



Radial head arthroplasty: fixed-stem implants are not all equal—a systematic review and meta-analysis

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Background: Numerous fixed-stem implants exist for radial head arthroplasty; therefore, we conducted a systematic review to compare the safety and efficacy of different types of fixed-stem implants.

Methods: We conducted a literature search, updated from a previous systematic review, to identify studies evaluating a fixed-stem radial head arthroplasty implant for any indication. We extracted data on revision rates, specific complications, and functional scores. We pooled results across studies using a random-effects method, using proportions for dichotomous data and mean values for functional scores. We analyzed outcomes by indication and specific implant.

Results: We included 31 studies. Studies included patients with radial head fractures only, terrible-triad injuries, or Essex-Lopresti injuries or included a heterogeneous population. We identified 15 different fixed-stem implants. The results of our analysis revealed that patients with terrible-triad injuries may be at an increased risk of revision and instability and patients with Essex-Lopresti injuries may be at an increased risk of arthritis, capitellar erosion, and osteolysis. After removing these outliers and pooling the results by specific device, we observed variability across devices in the rates of revision, arthritis, capitellar erosion, instability, and osteolysis, as well as in functional scores.

Conclusion: Differences were seen across different implants in revision rates, certain complications, and functional scores. This study highlighted that these devices should be evaluated within the context of the patient population under examination, as patients with Essex-Lopresti or terrible-triad injuries may demonstrate worse outcomes relative to those with a fracture only.

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Radial head fractures account for approximately one-third of all adult elbow fractures.^{17,36} Under the Mason classification system, radial head fractures are classified as either with displacement or without displacement.^{19,36} Radial head arthroplasty (RHA) is a surgical option for displaced radial head fractures.¹ Current RHA can be classified as unfixed or fixed depending on how rigidly secured the implant is within the radial neck. Unfixed, or loose, implants have smooth shafts and allow for motion to occur within the medullary canal.¹ Fixed, or press-fit, implants rigidly secure the

implant within the canal of the radial neck.¹ The type of implant may influence elbow stability and postoperative outcomes.⁴

Agyeman et al¹ conducted a systematic review to study the differences between the 2 fixation methods of RHA: fixed and unfixed. They concluded that implant fixation type does not appear to affect functional outcomes; however, their results suggested that rigidly fixed implants may increase the risks of revision and overall complications.

Numerous fixed-stem implants exist, with devices being manufactured by various companies. Currently, all fixed-stem RHA implants have been considered equal; therefore, we conducted a systematic review to evaluate the different types of fixed-stem implants in terms of their safety and efficacy. We hypothesized that differences exist between these implants and they should not be considered the same.

Institutional review board approval was not required for this systematic review.

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Methods

Search strategy

We conducted an updated systematic review using the same methodology reported by Agyeman et al.¹ Electronic literature searches were conducted in the MEDLINE and Embase databases using the following search algorithm: radial head AND (arthroplasty OR prosthesis OR replacement). The search was conducted from January 22, 2017—as this was the date reported by Agyeman et al—to November 20, 2018.

Eligibility criteria

We included any clinical study published in English evaluating the use of an RHA device for any indication; however, we only included studies that evaluated a fixed-stem implant.

Data extraction

We collected information from each study including the year of publication, country of publication, study design, follow-up period, patient demographic characteristics, indications, and specific device. We also extracted outcome data to compare revision rates (secondary surgery for implant revision or removal), specific complication rates (arthritis, capitellar erosion, instability, and osteolysis), and functional scores (reported with either the Mayo Elbow Performance Score [MEPS] or Disabilities of the Arm, Shoulder and Hand [DASH] score).

Data analysis

We analyzed the outcome data using Open Meta-analyst software, pooling results across studies for each fixed-stem device using the DerSimonian-Laird random-effects method.³⁸ Dichotomous data (revision and complications) were reported as the proportion of patients experiencing the event, and continuous data

(function) were reported as mean scores on the MEPS or DASH questionnaire, with the associated 95% confidence intervals (CIs) for each estimate. For the MEPS, a higher score is indicative of a more favorable outcome, whereas for the DASH questionnaire, a lower score is more favorable. We also analyzed outcomes by injury type (ie, fracture only, heterogeneous population, Essex-Lopresti, or terrible triad) to investigate if certain patient populations demonstrated an increased risk of experiencing an event. If so, we conducted sensitivity analyses removing such outliers to limit the influence of confounding factors when interpreting the results and comparing effect estimates between the different implants. We also performed a subgroup analysis, grouping devices as either bipolar or monopolar implants.

Results

Search results

We screened a total of 117 titles and abstracts (Fig. 1). Of these, 39 were included for full-text review, and a total of 9 studies were deemed eligible.^{13,14,20,21,27,29,31,34,35} In addition, 22 studies from the publication by Agyeman et al¹ were eligible,^{2,3,5,7-12,15,16,18,22-26,28,30,32,33,37} giving a total of 31 studies for the final analysis.

Description of included studies

The included studies were published from 2001 to 2018 and were conducted across 15 different countries (Table 1). The study sample sizes for each RHA device ranged from 6 to 63 patients, with an average length of follow-up ranging from 10.5 to 110.4 months (9.2 years). The average age of the patients ranged from 36 to 62 years, and the proportion of male patients ranged from 12.5% to 83.3%. In terms of the indications for surgery, the majority of studies included patients with radial head fractures only (23 studies), whereas the remaining studies included a heterogeneous population (5 studies), patients with a terrible-triad injury (2 studies), or patients with an

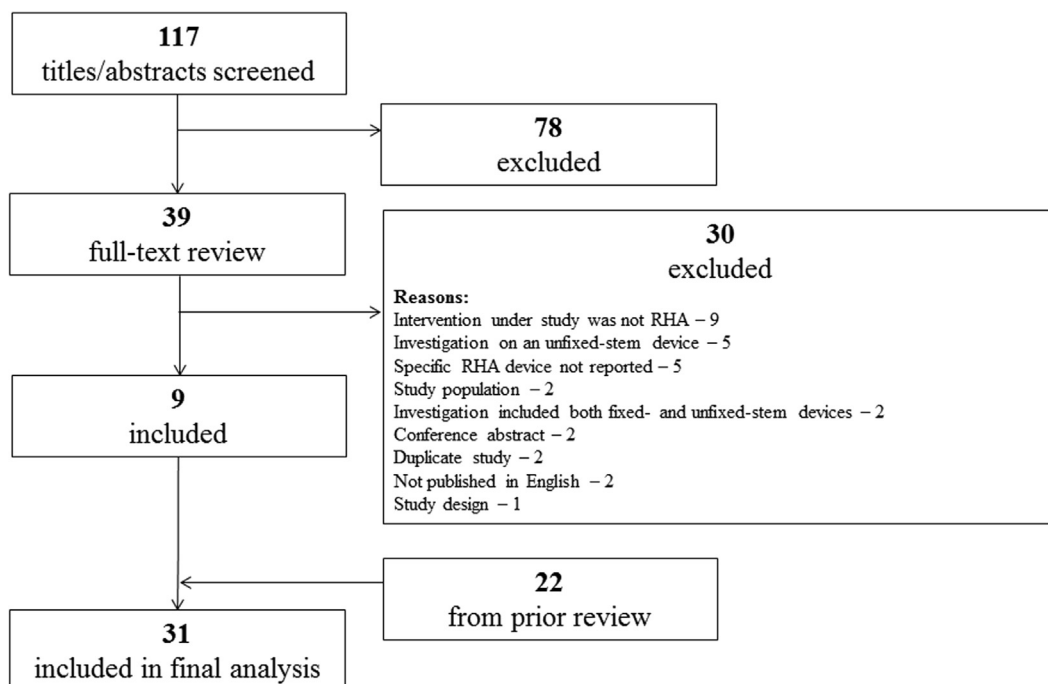


Figure 1 Flow diagram of included studies. RHA, radial head arthroplasty.

Table 1
Included studies

Author, year	Country	Design	Patients, n	Average follow-up, mo	Age, yr	Male/female, n	Indication	Device (company)
Gramlich et al, ¹³ 2019	Germany	Retrospective	35	32.4	48	22/13	Fractures only	MoPyC (Tornier)
Hari Krishnan, and Gupta, ¹⁴ 2019	India	Prospective	30	24	36	21/9	Fractures only	rHead (SBI/Stryker)
Laflamme et al, ²⁰ 2017	Canada	Retrospective	36	48	52.8	28/29	Fractures only	ExploR (Zimmer-Biomet)
Laumonerie et al, ²¹ 2017	France	Retrospective	36	110.4	NR	NR	Fractures only	Guepar (SBI/Stryker)
			24	36.7	NR	NR	Fractures only	Evolutive (Aston Medical)
			10	62.8	NR	NR	Fractures only	rHead RECON (SBI/Stryker)
			7	53.2	NR	NR	Fractures only	rHead (SBI/Stryker)
Nestorson et al, ²⁷ 2017	Sweden	Retrospective	8	75.1	59.1	NR	Fracture only	rHead (SBI/Stryker)
			10	56	50.2	NR	Fracture only	Anatomic Radial Head (Acumed)
Ricon et al, ²⁹ 2018	Spain	Retrospective	18	79.8	48	13/5	Fractures only	MoPyC (Tornier)
Rodriguez-Quintana et al, ³¹ 2017	Puerto Rico	Prospective	14	24	54.71	6/8	Terrible-triad injuries	Anatomic Radial Head (Acumed)
Sullivan et al, ³⁴ 2017	United States	Retrospective	19	10.5	NR	NR	Fracture only	Radial Head Prosthesis (Synthes)
			63	19.1	NR	NR	Fracture only	ExploR (Zimmer-Biomet)
Tarallo et al, ³⁵ 2017	Italy	Retrospective	31	30	52	21/10	Fractures only	Anatomic Radial Head (Acumed)
Allavena et al, ² 2014	France	Retrospective	22	50	44	15/7	Terrible-triad injuries	Guepar (SBI/Stryker)
Berschback et al, ³ 2013	United States	Retrospective	13	33	46	8/5	Essex-Lopresti injuries	Anatomic Radial Head (Acumed)
Brinkman et al, ⁵ 2005	Holland	Retrospective	11	24	43	8/3	Fractures only	Judet (Tornier)
Burkhardt et al, ⁷ 2010	Germany	Retrospective	17	106	44.1	14/3	Heterogeneous population	Judet (Tornier)
Celli et al, ⁸ 2010	Italy	Retrospective	16	41.7	46.1	11/5	Fractures only	Judet (Tornier)
Chapman et al, ⁹ 2006	United States	Retrospective	16	37	50	9/7	Heterogeneous population	Solar (Stryker)
Dotzis et al, ¹⁰ 2006	France	Retrospective	12	63	44.8	10/4	Fractures only	Judet (Tornier)
El Sallakh, ¹¹ 2013	Egypt	Retrospective	12	42	39	5/7	Fractures only	Anatomic Radial Head (Acumed)
Gauci et al, ¹² 2016	France	Retrospective	52	46	52	30/35	Heterogeneous population	MoPyC (Tornier)
Heijink et al, ¹⁵ 2016	The Netherlands	Retrospective	25	50	55	7/18	Fractures only	RHS (Tornier)
Katthagen et al, ¹⁶ 2013	Germany	Retrospective	29	25	60	8/23	Heterogeneous population	Corin (Corin Group)
Kodde et al, ¹⁸ 2016	The Netherlands	Retrospective	30	48	48	9/21	Fractures only	Judet (Tornier)
Levy et al, ²² 2016	United States	Retrospective	15	26	62	9/6	Fractures only	Anatomic Radial Head (Acumed)
Lim and Chan, ²³ 2008	Singapore	Retrospective	6	29.7	53	2/4	Fractures only	Vitalium (Howmedica)
Lopiz et al, ²⁴ 2016	Spain	Retrospective	14	42	54	6/8	Fractures only	MoPyC (Tornier)
Moro et al, ²⁵ 2001	Canada	Retrospective	24 (25 elbows)	39	54	11/13	Fractures only	Richards (Smith & Nephew)
Mou et al, ²⁶ 2015	China	Retrospective	12	60.8	41	6/6	Fractures only	Anatomic Radial Head (Acumed)
Popovic et al, ²⁸ 2007	Belgium	Retrospective	51	101	51	32/19	Fractures only	Judet (Tornier)
Ricon et al, ³⁰ 2012	Spain	Retrospective	28	32	54	11/17	Fractures only	MoPyC (Tornier)
Rotini et al, ³² 2012	Italy	Retrospective	30 (31 elbows)	24	44	19/11	Heterogeneous population	rHead (SBI/Stryker)
Sarris et al, ³³ 2012	Greece	Retrospective	32	27	54	20/12	Fractures only	MoPyC (Tornier)
Viveen et al, ³⁷ 2017	The Netherlands	Prospective	16	75	49	2/14	Fractures only	Judet (Tornier)

NR, not reported.

Essex-Lopresti injury (1 study). Among the 31 included studies, the authors of 24 studies declared no financial conflicts or competing interests, 4 studies were published by authors who received benefits or consulting fees from third parties, and such disclosures were not reported in the remaining 3 studies.

In terms of the specific fixed-stem implants, the studies evaluated devices from Acumed (Anatomical Radial Head [versions not reported; Hillsboro, OR, USA]), Aston Medical (Evolutive; Surrey, UK), Corin Group (Corin; Cirencester, UK), Howmedica (Vitalium; IN, USA), Phoenix Surgical (Cape Town, South Africa), SBI/Stryker (Guepar, rHead, rHead RECON, and Solar; Kalamazoo, MI, USA), Smith & Nephew (Richards; London, UK), Synthes (Radial Head Prosthesis; Warsaw, IN, USA), Tornier (Judet, MoPyC, and RHS; Edina, MN, USA), and Zimmer-Biomet (ExploR; Warsaw, IN, USA).

Revision rates

Figure 2 displays the revision rates by indication. Studies on patients with terrible-triad injuries demonstrated a remarkably higher event rate than studies on the other patient populations and were removed from the analysis of revision rates by specific RHA device (Fig. 3). Relative to the overall revision rate for all fixed-stem devices (11.7%; 95% CI, 8.5%–14.9%), pooled rates were lower, based on the point estimates, for 7 of the 15 different devices, ranging between 4.4% and 10.5%: Anatomic Radial Head (Acumed), ExploR (Zimmer-Biomet), Judet (Tornier), Phoenix Surgical device, Vitalium (Howmedica), Radial Head System (Tornier), and Radial Head Prosthesis (Synthes). The remaining devices demonstrated revision rates ranging between 13.8% and 60%.

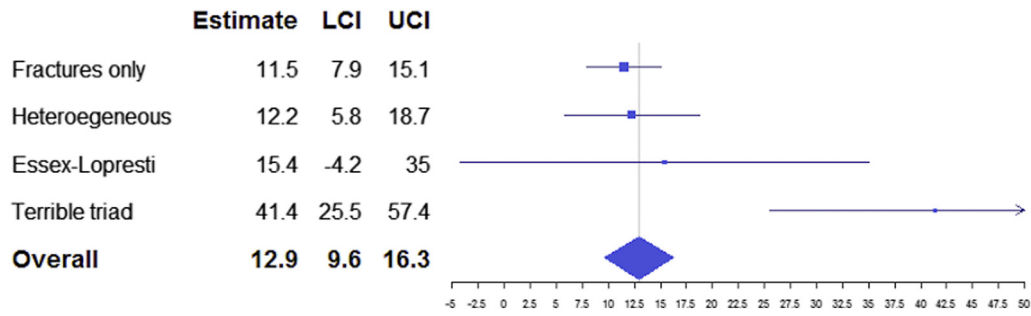


Figure 2 Revision rates (percentages) by indication. LCI, lower limit of confidence interval; UCI, upper limit of confidence interval.

Complications

Patients with Essex-Lopresti injuries demonstrated remarkably higher rates of arthritis and were not included in the analysis of arthritis rates by specific RHA device (Fig. 4). Relative to the overall rate of development of arthritis for all fixed-stem devices (34.6%; 95% CI, 18%–51.2%), pooled rates were lower for 5 of the 9 different devices included in the analysis, ranging from 4.5% to 28.2%: Guepar (SBI/Stryker), Anatomic Radial Head (Acumed), Corin (Corin Group), Richards (Smith & Nephew), and rHead (SBI/Stryker). The remaining devices demonstrated arthritis rates ranging between 44% and 61.6%.

Patients with Essex-Lopresti injuries also showed a markedly increased risk of capitellar erosion and were removed from the analysis by RHA device (Fig. 5). Relative to the overall rate of capitellar erosion for all fixed-stem devices (20.1%; 95% CI, 12.4%–27.8%), pooled rates were lower for 5 of the 10 different devices eligible for the analysis, ranging from 1.9% to 18%: Richards (Smith & Nephew), Anatomic Radial Head (Acumed), Judet (Tornier), Radial Head System (Tornier), and rHead (SBI/Stryker). The

remaining devices demonstrated capitellar erosion rates ranging between 20.8% and 60%.

Patients with terrible-triad injuries showed a substantially higher rate of instability and were removed from the analysis by RHA device (Fig. 6). Relative to the overall rate of instability for all fixed-stem devices (5.7%; 95% CI, 3.1%–8.2%), pooled rates were lower for 4 of the 11 different devices included in the analysis, ranging from 1.7% to 4.4%: Corin (Corin Group), Anatomic Radial Head (Acumed), Solar (Stryker), and Judet (Tornier). The remaining devices demonstrated instability rates ranging between 6.7% and 19.9%.

The rate of osteolysis was markedly greater in patients with an Essex-Lopresti injury, and such studies were removed from the analysis by RHA device (Fig. 7). Relative to the overall rate of osteolysis for all fixed-stem implants (40.1%; 95% CI, 27%–53.2%), pooled rates were lower for 6 of the 13 different devices eligible for the analysis, ranging from 1.7% to 39.9%: Corin (Corin Group), Anatomic Radial Head (Acumed), MoPyC (Tornier), Radial Head System (Tornier), Guepar (SBI/Stryker), and rHead (SBI/Stryker). The remaining devices demonstrated osteolysis rates ranging between 43.8% and 94.7%.

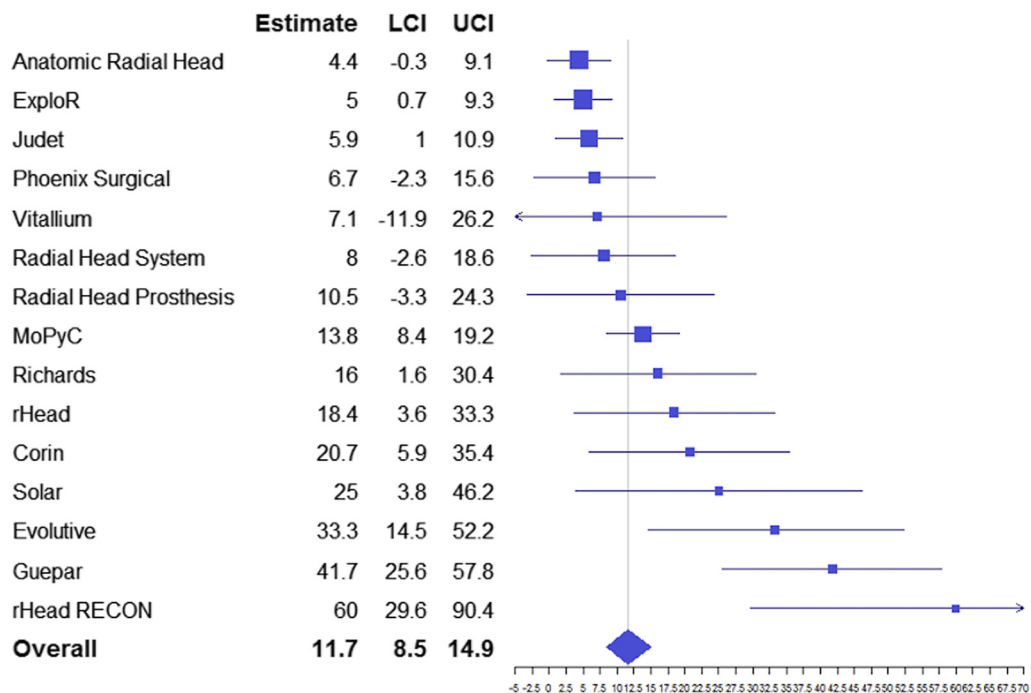


Figure 3 Revision rates (percentages) by device. Studies on patients with terrible-triad injuries were removed. LCI, lower limit of confidence interval; UCI, upper limit of confidence interval.

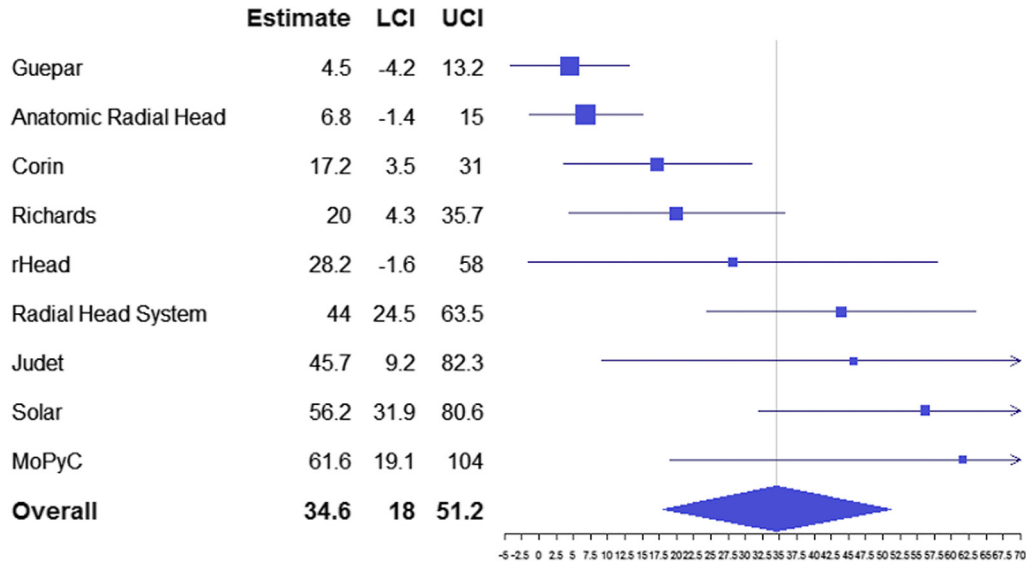


Figure 4 Arthritis rates (percentages) by device. Studies on patients with Essex-Lopresti injuries were removed. LCI, lower limit of confidence interval; UCI, upper limit of confidence interval.

Function

Figure 8 shows the analysis of function via the MEPS by RHA device. Relative to the overall MEPS for all fixed-stem implants (88.6 points; 95% CI, 86.6-90.5 points), pooled scores were greater for 4 of the 12 different devices eligible for the analysis, ranging from 89.6 to 96.2 points: ExploR (Zimmer-Biomet), Anatomic Radial Head (Acumed), MoPyC (Tornier), and Radial Head System (Tornier). The remaining devices demonstrated MEPS values ranging from 80 to 88 points.

Figure 9 shows the analysis of function on the DASH questionnaire by RHA device. Relative to the overall DASH score for all fixed-stem implants (15.2 points; 95% CI, 13.1-17.4 points), pooled scores were more favorable for 5 of the 11 different devices eligible for the

analysis, ranging from 8.8 to 13.9 points: ExploR (Zimmer-Biomet), Judet (Tornier), Anatomic Radial Head (Acumed), Vitallium (Howmedica), and Evolutive (Aston Medical). The remaining devices demonstrated DASH scores ranging from 16.1 to 27.5 points.

Subgroup analysis

Of the 15 devices identified in this review, 9 were monopolar (Anatomic Radial Head, Corin, ExploR, MoPyC, Radial Head Prosthesis, rHead, Richards, Solar, and Vitallium) and 6 were bipolar (Evolutive, Guepar, Judet, Phoenix Surgical, rHead RECON, and RHS). The results of these analyses are summarized in Table II. Overall, monopolar devices demonstrated more favorable results

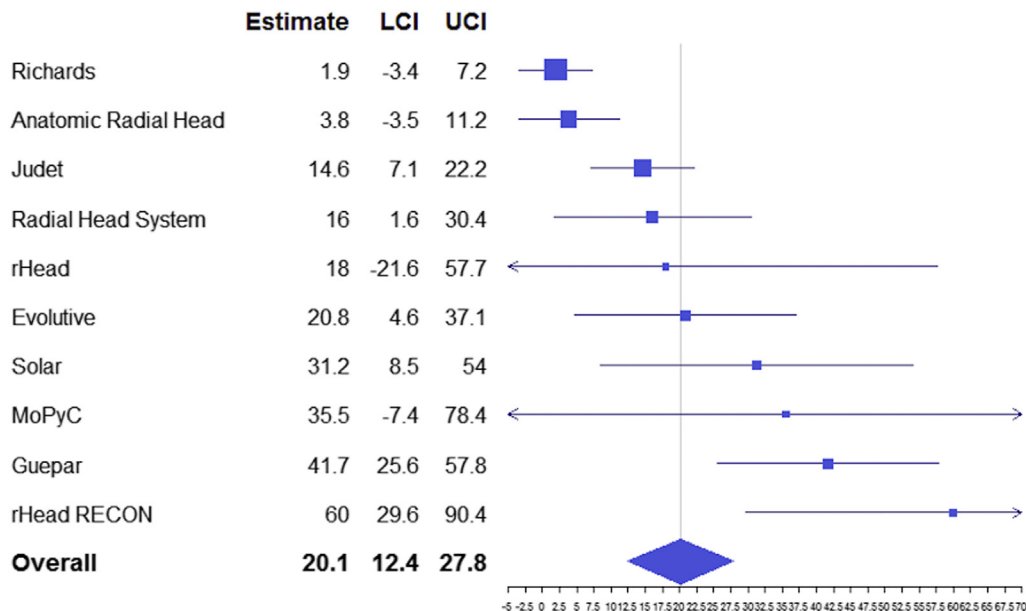


Figure 5 Capitellar erosion rates (percentages) by device. Studies on patients with Essex-Lopresti injuries were removed. LCI, lower limit of confidence interval; UCI, upper limit of confidence interval.

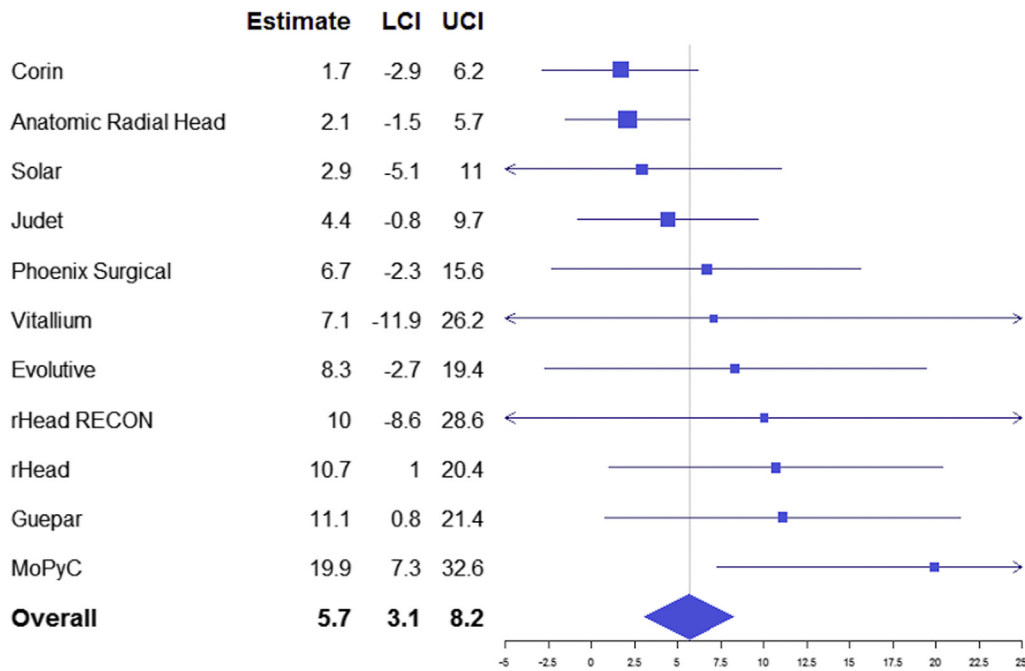


Figure 6 Instability rates (percentages) by device. Studies on patients with terrible-triad injuries were removed. LCI, lower limit of confidence interval; UCI, upper limit of confidence interval.

for the majority of outcomes, except for DASH scores, in terms of the pooled point estimates; however, the analyses may be confounded by wide CIs and a high degree of heterogeneity.

Discussion

Main findings

This systematic review and meta-analysis provided evidence highlighting that all fixed-stem RHA implants should not be

considered equivalent to each other. Differences were seen between different devices (15 in total) across numerous outcomes, which included rates of revision, arthritis, capitellar erosion, instability, and osteolysis, as well as functional scores via either the MEPS or DASH questionnaire. When all evaluated outcomes were considered, the Anatomic Radial Head (Acumed) and ExploR (Zimmer-Biomet) devices generally performed well across most outcomes whereas rHead RECON (SBI/Stryker), Guepar (SBI/Stryker), Solar (SBI/Stryker), and MoPyC (Tornier) devices tended to

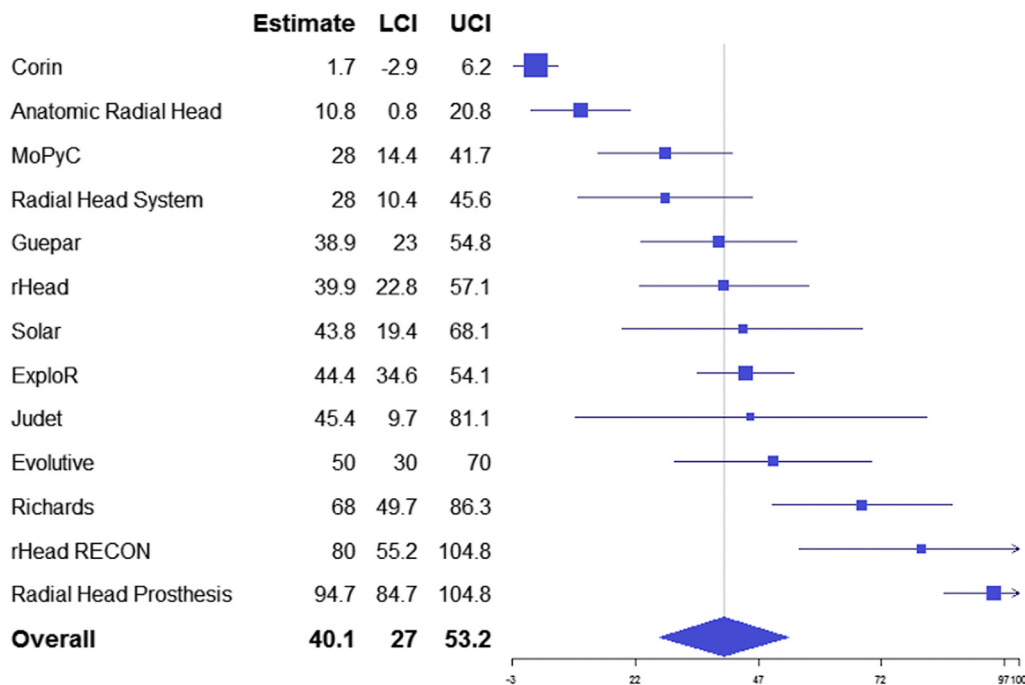


Figure 7 Osteolysis rates (percentages) by device. Studies on patients with Essex-Lopresti injuries were removed. LCI, lower limit of confidence interval; UCI, upper limit of confidence interval.

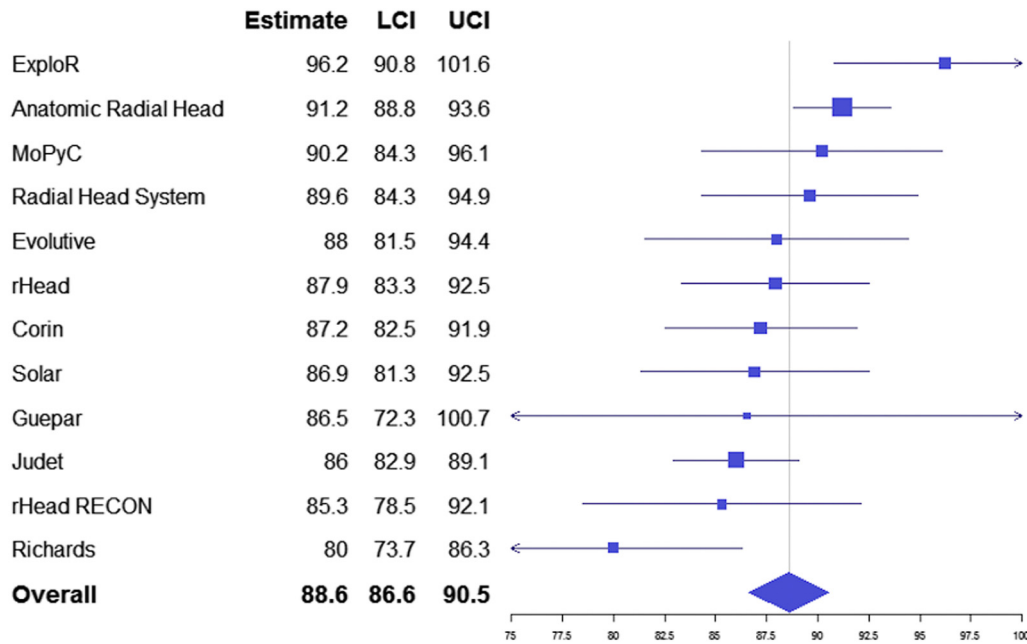


Figure 8 Mean functional scores by device: Mayo Elbow Performance Score. *LCI*, lower limit of confidence interval; *UCI*, upper limit of confidence interval.

show less favorable results; however, such conclusions are dependent on which of these outcomes are considered most important.

Agyeman et al¹ reported overall revision rates of 7.9% for fixed-stem implants and 3.1% for unfixed stems. We calculated a revision rate of 11.7% for fixed-stem implants, as the additional studies included since the publication by Agyeman et al generally reported revision rates higher than 7.9%^{13,14,20,21,27,29,31,34}; however, when we performed subgroup analysis by the specific RHA devices, revision rates were as low as 4.4% and as high as 60%, demonstrating how problematic it can be to group different devices together based on one similar characteristic. In addition, we noted that outcomes may be influenced by the type of patient receiving an RHA. Specifically, we saw evidence to suggest that patients with Essex-Lopresti or

terrible-triad injuries may be at a greater risk of development of certain complications. This finding indicates that we should also evaluate these devices within the context of the patient population. Of note, there is currently no gold standard as to what are clinically important thresholds for revision and complication rates, and what is considered acceptable may vary from surgeon to surgeon. In addition, many of the reported complications may be based purely on radiographic findings within a given study, and it is unclear how many patients experiencing these complications may actually be symptomatic. In terms of the reasons for revision reported in the included literature, the data suggested that the most common reason for revision was to treat elbow joint stiffness and limited range of motion (making up approximately 31% of these revisions), followed by implant loosening, subluxation, and pain unrelated to

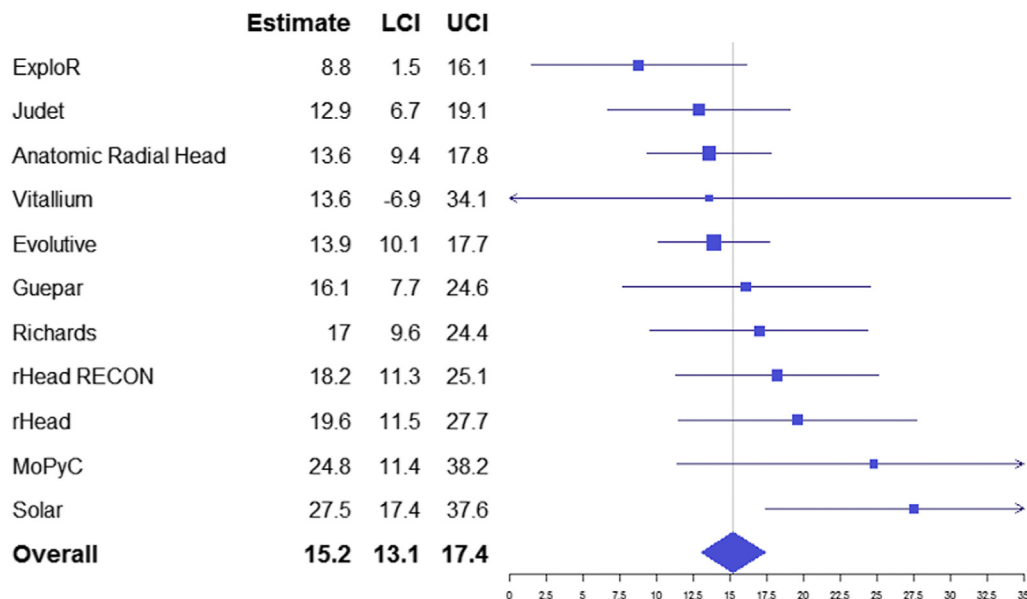


Figure 9 Mean functional scores by device: Disabilities of the Arm, Shoulder and Hand score. *LCI*, lower limit of confidence interval; *UCI*, upper limit of confidence interval.

Table II
Subgroup analysis: monopolar vs. bipolar implants

Outcome	Pooled estimate across monopolar implants	Pooled estimate across bipolar implants
Revision		
No. of studies	22	13
Estimate (95% CI), %	10.0 (6.7-13.4)	14.5 (7.8-21.2)
P value for effect estimate	<.001	<.001
I ² for heterogeneity, %	44.33	78.92
P value for heterogeneity	.014	<.001
Arthritis		
No. of studies	10	9
Estimate (95% CI), %	28.3 (13.0-43.5)	40.8 (12.6-69.0)
P value for effect estimate	<.001	.005
I ² for heterogeneity, %	89.8	97.66
P value for heterogeneity	<.001	<.001
Capitellar erosion		
No. of studies	9	11
Estimate (95% CI), %	18.7 (6.8-30.5)	20.7 (12.5-28.9)
P value for effect estimate	.002	<.001
I ² for heterogeneity, %	94.61	67.57
P value for heterogeneity	<.001	<.001
Instability		
No. of studies	10	9
Estimate (95% CI), %	5.6 (1.5-9.6)	7.0 (3.4-10.7)
P value for effect estimate	.007	<.001
I ² for heterogeneity, %	46.89	0
P value for heterogeneity	.05	.879
Osteolysis		
No. of studies	15	9
Estimate (95% CI), %	36.1 (19.1-53.0)	46.8 (24.0-69.5)
P value for effect estimate	<.001	<.001
I ² for heterogeneity, %	96.11	95.33
P value for heterogeneity	<.001	<.001
MEPS		
No. of studies	17	10
Estimate (95% CI), points	89.48 (87.05-91.92)	87.03 (84.24-89.81)
P value for effect estimate	<.001	<.001
I ² for heterogeneity, %	73.64	50.98
P value for heterogeneity	<.001	.031
DASH score		
No. of studies	12	7
Estimate (95% CI), points	16.17 (12.76-19.59)	14.57 (11.71-17.42)
P value for effect estimate	<.001	<.001
I ² for heterogeneity, %	24.6	35.93
P value for heterogeneity	.202	.154

CI, confidence interval; MEPS, Mayo Elbow Performance Score; DASH, Disabilities of the Arm, Shoulder and Hand.

implant loosening. This finding is consistent with the most commonly reported complications identified in the report by Agyeman et al.¹ There may also be inconsistency in the criteria used to define some of the reported complications. For example, most of the studies providing data on the incidence of arthritis stated that they followed the Broberg-Morrey classification to measure the severity of ulnohumeral osteoarthritis⁶; however, there were still a number of included studies that did not specify their method of measuring arthritis. Standardized definitions and reporting of outcomes would ensure comparability between studies and greater confidence in the pooled estimates.

In a previously published network meta-analysis of randomized controlled trials (RCTs) on displaced radial head fractures, we found that RHA resulted in better function and reduced postoperative complications compared with open reduction–internal fixation.³⁶ Regarding the limited amount of evidence (only 4 RCTs), none of the included RCTs directly compared 2 different fixed-stem implants or compared fixed vs. unfixed stems. Such comparisons are currently limited to either prospective or retrospective cohort studies. In terms of fixed vs. unfixed stems, 1 prospective and 2 retrospective cohort studies found similar pain and functional outcomes with both implant fixation techniques; however, it was

reported that fixed-stem implants led to greater osteolysis. It is unclear whether the higher rate of radial neck osteolysis is clinically meaningful and actually compromises pain or functional outcomes.^{3,20,31} Regarding studies directly comparing fixed-stem devices with each other, they also found differences in outcomes between different devices,^{13,21,27,34} providing some further support that not all fixed-stem RHA implants are the same.

Limitations

A limitation of this study was the lack of randomized trial evidence. The analysis predominantly comprised data from observational studies (either case series or cohort studies), with variable follow-up lengths and small sample sizes. Higher-quality evidence, with direct comparisons, consistent outcome reporting, and comparable patient populations, would provide greater confidence in estimating the comparative effects between the different devices. In addition, certain devices may have been represented by a small number of studies. For example, the analysis of revision rates included 7 studies that evaluated the Judet (Tornier) device but only 1 study that evaluated the rHead RECON (SBI/Stryker). This may put into question the precision in the estimate for devices similar to the latter (ie, with limited data), and additional evidence on the device may change the observed outcome. Finally, definitions and criteria for an outcome to be considered a “study event” are subjective and may be inconsistent across studies, which could affect the reported estimates. Future researchers in this area should collaborate to standardize, as much as possible, the process of assessing these outcomes.

Conclusion

This systematic review and meta-analysis provided evidence that fixed-stem RHA implants should not be considered equivalent to each other. Differences were seen in revision rates, postoperative complications, and functional scores. This study highlighted that these devices should be evaluated within the context of the patient population under examination, as patients with Essex-Lopresti or terrible-triad injuries may demonstrate worse outcomes relative to patients with isolated fractures only. Additional high-quality evidence is needed to further support these conclusions.

Disclaimer

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