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A radial head prosthesis that aligns with the forearm axis of rotation: a retrospective multicenter study

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ABSTRACT

Background: Advancements in technique and devices and a better understanding of forearm kinematics have contributed to the improvement in outcomes following radial head arthroplasty. The results of radial head arthroplasty depend on the inherent variability of the proximal radial anatomy and on the subsequent difficulties in attaining anatomic positioning of the prosthesis. A monobloc prosthesis with an anatomical head that is aligned with the patient's axis of forearm rotation has been recently introduced. We report the clinical and radiographic outcomes for patients across multiple centers who received this radial head implant with a minimum of 2-year follow-up.

Methods: This was a multi-institution retrospective follow-up including 6 centers and multiple surgeons. A total of 114 cases were performed prior to July 20, 2019, of which 52 (46%) responded to request for follow-up. Data collected included Mayo Elbow Performance Score, Disabilities of the Arm, Shoulder and Hand scores, visual analog scale (VAS) for pain, major complications, and reoperations. Major complications were defined as any prosthesis-related event which may or may not have required reoperation.

Results: The mean Mayo Elbow Performance Score was 87.0 (range, 55-100), with 46% (24/52) scoring a 100. The mean VAS for pain at rest was 0.9 (range, 0-10), and the mean VAS for pain while unscrewing a bottle cap was 1.9 (range, 0-10). The mean Disabilities of the Arm, Shoulder and Hand score was 19.6 (range, 0-88.6). We recorded a total of 4 major complications, 3 of which required reoperations, for a rate of 7.6% and 5.7%, respectively.

The University of New Mexico Health Sciences Office of Research Human Research Protections Program approved this study (IRB: #20-447).
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Discussion: The current results, collected from 6 institutions and multiple surgeons, are comparable to those of other similar series for radial head prostheses. Our series had lower rates of complications and reoperations. There were no cases of stem loosening. The alignment of the radial head to the forearm axis of rotation may restore forearm kinematics. This design may lead to radiocapitellar contact pressures that are more physiologic in load transmission.

Level of evidence: Level IV; Retrospective Series

Radial head arthroplasty (RHA) cases have more than doubled over the last decade and are anticipated to continue to rise.[23,41] Advancements in technique and a better understanding of forearm kinematics have contributed to the improvement in outcomes following RHA.[54]

Radial head injuries often occur with concomitant ligament injury.[47] Reports have described the importance of the proximal radius for elbow stability especially in cases with ligament insufficiency.[3,36,57] In these cases, the goal of RHA is to restore posterolateral, valgus, and axial stability through radiocapitellar contact.[49]

Considerable forces are transmitted across the radiocapitellar joint.[1,31] Following irreparable radial head fracture, radiocapitellar stability must be restored in order to return an acceptable level of function.[8,32,33,40,51] Van Riet et al discussed the importance of radial head position and orientation.[50] Malpositioned implants can lead to increased radiocapitellar contact pressures which may accelerate capitellar wear.[27,33,40,46] However, when the radiocapitellar joint is reconstructed with near anatomic positioning, these pressure changes may be minor[17] and potentially below the threshold for erosive damage.[9]

Design of radial head replacements has evolved due to extensive anthropometric study and improved understanding of the loading mechanics at the radiocapitellar joint.[1,27,28,42,46,47] Radial head replacements can be monobloc or bipolar, have a fixed or nonfixed stem, and vary in head design. The results of RHA depend on the inherent variability of the proximal radial anatomy[4] and on the subsequent difficulties in attaining anatomic positioning of the prosthesis.[7,52] Common complications following RHA include capitellar erosion, osteolysis with implant loosening, stiffness, and pain,[17,28,48] with stiffness and pain accounting for a high percentage of revisions.[55] Many studies have discussed the impact of surgical technique and prosthesis fit on achieving satisfactory outcomes.[5,28,48]

The importance of continued innovation in radial head prosthesis design has been mentioned.[24,54] A monobloc prosthesis with a fixed long stem and an anatomical head that is aligned with the axis of forearm rotation was recently introduced. Our purpose was to report the clinical and radiographic outcomes for patients across multiple centers who received this radial head replacement with a minimum of 2-year follow-up.

Methods

This was a multi-institutional retrospective follow-up including 6 centers and multiple surgeons. Institutional review board approval was attained prior to study initiation. Cases were reviewed for the Align radial head prosthesis, treating radial head pathology across all indications including fracture, arthritis, and revision surgery (Skeletal Dynamics, Miami, FL, USA) from 2013 to 2019. A total of 114 cases were performed prior to July 20, 2019, of which 52 responded to the request and agreed to follow-up. The patient characteristics recorded were age, side dominance, and gender.

The 100-point Mayo Elbow Performance Score (MEPS) was completed for each patient. Categorical scoring of 90-100 indicated an excellent score; 75-89 indicated a good score; 60-74 indicated a fair score; under 60 indicated a poor score. Patients completed the 11-item Quick Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire[19] and a 10-point visual analog scale (VAS) for pain at rest and when unscrewing a bottle cap. A major complication was defined as a reoperation or periprosthetic fracture. A minor complication was defined as pain, stiffness, or radiographic evidence of heterotopic ossification. Functional assessment included goniometric measure of elbow flexion, elbow extension, forearm supination, and forearm pronation for the operative and nonoperative arm. A dynamometer was used to quantify grip strength for the operative and nonoperative arm.

Postoperative radiographs were evaluated for capitellar wear, osteolysis, radiolucent lines, and prosthesis loosening.[6] Each radiographic variable was independently graded by 2 fellowship-trained upper extremity surgeons. Stages describing the qualitative appearance of the capitellum were used to evaluate the presence of wear. Stage I showed increased subchondral density. Stage II showed early erosion. Stage III showed substantial, readily apparent erosion.[7] The presence of osteolysis was described based on its position in proximity to the stem.[37] Radiolucent lines were quantitatively described using the method developed by Fehringer et al.[12] A prosthesis was defined as loose when there was a change in position from prior imaging with associated bony effects.[42]

Surgical procedure

In order to identify the axis of forearm pronosupination, the ulnar fovea was marked prior to incision. Radial head fragments were removed and reassembled for sizing. With the forearm positioned in neutral, sizing guides were used to assess radial neck length. Additional radial neck resection proximal to the fracture site was usually performed. The radial canal was prepared with manual rasps until adequate fit was reached. The trial prosthesis was inserted and evaluated with fluoroscopy to confirm appropriate length and therefore prevent overstuffing. On a true anteroposterior forearm view, the proximal level of the radial head must be at or distal to the corner formed by the lesser and greater sigmoid notches. Proper radial head diameter is confirmed by ensuring the apex of the capitellum is aligned with the center of the prosthetic radial head.

Following final stem impaction, the radial head implant was side loaded onto the stem. With the forearm in neutral rotation, the proximal part of the head alignment tool was attached to the radial head and the distal part was placed on the ulna fovea (Fig. 1).[18] This aligns the prosthetic radial head to the axis of forearm rotation (Fig. 2). There is anatomical variability in offset between the radial head and neck and between the radial neck and radius shaft. The radial head-to-neck angle is approximately 7 degrees, and the radial neck-to-shaft angle is approximately 17 degrees.[43,53] The implant guide is designed to restore this anatomical axis.

Figure 1 – Intraoperative photograph showing the instrument aligning the radial head prosthesis with the forearm axis of rotation.

Results

Clinical outcomes

Across the study sites, data for 52 patients were compiled with a mean age of 61.3 years (range, 26-85) and a mean follow-up term of 49.7 months (range, 24-100) (Table I). The mean MEPS was 87.0 (range, 55-100), with 46% (24/52) scoring a 100. Categorical classification of MEPS showed 79% (41/52) of patients with an excellent or good score (75-100) (Fig. 3). A poor score was seen in 5.77% (3/52) of patients. The mean DASH score was 19.6 (range, 0-88.6) (Fig. 4). The mean VAS for pain at rest was 0.9 (range, 0-10), and the mean VAS for pain while unscrewing a bottle cap was 1.9 (range, 0-10). The mean elbow arc of motion was 120 degrees (±19) and was 88% of the contralateral elbow. The mean grip was 53 pounds (±27) and was 89% of the contralateral grip.

Radiographic outcomes

Minimal proximal bone resorption immediately below the collar was seen in 72% of cases (23/32) at a mean follow-up of 64.5 months (Fig. 5). One patient (67-year-old female) had stage I capitellar wear at 68 months postoperatively, and one patient (66-year-old male) had stage II capitellar wear at 54 months postoperatively. One patient (62-year-old female) had a mean stem radiolucency of 0.8 mm at 58 months postoperatively, and one patient (64-year-old female) had a mean stem radiolucency of 1.7 mm at 35 months postoperatively. No patients had evidence of osteolysis or a change in implant position which would indicate loosening.

Complications

We recorded a total of 4 major complications and 3 reoperations, for a rate of 7.6% and 5.7%, respectively. A 73-year-old female had a periprosthetic proximal radius fracture at 49 months following a fall onto an outstretched hand. This fracture was treated nonoperatively and healed with a stable implant at 2 years after periprosthetic fracture which was 5 years after the primary arthroplasty. One patient (46-year-old male) with continued pain had the implant removed at 12 months. Radiographic evaluation of this patient showed moderate capitellar wear and excessive implant length consistent with overstuffing by radiographic parameters. Following implant removal, the pain subsided, but limited elbow motion and forearm rotation persisted. A 77-year-old female, whose initial injury was a terrible triad, had removal of the implant at 47 months due to ulno-humeral chrondrolysis and was converted to a total elbow. A 53-year-old male patient with a body mass index of 44 had a fracture of the neck of the implant at 18 months postoperatively and was treated with implant removal.

Discussion

Radial head replacement is a treatment option for comminuted articular radial head fractures. When treating radial head fractures that are greater than 3 parts,[29] the fixation is

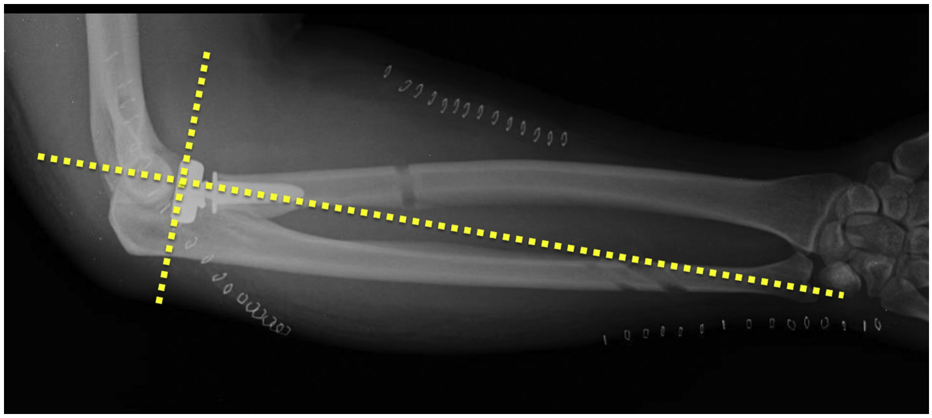

Figure 2 – Postoperative radiography showing the radial head implant aligned with the forearm axis of rotation.

Table I – Details for radial head arthroplasty in 52 patients across 6 institutions.

N = 52	Mean	Standard deviation
Age (yr)	61.3	12.8
Follow-up (mo)	49.7	21.7
F/E arc	120	19
F/E % contra	88	0.1
P/S arc	155	36
P/S % contra	95	0.2
Grip (pounds)	53	27
Grip % contra	89	0.2
DASH	19.6	20.9
MEPS	87	14.7
VAS rest	0.9	2.0
VAS active	1.9	2.8

F/E arc, elbow arc of flexion and extension; *F/E % contra*, elbow arc of flexion and extension as a % of the contralateral side; *P/S arc*, forearm arc of pronosupination; *P/S % contra*, forearm arc of pronosupination as a % of the contralateral side; *grip % contra*, grip strength as a % of the contralateral side; *DASH*, Disabilities of the Arm, Shoulder, and Hand score; *MEPS*, Mayo Elbow Performance Score; *VAS rest*, visual analog scale for pain at rest; *VAS active*, visual analog scale for pain while unscrewing a bottle cap.

known to be difficult with unreliable outcomes. We report clinical and radiographic outcomes for a single radial head implant across multiple institutions and surgeons. Fifty-two patients from 6 institutions were included in the study. The results for MEPS (87.0) and DASH (19.6) scores are comparable to other short-term retrospective series.[2,11,21,45,57] The rates of major complication (7.6%) and reoperation (5.7%) for this cohort were lower than those reported in the literature.[16,22,38,55,56] The literature has demonstrated that the majority of reoperations following RHA occur in the first 2 years following index surgery. Kupperman et al reviewed the literature and found a reoperation rate of 10.7% for RHA at 2 years.[25] A national database study by Reinhardt et al reported that 17.6% of RHA cases required reoperation at a mean of 8 months.[38]

Complications following RHA are variable, with pain, elbow stiffness, and loosening being the most commonly

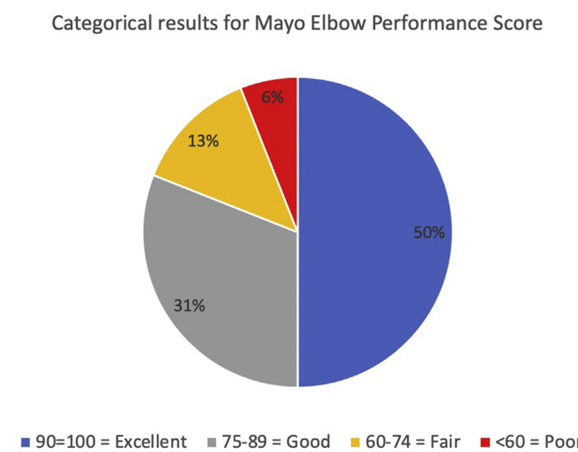

Figure 3 – Categorical allocation of Mayo Elbow Performance Scores across 52 patients and 6 institutions.

reported complications.[56] Stiffness is a common consequence of elbow trauma regardless of treatment. Its etiology following RHA is multifactorial, with prosthesis overstuffing being predictive of failure.[46,56] Excessive implant length can lead to increased radiocapitellar and ulnohumeral joint contact stresses which can result in pain and degenerative changes.[46] Rates of loosening may be affected by stem design,[48] with some postulating that surgical technique may also play a role.[41,46]

Radial head implants vary in design. The implant can be a monobloc or have a ball and socket joint between the head and the stem. The latter, a bipolar design, are intended to freely align to the capitellum to minimize wear. The stem can be securely stabilized by bony ingrowth or cement, or it can be polished to allow motion in the medullary canal. Polished stems are intended to act as a spacer and spin inside the canal with the intention of favoring the capitellum. The prosthetic radiocapitellar surface can be flat or concave. The latter provides more stability but must be precisely implanted to avoid capitellar wear. Well-affixed monobloc heads are intended to imitate native anatomy.

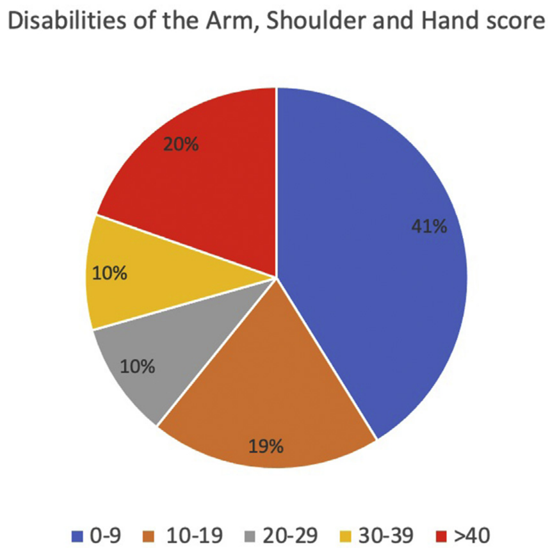

Figure 4 – Score ranges for Disabilities of the Arm, Shoulder and Hand across 52 patients and 6 institutions.

Figure 5 – Postoperative radiography showing stress shielding on the radial neck.

Unfortunately, unacceptably high rates of implant revision and removal demonstrate the need for continued advancement in prosthesis design. Vannabouathong et al reported outcomes for fixed-stem implants with results stratified by manufacturer. Revision rates for some implants were as high as 60%.[55] The authors concluded that clinical outcomes, complications, and revision were impacted by implant design. Outside of the well-recognized insufficiency of silicone implants, there is no consensus on the optimal radial head implant design. Three implant comparisons are widely discussed: monopolar vs. bipolar, loose stem vs. well-fixed stem, and anatomic vs. nonanatomic design.

Bipolar radial heads have the capability to orient to the capitellum which may improve radiocapitellar contact stresses, minimizing the potential for capitellar wear.[20] Monopolar radial heads have demonstrated greater stability in various testing parameters which may provide more native concavity compression of the radiocapitellar joint.[30,36] The value of a stable prosthesis is more pronounced in cases with concomitant soft tissue disruption and elbow dislocation, where the radial head is needed to stabilize the joint.[8] In spite of these individual characteristics, testing has shown higher incidences of radiocapitellar subluxation in monopolar implants and higher incidences of capitellar wear in bipolar implants.[48] In a systematic review, Heijink et al concluded that prosthesis polarity does significantly affect Mayo elbow scores.[16] Because the radial head not only transmits axial loads but also transverse loads,[35] a bipolar implant may produce higher localized contact stresses when subjected to an increased lateral load. To date, the literature has not provided agreement on the superiority of prosthesis design regarding radial head polarity.[10,15,34]

Smooth polished stem radial head implants are intended to not osseointegrate to the radius, to function as a spacer, and to rotate within the canal. The proposed value being that stem rotation decreases radial head-capitellar surface motion. Szmit et al reported that loose stems did reduce radiocapitellar contact stress though the common consequential finding of an increased contact area did not occur.[44] These loose stems may not have the ability to transmit forces in a physiologic manner. Complications with polished stems may include high rates of periprosthetic osteolysis and stiffness.[26,56]

There are two techniques that provide a rigidly fixed stem; the use of bone cement and an ingrowth stem surface inserted with a press fit for stability during the ingrowth process.[13] Stable bony fixation may contribute to the long-term survival of the implant. Cement fixation has well-recognized drawbacks.[37] Stems with porous ingrowth surface can provide stable long-term fixation but require a stable initial press-fit fixation to create an environment suitable for ingrowth. Failure to achieve initial stable fixation can result in progressive osteolysis, where the loose stem with a rough surface erodes into the endosteal bone surface. Initial press-fit stability may be facilitated by longer prosthetic stems which provide better initial 3-point fixation. Well-fixed stems may result in stress shielding with bone resorption around its most proximal part. Recent evidence supports the premise that asymptomatic proximal resorption may be a short-term phenomenon that stabilizes with time.[8,14] Our radiographic finding of a stable well-fixed stem with proximal stress shielding is consistent with previous reports, without progression of the stress shielding over multiple years of follow-up once the process is stabilized.[8,37,39,42]

Anatomy replicating radial heads is intended to reduce radiocapitellar contact stresses through a deeper, more conforming dish. This characteristic may improve function by providing an anatomic proximal radioulnar joint articulation.[40] Despite these theoretical advantages, proper implant positioning is essential to achieve the desired outcomes but difficult to achieve. Additionally, anatomical variation between individuals makes the concept difficult to apply to the population at large. Alignment of the prosthetic head to the forearm axis of rotation results in maintenance of anatomic radiocapitellar position during pronosupination (Fig. 6).

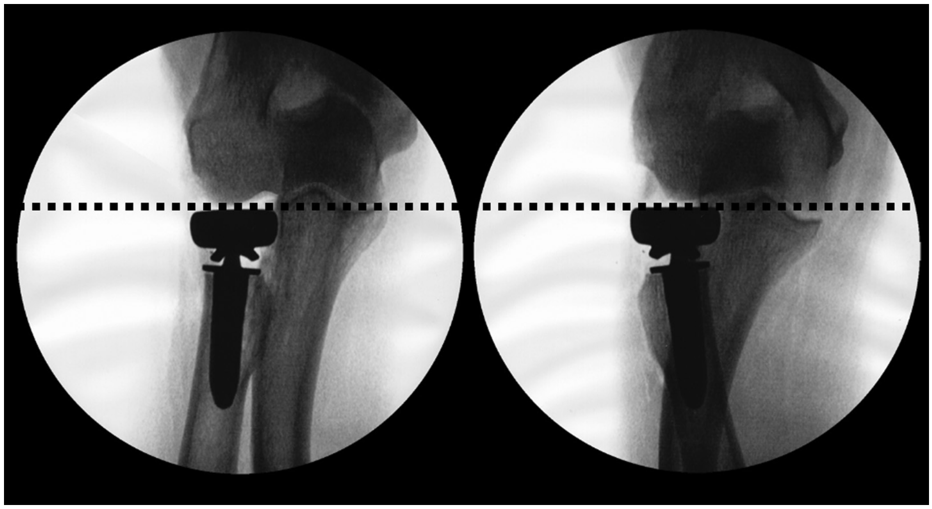

Figure 6 – Intraoperative fluoroscopy showing maintenance of radiocapitellar orientation and joint congruity during pronosupination and proper prosthetic neck length.

The retrospective nature of the work is a limitation due to the inherent risk of selection bias with this study design. The data herein were aggregated for all RHA indications. Results were not stratified by indication as this information was not consistently available across all centers. The data are also subject to measurement variability as they were collected by numerous clinicians. The multicenter design contributed to a high rate of attrition. Therefore, the outcomes represent a low proportion of all patients who received this prosthesis. While our conclusions may be limited by the multicenter study design, this design also expands the generalizability of the results. Preoperative evaluation, surgical approach, surgical skill, and postoperative protocols differ between surgeons. This lack of uniformity may demonstrate the reproducibility of the results.

Conclusion

An anatomic radial head prosthesis that is aligned to the axis of forearm rotation produces satisfactory short-term outcomes across multiple surgeons and institutions. The rate of reoperation was lower than historical data for radial head arthroplasty outcomes'. The prosthesis has a monobloc design, a concave radiocapitellar surface, a press-fit long stem with ingrowth surface, and a mechanism for alignment of the radial head to the forearm axis of rotation. This design combines the theoretical benefits of improved radiocapitellar contact of a bipolar implant with the physiologic load transmission and stability of a monobloc implant. Further investigation is required in order to determine results at a longer term of follow-up.

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Conflicts of interest: DMM has a consulting teaching and advising relationship with Skeletal Dynamics. HBB discloses a relationship with Skeletal Dynamics including payment for faculty responsibilities. The other authors, their immediate families, and any research entity with which they are affiliated did not receive any financial payments or other benefits from any commercial entity related to the subject of this article.

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