Functional outcomes post-radial head arthroplasty: a systematic review of literature

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ABSTRACT

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Conflicts of Interest

None declared

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Background The present study was conducted to determine the quality and content of research on the functional outcomes and complications post-metal radial head arthroplasty (RHAP).

Methods A comprehensive search of medical databases for studies reporting on functional outcomes of patients undergoing metallic RHAP was conducted. The Structured Effectiveness Quality Evaluation Scale (SEQES) was used to evaluate quality of the studies.

Results We identified 21 Sackett's Level IV studies reporting on 391 radial heads. The mean duration of follow-up was 47.2 months and the mean (SD) age of patients was 48.4 years (6.9 years). The male to female ratio was found to be 1.05 : 1 and the dominant arm was involved in 54% of patients. When functional outcomes achieved post-RHAP were compared with normative scores, the comparison suggested that RHAP has good to excellent functional outcomes in short- to mid-term follow-up. The weighted mean (SD) Mayo Elbow Performance Score was 85.8 (4.1) (95% confidence interval 85.3 to 86.3). Incidences of implant removal (3.06%) and revision (2.22%) were found to be low.

Conclusions There is consistent low-quality evidence of positive functional outcomes following RHAP. The heterogeneity of type of implant, patient characteristics and outcome measures used, along with an inadequate reporting of study details, restrict any definitive conclusions being made.

INTRODUCTION

Radial head fractures (RHF) constitute one-third of the fractures around the elbow joint and 1.5-4% of all fractures [1-3]. Typically caused by a fall on an outstretched arm, RHF's occur in younger, working individuals with mean age range of 30 years to 40 years [1,2,4,5]. One-third of individuals who sustain a RHF will also sustain concurrent injuries to adjacent bones (fractures of the capitellum, coronoid or proximal ulna) and/or ligaments (disruption of lateral or medial collateral ligament or interosseous membrane) [1,4,6], with posterior dislocation of the elbow and coronoid fractures being the most common. These associated injuries form the crux on which RHF's are classified [2], and also on which the treatment decision-making is based.

When RHF's are isolated and minimally displaced, unequivocally, they are managed by closed reduction followed by early mobilization [7-9]. It is when they are comminuted and/or associated with concomitant injuries that appropriate management is less clear. Historically, excision of radial head was performed; however, it became less popular [8,10-12] as concerns over its long-term outcomes were raised [5,8,10-12]. Biomechanical and cadaveric studies facilitated an understanding of the role of radial head in the elbow joint complex and the importance of preserving it [13-17]. As a matter of course, excisions were replaced with open reduction and internal fixation (ORIF) for complex RHF [18-21]. Although ORIFs usually

lead to satisfactory results when performed by an experienced surgeon, they are time and technique intensive procedures. Also, ORIFs have been reported to result in increased incidence of future hardware removal, avascular necrosis of radial head, non-union and displacement of fracture [18,19,22]. There is a long immobilization period followed by extensive postoperative rehabilitation. The replacement of radial head (hereafter referred to as radial head arthroplasty; RHAP) provides a reasonable option in such a scenario [9,21]. RHAP avoids the tenuous fracture fixation in the setting of an associated injury where maintenance of joint stability would be compromised by inefficient fracture fixation [8,23,24]. It has shorter learning curves than ORIF and prevents complications as a result of radial head excision [22].

A variety of materials have been used for the fabrication of radial head implants, including silicone rubber, vitallium, copper, cobalt-chromium, titanium and, more recently, pyrocarbon [22,25]. The use of silicone [26] was discontinued after its mechanical properties were found to be inadequate to counteract the valgus and axial loading at the radiocapitellar joint [27,28]. Some studies also reported implant fracture and inflammatory synovitis in the long term [29-31]. Conversely, metal implants were reported to be rigid and capable of withstanding the deforming forces [31,32]. To replace the complex and highly variable radial head, two basic conceptual designs evolved and are now most commonly used: (i) a polished stem

with a monopolar or modular head designed to act as a spacer and (ii) a rigidly fixed stem with a bipolar or monopolar head [33,34]. Bipolar prostheses are as capable as the monoblock prostheses with respect to maintaining congruency of the radial head with the capitellum and sigmoid notch during the range of motion (ROM) of the elbow and restoring valgus stability [33,35,36].

Many trials in the past have examined the outcomes of RHAP [37], although no attempts have been made to summarize the literature in a systematic manner. Hence, the present systematic review aimed to determine: (i) the quality of the evidence reporting on the functional outcomes of RHAP; (ii) the patient characteristics, indications and contraindications of RHAP; (iii) the objective and self-reported functional outcomes of RHAP; and (iv) radiological outcomes and complications post-RHAP.

MATERIALS AND METHODS

Search strategy

A literature search of the electronic databases of MEDLINE (1966 to October 2013), CINAHL (1982 to October 2013) and Embase (1980 to October 2013) was conducted. After consultation with a medical librarian, the keywords 'radial head' AND 'metal' AND 'arthroplasty' OR 'replacement' AND/OR 'functional outcomes' were used with limits 'English'. The search was developed and conducted by one of the authors (M.K.) and was last updated in October 2013. A manual reference check of all retrieved studies and recent literature reviews was performed to identify additional relevant studies.

Eligibility criteria

Two reviewers (M.K. and J.M.) independently scanned the titles and abstracts of the retrieved articles for their potential relevance. For studies to be included in the review, inclusion criteria were applied: (i) the studies reported on primary (acute or delayed) metal radial head replacement surgery and (ii) at least one functional outcome post radial head arthroplasty was examined. All study designs except case reports, descriptive literature reviews, and cadaveric and biomechanical studies were excluded from the review. Additionally, letters to editors, conference abstracts, meetings proceedings, editorials, monographs and textbook chapters were excluded. Secondary studies, if any, were not included in the review to avoid double counting of the patients (Fig.1). Both reviewers (M.K. and J.M.) examined the full texts of the potential studies before finalizing their inclusion in the review. Any disagreements were resolved by in-person discussions.

Assessment of methodological quality of included studies

The methodological quality of the included studies was assessed independently by the two reviewers using the Structured Effectiveness Quality Evaluation Scale (SEQES)

[38,39]. The SEQES is a valid 24-item scale with a global score of 0 to 16 (low quality), 17 to 32 (moderate quality) and 33 to 48 (high quality) [39]. Sackett's Level of Evidence (LOE) [40] was used to categorize individual studies.

Data extraction

Study characteristics such as study design, clinical setting, population characteristics (demographics), the timing and type of arthroplasty, indication for arthroplasty, pain and functional outcomes (both self-reported and physical performance measures) were extracted on a data extraction form designed *a priori* and piloted. Information pertaining to surgical technique, radiological outcome, postoperative complications and post-operative rehabilitation protocol was also documented (M.K. and J.M.).

Statistical analysis

Data were summarized descriptively when appropriate. Outcome measurement results were pooled confidence interval (95% CI) and weighted means (weighted by sample size) were calculated. The agreement on methodological quality assessment was determined by percentage agreement and weighted kappa [41] for individual items on the SEQES. The intraclass correlation coefficient [42] was calculated to determine agreement on the global SEQES score. All calculations were performed using SPSS, version 20.0 (SPSS Inc. Chicago, IL, USA).

RESULTS

Literature search and study characteristics

The electronic comprehensive literature search identified 21 studies accounting for a total of 391 radial head implants that were included in the final analyses (Table 1). A detailed schema of the literature search is given in Fig.1. The agreement between the reviewers was 100% on the LOE, and >90% on items of the critical appraisal tool. The chance corrected agreement was kappa >0.85. The intraclass correlation coefficient was found to be 0.92 (95% confidence interval, 0.78 to 1.00). All included studies that reported on the functional outcomes of RHAP were graded as Sackett's Level IV evidence (Table 2).

The majority of the studies were published between 1990 and 2000 and 2006 and 2008, reflecting the time during which new implants were being designed and tested. As such, most of these studies reported only short- to medium-term follow-up. Most of the studies were carried out in Europe [13,17–25,35,36,43–50] (47.62%) and North America [34,51–55] (33.33%) followed by South East Asia, predominantly China [56–58] (14.29%) and Australia [21] (4.76%). The radial head implants varied in design with respect to their modularity and component mobility. The most frequently reported radial head implants are given in Table 3.

With respect to follow-up, a mean duration of 47.2 months (95% CI 34.7 months to 59.8 months) (lower quartile 30.9

Fig. 1 PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram for study selection

months; median 39 months; upper quartile 57.6 months) was noted. The study by Harrington et al. remained the longest duration of follow-up in the RHAP literature, with a mean follow-up of 12.1 years (minimum 6 years, maximum 29 years) [53].

Patient recruitment rate was found to be greater than 90%. The mean (SD) age for the participants was 48.4 years (6.9 years) (95% CI 45.4 years to 51.4 years). There were 185 male and 175 female participants with a male:female ratio of 1.05:1. This male:female ratio is consistent with the ratio reported in the literature [4]. The most commonly reported indication for acute RHAP was complex radial head fractures (Mason Type 3 and 4) along with concomitant elbow injuries that threatened the stability of the elbow joint. Residual pain and stiffness from previous failed resection or internal fixation was found to be the indication for delayed arthroplasty. Less common indications included traumatic elbow instability, previously failed excision or fixation, failed silicone replacement. The contraindications that are described in the literature include open fractures with risk of infection, chondral lesion

or avascular necrosis of capitellum and known allergy to metal used in the implant.

The most common mechanism of injury reported was a fall on outstretched hand (68.4%) followed by a fall from a height (>6 feet) (14%) and motor vehicle accident (9.2%). There were a few direct injuries to the elbow (7.6%) and only two cases (0.8%) of sports-related injuries. The dominant hand was involved in 54.3% of participants in 13 [21,34,43–46,48,49,51–55,57,58] studies that reported hand dominance.

Surgical technique and postoperative rehabilitation protocol

All included studies described the surgical technique, with the posterolateral Kocher's approach being the most commonly used. The rationale for the size of radial head prosthesis was given with respect to the specific type of implant. The protocol for postoperative rehabilitation included early mobilization under the supervision of a hand therapist, within 1 day or 2 days of surgery, supplemented with an extension splint at

Table 1 Summary of study and patient characteristics

Author	Publication year	Prosthesis	Years of investigation	Duration of follow-up (months)	Number of radial heads	Age (years)	Gender	
							Male	Female
Ashwood et al.	2004	Titanium	1996 to 2001	33.6 (14.4 to 51.6)	16	45 (21 to 72)	8	8
Brinkman et al.	2005	Judet	1999 to 2003	24 (12 to 48)	11	43 (26 to 61)	8	3
Burkhart et al.	2010	Judet	1997 to 2001	106 (78 to 139)	17	44.1 (25 to 60)	14	3
Celli et al.	2010	Judet	2000 to 2007	41.7 (12.3 to 86.3)	16	46.1 (27 to 74)	11	5
Chapman et al.	2006	Vitallium	1996 to 2000	A: 30 (24 to 44) D: 37 (23 to 51)	A: 8 D: 8	A: 50 (19 to 83) D: 50 (40 to 82)	A: 5 D: 4	A: 3 D: 4
Chien et al.	2010	EVOLVE	2002 to 2008	38.3 (20 to 70)	13	37 (16 to 63)	9	4
Doornberg et al.	2007	EVOLVE	NA	40 (24 to 55)	27	52 (22 to 71)	13	14
Dotzis et al.	2006	Judet	1992 to 2003	63 (12 to 144)	14	44.8 (18 to 85)	10	4
Grewal et al.	2006	EVOLVE	1999 to 2003	24.5 (12 to 48)	26	54 (31 to 80)	9	17
Harrington et al.	2000	Titanium	1961 to 1990	145.2 (72 to 348)	20	46 (21 to 75)	7	13
Judet et al.	1996	Judet	1988 to 1995	A: 49 (24 to 65) D: 43 (24 to 72)	12	A: 43.4 (25 to 63) D: 32.7 (18 to 54)	A: 2 D: 4	A: 3 D: 3
Knight et al.	1993	Vitallium	NA	54 (24 to 96)	31	57 (21 to 83)	12	19
Lim et al.	2008	Vitallium	2001 to 2005	29.7 (13 to 54)	6	53.3 (21 to 75)	2	4
Moro et al.	2001	Titanium	NA	39 (26 to 58)	25	54 (27 to 84)	11	13
Muhm et al.	2011	EVOLVE	2001 to 2009	ST: 19.2 (12 to 27) MT: 61.2 (36 to 86)	ST: 10 MT: 15	ST: 58 (22 to 81) MT: 59.5 (39 to 84)	ST: 4 MT: 8	ST: 6 MT: 7
Popovic et al.	2000	Judet	1994 to 1996	32 (24 to 56)	11	52.7 (22 to 68)	6	5
Shore et al.	2008	EVOLVE	1993 to 2004	96 (24 to 168)	32	54.1 (32 to 93)	13	19
Smets et al.	2000	Judet	1995 to 1999	25.2 (5 to 48)	15	46.4 (20 to 64)	6	9
Wretenberg et al.	2006	Link	1994 to 200	44.4 (12 to 84)	18	52 (29 to 82)	11	7
Zhao et al.	2007	Titanium	2003 to 2004	23.7 (18 to 31)	10	38 (26 to 54)	8	2
Zunkiewicz et al.	2012	Katalyst	2004 to 2006	34 (24 to 48)	30	NA	NA	NA
Total				47.2 (29.8) (95% CI 34.7 to 59.8) Range 19.2 to 145.2	391	48.4 (6.9) (95% CI 45.4 to 51.4)	185	175
							M:F = 1.05:1	

A, acute group; D, delayed group; ST, short-term group; MT, mid-term group; NA, not available; CI, confidence interval; M, male; F, female.

night. Only in two studies that employed Link [50] and Katalyst [59] implants was postoperative immobilization of 7 days to 10 days followed by supervised active-assisted ROM exercises. Whether this long immobilization period was related to the biomechanical design of implant or the clinical intuition of the surgeon is unknown. The active and passive stretching and strengthening were initiated within 6 weeks to 8 weeks after the surgery, depending on the extent of associated injuries and elbow stability.

ROM

ROM was documented in 20 out of 21 studies, except Brinkman et al. [47], and was measured either with a manual goniometer or the computerized NK hand evaluation system. The exact procedure and reference point used were described in only three [36,52,55] of 20 studies. The weighted postoperative

means (weighted on sample size) for both elbow flexion and extension and forearm rotation were calculated for the implants included in the review (Table 4). Greater restriction of ROM was seen in the Link [50] and Katalyst [59] implant groups in the given duration of follow-up. Whether this difference is attributable to the specific implant, patient characteristics, or the longer immobilization period after surgery needs to be evaluated further. No difference was found in the ROM outcome between the acute and delayed group for flexion ($t_{26} = 3.25$, $p > 0.001$), extension ($t_{26} = 1.26$, $p > 0.001$), pronation ($t_{26} = 0.63$, $p > 0.001$) or supination ($t_{26} = -0.70$, $p > 0.001$). The mean ROM for flexion and extension was higher in the vitallium implant group: 143.3° and 18.2° , respectively. No pattern was seen in the mean ROM of rotations [i.e. mean ROM for pronation was highest in the titanium cohort (77.4°) and mean ROM for supination was highest in the Judet cohort (72.4°)].

Table 2 Study quality of the included studies based on Structured Effectiveness Quality Evaluation Scale (SEQES) criteria

	Study question	Study design							Subjects				Intervention			Outcomes			Analysis				Recommendations				Percentage of total	
Author	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	Total	score		
Ashwood et al.	1	0	0	0	0	1	1	1	1	1	1	2	2	1	0	1	1	1	0	0	0	1	1	1	18	37.5		
Brinkman et al.	1	0	1	1	0	1	1	2	1	1	1	2	2	1	0	1	1	1	0	0	0	1	1	2	22	45.8		
Burkhart et al.	2	0	0	0	0	1	1	0	1	1	1	2	2	1	0	2	1	1	1	1	0	1	2	2	23	47.9		
Celli et al.	1	0	0	0	0	1	1	2	1	1	1	2	1	1	0	2	1	1	1	0	0	1	2	2	22	45.8		
Chapman et al.	2	0	0	0	0	1	1	0	1	1	2	2	2	1	0	2	1	2	2	1	1	1	2	2	27	56.3		
Chien et al.	1	0	0	0	0	1	1	0	1	2	1	2	2	1	0	1	1	1	0	0	0	1	1	2	19	39.6		
Doornberg et al.	1	0	0	0	0	1	1	0	1	1	1	2	2	1	0	2	1	1	0	0	0	1	2	2	20	41.7		
Dotzis et al.	2	0	0	0	0	1	1	0	1	1	1	2	2	1	0	2	1	0	0	0	0	1	2	2	20	41.7		
Grewal et al.	2	0	2	2	0	1	1	2	1	2	2	2	2	2	0	2	1	2	2	2	2	1	2	2	37	77.1		
Harrington et al.	2	0	0	0	0	1	1	0	1	1	1	2	2	1	0	1	1	1	0	0	0	1	2	2	20	41.7		
Judet et al.	2	1	1	0	0	1	1	0	1	1	1	2	1	1	0	1	1	1	0	0	0	1	2	1	20	41.7		
Knight et al.	2	0	0	1	0	1	1	0	1	1	2	2	2	1	0	1	0	1	0	1	0	1	2	2	22	45.8		
Lim et al.	2	0	0	0	0	1	1	0	1	1	2	2	2	1	0	2	1	1	0	0	0	1	2	2	22	45.8		
Moro et al.	2	0	0	0	0	1	1	2	1	1	2	2	2	1	0	2	1	1	2	2	2	1	2	2	30	62.5		
Muhm et al.	1	0	0	0	0	1	1	0	1	2	2	2	2	1	0	2	1	0	2	2	2	1	2	2	27	56.3		
Popovic et al.	2	0	2	2	0	1	1	0	1	1	2	2	2	1	0	2	1	1	0	0	0	1	2	2	26	54.2		
Shore et al.	2	0	0	0	0	1	1	0	1	2	2	2	2	1	0	2	1	1	2	2	1	1	2	2	28	58.3		
Smets et al.	2	0	0	0	0	1	1	0	1	1	1	2	1	1	0	1	1	1	0	0	0	1	1	1	17	35.4		
Wretenberg et al.	1	0	0	0	0	1	1	0	1	2	1	2	1	1	0	1	1	1	0	0	0	0	1	2	17	35.4		
Zhao et al.	1	0	0	0	0	1	1	0	1	1	1	2	2	1	0	1	1	1	0	0	0	1	2	1	18	37.5		
Zunkiewicz et al.	2	0	0	2	0	1	1	2	1	2	2	2	2	1	0	2	1	1	2	1	1	0	2	2	30	62.5		

Table 3 Frequency of reporting of radial head implants in literature

Type of implant	Frequency (n)
EVOLVE [34,48,52,55,56]	31.46% (123)
Judet [35,36,43–45,47,49]	24.46% (96)
Titanium [21,53–55,57]	18.16% (71)
Vitallium [46,51,58]	13.55% (53)
Katalyst [59]	7.67% (30)
Link [50]	4.60% (18)

n, number of radial head implants.

Elbow strength

Grip strength was evaluated in nine studies [21,36,44,45,48,52–55,57,58] using either the hydraulic Jamar hand dynamometer (Sammons Preston Inc., Bolingbrook, IL, USA) or the computerized NK hand evaluation system (Table 5). The overall decrease in grip strength on the involved side was approximately 12.4% compared to the contralateral side. Isometric strength was reported in five out of 21 studies [36,52,53,55,57] and a greater average loss was found in supination (19%) and pronation (15.5%) compared to flexion (13%) and extension (14%).

Where the nondominant hand was involved, none of the studies adjusted for the normative difference in dominant and nondominant hand. Muhm et al. reported no significant difference in the grip strength in short- and mid-term follow-up groups [48].

Stability of elbow joint

Stability of elbow joint post RHAP was evaluated in 13 out of 21 studies [21,36,43,44,46–50,52–54,58] on the basis of clinical examination and radiographs post-RHAP. None of the studies reported symptomatic valgus or posterolateral instability or ulnohumeral subluxation. Knight et al. reported one patient with moderate valgus instability postoperatively, although that patient was asymptomatic at a mean follow-up of 4.5 years [46].

Patient-reported outcome measures

The Mayo Elbow Performance Index (MEPI) is a clinician-based outcome measure that evaluates pain, ulnohumeral motion, stability and ability to perform five functional tasks [60,61]. It was the most frequently used outcome measure, besides the Broberg and Morrey functional rating system (Table 6). The total MEPI scores can range from 5 to 100, with higher

Table 4 Elbow range of motion

Implant	Range of motion			
	Flexion	Extension	Pronation	Supination
Vitallium	143.3 (10.8) (139.9 to 146.5)	18.2 (4.1) (16.9 to 19.4)	70.9 (12.1) (67.3 to 74.5)	72.1 (9.2) (69.4 to 74.9)
Titanium	137.9 (11.3) (135.2 to 140.7)	17.8 (9.6) (15.1 – 20.5)	77.4 (2.18) (76.8 to 77.9)	71.4 (5.7) (70 to 72.8)
Judet	131.54 (4.8) (130.5 to 132.58)	16.2 (3.3) (15.3 to 17.1)	72.4 (10.6) (70.1 to 74.7)	74.0 (10.9) (71.6 to 76.3)
EVOLVE	129.3 (5.7) (128.3 to 130.4)	17.2 (5.9) (16.1 to 18.4)	70.6 (5.1) (69.7 to 71.6)	62.7 (8.3) (61.2 to 64.3)
Katalyst	126	NA	69	74
Link	125	NA	80	75

Values are given are weighted means (SE) as per the sample size (95% confidence interval).

NA, not available.

Table 5 Elbow strength post radial head arthroplasty

Author	Prosthesis	Strength parameter	Measured	Impairment
Ashwood et al.	Titanium	Grip strength	Jamar dynamomter	Reduced by 12%
Harrington et al.		Grip strength	Dynamometer	Reduced by 10%
		Isometric strength	NA	Flexion by 10%
				Extension by 13%
				Pronation by 13%
				Supination by 19%
Moro et al.		Grip strength	NK hand evaluation system	Reduced by 18%
Zhao et al.		Isometric strength	LIDO work set	Pronation by 17%
				Supination by 18%
Burkhart et al.	Judet	Grip strength	Jamar dynamomter	Reduced by 8%
Dotzis et al.		Grip strength	Jamar dynamomter	Reduced by 10%
Popovic et al.		Isometric strength	Simple tensiometer	Mild loss (25% of patients)
Lim et al.	Vitallium	Grip strength		Reduced by 10%.only significant in two patients: 57% and 75%
Grewal et al.	EVOLVE	Grip Strength	NK hand evaluation system	14%
		Isometric strength	LIDO work set	Flexion by 20%
				Extension by 19%
				Pronation by 22%
				Supination by 28%
Muhm et al.		Grip strength	Jamar dynamomter	Reduced by 15%
Shore et al.		Grip strength	NK hand evaluation system	Significantly reduced
		Isometric strength	LIDO work set	Significantly reduced

NA, not available.

scores reflecting better outcomes. The cumulative score can then categorized into four subsets of poor (0 to 59), fair (60 to 74), good (75 to 89) and excellent (90 to 100). It has been validated for use in elbow disorders [60,62]. The weighted mean (SD) (on sample size) at the follow-up for MEPI was found to be good: 85.8 (4.1) (95% CI 85.3 to 86.3) The weighted mean (SD) (weighted on sample size) for the

Broberg and Morrey functional rating system was found to be excellent: 85.6 (3.3) (95% CI 84.5 to 86.6)

The Disabilities of Arm, Shoulder and Hand (DASH) questionnaire [63] was reported in nine out of 21 studies [34,43–45,48,51,52,58,59] (Table 7). Comprising a region-specific outcome measure, DASH evaluates the symptoms, daily activities, sleep and social and work function based on

Table 6 Patient-reported functional outcome post radial head arthroplasty

Author	Follow-up (months)	Outcome measure	Mean score	Excellent	Good	Fair	Poor
Ashwood et al.	33.6 (14.4 to 51.6)	Mayo Elbow Performance Index Weighted mean (SD) = 85.8 (4.1) (95% CI 85.3 to 86.3)	87 (65 to 100)	50%	31.3%	18.8%	0
Burkhart et al.	106 (78 to 139)		90.83 (74 to 100)	35.3%	58.8%	5.9%	
Celli et al.	41.7 (12.3 to 86.3)		89.4 (50 to 100)	75%	12.5%		12.5%
Chapman et al.	A: 30 (24 to 44) D: 37 (23 to 51)		A: 90 (11.02) (75 to 100) D: 83.75 (11.88) (60 to 100)	A: 50% D: 25%	A: 50% D: 62.5%		D: 12.5%
Chien et al.	38.3 (20 to 70)	Broberg and Morrey system Weighted mean = 85.6 (3.3) (95% CI, 84.5 to 86.6)	86.92 (13.77) (60 to 100)	61.5%	23.1%	15.9%	
Doornberg et al.	40 (24 to 55)		85 (30 to 100)	48.2%	33.3%	11.1%	7.4%
Dotzis et al.	63 (12 to 144)		NA	42.9%	28.6%	7.1%	7.1%
Grewal et al.	24.5 (12 to 48)		80.5 (16.7) (9 to 100)	50%	16.6%	25%	8.3%
Moro et al.	39 (26 to 58)		80.36 (16.4) (42 to 100)	24%	44%	20%	12%
Shore et al.	96 (24 to 168)		83 (19) (32 to 100)	53.1%	12.5%	21.9%	12.5%
Smets et al.	25.2 (5 to 48)		85 (15.7) (50 to 100)	46.7%	20%	20%	13.3%
Zhao et al.	23.7 (18 to 31)		NA	50%	40%	10%	
Zunkiewicz et al.	34 (24 to 48)		92.1 (65 to 100)				
Harrington et al.	145.2 (72 to 348)		88 (67 to 100)	60%	20%	10%	10%
Judet et al.	A: 49 (24 to 65) D: 43 (24 to 72)		NA	25%	58.33%	16.7%	
Lim et al.	29.7 (13 to 54)		78.42 (17.13) (48.5 to 100)	16.7%	50%	16.7%	16.7%
Muhm et al.	ST: 19.2 (12 to 27) MT: 61.2 (36 to 86)		ST: 82.3 MT: 85.2	ST: 80% MT: 66.6%			
Popovic et al.	32 (24 to 56)		NA	36.4%	36.4%	18.2%	9.1%
Brinkman et al.	24 (12 to 48)		NA	54.5%	45.5%		
		Andrew Elbow Score	NA	72.7%	27.3%		

NA, not available; A, acute group; D, delayed group; ST, short-term group; MT, mid-term group; CI, confidence interval.

Table 7 Patient-reported functional outcome score on Disabilities of Arm, Shoulder and Hand (DASH) questionnaire post radial head arthroplasty

Study	Prosthesis	Mean DASH Score
Chapman et al.	Vitalium	A: 24.18 (22.02) (5.8 to 71) D: 30.58 (20.28) (12.5 to 75)
Lim et al.		13.62 (5.56) (0 to 65)
Burkhart et al.	Judet	9.8 (0 to 34)
Celli et al.		11.4 (0 to 36.61)
Dotzis et al.		23.9 (0 to 65.8)
Doornberg et al.	EVOLVE	17 (0 to 82)
Grewal et al.		24.4 (21.4) (0 to 59.2)
Muhm et al.		ST: 27.8 MT: 24.9
Zunkiewicz et al.	Katalyst	13.8 (0 to 52.5)
Overall		Weighted mean = 18.1 (5.9) (95% CI, 17.1–18.9)

A, acute group; D, delayed group; ST, short-term group; MT, mid-term group; CI, confidence interval

21 questions rated on a Likert scale of 0 to 4 [63]. The higher the DASH score, the greater the level of functional impairment. It has demonstrated excellent psychometric properties in the evaluation of elbow disorders and is the most frequently used outcome measure [60]. In our review, the weighted mean (SD) (weighted on sample size) for DASH scores was found to be 18.1 (5.9) (95% CI 17.1 to 18.9). The studies reporting on Judet and Katalyst implants reported an overall lower DASH score, although this finding is not conclusive as a result of the wide range of DASH scores observed in the trials.

Some of the other patient-reported outcome measures included a generic tool such as Short form-36 (SF-36) [64] and elbow joint specific tools, American Shoulder and Elbow Surgeons-Elbow (ASES-e) Evaluation tool [65] and the Patient Rated Elbow Evaluation [66]. The inclusion of a generic tool such as the SF-36 not only provides a comprehensive evaluation of quality of life post surgery, but also can be used to rationalize poor outcomes in patients with unexplained cause. Only three studies reported on the SF-36 [52,54,55].

Residual pain and patient satisfaction

Residual pain as an outcome measure post RHAP was reported in 16 out of 21 studies [21,36,43,44,46–50,52–54,58]. It was

Table 8 Complications post radial head arthroplasty

Prosthesis	Removal of implant	Revision surgery related to implant	Neurologic complications	Periprosthetic lucency	Heterotrophic ossification	Degenerative changes	Capitellar erosion	Complex regional pain syndrome
Titanium	4 (5.88%)	0 (0%)	4 (5.88%)	34 (50.00%)	17 (25.00%)	14 (20.58%)	18 (26.47%)	2 (2.94%)
Judet	0 (0%)	3 (3.12%)	3 (3.12%)	1 (1.04%)	18 (18.75%)	13 (13.54%)	6 (6.25%)	1 (1.04%)
Vitallium	2 (3.77%)	2 (3.77%)	4 (7.55%)	14 (26.42%)	4 (7.55%)	9 (16.98%)	5 (9.43%)	0 (0%)
EVOLVE	0 (0%)	1 (1.09%)	6 (6.59%)	51 (56.04%)	43 (47.25%)	39 (42.85%)	18 (19.78%)	1 (1.09%)
Link	5 (27.78)	0 (0%)	0 (0%)	7 (38.89%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Katalyst	0 (0%)	2 (6.67%)	0 (0%)	24 (80%)	13 (43.33%)	22 (73.33%)	0 (0%)	0 (0%)
Overall rate	11 (3.06%)	8 (2.22%)	17 (4.73%)	131 (36.49%)	95 (26.46%)	97 (27.02%)	47 (13.09%)	4 (1.11%)

most commonly measured using a visual analogue scale (VAS) of 0 to 10, where 0 represents no pain and 10 is the worst pain ever, or with the ASES-e pain subscale [65]. One plausible rationale behind not using a separate pain outcome measure in the five studies could be that the level of pain intensity measurement is closely integrated in the total raw scores of MEPI and the Broberg and Morrey rating system. However, future studies should resort to using reliable and validated pain scales to measure pain outcomes because individual scores on pain subscale are more valid rather than the aggregate score. Furthermore, there is lack of evidence suggesting any concordance between the pain score of MEPI or the Broberg and Morrey functional rating system and the VAS pain [67], confounding the final result.

Generally, patients reported improvement in the pain level at subsequent postoperative follow-up visits, with 9% of participants requiring analgesics on a regular basis. There were seven cases of wrist pain that were not found to be associated with radiological evidence of altered ulnar variance [21,49,58]. In eight out of 21 studies [21,43,48–50,52,58,59] that reported on patient satisfaction, the outcome was found to be satisfactory [21,43,48–50,52,58,59]. Patient satisfaction was measured with a VAS of 0 to 10 or with the ASES-e satisfaction subscale. Wretenberg et al. devised their own satisfaction scale [50].

Radiographic outcome

All 21 studies reported radiographic outcome post RHAP. The most common assessment criteria included the presence of periprosthetic lucencies, heterotrophic ossification, capitellar erosions or sclerosis and post-traumatic degenerative changes. There was significant heterogeneity in the classification used for radiolucent lines and the definition of what should be considered as a significant radiological change was not uniform across the studies.

Evidence of periprosthetic loosening and capitellar erosions were reported with both monoblock and bipolar prosthesis [36,44,50]. We found that the radiological complications of periprosthetic lucencies, heterotrophic ossification, capitellar erosion and degenerative changes were reported most with

the Katalyst and EVOLVE (Wright Medical Technology, Arlington, TN, USA) prosthesis. There were no reports of symptomatic periprosthetic loosening or implant failure.

Postoperative complications

Superficial wound infections were reported in three out of 391 cases (0.77%) and resolved completely with oral antibiotics [21,54] (Table 8). Deep postoperative infection was reported in one case of EVOLVE prosthesis, which was removed as a result of an associated elbow contracture [34]. Transient neuropathy of ulnar nerve and posterior interosseous nerve were the most commonly reported neurological complications (seven out of 391 cases; 4.73%). In the majority of these cases, the symptoms resolved spontaneously with no residual disability. There were only two reported cases where transposition of the ulnar nerve was required [51,55]. The notable finding is that, notwithstanding of the relatively high prevalence of the neurological complications, they were inconsistently reported on clinical examination. None of the studies provided survivorship analysis. Implant removal was required in 11 out of 391 radial head implants (3.06%) and eight out of 391 required revision surgeries (2.22%). The low revision rates may indicate a high success rate with RHAP or may simply be attributed to the deficient reporting of the revision rates.

DISCUSSION

An improved understanding of the elbow complex biomechanics and the role played by the radial head in physiological elbow function has led to substantial improvements in the design of radial head implants, as well as the material used. This trajectory of this improvement has been previously addressed in the literature. However, how this improvement in the implant design translates to improved function post-radial head arthroplasty has never been documented. If advancement of the radial head implant design is achieved with documented biomechanical and cadaveric studies, and if this might then morph to improve functional outcomes, then lower complication rates and improved implant survival remain to be examined in a methodological and rigorous

manner. The purpose of our review was to systematically assess the literature for the functional outcomes (both self-reported and physical performance) of radial head arthroplasty. We also explored the literature with respect to the type of radial head implants, characteristics of patients who undergo RHAP, radiological outcomes and their complications.

Literature, *per se*, we identified several shortcomings. There was considerable heterogeneity with respect to patient population, implant type, outcome measures, duration of follow-up and the lack of an independent outcome assessor. These factors, combined with the absence of any comparison groups (ORIF/excision/implant designs), limited our ability to perform meta-analyses that would explain any observed pattern of results or sources of disagreement between the findings. As a result, we were unable to draw any conclusion about the superiority of a specific implant design, surgical technique or postoperative rehabilitation protocol over another. The quandaries of performing randomized controlled trials of surgical interventions are well established, causing the literature to be replete with observations of a small subset of patients (in this case traumatic). However, it is in a scenario such as ours that the need for head-to-head comparative trials using different implant designs or surgical techniques (RHAP versus ORIF) is required for the evidence to move forward.

Furthermore, for outcomes such as ROM and strength (isometric and grip), the style of reporting varied, where either the actual value, percentage loss or a range was given. This made it impossible to pool the study results. A trend towards higher mean flexion and extension ranges was observed in the vitalium implant cohort, whereas no pattern was observed for elbow rotation movements. We firmly believe that the outcomes of ROM and strength are attributes of the surgical technique and postoperative rehabilitation protocol as much as they are of the implant design. If we assume that the surgical expertise of the surgeons in the RHAP studies was similar, and we know from the review that the postoperative protocol was synonymous, can we then say that any differences in the physical performance measures were solely a result of the implant design? This is probably not the case.

The fracture classification system also varied and so did the definition of radiographic variables in the included studies. However, again, as a result of considerable variability in the method of reporting, where studies either report the raw MEPI score or categorical ranking, we were unable to compare results across different studies and implant designs. When the categorical rankings are reported instead of raw scores (as in the case of most of the RHAP studies), they should be preceded by an evaluation of the validity and interpretability of the categories with validated measures. This was seldom carried out. Similarly, pain and level of satisfaction were not assessed using validated methods.

With respect to implant, the estimated (low) failure rate might be very imprecise. A lack of standardized reporting of complications and revision rates may result in some complications being missed because the care may have occurred at a different centre. Without regular and ongoing follow-up, most

complications or implant failures may go undetected. Data on missing patients were reported in very few studies and, when reported, any effects or reasons were not given. These factors combined could result in an under-estimation of the rate of failure. Also, failure depends on the wear and tear of the implant, which is a temporal concept. Considering the mean follow-up of 3.9 years for RHAP patients in the literature, it is highly likely that the 'word is not yet out'.

Out of the 21 included studies, 23.8% ($n = 5$) of the studies collected data retrospectively and 19.04% ($n = 4$) reported the results at more than one time point. Only one study included multivariate analyses [52], as a result of which the interaction between the patient characteristics and the outcome of the surgery could not be evaluated. Uncertainty persists with respect to the determinants (patient-related, socioeconomic, education, work status, etc.) of optimal postoperative outcomes. Subsequently, these methodological shortcomings reflected on the individual and global score of SEQES. We found that 95% ($n = 20$) of the studies were of moderate quality (i.e. global scores between 17 and 32). Most of the studies were graded as Sackett's Level IV evidence.

Future directions

Future trials must involve meticulously planned randomized controlled trials to compare RHAP with other operative techniques such as excision of the radial head or open reduction and internal fixation. The patients' demographic and functional outcome data should be collected at baseline (i.e. the acute postoperative period) and continued at regular intervals in the long term. Validated outcomes must be used and administered by a trained individual. Patient attrition should be kept to a minimum, and this should be accounted for in the power calculation. There is a need for collective responsibility amongst the authors of papers and journal editors for transparent, comprehensive and standardized reporting of all outcomes and study characteristics so that future meta-analyses can be conducted. Simultaneously, cost-effectiveness studies of radial head arthroplasty, from the perspectives of the healthcare payer, patient and the society, must be conducted.

Conclusions

Radial head arthroplasty consistently leads to improved functional outcomes, as is evident from the reviewed literature. However, the consistent low quality of evidence and poor reporting standards reduce any confidence in the findings. To effectively evaluate the mid- to long-term outcomes of radial head arthroplasty, future clinical trials should be designed to prospectively compare implant designs and operative techniques with validated outcomes.

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