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ORIGINAL ARTICLE

Radial head replacement with a bipolar system: an average 10-year follow-up

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Background: We report the long-term results of a cohort of patients after radial head replacement with a bipolar design and a smooth cementless stem at a mean follow-up of 10.4 years.
Methods: Of 17 possible patients from a previous minimum 2-year follow-up study, 16 were available for review. Patients were assessed using clinical and radiographic examination and with standardized outcome measures. Range of motion, stability, and radiographic evaluation of implant loosening and joint degeneration were assessed. Comparisons were performed using the Wilcoxon signed rank test for unequal groups.
Results: The average follow-up was 10.5 years (range, 8.5-12 years). The median visual analog scale was 1 (range, 0-5), Minnesota Elbow Performance Index was 93 (range, 70-100), and the Disabilities of the Arm, Shoulder and Hand was 7.5 (range, 0-53). Range of motion was decreased on the operative side compared with the nonoperative side for flexion/extension ($P = .005$) and pronation/supination ($P = .015$). Grip strength was decreased on the affected side ($P = .045$). No patients had elbow instability. Significant arthritic changes developed in 2 patients at the ulnohumeral joint. The median cantilever quotient was 0.4 (range, 0.30-0.50). Osteolysis in zones 1 to 7 was found in all but 2 patients. The median stem radiolucency was 0.5 mm (range, 0.2-0.9 mm). No reoperations occurred since our previous report. Implant survival in this cohort was 97%.
Conclusion: Bipolar radial head prosthesis with a smooth cementless stem effectively restores elbow stability and function after comminuted radial head fractures with or without concomitant elbow instability. Our study demonstrates excellent long-term implant survival.
Level of evidence: Level IV; Case Series; Treatment Study

Keywords: radial head; bipolar; radial head fracture; outcomes; radial head arthroplasty; elbow reconstruction

A number of radial head replacement (RHR) prostheses are currently available and approved by the United States Food and Drug Administration for the treatment of radial head fractures. Failure of early silicone implants via fragmentation[21,23] led to the development of metallic prostheses. Most of these were nonanatomic monobloc implants. These monobloc implants have been reported to have difficulty restoring the native biomechanics of the elbow given the complexity of the proximal radioulnar and radiocapitellar joints, including the natural 10° to 15° offset at the radial neck and the elliptical shape of the radial head. Bipolar radial head implants were developed to enhance joint congruity by allowing the head to pivot in response to the capitellum as it proceeds through an arc of motion. Although proponents argue

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that the bipolar design more accurately restores native elbow and forearm kinematics and decrease contact stresses,[22] opponents voice concern for potential joint instability resulting from the loss of a fixed concavity-convexity match that unipolar implants provide.[5,6]

Early results using the Katalyst (Integra, Plainsboro, NJ, USA) bipolar implant, with a minimum 2-year follow-up (mean, 34 months), have been reported. Short-term patient-reported outcomes were encouraging in a cohort of 29 patients (30 implants), with a 0% incidence of hardware migration and 97% implant survival.[23] We report the long-term clinical outcomes for patients who underwent RHR using this same implant. We hypothesized that patients would not experience significant functional or radiographic deterioration over this time period.

Materials and methods

We attempted to repeat the 2-institution format of the first study; however, the investigator from 1 institution had departed so there was no access to the records. Thus, only the patients from 1 of the 2 institutions could be monitored. All patients agreed to participate with an understanding of the research protocol. There were 19 consecutive patients (19 implants) enrolled into our initial study at that single center, having undergone RHR with the bipolar implant between March 2004 and October 2006. The Katalyst Radial Head is a bipolar implant with a smooth cementless stem and 15° of freedom in all directions from the neutral position. The adjustable stem design allows the surgeon to adjust the length of the construct in situ.

At the time of surgery, the radial head was resected in all patients and replaced with a bipolar radial head arthroplasty implant. This was due to an acute fracture or fracture-dislocation resulting in an irreparable radial head in 15 patients. Four patients received a radial head arthroplasty for post-traumatic arthritis or in the setting of elbow reconstruction indicated by failed previous surgery at other institutions (Table I). Surgical technique and postoperative protocols were performed as described previously.[23]

Table I Patient-specific injuries and involved structures

Patient	Injuries
1	Radiocapitellar and proximal radioulnar arthritis, ulnar nonunion, elbow contracture
2	Radial head fracture
3	Radial head fracture, ulnohumeral dislocation, LCL rupture, coronoid shear fracture
4	Radial head fracture, ulnohumeral dislocation, coronoid fracture
5	Radial head fracture, post-traumatic radiocapitellar arthritis
6	Radial head fracture, LCL rupture
7	Radial head fracture, LCL rupture, ulnohumeral dislocation
8	Radial head fracture, ulnohumeral dislocation
9	Radial head fracture, LCL rupture, ulnohumeral dislocation, distal radius fracture
10	Radial head fracture, ulnohumeral dislocation, coronoid fracture, MCL/LCL rupture
11	Radial head/neck fracture, olecranon fracture, LCL rupture, radiocapitellar arthritis
12	Radial head/neck fracture, LCL rupture, capitellar OCD
13	Radial head fracture, LCL rupture
14	Radial head fracture, coronoid fracture, ulnohumeral dislocation, LCL rupture
15	Radial head fracture, posterior interosseous nerve palsy
16	Radial head fracture, coronoid fracture, LCL rupture
17	Radial head fracture, proximal ulnar fracture, distal humeral nonunion
18	Radial head fracture, radiocapitellar arthritis, stiffness, ulnohumeral dislocation
19	Radial head fracture, LCL rupture, coronoid fracture, capitellar OCD

LCL, lateral collateral ligament; *MCL*, medial collateral ligament; *OCD*, osteochondritis dissecans.

Patients were seen solely for the purposes of this study by an independent examiner. Each completed a Mayo Elbow Performance Index (MEPI), a 10-point visual analog scale (VAS) pain score (0 = no pain; 10 = severe pain), and a Disabilities of the Arm, Shoulder and Hand (DASH) survey. Elbow and forearm range of motion was measured with a standard goniometer, and grip strength was measured using a Jamar dynamometer (Sammons Preston, Inc., Bolingbrook, IL, USA). Elbow stability was assessed by physical examination.

Standardized neutral rotation anteroposterior, oblique, and lateral radiographs of the affected elbow were obtained (Figs 1 and 2). Radiographs were analyzed twice, with recordings made of any lucency about the prosthetic stem,[8,18] heterotopic bone formation,[12] ratio of exposed prosthesis to total implant length,[20] and joint degeneration.[3] Periprosthetic osteolysis was divided into 7 zones based on the lateral radiographic images as described by Popovic et al.[18] Stem lucency, as described by Fehringer et al,[8] was measured using orthogonal views of the elbow to calculate the maximum lucency between the implant stem and endosteal bone.

Heterotopic bone formation was graded according to the system described by Hastings and Graham.[12] The cantilever quotient, which measures the percentage of prosthesis not contained within the bone, was measured as the length of the exposed portion of the implant divided by the total length of the implant using the lateral radiograph.[20] A biomechanical study demonstrated that a value less than 0.35 confers stability, suggesting a high likelihood of achieving bone ingrowth. In contrast, implants with a quotient of 0.6 or greater were unstable and at high risk for failing to ingrow. Values between 0.35 and 0.6 were considered at moderate risk of failing to attain bone ingrowth.[20]

Joint degeneration was graded using the system described by Broberg and Morrey.[3] The median stem lucency and cantilever quotient values were not originally calculated as part of our minimum 2-year follow-up study. To optimize the comparison with the 10-year data, we retrospectively reviewed the 2-year radiographs and performed these same calculations.

Statistical comparisons of continuous outcomes were made using the Wilcoxon signed rank test for non-normally distributed groups. In accordance with this, median values are reported rather than mean values to minimize bias of the summary statistic (means are

Figure 1 Anteroposterior radiograph of the left elbow taken at the final follow-up. Note the stable bipolar radial head component with the stem aligned with the intramedullary canal of the radius.

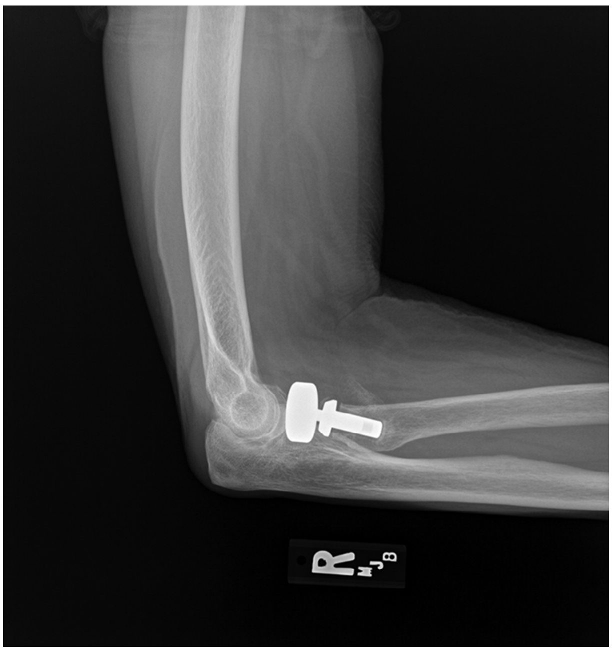

Figure 2 Lateral radiograph of the left elbow taken at the final follow-up. Note the stable bipolar radial head component with the stem aligned with the intramedullary canal of the radius.

inferior to medians in the description of non-normally distributed data because they are subject to skewing toward the side of the data with the longer tail). The level of significance was set to $P < .05$, and all tests were 2 tailed.

Results

Clinical outcomes

At an average of 10.5 years (range, 8.5-12 years) after surgery, 16 of 17 possible patients from the previous minimum 2-year follow-up study were available for review. Of the original 19 patients with well-functioning implants, 2 had died and 1 was lost to follow-up.

Clinical outcomes are presented in Table II. The median VAS was 1 (range, 0-5), the median DASH score was 7.5 (range, 0-53), and the median MEPI score was 93 (range, 70-100). Comparisons to our prior study can be found in Table III. As assessed by the MEPI, there were 8 excellent, 7 good, 1 fair, and 0 poor results. Arcs of motion were decreased on the operative side vs. the unaffected limb for flexion/extension (130° [range, 115°-140°] vs. 140° [range, 122°-150°]; $P = .005$), pronation (65° [range, 45°-75°] vs. 70° [range, 60°-85°]; $P = .015$), supination (80° [range, 5°-85°] vs. 85° [range, 65°-85°]; $P = .015$), and pronation/supination (140° [range, 80°-155°] vs. 150° [range, 145°-155]; $P = .009$). Grip strength was also diminished (36 kg [range, 9-51 kg] vs. 39 kg [range, 14-60 kg]; $P = .045$). Comparisons to our prior study revealed no differences in pain/functional scores or range of motion between 2-year and 10-year follow-up studies ($P > .05$, Table II). Grip strength was not assessed in the first study, so no comparisons could be made. No elbow instability was found. Family members of the 2 deceased patients stated the patients' elbows were well functioning at the time of death.

There were 3 patients who underwent reoperation within 1 year for stiffness and 1 patient whose implant was revised at 14 days for instability secondary to implant undersizing and subsidence. When only the revised patients were analyzed, the VAS, MEPI, and DASH scores were not statistically different compared with the nonrevised population ($P > .05$). No patients underwent reoperation between the time of data collection for the previous report and that of this report.

Radiographic outcomes

Significant arthritic changes (Broberg grade 3) developed in 2 patients (13%) at the ulnohumeral joint (Fig. 3). This differs from our prior investigation where no patients had grade 3 changes and only 1 patient had grade 2 degenerative changes. These patients with advanced degenerative changes interestingly reported VAS of 0 and 1 with MEPI of 100 and DASH of 9.5 and 17.5, inferring favorable clinical outcomes despite the development of radiographic arthritic changes.

Limited heterotopic ossification (HO; Hastings grade I) was demonstrated in 8 patients (50%), with most of the ectopic bone formation occurring near the anterior and lateral margins of the radial neck. However, there was no evidence of HO progression in these patients since our prior study. These 8 patients were originally indicated for arthroplasty secondary to trauma. One patient developed a functional limitation in

Table II Clinic and radiographic comparisons

Variable	10-year follow-up	2-year follow-up	*P* value*
	Median (range)	Median (range)	
Clinical data			
Visual analog scale	1 (0-5)	2 (0-5)	.065
MEPI	93 (70-100)	95 (70-100)	.928
DASH	7.5 (0-53)	11 (0-53)	.437
Flexion/extension arc, °	130 (115-140)	138 (120-150)	.385
Pronation/supination arc, °	140 (80-155)	135 (105-155)	.664
Radiographic data			
Cantilever quotient	0.4 (0.3-0.5)	0.4 (0.3-0.5)	.42
Stem radiolucency	0.5 (0.2-0.9)	0.5 (0.2-1.0)	.61

MEPI, Mayo Elbow Performance Index; *DASH*, Disabilities of the Arm, Shoulder, and Hand.
* $P < .05$ denotes statistical significance.

Table III Clinical measures and outcomes at final follow-up

Measurements and outcomes	Range of motion and scores	*P* value*
	Mean ± SD	
Flexion		.179
Injured elbow, °	140 ± 6	
Normal elbow, °	140 ± 6	
Extension		.002
Injured elbow, °	10 ± 8	
Normal elbow, °	0 ± 3	
Elbow arc of motion		.005
Injured elbow, °	130 ± 8	
Normal elbow, °	140 ± 6	
Supination		.046
Injured elbow, °	80 ± 21	
Normal elbow, °	85 ± 6	
Pronation		.032
Injured elbow, °	65 ± 9	
Normal elbow, °	70 ± 8	
Forearm arc of motion		.024
Injured elbow, °	140 ± 22	
Normal elbow, °	150 ± 7	
Grip		.045
Injured elbow, kg	36 ± 13	
Normal elbow, kg	39 ± 15	
Visual analog scale	1 ± 1	–
MEPI	93 ± 9	–
DASH	8 ± 12	–

SD, standard deviation; *MEPI*, Mayo Elbow Performance Index; *DASH*, Disability of the Arm, Shoulder and Hand questionnaire.
* $P < .05$ indicates statistical significance.

pronation/supination in the setting of HO (Hastings grade IIB). The median cantilever quotient was 0.4 (range, 0.3-0.5). This result closely resembles our minimum 2-year follow-up radiographs, which demonstrated a median cantilever quotient of 0.4 (range, 0.3-0.5, $P = .42$).

Osteolysis in zones 1 to 7 was found in all but 2 patients, who demonstrated osteolysis in zones 4 to 7, and the median stem radiolucency was 0.5 mm (range, 0.2-0.9 mm). No evidence of significant, progressive radiolucency was found compared with our prior study (median, 0.4; range, 0.2-1.0; $P = .61$). There were no cystic lesions suggestive of advanced polyethylene wear.

Discussion

RHR has been shown to restore elbow and forearm kinematics while preventing longitudinal forearm instability.[1,3,17] We report favorable clinical and radiographic results at a mean follow-up of more than 10 years for patients who underwent an RHR using a bipolar prosthesis with a smooth stem and a metallic head.

Many radial head implant designs have shown satisfactory short-term to midterm clinical efficacy, with the longest reported mean follow-up studies nearing 10 years.[2,4,7,9,15,18,23] The current study demonstrated good to excellent MEPI scores in 15 patients (94%), with 1 patient reporting a fair outcome and no patients reporting a poor outcome. With the exception of 1 patient, no patients reported a VAS greater than 3 or a DASH score above 22. These findings are consistent with our previous multicenter study evaluating this implant with a minimum 2-year follow-up that included the current study's patient cohort.[23] The interval period revealed no additional revision procedures or functional deterioration in this patient population. Similar good to excellent clinical results were found in 3 recent midterm follow-up investigations for other implant designs with both smooth-cemented and press-fit stems.[13-15] However, press-fit stems were found to have a higher implant revision rate at 11%.[14]

Grip strength was on average 4 kg weaker in the operative limb. Elbow range of motion in the affected limb was decreased by a mean of 7° and forearm rotation by a mean of 14° compared with the unaffected limb. These were shown to be statistically significant but may not be clinically significant and are consistent with prior investigations.[9,15,23]

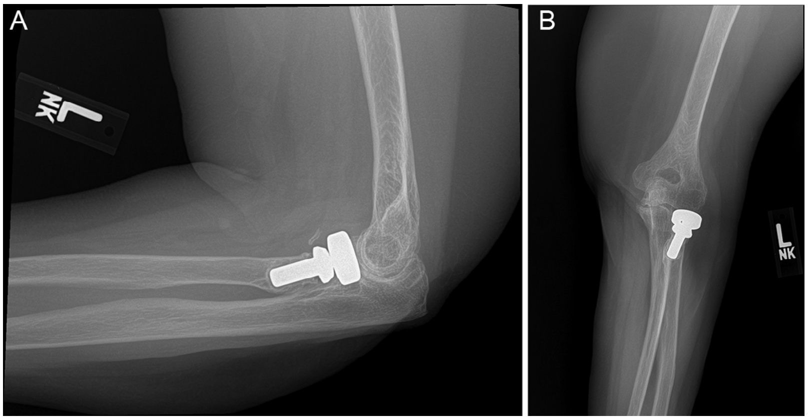

Figure 3 (**A**) Anteroposterior and (**B**) lateral elbow radiographs at final follow-up show moderate (Broberg grade III) degenerative changes at the ulnohumeral joint.

Furthermore, the combined flexion-extension and pronation-supination arcs of motion were within the functional ranges for all patients.[16]

Substantial forearm range of motion limitation secondary to HO in the setting of RHR has been reported; however, only 1 patient (6%) in our series developed a functional limitation secondary to HO in pronation/supination.[2,4,12,15,23] Patients in our cohort received prophylaxis with indomethacin (75 mg/d) for 3 weeks. Although HO prophylaxis is controversial, this may have contributed to the relatively low rate seen in this study.

Significant arthritic changes (Broberg and Morrey grade 3) were seen in 2 patients (13%) compared to 0% of the cohort at a minimum 2-year follow-up.[23] Evidence of mild-moderate arthritic change was seen in 8 patients (50%). However, radiographic degenerative changes were not correlated with poorer clinical outcomes, and similar rates of arthritic progression have been reported in other investigations.[2,4,15] Whether the joint degeneration develops secondary to the inciting injury or altered joint mechanics remains controversial.[2] Regardless, the development of severe, symptomatic elbow arthritis at 10 years after RHR did not occur in our cohort.

Popovic et al[18] reported radiographic outcomes of cemented smooth-stemmed, metallic head bipolar devices at an 8.4-year mean follow-up, finding a high incidence of progressive radiolucency at the bone-cement interface. With their zone-based classification system, they reported 16 patients (31%) experiencing progressive radiolucency over time. This classification system does not aid itself particularly well to statistical comparison because these figures are purely descriptive in nature. Nevertheless, the group reported no known clinical implications or need for implant revision despite the changes seen.

We observed radiolucency in Popovic zones 1 to 7 in all but 2 patients, who still demonstrated radiolucency in zones 4 to 7. Lucency around a smooth cementless stem is expected to some degree and should not be of concern if there is minimal progression on serial radiographs. When the objective radiographic parameters of median stem radiolucency and median cantilever quotient were compared, there was no significant difference in lucency around the stem at final follow-up compared with our minimum 2-year outcome study.

Our median cantilever quotient was in the intermediate risk category for loosening based on the study by Shukla et al.[20] This study notably used a porous-coated stem implant, and so the classification system may not be appropriate for our smooth-stemmed implant. Some radiolucency is to be expected for a smooth stem design, even on initial postoperative radiographs.

There is evidence that nonprogressive radiolucency does not correlate with poor clinical results, particularly for smooth-stemmed implants. A recent midterm follow-up investigation evaluating the results of a modular smooth stem implant also reported high rates of stem lucency without evidence of functional deterioration or clinical consequences.[15] Two other independent studies quantified stem radiolucency for smooth-stemmed RHR. They suggested that radiolucent lines are likely to occur in nearly all patients with a RHR. They also concluded that no correlation can be made between the degree of lucency or poor function.[2,8] However, Fehringer et al[8] reported variable severity of proximal radial forearm pain in two-thirds of their patients after RHR. Our findings suggest that stem lucency on radiographs does not result in functional deterioration at a mean of 10 years. Further clinical investigation with very long-term follow-up would be helpful to confirm these results.

Implant survival at a mean of 10 years was 97%. One patient was revised 14 days after the index procedure for instability secondary to implant undersizing and subsidence. This should be attributed to surgeon error and not implant design. Implant survival in our study compares favorably to RHR investigations with a minimum follow-up of at least 5 years.[4,10,15,18,19] The superiority of a bipolar vs. monopolar design has not been firmly established. Some have argued that the bipolar design provides more accurate restoration of radiocapitellar tracking, with greater contact area and less point loading than a fixed monopolar design.

Biomechanical superiority of bipolar vs. monopolar implants remains a topic of debate in both the clinical and laboratory settings,[2,6,11,22,23] with some authors demonstrating improved stability of a monopolar design attributable to the fixed concavity-convexity match of the radiocapitellar joint that can resist translation forces better than a bipolar design.[5,6] However, in the setting of an intact or an appropriately repaired lateral collateral ligament complex, this increased risk of instability with a bipolar design may not translate into clinically relevant joint instability. No instances of elbow instability were reported in this series with the exception of the 1 technical failure that was revised at 2 weeks, and no additional cases were seen in our first report either, supporting prior biomechanical reports that bipolar implants result in a low incidence of posterolateral instability and restore physiologic radiocapitellar alignment and tracking. However, potential complications unique to the bipolar design, such as implant dissociation and polyethylene-induced osteolysis, have been described but were not witnessed in this study.[11]

This study has several limitations. First, the study is retrospective with a small sample size. However, patient follow-up was excellent in our cohort (95%). Because of the tertiary referral nature of our practice, our study population may not represent a typical population seen by the average orthopedic surgeon. The variability in injury mechanism, associated injuries, severity, and repairs must also be taken into account because these may lead to differences in patient outcomes.

Conclusion

At a mean of approximately 10 years, a bipolar radial head prosthesis with a smooth stem demonstrated excellent long-term implant survival and effective restoration of elbow stability and functionality after comminuted radial head fractures. No substantial radiographic or clinical deterioration was noted between a 2-year and 10-year outcome evaluation in the same patient cohort, with the exception of a 13% incidence of radiographic arthritis progression that was not present in the earlier report. This is the longest-term follow-up study of a smooth-stemmed, cementless, bipolar radial head replacements in the literature to date.

Disclaimer

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