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Does radial head implant fixation affect functional outcomes? A systematic review and meta-analysis

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Background: Radial head arthroplasty is used in the treatment of nonreconstructible radial head fractures. Although traditional implants have been loosely fixed, smooth stemmed implants functioning more as spacers, modern designs have introduced press-fit, tapered implants that articulate at the capitellum with more rigidly maintained congruity. Cemented implants also use rigid initial fixation. This study was conducted to help determine which fixation method results in better functional outcomes: "fixed" or "unfixed."
Methods: A systematic review and meta-analysis was used. We identified 63 articles via 3 databases. Ten non-English or articles with insufficient text were excluded, and 17 others did not contain sufficient data or follow-up. The remaining 36 articles were qualitatively and quantitatively reviewed.
Results: We identified 36 populations, with 878 unduplicated patients: 522 fixed and 356 unfixed. Respectively, mean follow-up in months was 46.2 and 37.4. Average Mayo Elbow Performance Scores were 85.9 and 88.2 ($P = .08$). Average Disabilities of the Arm, Shoulder and Hand scores were 17.1 and 18.7 ($P = .47$). Average final flexion/extension arcs were 119.1° and 115.8° ($P = .08$). Revision rates were 7.9% and 3.1%, and complication rates were 25.5% and 13.2%. Relative risks of revision and complications for the fixed cohort were 2.48 ($P = .006$) and 1.88 ($P < 0.0001$), respectively.
Conclusions: Implant fixation type does not appear to affect functional outcomes of radial head arthroplasty. However, rigidly fixing the implant may increase the risks of revision and complications.
Level of evidence: Level IV; Systematic Review
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Keywords: Radial; head; arthroplasty; replacement; prosthesis; fixation; press-fit

Radial head arthroplasty is indicated in cases of displaced, unreconstructible radial head fractures and radial head fractures associated with elbow dislocation or significant ligamentous injury.[15] Current radial head prosthesis designs can be classified as loosely or rigidly fitting.[1,10] Loose, or "unfixed" stems, have smooth shafts and are placed in an uncemented fashion, which allows stem motion to occur within the medullary canal (Fig. 1). Press-fit, cemented, or other "fixed" stem designs intend to rigidly secure the implant within the canal of the radial neck[9,16,20] (Fig. 2).

This meta-analysis was conducted to evaluate the differences in clinical outcomes between patients receiving fixed or unfixed radial head prosthetic implants. We hypothesized

Institutional Review Board approval was not required for this review.

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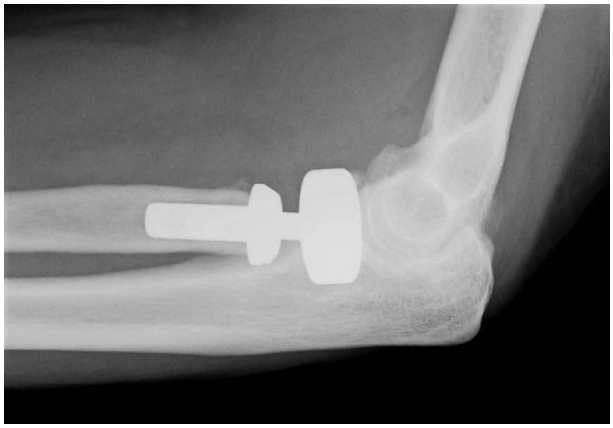

Figure 1 Radial head arthroplasty using a smooth, loosely fit stem.

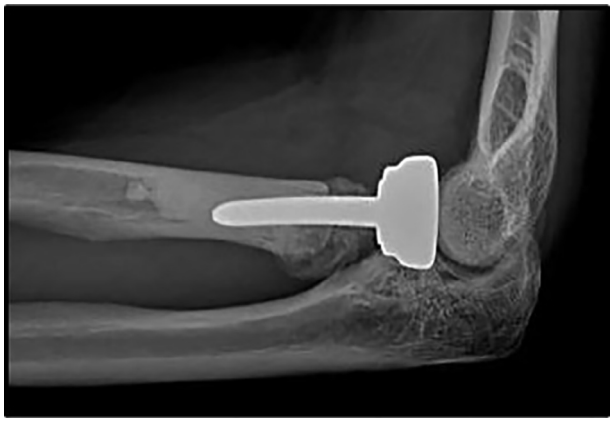

Figure 2 Radial head arthroplasty using a cemented, fixed stem.

that no significant differences would exist with respect to these parameters in patients who underwent radial head arthroplasty (Fig. 1, Fig. 2).

Materials and methods

A systematic review was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines using a PRISMA checklist (Fig. 3). Two study authors (K.D.A. and D.D.) independently conducted the search on January 22, 2017, using PubMed, Embase, and MEDLINE databases. The electronic search citation algorithm used was (radial head) AND (arthroplasty) OR (prosthesis) OR (replacement). Only full-text studies written in English and Level I to IV evidence clinical studies were eligible for inclusion into this study. All references cited in the original studies were cross-referenced to ensure they had already been reviewed.

The search identified 63 articles (43 PubMed, 20 Embase). Ten populations were excluded because the studies were not written in English or full text. An additional 17 populations were excluded due to inadequate data, including 7 studies that did not have adequate 24-month follow-up, and 10 studies having duplicate data sets or no explicit mention of implant type or fixation technique. This left 36 study groups included for analysis.

All included patients underwent radial head arthroplasty for intra-articular or intra-articular and extra-articular elbow pathology. The minimum required follow-up duration was 24 months. All patients were assigned into the fixed cohort or unfixed cohort, depending on the type of radial head arthroplasty performed. The dependent variables analyzed were derived from the dependent variables used in the respective populations. These included year of publication, country of publication, study group/hospital, level of evidence, study design, inclusion period, number of patients, number lost to follow-up, mean follow-up, and indications for surgery.

Also assessed were the following functional and clinical outcome measures. Intended functional outcome scores were Mayo Elbow Performance Score (MEPS), Disabilities of the Arm, Shoulder, and Hand (DASH), the 11-item version of the DASH, visual analog scale, 12-Item Short Form Health Survey, The American Shoulder and Elbow Surgeons Elbow Questionnaire, and the Patient Rated Elbow Evaluation. Average ranges of motion (flexion-extension and supination-pronation arcs of motion) were intended to be included for each population. Intended clinical outcomes included reoperations, revisions, and all reported complications.

All continuous data (MEPS, DASH and range of motion) were reported as standardized mean differences, where available. Dichotomous data (revision and complication rates) were reported as risk ratios. Given the inherent heterogeneity of the pooled data, random effects models were used. For all differential statistical analysis performed in this review, $P < .05$ was considered statistically significant.

Results

A total of 878 patients (fixed, 522; unfixed, 356) were identified in the 36 populations (Table S1 and Table S2). The fixed group was predominantly composed of women (278 women, 272 men), and the unfixed group was overwhelmingly male (189 men, 34 women). Mean age was 49.4 years (fixed, 49.3 years; unfixed, 49.7 years), and mean follow-up was 45.2 months (fixed, 46.2 months; unfixed, 37.4 months). The most common surgical indication was "fracture" (71.0% overall; 77.7% fixed, 54.5% unfixed). Most studies (89.0%) were retrospective articles and of Level IV evidence.

Functional outcomes were ascertained by use of the most reliably reported measures: MEPS, DASH scores, and flexion-extension arcs. Most studies reported a MEPS (84.2% overall; 81.4% fixed, 90.9% unfixed; Table I). Overall mean MEPS was 86.7 (range, 71.0-96.0), with no statistically significant difference between groups (fixed, 85.9; unfixed, 88.2; 95% confidence interval (CI), –5.8 to 1.2; $P = .08$). Overall mean DASH score was 17.3, with no statistically significant difference between groups (fixed, 17.1; unfixed, 18.7; 95% CI, –8.3 to 4.2; $P = .47$). Overall mean flexion-extension arc was 118.4°, with no statistically significant difference between groups (fixed, 119.1°; unfixed, 115.8°; 95% CI, –4.4° to 12.1°; $P = .08$).

We also assessed revision rates and complications. The overall revision rate among both groups was 5.8% (fixed, 7.9%; unfixed, 3.1%), with a significant increased risk of revision surgery when rigid fixation was used (risk ratio:

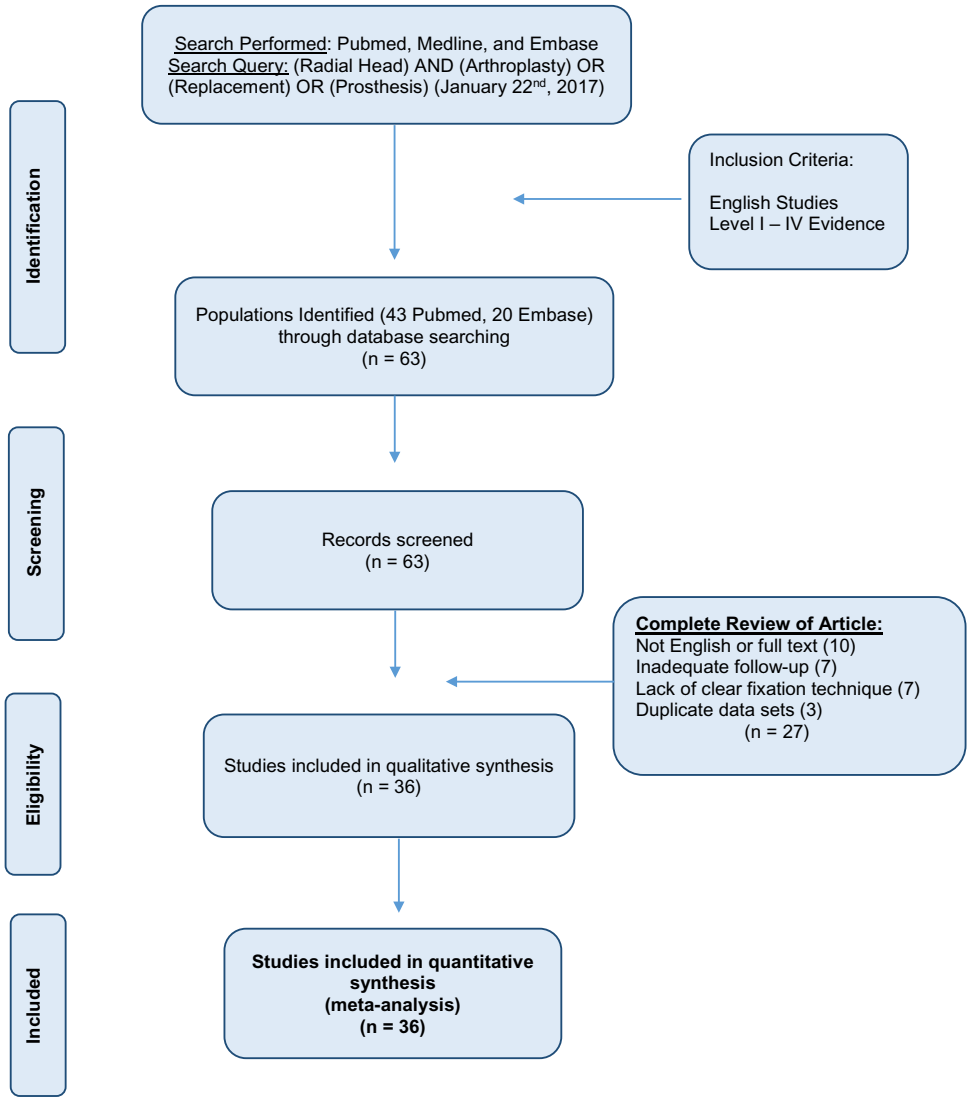

Figure 3 Representative flow chart of systematic review process using Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.

Table I Summary of statistical results of fixed vs. unfixed

Variable	Fixed	Unfixed	95% CI	*P* value
Follow-up, mo	46.2 ± 21.1	37.4 ± 20.9		
MEPS	85.9 ± 6.1	88.2 ± 3.4	−5.9 to 1.2	.084
DASH	17.1 ± 6.3	18.7 ± 5.4	−8.3 to 4.2	.473
Flexion/extension, °	119.1 ± 14.8	115.8 ± 8.2	−4.4 to12.1	.082
Revision rate (relative risk)	2.48	0.39	1.3 to 4.8	.006
Complication rate (relative risk)	1.88	0.53	1.4 to 2.6	<.001

CI, confidence interval; *MEPS*, Mayo Elbow Performance Score; *DASH*, Disabilities of the Arm and Hand.
Continuous data are presented as the mean ± standard deviation.

fixed, 2.48; unfixed, 0.39; $P = .006$). The overall complication rate was 20.2% (25.5% fixed, 13.2% unfixed), with a significant increased risk of complication when rigid fixation was used (risk ratio: fixed, 1.88; unfixed, 0.53; $P < 0.0001$). Of note, not all authors reported complications (26 of 36 populations; 72.2% of articles), and where mentioned, even fewer detailed specifics (19 of 36 populations; 52.8% of articles). The latter, more detailed articles comprised a population of 520 patients (327 fixed, 193 unfixed; 59.2% of all study patients).

The level of detail and severity provided for complications varied from study to study per the discretion of the operating surgeon. Of the complications explicitly reported for fixed populations, implant loosening was most commonly reported (28 patients [8.6%]), followed by elbow stiffness/clinically heterotopic ossification (26 patients [8.0%]), and ulnar nerve palsy (14 patients [4.3%]). For unfixed populations, elbow stiffness was the most reported complication (19 patients [9.8%]), followed by ulnar neuropathy (7 patients [3.6%]) and loosening (4 patients [2.1%]). Therefore, elbow stiffness was the overall most common complication (45 patients [8.7%]), followed by implant loosening (32 patients [6.2%]) and ulnar neuropathy (21 patients [4.0%]).

Discussion

Radial head arthroplasty is the optimal method of managing radial head fractures that are not amenable to repair.[15] Often times, implants are loosely placed smooth-stemmed devices that function more as spacers. Modern designs have introduced press-fit, tapered implants that articulate at the capitellum with more rigid congruity.[2] Similarly, cemented implants also use implant-to-bone fixation to ensure stability of the arthroplasty.[1,15] Which fixation method results in better functional outcome is currently debated,[1,2,10] and the purpose of our study is to help resolve this argument. According to our meta-analysis data, functional outcomes may not differ between the two. However, when considering revision and complication risks, reported data tend to favor a loosely placed implant.

Clinical outcomes suggest that rigidly fixed implants more often undergo revision and have a higher complication rate, and recent publications have noted similar findings.[11,12] We can postulate some potential explanations. For one, accurate sizing and positioning of press-fit stems is paramount for proper biomechanical function of the new radiocapitellar articulation.[1] Oversizing or otherwise malpositioning a fixed radial head arthroplasty may "overstuff" or malalign the radiocapitellar articulation.[1,7,13,15] Overstuffing is associated with a variety of known complications, including radial neck fractures secondary to poorly dispersed hoop stresses, chronic pain, and capitellar wear.[1,5,7,17] In these events, removal of hardware is often necessitated, thereby increasing the rates of revision and reoperation in this cohort.[17,19]

Other examples of complications that occur primarily in the fixed cohort include radial neck fracture and radial head impingement.[4,11] Radial head impingement occurs when a well-fixed radial head does not have adequate ligamentous support and subluxates posteriorly in extension. As the elbow is flexed, the rim of the subluxated radial head impinges on the apex of the convexity of the capitellum. With this "edge-binding," patients clinically experience locking, followed by a click or clunk, as the radial head reduces during flexion.[3]

The clinical significance of such complications does not appear to affect functional performance as identified by MEPS, DASH scores, and flexion extension arcs. Furthermore, certain findings, including loosening, ligamentous instability, and stiffness, present irrespective of fixation type, with inconclusive clinical impact.[7] Studies did reveal increased rates of symptomatic loosening requiring explantation for press-fit prostheses,[6,8,14] which was not necessarily the case for cementing[7,18] (Fig. 4 and Fig. 5).

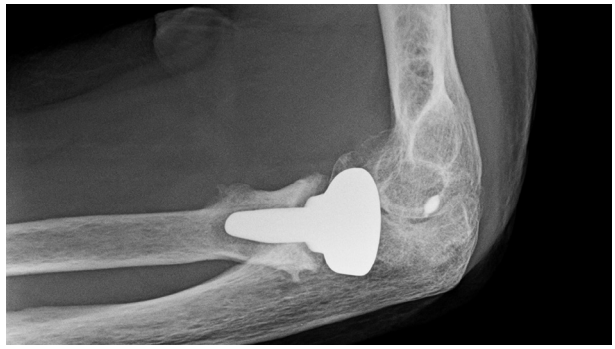

Figure 4 Press-fit radial head arthroplasty showing osteolysis, chondral degeneration, and displacement (lateral view).

Figure 5 Press-fit radial head arthroplasty showing osteolysis, chondral degeneration, and displacement (anteroposterior view).

A recently published single-institution retrospective Level III study comparing fixed (press-fit porous coated) and unfixed (smooth stemmed) cohorts did not identify any statistical difference in subjective functional outcome (DASH and MEPS).[11] The fixed implants were, however, significantly associated with increased rates of complications, namely osteolysis, as well as limitation in range of motion. They also observed a trend toward overstuffing the press-fit implants. The observations of their study parallel our findings.

As with all meta-analyses, our study is not without limitations. There is the potential for selection bias because studies may have been unintentionally omitted during the

article gathering phase. Permitting English-only, full-text articles also subjects the report to publication bias. Given the heterogeneity in data reporting—including a number of papers not reporting all parameters intended for assessment—we may have inadvertently skewed mean functional outcomes. However, in a modest effort to control for variability, we stratified each population by indication and then made calculations reciprocally for the most common indication.

Because most of the papers reported populations of "isolated" fractures, these data were selected and subsequently analyzed (Table S3). Results were largely identical to those of the full cohorts, with the exception of insignificantly increased risk of complications with rigid implant fixation. These findings should be approached with some caution because the likelihood that all included "isolated" radial head fractures were in fact isolated is low. Finally, because data interpretation ultimately depends on quality of the information gathered, our study validity may be limited by the respective levels of evidence.

Conclusion

Implant fixation type does not appear to affect functional outcomes of radial head arthroplasty. However, rigidly fixing the implant may increase the risks of revision and complications. Unfortunately, our meta-analysis was not able to identify the causative factors for these findings or to stratify complications by severity.

Disclaimer

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Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jse.2018.07.032.

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