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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]

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

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.