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Why does radial head arthroplasty fail today? A systematic review of recent literature

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- Since the introduction of the radial head prosthesis (RHP) in 1941, many designs have been introduced. It is not clear whether prosthesis design parameters are related to early failure. The aim of this systematic review is to report on failure modes and to explore the association between implant design and early failure.
- A search was conducted to identify studies reporting on failed primary RHP. The results are clustered per type of RHP based on: material, fixation technique, modularity, and polarity. Chi-square tests are used to compare reasons for failure between the groups.
- Thirty-four articles are included involving 152 failed radial head arthroplasties (RHAs) in 152 patients. Eighteen different types of RHPs have been used.
- The most frequent reasons for revision surgery after RHA are (aseptic) loosening (30%), elbow stiffness (20%) and/or persisting pain (17%). Failure occurs after an average of 34 months (range, 0–348 months; median, 14 months).
- Press-fit prostheses fail at a higher ratio because of symptomatic loosening than intentionally loose-fit prostheses and prostheses that are fixed with an expandable stem ($p < 0.01$).
- Because of the many different types of RHP used to date and the limited numbers and evidence on early failure of RHA, the current data provide no evidence for a specific RHP design.

Keywords: elbow; failure; radial head prosthesis; removal; replacement; revision

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Introduction

Since the introduction of the radial head prosthesis (RHP) in 1941,[1] many alterations in designs and materials have been proposed and tried that have varied in terms of material, fixation technique, modularity, and polarity. Radial head arthroplasty (RHA) is predominantly used to treat comminuted radial head fractures and other, less common, chronic posttraumatic sequels as nonunion, posttraumatic arthritis and elbow instability.[2,3]

During the past 75 years, moderate to good results have been reported for both primary[4,5] and revision surgery of RHA.[6] Implant revision and removal rates up to 8% at four years have been described.[4] More recent studies showed conflicting 10-year survival numbers ranging from 61% to 97%.[5,7]

This raises questions of whether implant- or fixation-related factors may be related to early failure. Except in the case of silicone RHPs, that have previously proved to be biologically and biomechanically insufficient, with a substantial risk of fragmentation of the implant[8–10] resulting in silicone synovitis, it is unclear which type of metallic RHP is superior. Taking the enormous discrepancies in failure rates into account, the aim of the current study was to report on failure modes of RHPs in recent years and to explore the association between implant design and early failure.

Materials and methods

Search strategy

This systematic review was based on Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[11,12] A comprehensive literature search was conducted with the assistance of a clinical librarian using

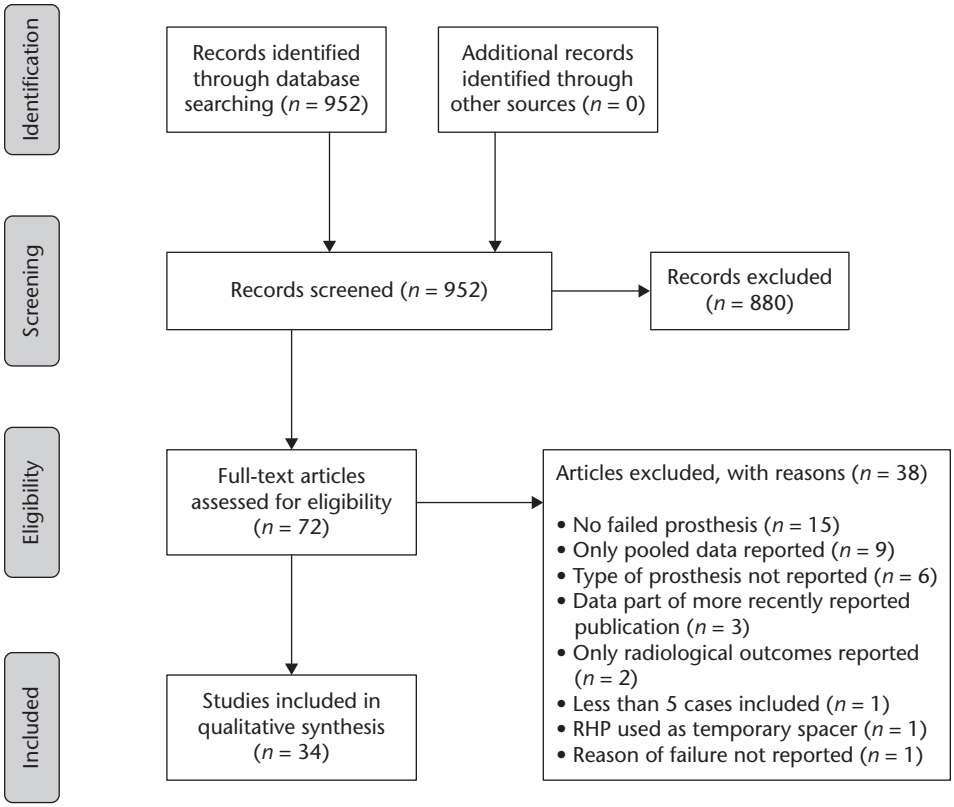

Fig. 1 Flowchart.
Note. RHP, radial head prosthesis.

the following terms: radius[MeSH], radius fractures[MeSH], arthroplasty, replacement[MeSH], joint prosthesis[MeSH], radial head[tiab], replacement[tiab], arthroplasty[tiab], prosthesis implantation[tiab], and prosthesis[tiab]. The PubMed/MEDLINE and Embase databases were searched using the filters "English" and "humans" for the period from January 1941 to the date of search (10 September 2018). The start date was chosen as the first documentation of a radial head replacement by Speed dating back to 1941.[1]

Inclusion and exclusion criteria

This review was intended to include patients with a minimum age of 18 years who underwent revision surgery of their metallic of pyrocarbon RHA for any reason. Articles written in English and evaluating original clinical data on primary pyrocarbon or metallic RHPs requiring revision surgery were considered, regardless of the level of evidence. Only articles including at least five cases with a minimum of follow-up of two years were considered. No minimum of failed RHPs per article was set.

A study was excluded if the type of prosthesis and/or the mode of failure was not reported and was not provided by the author on request. Moreover, silicone RHPs were excluded, since these prostheses have been shown to be inferior and presumably would not be implanted nowadays.[8]

Study selection

Three authors independently assessed all titles and abstracts and identified eligible articles (IFK, JV and AH). Two authors (IFK and JV) assessed the full text of all eligible studies and made the final decision regarding inclusion. Disagreements were settled by discussion. With the use of this strategy, 952 articles were identified. After the screening of the title, abstract, methodology and results, 72 articles were found to be potentially eligible for inclusion. The full text of these studies was analysed, and the reference lists of all eligible publications were manually checked for additional studies potentially meeting the inclusion criteria. After application of the inclusion and exclusion criteria, 34 studies were finally included. The additional 38 articles were excluded for various reasons (Fig. 1).

Outcome parameters

The primary outcome of the current study is the failure mode of the RHP as defined in the included articles. Secondary outcome measures are [1] the time between primary surgery and failure (i.e. time to failure) and [2] the type of

revision surgery (i.e. removal of the prosthesis, replacement with another RHP or revision surgery to a total elbow arthroplasty (TEA) or radiocapitellar prosthesis).

Data analysis

To summarize the data, descriptive statistics were used. Only 18 of the 34 included studies reported data on individual patients. The other 16 studies reported only pooled data on age at time of primary surgery. As a consequence, analyses covering all 34 studies had to be performed on the aggregated study level, with the data on the individual patients pooled per study. In 14 articles (67 patients), no data are available on the time to failure. In the remaining patients (n = 85), the Kruskal–Wallis test is used to compare time to failure per type of fixation. To compare the reason of failure related to polarity, Fisher's exact test is used. In addition, for comparison of the failure mode related to the type of fixation, Chi-square tests are used, followed by a post hoc analysis.

Results

Thirty-four articles involving a total of 152 failed RHAs in 152 individual patients were included. The number of failed RHAs per study ranged from 1 to 22. All studies were case series (level-IV therapeutic studies). The oldest article was published in 1993, and the most recent article was published in 2018.

Population characteristics

Mean age at time of primary surgery was 50 years (SD = 10). The studies included 18 different types of RHPs. Most frequent used prostheses, representing 53% of all prostheses, included the Evolve Modular Radial Head (Wright Medical Group, Arlington, Tennessee) (n = 45, 30%), the MoPyC radial head (Tornier, Montbonnot, France) (n = 23, 15%) and the Guepar (De Puy Synthes, Johnson & Johnson, West Chester, Pennsylvania) (n = 15, 10%). Most prostheses were either intentionally loose-fit (n = 53, 35%) or press-fit (n = 47, 31%). A smaller proportion was placed with use of cement (n = 29, 19%) or had an expandable stem (n = 23, 15%). Regarding implant material, 127 implants (84%) were made of non-specified metal (including titanium and cobalt chromium), 23 (15%) were made of pyrocarbon and 2 (1%) were made of Vitallium. Regarding polarity, 106 prostheses (70%) were monopolar and 46 (30%) were bipolar (Table 1).

Primary outcome – failure mode

The most prevalent failure mode was symptomatic aseptic loosening, occurring in 46 (30% of all failures) patients (Fig. 2). Of these 46 prostheses, 25 were placed press-fit, in 11 cement was used, six were intentionally loose-fit, and four had an expandable stem. Post hoc analyses revealed that symptomatic aseptic loosening was significantly more frequently the reason for revision in press-fit prostheses (25/47 press-fit prostheses) compared to intentionally loose-fit prostheses (11/29 intentionally loose-fit prostheses) and prostheses with an expandable stem (4/23 prostheses with an expandable stem) ($p < 0.01$) (Fig. 2).

A second failure mode was elbow stiffness (n = 30, 20% of all failures). Intentionally loose-fit prostheses were more frequently revised for elbow stiffness than press-fit prostheses (20/53 loose-fit prostheses versus 3/47 press-fit prostheses, $p < 0.01$) (Fig. 2). Among the 20 intentionally loose-fit prostheses, monoblock designs failed more often than modular designs (6/6 intentionally loose-fit monoblock prostheses versus 14/47 intentionally loose-fit modular prostheses, $p < 0.01$).

Other modes of failure were persistent pain (n = 26, 17% of all failures), overstuffing (n = 13, 9% of all failures) and dissociation of the prosthesis (n = 8, 5% of all failures). Of the eight dissociated prostheses, five were bipolar and three were monopolar (Fig. 3). Ulnohumeral arthritis was the reason for revision in six cases. Cemented prostheses (5/29 cemented prostheses) were more often revised for ulnohumeral arthritis than press-fit (0/47 press-fit prostheses) and intentionally loose-fit prostheses (5/29 versus 0/47 versus 0/53 versus, $p < 0.01$) (Fig. 2). All failures due to instability involved bipolar prostheses ($p < 0.01$) (Fig. 3). In one case with instability, only the head of the prosthesis was revised because of under sizing.

Secondary outcomes

Time to failure

Time to failure was reported in 85 patients and ranged from 0–348 months (mean 34 months; median 14 months) (Table 1). Mean time to failure was 53 months for press-fit prostheses (n = 29), 36 months for prostheses with an expandable stem (n = 14), 27 months for cemented prostheses (n = 16), and 17 months for intentionally loose-fit prostheses (n = 26). Intentionally loose-fit prostheses failed earlier compared to press-fit prostheses ($p < 0.01$).

Type of revision surgery

Sixty-nine per cent (n = 105) of the revision surgeries involved removal of the prosthesis. In another 25% (n = 38) the prosthesis was removed and a new RHP was implanted. In addition, five RHPs were revised to TEAs (3%) and four RHPs were revised to radiocapitellar prostheses (3%) (Table 1). In only two out of five revisions to a TEA the indication for revision was ulnohumeral arthritis.

Table 1. Included studies.

Study number	First author	Year	Study design	Failed prosthesis (*n*)	Type of prosthesis	Material	Polarity	Modularity	Fixation	Removals (*n*)	Replacement by RHP (*n*)	Revision to TEA or RC (*n*)	Mean follow-up (mo)
1	Ricón[13]	2018	Case series	3	MoPyC (Tornier)	PC	Mono	Modular	Expansion stem	3	0	0	72
2	Kachooei[14]	2018	Case series	3	Mixed	CC	Bi	Modular	Mixed	0	0	3 to RC	28
3	Sershon[7]	2018	Case series	1	Katalyst (Integra)	CC	Bi	Modular	Int. Loose	0	1	0	1
4	Viveen[6]	2017	Case series	8	Mixed	Mixed	Mixed	Mixed	Mixed	0	8	0	19
5	Strelzow[15]	2017	Case series	2	Evolve (Wright)	CC	Mono	Modular	Int. Loose	0	2	0	NA
6	Hackl[16]	2017	Case series	5	MoPyC (Tornier)	PC	Mono	Modular	Expansion stem	0	4	1 to TEA	25
7	Laumonerie[5]	2017	Case series	19	Mixed	CC	Mixed	Modular	Mixed	19	0	0	NA
8	Laflamme[17]	2017	Case series	1	ExploR (Biomet)	CC	Bi	Modular	Press-fit	0	1	0	6
9	Kachooei[18]	2016	Case series	22	Mixed	CC	Mono	Modular	Mixed	19	3	0	22
10	Van Hoecke[19]	2016	Case series	2	Judet CRF II (Tornier)	CC	Bi	Modular	Cemented	1	0	1 to TEA	94
11	López[20]	2016	Case series	4	MoPyC (Tornier)	PC	Mono	Modular	Expansion stem	1	3	0	NA
12	Heijink[21]	2016	Case series	1	RHS (Tornier)	Metal	Bi	Modular	Cemented	1	0	0	24
13	Kodde[22]	2016	Case series	3	RHS (Tornier)	Metal	Bi	Modular	Press-fit	0	2	1 to RC	62
14	Moghaddam[23]	2016	Case series	7	Evolve (Wright)	CC	Mono	Modular	Int. Loose	4	3	0	NA
15	Levy[24]	2016	Case series	2	Acumed	CC	Mono	Modular	Press-fit	0	2	0	12
16	Yan[25]	2015	Case series	1	Radius Head Comp. (Link)	CC	Mono	Monoblock	Int. Loose	0	1	0	NA
17	Neuhaus[26]	2015	Case series	13	Mixed	CC	Mixed	Mixed	Mixed	13	0	0	12
18	Schnetzke[27]	2014	Case series	6	Evolve (Wright)	CC	Mono	Modular	Int. Loose	4	2	0	NA
19	Allavena[28]	2014	Case series	5	Guepar (DePuy)	CC	Bi	Modular	Cemented	4	1	0	28
20	Watters[29]	2014	Case series	3	Evolve (Wright)	CC	Mono	Modular	Int. Loose	0	0	3 to TEA	NA
21	Katthagen[30]	2013	Case series	1	Corin Radial Head (Corin)	CC	Mono	Monoblock	Press-fit	1	0	0	NA
22	Sarris[31]	2012	Case series	2	MoPyC (Tornier)	PC	Mono	Modular	Expansion stem	2	0	0	1
23	Flinkkilä[32]	2012	Case series	9	Mixed	CC	Mono	Modular	Press-fit	9	0	0	NA
24	Rotini[33]	2012	Case series	2	rHead (Sbi)	CC	Mixed	Modular	Press-fit	2	0	0	18
25	Zunkiewicz[34]	2012	Case series	1	Katalyst (Integra)	CC	Bi	Modular	Int. Loose	0	1	0	NA
26	Ricón[35]	2012	Case series	3	MoPyC (Tornier)	PC	Mono	Modular	Expansion stem	3	0	0	38
27	Lamas[36]	2011	Case series	5	MoPyC (Tornier)	PC	Mono	Modular	Expansion stem	5	0	0	NA
28	Burkhart[37]	2010	Case series	2	Judet CRF II (Tornier)	CC	Bi	Modular	Cemented	0	2	0	0
29	Doornberg[38]	2007	Case series	2	Evolve (Wright)	CC	Mono	Modular	Int. Loose	2	0	0	NA
30	Wretenberg[39]	2006	Case series	5	Radius Head Comp. (Link)	CC	Mono	Monoblock	Int. Loose	5	0	0	NA
31	Brinkman[40]	2005	Case series	2	Judet CRF II (Tornier)	CC	Bi	Modular	Cemented	0	2	0	9
32	Harrington[41]	2001	Case series	4	Richards (Smith & Nephew)	Titanium	Mono	Monoblock	Press-fit	4	0	0	237
33	Smets[42]	2000	Case series	1	Predecessor of Judet CRF II (Tornier)	CC	Bi	Modular	Cemented	1	0	0	8
34	Knight[43]	1993	Case series	2	Osteonics radial head prosthesis (Stryker Howmedica)	Vitallium	Mono	Monoblock	Press-fit	2	0	0	NA
			Total	**152**						**105**	**38**	**9**	**36**

Note. NA, Not applicable; RHP, radial head prosthesis; TEA, total elbow arthroplasty; RC, radiocapitellar prosthesis; CC, cobalt-chromium; PC, pyrocarbon; Mono, monopolar; Bi, bipolar; Int. Loose, intentionally loose-fit.

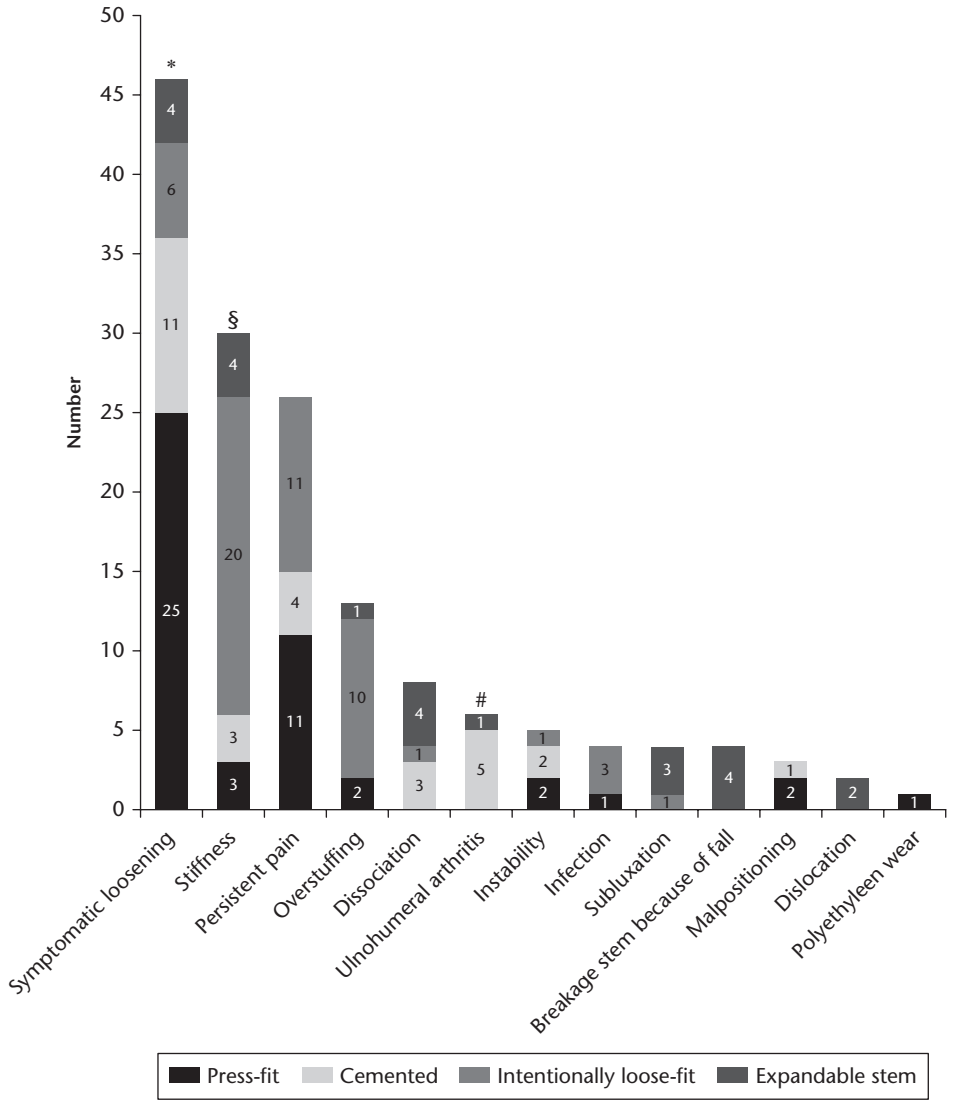

Fig. 2 Failure modes divided per type of fixation.

*Press-fit prostheses fail more often because of symptomatic loosening compared to intentionally loose-fit prostheses and prostheses with an expandable stem ($p < 0.01$).
§Intentionally loose-fit prostheses fail more often because of stiffness compared to press-fit protheses ($p < 0.01$).
#Cemented prostheses fail more often because of ulnohumeral arthritis compared to press-fit prostheses and intentionally loose-fit prostheses ($p < 0.01$).

Discussion

This systematic review shows that the most frequent failure modes of RHAs are symptomatic aseptic loosening (30%), stiffness (20%) and persistent pain (17%) at an average time to failure of 34 months. Post hoc analyses revealed that press-fit RHPs failed more often because of symptomatic aseptic loosening (25/47 prostheses) compared to intentionally loose-fit prostheses (5/43 prostheses) and prostheses with an expandable stem (4/23 prostheses). In addition, intentionally loose-fit prostheses failed earlier compared to press-fit prostheses (17 versus 53 months, respectively).

Aseptic loosening is a frequently encountered problem. Radiolucencies around the prosthesis are frequently reported and seem to occur mostly shortly after implantation. Whether these radiolucencies also mean that a prosthesis is loose, is not always not clear. Subcollar resorption is often reported with press-fit prostheses, but seems to be stationary after one to two years, without progression to loosening and without clinical symptoms.[22] In cases of progressive radiographic signs of loosening, a poor clinical outcome could be expected. In those cases, an additional computed tomography scan (CT scan) with or without a bone scan could be performed to investigate whether loose bodies are present and to assess the chondral condition of

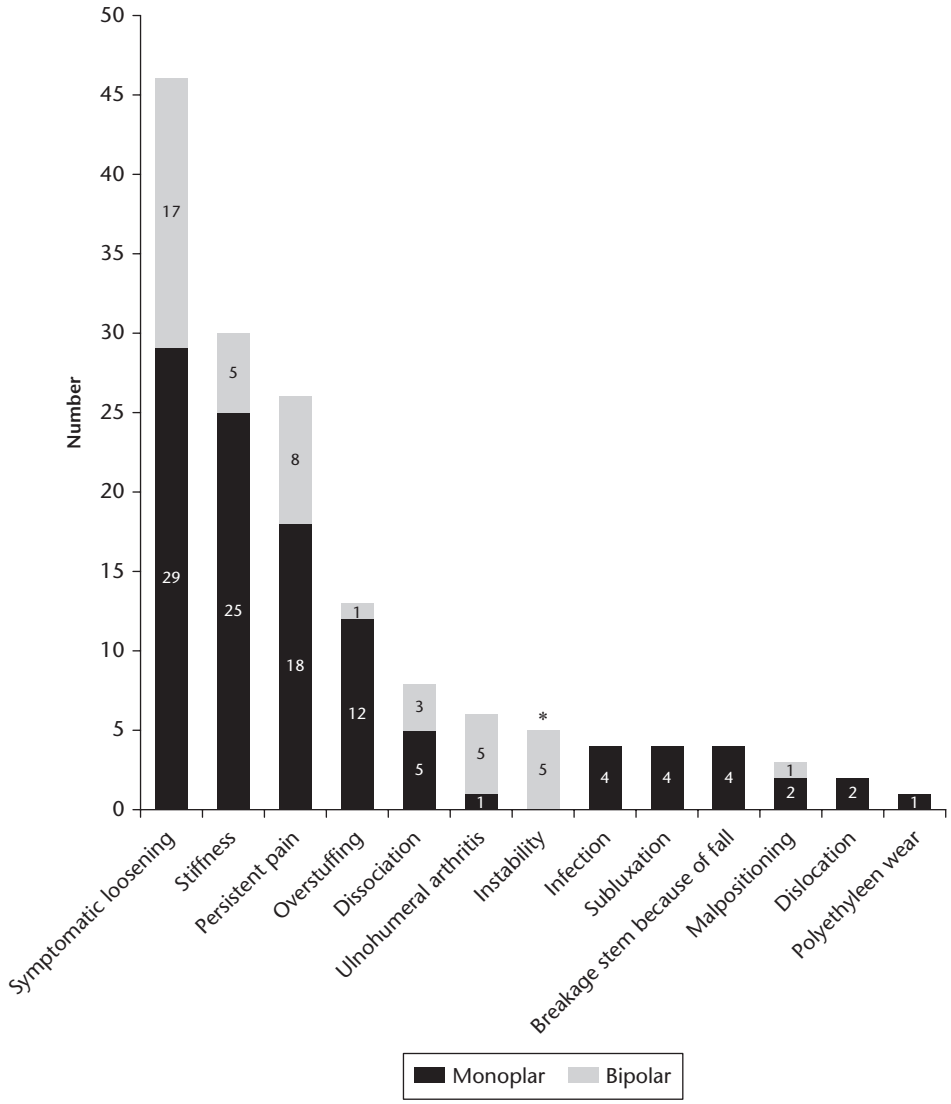

Fig. 3 Failure modes divided into monopolar and bipolar.

*Bipolar prostheses fail more often because of instability compared to monopolar prostheses ($p < 0.01$).

the capitellum and the ulnohumeral joint, in order to plan the appropriate treatment. Our analysis showed that 27% of the monopolar implants and 37% of the bipolar implants failed because of symptomatic aseptic loosening ($p = 0.3$). In contrast, van Riet et al. had observed more loosening with monopolar compared to bipolar prostheses.[44] It has been hypothesized that poor bone ingrowth onto the stem of the press-fit prosthesis due to micromotion of the prosthesis within the medullary canal is one of the causes of aseptic loosening in monopolar implants.[32,45] Possibly the bipolar design results in reduced stress and micromotion at the implant–bone interface.[32,45]

Obviously, most indications for revision of RHA are associated with pain in the elbow or forearm. Pain is the symptom, not the cause and pain can have many reasons other than a failed prosthesis. Interestingly, 26 patients (17% of all failures) underwent revision surgery solely for persisting pain. The question is what the underlying pathology (i.e. true failure mode) in these cases had been. O'Driscoll and Herald suggested that pain in the proximal forearm in patients with a press-fit RHP is a strong indicator for symptomatic loosening, even in the absence of radiographic signs of loosening.[46] In the analysis 11/26 revisions for pain involved press-fit prostheses. This could imply that the prostheses could have been loose in this group. However, the remaining 15/26 prostheses were cemented in place or intentionally loose-fit. Further studies on this phenomenon are needed.

Moreover, this study revealed that intentionally loose-fit protheses failed earlier compared to press-fit protheses

(a mean time to failure of 17 versus 53 months, respectively). A possible explanation for this from our data could be that intentionally loose-fit protheses failed more often because of stiffness compared to press-fit protheses. In general, stiffness is a problem encountered early on after elbow trauma and/or surgery[47-49] and could have different underlying problems in the case of RHAs: over sizing of the head, stiffness because of the (surgically) injured soft tissues around the elbow joint or a loose stem followed by migration of the implant. A clear explanation in the cases of the patients included in this study remains unknown, since no additional data were available.

The strengths of the current review are the selection criteria for our studies that were set to include series with enough patients and follow-up time of the implants. As far as we know, there has been only one other review on revisions of RHPs.[3] The primary objective of that review was to determine the incidence of revision or removal after RHPs placed for acute fractures. According to that review, the main reason for revision surgery was heterotopic ossification (HO). However, in the current study, there were no cases of HO at all. This discrepancy is likely the result of the fact that Kachooei et al.[3] included a radiographic outcome study by Ha et al. that described nearly all cases having HO (33 patients).[50] The study by Ha et al. was excluded in the current review because the follow-up was too short and the types of RHPs used unclear.

Several limitations are recognized. Due to the small numbers it was not possible to perform a meta-analysis on the extracted data. Since there are many different types of RHP included (n = 18), it is, with the relatively small numbers of primary implantations and revision cases, not possible to draw firm statistical conclusions. Moreover, prosthesis polarity, material, and fixation technique are not independent of each other. Thus, there are only eight combinations in practice, instead of the maximum of 32 possible combinations (two different polarities, four different materials, and four different techniques of fixation). These eight possible combinations reflect the true spectrum of available prostheses.[4]

Other limitations are the lack of reports in some studies on perioperative findings and individual time to failure of primary RHPs. In only 85 of the 152 patients the individual time to failure was reported. Then, although intentionally loose-fit prostheses were shown to fail earlier than press-fit prostheses, most other possible statistical comparisons of times to failure between the different fixation methods seemed to be underpowered. Also, studies regarding RHA are mostly mid-term follow-up. There are only a few studies with long-term follow-up (more than 10 years) available in the literature.[7,19]

In order to make a meta-analysis possible, a more uniform way of reporting indications for revision surgery and results is important. We think that the development of guidelines for standardized patient reported outcome measures (PROMs) and registration of clinical and radiographic outcomes is essential. National arthroplasty registries should play a leading role in this. Moreover, the outcomes after removal or revision of an RHP should be registered as well, as it is currently unknown which one is the preferred treatment for failed RHA and this choice seems to be more dependent on the preference of the hospital or surgeon, rather than on some level of evidence.[18]

Conclusions

In conclusion, the most frequent reasons for revision surgery after primary RHA are symptomatic (aseptic) loosening, elbow stiffness and/or persisting pain. Other, less common indications are technical failures such as overstuffing and dissociation of the implant. Failure occurs after an average of 34 months and the majority of the failed prostheses are removed. Taking into account the many different types of RHPs used and the various indications for revision surgery, the current data do not support a preference for a specific RHP design over one other. Guidelines for standardized follow-up are needed to improve our understanding of why RHPs fail.

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ICMJE CONFLICT OF INTEREST STATEMENT

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