J Shoulder Elbow Surg (2023) 32, 353–363

ELSEVIER

Journal of Shoulder and Elbow Surgery

www.elsevier.com/locate/ymse

Risk of radial head arthroplasty revision is correlated with radial head diameter: a multicenter analysis of 405 cases

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Background: Radial head arthroplasty (RHA) is commonly used for the treatment of comminuted radial head fractures. Indications as well as implant types continue to evolve. RHA has had good outcomes with midterm longevity. The literature is limited to small case series with varying implant types, and larger studies are needed to determine the optimal implant type and radial head diameter.
Methods: A retrospective analysis of RHA cases performed by 75 surgeons at 14 medical centers in an integrated health care system between 2006 and 2017 was completed. Patient demographics, comorbidities, implant type and head diameter, and indications for revision were recorded. Patients' in-person clinical visit data were recorded. Patients were also contacted via telephone at a minimum of 2 years to obtain abbreviated Disabilities of the Arm, Shoulder, and Hand questionnaire and Oxford scores. Implant survivorship was also captured within our integrated system.
Results: 405 cases met our inclusion criteria. Mean age was 51.5 ± 15.5 years (range 16-88 years) and more common in females (62%). Chart review and telephone follow-up was performed at a mean of 68.9 ± 31.5 months (range 24-146 months). Our study found that revision rate was positively correlated with increasing radial head diameter. A 26-mm head had 7.7 odds of revision compared to a size 18-mm head (95% confidence interval 1.2-150.1). More than 95% of revision cases were performed within the first 36 months of the index procedure. Obese patients had a significantly lower mean postoperative Oxford score (35.5) compared to controls (38.3) ($P = .02$). There was a significantly higher overall reoperation rate for terrible triad (18.4%) vs. isolated injuries (10.4%) ($P = .04$). There was no difference between Acumed Anatomic and Evolve radial head implants in overall reoperation, implant revision, postoperative range of motion, or patient-reported outcomes.
Conclusions: Risk of revision is directly correlated with implanted radial head diameter. There were no differences in outcomes and complications between the 2 main implants used. Individuals who did not undergo a revision by 3 years' time tend to retain the implant. Terrible triad injuries had a higher all-cause reoperation rate than isolated radial head fractures, but no difference in the rate of RHA revision. These data reinforce the practice of downsizing radial head implant diameter.
Level of evidence: Level IV; Case Series; Treatment Study

Keywords: Radial head arthroplasty; radial head replacement; revision; reoperation; terrible triad; radial head; elbow; radial head fracture

This study was approved by the Kaiser Permanente Southern California institutional review board (study no. 10597).

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https://doi.org/10.1016/j.jse.2022.09.024

Radial head fractures are the most common fractures about the elbow.[20] These fractures are more common in women and meet the criteria for fragility fractures.[6] Radial head arthroplasty (RHA) is most commonly indicated for comminuted radial head fractures that are irreparable.[9,11,21] These injuries are often associated with elbow dislocations (“terrible triad” injury)[15,27] or fractures of the ulna (Monteggia fracture).[16] RHA has been shown as superior to open reduction internal fixation in the setting of complex elbow instability and when the radial head fracture is comminuted in more than 2 pieces.[17] It can be inferred that the use of RHA will increase in the future with an aging population, and understanding the optimal indications and implants will be paramount.

Once the decision has been made to replace the radial head, the surgeon must decide on the type of implant. There is literature to support the use and survivorship of various radial head implants for each indication, but comparative data between indications or implants is lacking.[4] In addition, most series are smaller, uncontrolled, and with limited follow-up.[10,12,18] One systematic review included >700 patients from 30 different studies.[13] These large systematic reviews with many different studies also have limitations and imperfect conclusions. Another problem with many of the larger studies is that there is variation in implant design and the sample is heterogeneous. The 3 most commonly used RHA implant types are press-fit stems, loose-fitting stems, and bipolar stems.[1] Each type of implant has unique advantages and disadvantages based on design principles and indications. With the availability of numerous implants, there is no consensus on the superiority of the smooth vs. press-fit stem design.[1,26]

The goal of this study is to analyze a multicenter cohort from a single integrated health care system of >400 cases to determine survivorship, patient-reported outcomes, and risk factors for revision by indication, implanted head diameter, patient risk factors, and implant manufacturer/stem design. Our hypothesis was that there was no difference in revision or reoperation rate between the 2 main implant manufacturers.

Materials and methods

After institutional review board approval, a retrospective analysis of RHA performed by 75 surgeons at 14 medical centers in an integrated health care system between August 1, 2006, and December 31, 2017, was completed. Patients are members of a multispecialty integrated health maintenance organization with 14 medical centers that share a common electronic medical record (Epic, Verona, WI, USA), which includes the patients’ demographic data, imaging, implant data, as well as clinical and surgical notes. Radial head arthroplasties were identified through interfacility codes: “elbow arthroplasty, radial head,” “elbow replacement radial head,” and “radial head resection.” In addition, the following searches were also performed to ensure there were no miscoded cases: “elbow arthroplasty total” and “elbow arthroplasty, interpositional or fascial.”

Inclusion criteria included individuals who were skeletally mature with a radial head fracture treated with RHA. Each treating surgeon had discretion in indicating a patient for surgery and the choice of RHA implant. Patients who underwent an RHA for tumor diagnoses, Monteggia fracture dislocations, or revision surgery were excluded. Monteggia fractures were excluded because these variants are higher-energy injuries and require open reduction and internal fixation of the ulna with a plate. Many of these patients underwent reoperation for hardware removal of the plate and some with radial head revision. We did not want to confound the radial head revisions with hardware removals.

Traumatic radial head fractures were divided into 2 categories by an anonymized reviewer: isolated radial head fracture or terrible triad fracture-dislocations based on preoperative imaging and operative notes. Patient demographics, current health plan membership enrollment status, comorbidities, occupation, mechanism of injury, and fracture type were obtained from the electronic medical record. The implant record was reviewed to determine the manufacturer and size of the radial head implant. Implants were categorized as press-fit stem, loose-fitting stem or bipolar stem.

The patients in the health care system are financially disincentivized to seek medical care outside of the system, as it would require payment out of pocket. If a patient sought medical care at any of the 14 medical centers within the closed system, the data were captured, recorded, and used in this current analysis. Patient past medical history, smoking status, mental health diagnoses, and weight were obtained from the patient’s electronic medical record. Follow-up information was obtained in 3 ways. The first is the amount of clinical follow-up, which is the postoperative clinic visits patients saw a health care professional. Range of motion data were gathered from this data set. The second was the phone call follow-up, at which point abbreviated Disabilities of the Arm, Shoulder, and Hand questionnaire (QuickDASH) and validated patient-reported elbow outcome score (Oxford) were obtained. Approximately 45% of patients were available for follow-up via telephone at a minimum of 24 months. The third is the surveillance of survivorship of the implants. At time of analysis, 83% of the cohort was still enrolled in the health care system, meaning that most of the cohort was still on the insurance plan and within the health care system, and any revisions would be detected during our review.

Data analysis

The primary outcomes of interest were reoperation and revision rates based on implant manufacturer, radial head size, and patient demographic. A reoperation was defined by any surgical procedure performed after the index RHA procedure, including revision or removal of the RHA. A revision was defined as exchange or removal of the implant after the index RHA procedure. A Kaplan-Meier survivorship of radial head implants was also carried out. Data were queried in Excel (Microsoft, Redmond, WA, USA). Continuous patient characteristics were summarized with mean and standard deviation, and categorical characteristics were calculated as frequencies and percentages. All statistical analyses were conducted with SAS (version 9.4; SAS Institute, Cary, NC, USA) and statistical tests performed at an $\alpha = 0.05$ level, using 2-sided tests. Independent samples t tests were used to analyze continuous, parametric data whereas Kruskal-Wallis tests were used to compare continuous, nonparametric data. Chi-square and

Table I Patient demographics (N = 405)

Characteristic	n (%) or mean ± SD	Range
Bilateral cases	10 (2.5)	
Age, y	51.6 ± 15.5	16-88
Female sex	243 (62)	
Race		
White	207 (52.4)	
Hispanic	143 (36.2)	
Asian	25 (6.3)	
African American	25 (6.3)	
Dominant side indicator	191 (48.4)	
Occupation		
Sedentary	174 (43)	
Retired	84 (20.7)	
Light labor	57 (14.1)	
Labor	51 (12.6)	
Unemployed	25 (6.2)	
Unknown	14 (3.5)	
Mechanism of injury		
Ground-level fall	183 (45.2)	
Fall from height	146 (36)	
Sports	32 (7.9)	
Motorcycle	16 (4)	
Bike	14 (3.5)	
Altercation	10 (2.5)	
Unknown	3 (0.7)	
Arthritis	1 (0.2)	
Smoker	61 (15.1)	
Diabetes	87 (21.5)	
Obesity	159 (39.3)	
Psychiatric disease	114 (28.1)	
Injury to surgery, d	9.1 ± 10.5	0-8030
Current active members	328 (83)	
Deceased	14 (3.5)	
Time from surgery to chart review and phone call, mo	68.9 ± 31.5	24-146
Mean length of clinical follow-up, mo	9.6 ± 13.7	1-90
In-person follow-up length, n		
1-5 mo	197	
6-11 mo	75	
12-24 mo	36	
≥24 mo	37	

Fisher exact test were used to compare categorical variables. A multivariate logistic regression was used compare revision rate as a function of head size. A Kaplan-Meier survivorship curve and life table were used to analyze reoperation-free survival as a function of time.

Results

Patient demographics

Our search identified 721 cases; however, 316 were excluded because of miscoding, tumor diagnoses, or revision surgery, leaving 405 for analysis. Patient demographic information is summarized in Table I. The study cohort averaged 51.5 ± 15.5 years of age (range 16-88 years) and occurred more commonly in females (62%). Ten patients (2.5%) had bilateral RHA. The racial demographics were 52% White, 36% Hispanic, 6% Asian, and 6% African American. The dominant arm was involved in 48% of cases. There was a cross-section of sedentary occupations (43%), retirees (21%), and more active individuals. Falls from any height represented the primary mechanism of injury (81%). Mean time from injury to operative intervention was 9.1 ± 10.5 days (range 0-8030 days). In-person clinical follow-up with the treating surgeon averaged 9.6 ± 13.7 months (range 1-90 months). Chart review and telephone follow-up was at a minimum of 24 months postoperation, averaging 68.9 ± 31.5 months (range 24-146 months). Approximately 45% of patients were available for follow-up via telephone at a minimum of 24 months, but there was no difference between the 2 main manufacturer types. At the time of chart review, 83% of patients were still members of the integrated medical system, and 14 patients (3.5%) had passed away.

Outcomes based on medical comorbidities

QuickDASH and Oxford Elbow scores were analyzed for 4 comorbidities: smoking, diabetes, obesity, and history of depression or anxiety (Table II). In our cohort, 15% of patients were smokers. There was no difference between smokers and nonsmokers in Oxford (32.8 vs. 32.7, respectively, $P = .074$) or QuickDASH scores (29.4 vs. 19.6, respectively, $P = .088$). Diabetes was present in 21.5% of our patient population. There was no difference between diabetes patients and those without diabetes in Oxford (35.6 vs. 37.5, respectively, $P = .3$) or QuickDASH scores (23.4 vs. 20, respectively, $P = .27$). In our cohort, 39% of patients were considered obese (body mass index ≥30). Obese patients had a statistically significantly lower mean Oxford score (35.5) compared with controls (38.3, $P = .02$), but no significant difference in QuickDASH scores (22.1 vs. 19.1, $P = .067$). A psychiatric diagnosis was present in 28.1% of the patient cohort. There was no difference between patients with a psychiatric diagnosis and those without in Oxford (36.5 vs. 37.3, respectively, $P = .58$) or QuickDASH scores (21.3 vs. 20.5, respectively, $P = .37$).

Outcomes based on implant type

The implants used in this series include 207 Evolve (Wright Medical/Stryker, Kalamazoo, MI, USA), 155 Anatomic Radial Head (Acumed, Hillsboro, OR, USA), 16 rHead (Small Bone Innovations/Stryker, Kalamazoo, MI, USA), 11 Radial Head Replacement System (old version) (DePuy Synthes, Raynham, MA, USA), 6 Tornier Radial Head

Table II Subgroup analysis of QuickDASH and Oxford scores for smoking, diabetes, obesity and psychiatric disease

	With condition	Without condition	*P* value
Smoker, n (%)	61 (15.1)	343 (84.9)	
QuickDASH			
Mean (SD)	29.4 (26)	19.6 (19.5)	.09
Range	0-84.1	0-86.4	
Oxford			
Mean (SD)	32.8 (12.2)	37.7 (10.2)	.07
Range	7-48	2-48	
Diabetes, n (%)	87 (21.5)	318 (78.5)	
QuickDASH			
Mean (SD)	23.4 (20.9)	20.0 (20.4)	.27
Range	0-86.4	0-84.1	
Oxford			
Mean (SD)	35.6 (11.1)	37.5 (10.4)	.30
Range	2-48	6-48	
Obesity, n (%)	159 (39.3)	246 (60.7)	
QuickDASH			
Mean (SD)	22.9 (20.6)	19.1 (20.4)	.07
Range	0-86.4	0-72.7	
Oxford			
Mean (SD)	35.5 (10.48)	38.3 (10.5)	.02
Range	2-48	9-48	
Psychiatric, n (%)	114 (28.1)	291 (71.9)	
QuickDASH			
Mean (SD)	21.3 (25.4)	20.5 (18.5)	.37
Range	0-84.1	0-86.4	
Oxford			
Mean (SD)	36.5 (12.9)	37.3 (9.6)	.58
Range	6-48	2-48	

QuickDASH, Quick Disabilities of the Arm, Shoulder, and Hand; *SD*, standard deviation.

System (now Wright Medical/Stryker), 6 ExploR (Biomet Zimmer, Warsaw, IN, USA), 1 Katalyst (Smith & Nephew, Andover, MA, USA), and 3 unknown (Table III). The following analyses were made comparing only the Evolve (loose-fitting implant) and Acumed (press-fit implant) implants given the others had sample sizes too small to draw meaningful statistical conclusions.

Outcomes based on fracture type

Isolated radial head fractures

There was no difference in overall reoperation rate in 9 of 72 (12.5%) of Acumed implants vs. 7 of 81 (8.6%) of Wright implants (P = .61). There was no difference in revision rate in 4 of 72 (5.5%) of Acumed implants vs. 4 of 81 (4.9%) of Wright implants (P = .82). There was no difference between Acumed and Wright implants in terms of length of clinical follow-up (7 ± 8.9 vs. 11.1 ± 17 months, respectively, P = .44), QuickDASH (17.9 ± 19.4 vs. 16 ± 16.9, respectively, P = .72), Oxford (38.7 ± 9.9 vs. 39.3 ± 8.5, respectively, P = .95), and range of motion (Table IV). There was a difference in time from surgery to phone call follow-up (61.8 + 30 vs. 82.6 + 34.8 months, respectively, P = .01).

Terrible triad injuries

There were significantly more Wright implants used in the terrible triad cohort compared to Acumed (P = .008). There was no difference in overall reoperation rate in 5 of 32 (15.6%) of Acumed implants vs. 9 of 57 (15.8%) of Wright implants (P = .98). The reason for reoperation in the Acumed group was a manipulation under anesthesia (n = 1; 3.1%) for stiffness and in the Wright group it was resection of heterotopic ossification (n = 2; 3.5%). There was no difference in revision rate (radial head exchange or removal) in 4 of 32 (12.5%) of Acumed implants vs. 4 of 57 (7%) of Wright implants (P = .98). There was no difference between Acumed and Wright implants in terms of length of clinical follow-up (11.4 ± 11.3 vs. 9.4 ± 14 months, respectively, P = .08), QuickDASH score (25.2 ± 17.7 vs. 19.6 ± 20.3, respectively, P = .27), Oxford score (34.8 ± 10.6 vs. 37.9 ± 9.9, respectively, P = .32), and range of motion (Table V). There was no difference in time from surgery to phone call follow-up (67.5 + 26.3 vs. 71.7 + 27.8, respectively, P = .75).

Table III Number of cases based on implant and manufacturer

Number of cases	Implant name	Manufacturer
207	Evolve	Wright Medical now Stryker, Kalamazoo, MI
155	Anatomic Radial Head	Acumed, Hillsboro, OR
16	rHead	Small Bone Innovations, now Stryker, Kalamazoo, MI
11	Radial Head Replacement System (old version)	DePuy Synthes, Raynham, MA
6	Tornier Radial Head System	Tornier, now Stryker, Kalamazoo, MI
6	ExploR	Biomet Zimmer, Warsaw, IN
1	Katalyst	Smith & Nephew, Andover, MA
3	Unknown	

Isolated radial head vs. terrible triad injuries

There was a significantly higher overall reoperation rate for terrible triad (18.4%) vs. isolated injuries (10.4%, $P = .04$) and in length of clinical follow-up (10.6 + 13.3 vs. 8.5 + 13.2, respectively, $P = .02$) (Table VI). There was no difference between isolated and terrible triad injuries in the rate of removal or revision of radial head implant (5.4% vs. 8.7%, $P = .42$), time from surgery to phone call (70.6 ± 33.4 vs. 71.2 ± 28.4, $P = .88$), QuickDASH score (18.2 ± 18.8 vs. 21.1 ± 20.6, respectively, $P = .34$), Oxford score (38.3 ± 9.7 vs. 37.3 ± 10.2, respectively, $P = .5$), and range of motion.

Outcomes based on implant head size

Revision rate was positively correlated with increasing head size (Table VII). Using 18-mm head size as the reference, the odds ratio for revision was 2.0 for 20 mm (95% confidence interval [CI] 0.3-38.1), 3.1 for 22 mm (95% CI 0.6-57.4), 2.9 for 24 mm (95% CI 0.5-55.4), and 7.7 for 26 mm (95% CI 1.2-150.1). Table VIII reports the radial head size usage between years 2008 and 2017.

Survivorship analysis

Kaplan-Meier survivorship for radial head implants demonstrate that >95% of revision cases were performed within the first 36 months of the index procedure (Table IX). The life table showed a cumulative reoperation-free survival rate of 91.3%, with a 1-year survival rate of 95.1% (95% CI 93-97), a 2-year rate of 93% (95% CI 90-96), and a 3-year rate of 91% (95% CI 88-94). The Kaplan-Meier curve demonstrated an initial decline in survivorship within the first year after reoperation and plateaued after 3 years with a 4% decline in survivorship over the 12-year period (Fig. 1).

Reoperation and revisions

The most common indications for reoperation were revision (25.6%), stiffness (25.6%), hardware removal (15.4%), revision and stiffness combined (12.8%), ulnar nerve procedure (7.7%), revision of implant and ulnar nerve combined (5.1%), deep infection (5.1%), and instability (2.5%).

Discussion

RHA indications as well as the design, material composition, and methods of fixation have evolved to improve the ability to treat complex elbow pathology. There are recent systematic reviews that pool data from multiple studies to try to make conclusions about the optimal implant type and to compare complications between implants and indications.[13,26] There is substantial heterogeneity between studies and although they pool larger numbers, the power and strength of the conclusions are lacking. The purpose of our study was to improve the available data in the literature using a large database across multiple integrated centers to provide surgeons with information and help guide them when performing RHA surgery.

Emphasis on choosing a radial head diameter receives little attention in the discussion of RHA surgical techniques. One major finding of our study was the effect of the implanted radial head diameter on revision rate, which was positively correlated with increasing radial head diameter. This is an important finding because surgeons are attentive to matching the height to avoid "overstuffing" the joint but not the diameter of the radial head implant. Several studies that have evaluated methods to avoid overstuffing radial head height and have recommended placing the head height below the level of the coronoid[5] and to monitor gapping of the lateral ulnohumeral joint under fluoroscopy.[2] When it comes to deciding on the radial head diameter, the accepted technique is to match the inner articular dish of the radial head and choose the size that matches this diameter. Some surgeons may not practice this technique and choose to match the entire radius so that they can replicate the size of the bone and the cartilage. This second method may lead to an increased radial head diameter and, according to our data, put patients at risk for revision surgery, which we have shown increases significantly every 2 mm of diameter above 18 mm. With this information, it is best to undersize the radial head diameter to decrease the revision rate of RHA.

Table IV Outcomes based on implant type of isolated injury radial head replacement

	Acumed	Wright	*P* value
Number of cases	72	81	
Overall reoperation, n (%)	9 (12.5)	7 (8.6)	.61
Reoperation (nonimplant), n (%)			
Closed MUA	3 (1.4)	0 (0)	
Ulnar nerve surgery	1 (1.4)	2 (2.4)	
Débridement	0 (0)	1 (1.2)	
Irrigation and débridement	1 (1.4)	0 (0)	
Reoperation—revision/removal, n (%)	4 (5.5)	4 (4.9)	.82
Radial head removal	2 (2.8)	1 (1.2)	
Radial head revision	2 (2.8)	3 (3.7)	
Range of motion			
Extension			
Mean (SD)	14.3 (16.2)	10 (14.1)	.07
Range	−10 to 60	−10 to 62	
Flexion			
Mean (SD)	129.7 (15.46)	128.8 (12.3)	.32
Range	90-155	77-148	
Pronation			
Mean (SD)	77.1 (16.7)	80.4 (14.6)	.19
Range	20-90	10-90	
Supination			
Mean (SD)	71.2 (18.19)	73.0 (18.30)	.49
Range	15-90	−6 to 90	
Time to surgery phone call, mo			
Mean (SD)	61.8 (30)	82.6 (34.8)	.01
Range	21-131	22-146	
Length of clinical follow-up, mo			
Mean (SD)	7 (8.9)	11.1 (17)	.44
Range	0-53	1-81	
QuickDASH score			
Mean (SD)	17.9 (19.4)	16 (16.9)	.72
Range	0-84.1	0-59.1	
Oxford score			
Mean (SD)	38.7 (9.9)	39.3 (8.5)	.95
Range	7-48	18-48	

MUA, manipulation under anesthesia; *SD*, standard deviation; *QuickDASH*, Quick Disabilities of the Arm, Shoulder, and Hand.

This finding also supports the concept of a "spacer effect" where the radial head serves as a mechanical stabilizer to varus and valgus forces, as well as posterior lateral rotatory instability,[14] protecting the LUCL repair in the setting of a terrible triad.[3] In an MCL-deficient elbow, the radial head stabilizes the ulnohumeral joint in the elbow against valgus forces.[23] There is little discussion with regard to the importance of not oversizing the diameter of the RHA. It is possible that an 18-mm head may be sufficient for most patients, and the need for larger diameters is unnecessary to establish congruency, stability, and lower risk of revision when performing an RHA. Future biomechanical as well as clinical studies focusing on the optimal radial head diameter will be needed to validate this concept.

A variety of different implant types were represented in this cohort, including monopolar press-fit, loose-fit, and bipolar stems. This is similar to many of the previously published studies.[1,7,11,13,21] The 2 most commonly used implants at our institution were a press-fit monopolar or a loose-fitting monopolar stem. The design philosophy of the loose-fit stem allows the radial head and stem to find the best position in the shaft and act as a spacer block. The press-fit stems have a grit blast to allow ingrowth and have an immediate interference fit. The debate lies in the risk for revision surgery. Flinkkila et al have previously shown that a press-fit stem has more radiolucent lines in midterm follow-up indicating loosening of the stem, which later necessitated removal at an average of 11 months.[7] The numbers in that study were small, and recently there have been systemic reviews that have refuted this finding. Heijink et al[13] performed a systematic review of 727 patients from 30 studies and determined that there was no difference in revision rates among prostheses regardless of implant composition, fixation technique, or time until treatment.

Table V Characteristics of terrible triad injury radial head replacement surgery patients Acumed vs. Wright.

	Acumed	Wright	*P* value
Number of cases	32	57	.01
Overall reoperation, n (%)	5 (15.6)	9 (15.8)	.98
Reoperation (nonimplant), n (%)	1 (3)	4 (7)	.99
Resection of HO	0 (0)	1 (1.8)	
MUA	1 (3.1)	1 (1.8)	
HWR	0 (0)	1 (1.8)	
LCL repair	0 (0)	1 (1.8)	
Radial head revision/removal, n (%)	4 (12.5)	5 (8.8)	.98
Radial head removal	1 (3.1)	3 (5.3)	
Radial head revision	3 (9.4)	2 (3.5)	
Range of motion			
Extension			
Mean (SD)	12.9 (14.6)	12.2 (13.4)	.97
Range	−10 to 60	−20 to 50	
Flexion			
Mean (SD)	127.8 (12.6)	125.6 (17.9)	.93
Range	95-160	60-165	
Pronation			
Mean (SD)	74.2 (16.9)	75.5 (20.7)	.42
Range	30-90	–5 to 90	
Supination			
Mean (SD)	71.3 (16.3)	67.3 (22.8)	.77
Range	20-90	−8 to 90	
Time from surgery to phone call, mo			
Mean (SD)	67.5 (26.3)	71.7 (27.8)	.75
Range	25-106	23-130	
Length of clinical follow-up, mo			
Mean (SD)	11.4 (11.3)	9.4 (14)	.08
Range	1-52	1-90	
QuickDASH score			
Mean (SD)	25.2 (17.7)	19.6 (20.3)	.27
Range	0-54.5	0-68.2	
Oxford score			
Mean (SD)	34.8 (10.6)	37.9 (9.9)	.32
Range	11-48	16-48	

MUA, manipulation under anesthesia; *HO*, heterotopic ossification; *HWR*, hardware removal; *LCL*, lateral collateral ligament; *SD*, standard deviation; *QuickDASH*, Quick Disabilities of the Arm, Shoulder, and Hand.

The variability between studies weakens the conclusions. Our study had large numbers of press-fit monopolar stems and loose-fit monopolar stems, allowing us to perform a larger analysis between the 2 types of implants. We were able to show that there was no statistically significant difference between a press-fit stem and a loose-fit stem with regard to reoperation rates, revision rates, QuickDASH and Oxford scores, and range of motion between the 2 implant types. This was seen when compared between indications as well. Thus, our study showed that there is no advantage to recommending one implant over the other to obtain an optimal result with minimal complications and low risk for another surgery.

Our study echoes what has been previously shown in the literature in terms of terrible triad injuries having a higher reoperation rate compared to isolated radial head fractures.[22] Given that the revision due to implant factors was the same, reoperation is likely due to the complexity of the soft tissue injury. The most common indication for reoperation was stiffness, which is multifactorial in traumatic elbow injury.

In terms of demographics, the cohort is representative of the US urban population. The overall self-reported percentage of Whites in the United States was 61% and Hispanics 15% in the 2010 US census, whereas our cohort was 52% and 36%, respectively. The average age, gender, and mechanism closely mirrors that in the largest reports in the literature such as a 2016 report of 55 patients by Marsh et al[21] from Ontario, Canada. In terms of medical comorbidities, the study population correlated with recent US Centers for Disease Control prevalence reports of 39% obesity, 15% smoking, but had double the percentage of diabetic patients (20% in the study cohort, and 11% in the general US population). We were able to perform a subgroup analysis of outcome by medical comorbidities. This was

Table VI Characteristics of isolated vs. terrible triad injury radial head replacements

	Isolated injury (n = 222)	Terrible triad Injury (n = 103)	*P* value
Overall reoperation, n (%)	23 (10.4)	19 (18.4)	.04
Reoperation—revision/removal, n (%)	12 (5.4)	9 (8.7)	.26
Extension			
Mean (SD)	13 (16)	12.9 (13)	.42
Range	−10 to 80	−20 to 60	
Flexion			
Mean (SD)	129 (14)	126 (16)	.13
Range	120-140	120-135	
Pronation			
Mean (SD)	78 (17)	76 (18)	.35
Range	0-94	−5 to 90	
Supination			
Mean (SD)	71 (19)	69.2 (19.67)	.29
Range	−6 to 90	−8 to 90	
Time from surgery to phone call, mo			
Mean (SD)	70.6 (33.4)	71.2 (28.4)	.88
Range	20-146	23-136	
Length of clinical follow-up, mo			
Mean (SD)	8.5 (13.2)	10.6 (13.3)	.02
Range	0-81	1-90	
QuickDASH score			
Mean (SD)	18.2 (18.8)	21.1 (20.6)	.34
Range	0-84.1	0-77.3	
Oxford score			
Mean (SD)	38.3 (9.7)	37.3 (10.2)	.50
Range	7-48	11-48	

	Isolated injury (n = 222)	Terrible triad injury (n = 103)
Reoperation, n (%)	23 (10.4)	19 (18.4)
Indications for reoperation/revision		
Hardware removal	1 (0.5)	1 (1)
Lateral collateral ligament repair	0 (0)	1 (1)
MUA	1 (0.5)	3 (2.9)
Ulnar nerve procedure	3 (1.5)	0 (0)
Débridement, anterior capsulectomy	1 (0.5)	0 (0)
Débridement, capsulectomy,	1 (0.5)	0 (0)
Heterotopic ossification resection	1 (0.5)	1 (1)
Irrigation and débridement	1 (0.5)	0 (0)
Excision of heterotopic bone with ulnar nerve procedure	0 (0)	1 (1)
Proximal radioulnar synostosis excision and elbow	1 (0.5)	0 (0)
Radial head removal	3 (1.4)	4 (3.9)
Radial head removal, irrigation and débridement, wound VAC application	0 (0)	1 (1)
Radial head removal and lateral ligament repair	1 (0.5)	0 (0)
Radial head removal (disassociation)	1 (0.5)	0 (0)
Radial head removal, contracture release	1 (0.5)	1 (1)
Radial head revision	0 (0)	1 (1)
Radial head revision, resection of HO	1 (0.5)	1 (1)
Radial head revision and LCL repair/reconstruction	3 (1.4)	1 (1)
Radial head revision, capsulectomy	2 (0.9)	2 (1.9)
Radial head revision, posterior interosseous nerve release	1 (0.5)	0 (0)
Radial head revision, ulnar nerve release	0 (0)	1 (1)

SD, standard deviation; *QuickDASH*, Quick Disabilities of the Arm, Shoulder, and Hand; *MUA*, manipulation under anesthesia; *VAC*, vacuum-assisted closure; *HO*, heterotopic ossification; *LCL*, lateral collateral ligament.

Table VII Odds ratio for revision rate and head size relative to an 18-mm radial head diameter

	Radial head diameter, mm				
	18	20	22	24	26
No revision, n	36	92	117	75	28
Revision, n	1	5	10	6	6
% revision	2.7	5.2	7.9	7.4	17.7
Odds ratio (relative to 18 mm)	N/A	2	3.1	2.9	7.7
95% confidence interval		0.3, 38.1	0.6, 57.4	0.5, 55.4	1.2, 150.1

N/A, not applicable.

Table VIII Radial head size usage between years 2008 and 2017

Year	Total cases (n)	Radial head size (mm) by year											
		18		20		22		24		26		28	
		n	%	n	%	n	%	n	%	n	%	n	%
2008	21	0	0.0	10	47.6	3	14.3	5	23.8	3	14.3	0	0.0
2009	30	5	16.7	7	23.3	10	33.3	5	16.7	2	6.7	1	3.3
2010	40	4	10.0	8	20.0	12	30.0	11	27.5	4	10.0	1	2.5
2011	26	2	7.7	3	11.5	12	46.2	5	19.2	3	11.5	1	3.8
2012	45	4	8.9	12	26.7	10	22.2	11	24.4	7	15.6	1	2.2
2013	60	5	8.3	14	23.3	21	35.0	16	26.7	3	5.0	1	1.7
2014	30	1	3.3	8	26.7	12	40.0	6	20.0	3	10.0	0	0.0
2015	29	5	17.2	6	20.7	12	41.4	4	13.8	2	6.9	0	0.0
2016	36	4	11.1	9	25.0	15	41.7	4	11.1	4	11.1	0	0.0
2017	56	7	12.5	17	30.4	19	33.9	11	19.6	2	3.6	0	0.0
Total	373	36		94		126		78		33		5	

Table IX Life table for reoperation-free survival over the years

Time after operation	Survival, %	95% confidence interval
1 y	95.1	92.9-97.3
2 y	93	90.4-95.7
3 y	91.3	88.4-94.4

lacking in the largest series of radial head survivorship in the literature.[18,19,21] This is likely secondary to lack of power, insufficient capture of these risk factors, or lack of these particular risk factors in the respective study cohorts. Of the analyzed factors, we found a significant negative impact of obesity on Oxford scores. Obesity is a risk factor for pain and poorer outcomes after total hip arthroplasty[25] and total knee arthroplasty.[8] In a retrospective review of total elbow arthroplasty, obese patients had 3 times higher odds of secondary surgery at 2 years to remove the implant vs. nonobese controls.[24] It is possible that obese individuals have a more challenging technical aspect, and/or put greater mechanical stress on their radial head implants and articulating cartilage surfaces during activities of daily living, contributing to poorer outcomes in our cohort. This is an important finding to counsel patients with obesity and manage outcome expectations. Our study failed to show any difference related to smoking or presence of diabetes, which are usually the most commonly implicated comorbidities.

In terms of surgery-free survivorship, we found an approximate 10% secondary surgery rate over the study period, concentrated in the first 3 years postoperation. Clinical follow-up is most important in the first 3 years postoperation, as individuals who did not have an adverse outcome in the first 3 years tended to not require surgical intervention subsequently. This finding is consistent with past reports on survivorship and the timing of secondary surgery after RHR. In 2017, Laumonerie reported 8-year results on 77 bipolar RHR and found an unacceptably high 40% reoperation rate, but as in the current study concentrated in the first 36 months after the index procedure. Cristofaro et al[4] retrospectively reviewed 119 cases of RHR for unstable elbow injuries with concomitant radial head fracture and reported a 30% reoperation rate, peaking at 12

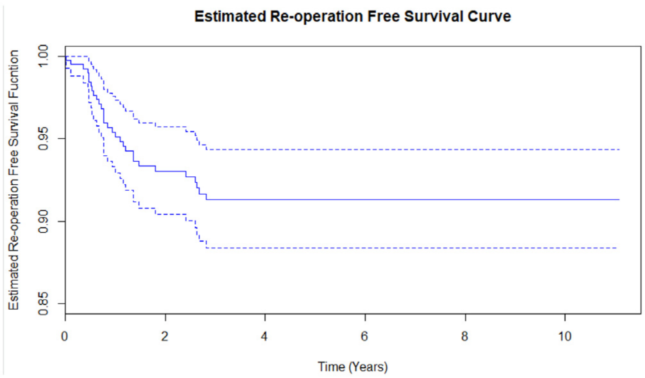

Figure 1 Kaplan-Meier reoperation-free survivorship curve for radial head arthroplasty surgery patients (N = 405).

months after the index procedure, with revision diagnosis closely matching our cohort.

Our study had limitations because of its retrospective nature. We lacked patient-reported outcomes on 55% of the cohort. Although these gaps were controlled with statistical methodology, it may bias outcome if the missing patients had inferior outcomes to those reporting. It did not affect survivorship or reoperation endpoints, as those were documented in the medical record and were able to be captured within our integrated health care system. Second, radiographs were not reviewed for loosening, lysis, or other implant-related issues, although the indication for reoperation is generally a clinical or functional one rather than radiographic. Radiographs were not consistently obtained, especially after the patient's last visit with a health care provider, and thus would not provide any meaningful data. In addition, surgeons made independent clinical decisions. Although this is more generalizable, we did not have uniform surgical indications. Because this is a retrospective cohort study, another possible confounder was due to reporting and recall bias. A limitation of this study is that the increase in family-wise error rate from multiple comparisons was not controlled. This study is preliminary, and we encourage replication.

Despite these limitations, we had the largest number of RHA patients in any single clinical study as of this writing. In addition, the patient population of the institution is completely insured and "captured," meaning that procedures were not denied based on insurance status, and the patients were required to have their procedures performed at one of the study institutions. Furthermore, dozens of surgeons contributed to this series, making it very generalizable to the community.

Conclusions

Our study has several significant findings. First, the risk of revision is highly correlated with increasing radial head diameter. Second, complications and reoperations postimplantation is directly dependent on concomitant ligamentous and bony injuries at the time of index procedure, not the radial head implant. Third, smoking, diabetes, or history of depression or anxiety did not have a negative effect on outcome, but obese patients had worse Oxford scores. Lastly, individuals that did not have a revision of the radial head by 3 years' time tend to retain the implant going forward. Knowledge of these findings might guide surgeons in treating these injuries and may help counsel patients accordingly.

Disclaimers:

Funding: No funding was disclosed by the authors.
Conflicts of interest: Raffy Mirzayan received honorarium and research grants from Arthrex not related to this manuscript. The other authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

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