Radial head fractures account for approximately one-third of all adult elbow fractures. Under the Mason classification system, radial head fractures are classified as either with displacement or without displacement. Radial head arthroplasty (RHA) is a surgical option for displaced radial head fractures. 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. Fixed, or press-fit, implants rigidly secure the implant within the canal of the radial neck. The type of implant may influence elbow stability and postoperative outcomes.

Agyeman et al. 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.
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 I). 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
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 (Vitallium; Hillsboro, OR, USA), Phoenix Surgical (Cape Town, South Africa), SBI/Stryker (Solar; MA, 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%: Anatomical Radial Head (Acumed), ExploR (Zimmer-Biomet), Judet (Tornier), Phoenix Surgical device, Vitallium (Howmedica), Radial Head System (Tornier), and Radial Head Prosthesis (Synthes). The remaining devices demonstrated revision rates ranging between 13.8% and 60%.

### Table I
Included studies

| Author, year | Country | Design | Patients, n | Average follow-up, mo | Age, yr | Male/female, n | Indication | Device (company) |
|--------------|---------|--------|-------------|-----------------------|---------|----------------|------------|-----------------|
| Gramlich et al,27 2019 | Germany | Retrospective | 35 | 32.4 | 48 | 22/13 | Fractures only | MoPyc (Tornier) |
| Hari Krishnan, and Gupta,22 2016 | India | Prospective | 30 | 48 | 37 | 19/12 | Fractures only | NH (Phoenix Surgical) |
| Laframme et al,26 2017 | Canada | Retrospective | 36 | 48 | 52.8 | 28/29 | Fractures only | ExploR (Zimmer-Biomet) |
| Laumonerie et al,41 2017 | France | Retrospective | 36 | 110.4 | NR | NR | Fractures only | ExploR (Zimmer-Biomet) |
| Nestorson et al,29 2017 | Sweden | Retrospective | 8 | 75.1 | 59.1 | NR | Fracture only | MoPyc (Tornier) |
| Ricon et al,28 2018 | Spain | Retrospective | 18 | 79.8 | 48 | 13/5 | Fractures only | MoPyc (Tornier) |
| Rodriguez-Quintana et al,27 2017 | United States | Retrospective | 14 | 24 | 54.7 | 6/8 | Terrible-triad injuries | Judet (Tornier) |
| Sullivan et al,34 2017 | Netherlands | Retrospective | 19 | 10.5 | NR | NR | Fracture only | Radial Head Prosthesis (Synthes) |
| Tarallo et al,35 2017 | Italy | Retrospective | 31 | 19.1 | NR | NR | Fracture only | MoPyc (Tornier) |
| Alleva et al,9 2014 | France | Retrospective | 22 | 50 | 44 | 15/7 | Terrible-triad injuries | Guepar (SBI/Stryker) |
| Berschback et al,5 2013 | United States | Retrospective | 13 | 33 | 46 | 8/5 | Essex-Lopresti injuries | Judet (Tornier) |
| Brinkman et al,5 2005 | Holland | Retrospective | 11 | 24 | 43 | 3/1 | Heterogeneous population | Judet (Tornier) |
| Burkhart et al,10 2012 | 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,16 2006 | France | Retrospective | 12 | 63 | 44.8 | 10/4 | Fractures only | Judet (Tornier) |
| Dotzis et al,17 2013 | Egypt | Retrospective | 12 | 42 | 39 | 5/7 | Fractures only | Judet (Tornier) |
| Gauci et al,18 2016 | France | Retrospective | 52 | 46 | 52 | 30/35 | Heterogeneous population | MoPyc (Tornier) |
| Heijink et al,19 2016 | The Netherlands | Retrospective | 29 | 50 | 55 | 7/18 | Fractures only | MoPyc (Tornier) |
| Katthagen et al,20 2013 | Germany | Retrospective | 25 | 50 | 55 | 7/18 | Fractures only | MoPyc (Tornier) |
| Kodde et al,21 2016 | United States | Retrospective | 15 | 48 | 48 | 9/2 | Judet (Tornier) | Solar (Stryker) |
| Lim and Chan,22 2008 | Singapore | Retrospective | 6 | 29.7 | 52 | 2/4 | Fractures only | MoPyc (Tornier) |
| Lopez et al,23 2016 | Spain | Retrospective | 14 | 42 | 54 | 6/8 | Fractures only | MoPyc (Tornier) |
| Moro et al,24 2001 | Canada | Retrospective | 24 (25 elbows) | 39 | 54 | 11/13 | Fractures only | Richards (Smith & Nephew) |
| Mou et al,25 2015 | China | Retrospective | 12 | 60.8 | 41 | 6/6 | Fractures only | MoPyc (Tornier) |
| Popovic et al,26 2007 | Belgium | Retrospective | 51 | 101 | 51 | 32/19 | Fractures only | Judet (Tornier) |
| Ricon et al,27 2012 | Spain | Retrospective | 28 | 32 | 54 | 11/17 | Fractures only | MoPyc (Tornier) |
| Rotini et al,28 2012 | Italy | Retrospective | 30 (31 elbows) | 24 | 44 | 19/11 | Heterogeneous population | MoPyc (Tornier) |
| Sarris et al,29 2012 | Greece | Retrospective | 32 | 27 | 54 | 20/12 | Fractures only | MoPyc (Tornier) |
| Viveen et al,30 2017 | The Netherlands | Retrospective | 16 | 75 | 49 | 2/14 | Fractures only | MoPyc (Tornier) |

NR, not reported.
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 44% and 61.6%.

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

**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 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.
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 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.

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

Agyeman et al\(^1\) reported overall revision rates of 7.9% for
fixed-stem implants and 3.1% for un
fixed 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

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

| Device          | Estimate | LCI   | UCI   |
|-----------------|----------|-------|-------|
| ExplorR         | 96.2     | 90.8  | 101.6 |
| Anatomic Radial Head | 91.2     | 88.8  | 93.6  |
| MoPyC           | 90.2     | 84.3  | 96.1  |
| Radial Head System | 89.6     | 84.3  | 94.9  |
| Evolutive       | 88       | 81.5  | 94.4  |
| rHead           | 87.9     | 83.3  | 92.5  |
| Corin           | 87.2     | 82.5  | 91.9  |
| Solar           | 86.9     | 81.3  | 92.5  |
| Guepar          | 86.5     | 72.3  | 100.7 |
| Judet           | 86       | 82.9  | 89.1  |
| rHead RECON     | 85.3     | 78.5  | 92.1  |
| Richards        | 80       | 73.7  | 86.3  |
| **Overall**     | **88.6** | **86.6** | **90.5** |

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**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.

| Device          | Estimate | LCI   | UCI   |
|-----------------|----------|-------|-------|
| ExplorR         | 8.8      | 1.5   | 16.1  |
| Judet           | 12.9     | 6.7   | 19.1  |
| Anatomic Radial Head | 13.6     | 9.4   | 17.8  |
| Vitallium       | 13.6     | -6.9  | 34.1  |
| Evolutive       | 13.9     | 10.1  | 17.7  |
| Guepar          | 16.1     | 7.7   | 24.6  |
| Richards        | 17       | 9.6   | 24.4  |
| rHead RECON     | 18.2     | 11.3  | 25.1  |
| rHead           | 19.6     | 11.5  | 27.7  |
| MoPyC           | 24.8     | 11.4  | 38.2  |
| Solar           | 27.5     | 17.4  | 37.6  |
| **Overall**     | **15.2** | **13.1** | **17.4** |
implant loosening. This finding is consistent with the most commonly reported complications identified in the report by Agyeman et al. 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 RHA resulted in better function and reduced postoperative outcomes; however, there was 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. 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. unfastened stems. Such comparisons are currently limited to either prospective or retrospective cohort studies. In terms of fixed vs. unfastened 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. Regarding studies directly comparing fixed-stem devices with each other, they also found differences in outcomes between different devices, 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.

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