression of the implants.

The implants of choice in patients with an associated ligamentous injury were monopolar,[81-83] although bipolar implants in patients in Group I studies did not depend on soft-tissue integrity.[39] This was an inherent limitation, as a bipolar implant is only used when there is malalignment of the proximal radius with respect to the capitellum. We found a statistically higher rate of re-operation for stiffness among monopolar implants. The causes of stiffness are multifactorial and constitute another confounding bias which was not accounted for in our study. Post-operative stiffness can be affected by the severity of the initial injury, heterotopic ossification, complex regional pain, degenerative changes and/or malpositioning of the implant.[34,38,84-86] However, no

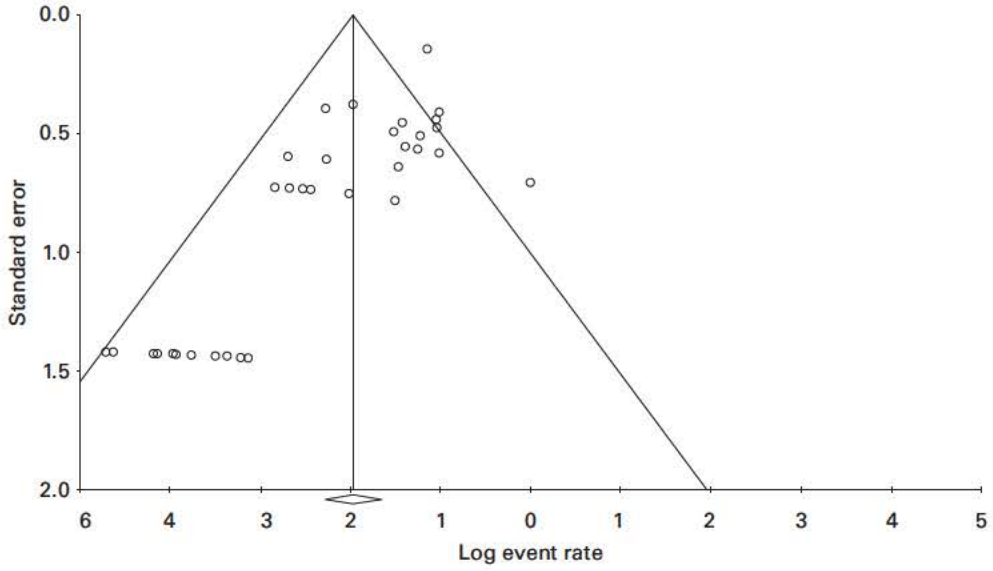

Fig. 5

Funnel plot of the included studies revealing asymmetry at the bottom. Smaller studies with higher rates of re-operation are less likely to be published. The Logit event rate for re-operation (x-axis) is presented against the standard error (y-axis). The standard error inversely corresponds to the sample size of the study.

significant differences in range of movement due to the design of the implant have been reported.[27]

The limitations associated with retrospective single-centre studies are a potential lack of heterogeneity in the sample, loss of data about follow-up and confounding bias. The 80 patients with failure of an RHA in Group I were from three single-centre retrospective studies which could lead to bias in the distribution of complications.[37-39] The selection of 2SDGI as the reference minimum follow-up was made due to the lack of any recommendations for follow-up and the need to reduce the risk of a beta type error for the primary hypothesis. This error would lead to confirming the null hypothesis when it was in fact false, while also rejecting the possibility of a significant complication due to a lack of follow-up. The classification of complications into four main reasons for failure constitutes a bias inherent in research performed using *a posteriori* consensus between two reviewers.

Our proposed standard minimum follow-up was not calculated for the functional outcomes of RHA. Giannicola et al[87] found that functional improvement after RHA progresses in the first post-operative year and then plateaus. Also the lack of data did not permit adjustment of the analysis according to the injuries which may be associated with fractures of the radial head. Clearly a meta-analysis focusing on the risk factors associated with failure of RHA needs to be performed to improve the understanding of the modes of failure.[88-90]

In conclusion, the minimum follow-up of patients who undergo an RHA in the literature is insufficient and we suggest that the rate of re-operation after RHA has been underestimated. The different methodologies used in each study do not allow for an adequate analysis of the results. We would advocate a minimum follow-up of three years to fully evaluate the complications after RHA. We also propose a new classification of the four main reasons for failure of an RHA, of which painful loosening has been shown to be the primary cause.

Take home message:

- The current literature underestimates the failure rate of radial head arthroplasty.
- A minimum follow-up of three years is required to evaluate the complications after RHA.
- There is a new definition for the four main reasons for failure of RHA.

Author contributions:

P. Laumonerie: Conception and design, Data acquisition, Analysis and interpretation, Critical revisions, Manuscript review, Statistical analysis, Study supervision.

N. Reina: Conception and design, Data acquisition, Analysis and interpretation, Critical revisions, Manuscript review.

P. Kerezoudis: Data analysis and interpretation, Critical revisions, Manuscript review, Statistical analysis.

S. Declaux: Data analysis and interpretation, Critical revisions, Manuscript review.

M. E. Tibbo: Data analysis and interpretation, Critical revisions, Manuscript review.

N. Bonnevialle: Data analysis and interpretation, Critical revisions, Manuscript review.

P. Mansat: Conception and design, Data analysis and interpretation, Critical revisions, Manuscript review, Approved final version of paper, Administration, technical and material support, Study supervision.

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