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Radial Head Replacement for Acute Radial Head Fractures: Outcome and Survival of Three Implant Designs With and Without Cement Fixation

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Objectives: To determine outcomes of radial head replacement (RHR) for acute fractures using 3 different implant designs with or without cement fixation.

Design: Retrospective.

Setting: Tertiary referral hospital.

Patients/Participants: One hundred fourteen elbows underwent RHR for an acute radial head fracture using either (1) a nonanatomic design and smooth stem (n = 60), (2) a nonanatomic design with a grit-blasted, ingrowth, curved stem (n = 21), or (3) an anatomic design with a grit-blasted ingrowth straight stem (n = 33). Cemented (25%) or uncemented (75%) fixation was used at the discretion of the treating surgeon.

Intervention: RHR.

Main Outcome Measurements: The primary outcome was implant survivorship free of revision or removal for any reason. All elbows were evaluated clinically (the Mayo Elbow Performance Score and reoperations/complications) and radiographically.

Results: Fourteen implants (12%) were revised. Of elbows with a minimum 2-year clinical follow-up, the average Mayo Elbow Performance Score was 88. The rate of survivorship free from revision was 92% [95% confidence interval (CI) = 87%–98%] at 2 years, 90% (CI = 84%–96%) at 5 years and 84% (CI = 75%–94%) at 10 years. The differences in survivorship between the 3 implants did not reach statistical significance, but the nonanatomic design with a grit-blasted ingrowth curved stem had a hazard ratio of 4.6 (95% CI = 0.9%–23%) for failure. There were no differences in survivorship between cemented versus uncemented stems. For those elbows with a minimum of 2 years of radiographic follow-up, implant tilt was observed in 10 (16%) elbows and loosening in 16 (26%) elbows. Stress shielding was present in 19 (42%) of well-fixed implants.

Conclusions: RHR for acute trauma leads to survivorship greater than 80% at 10 years. Radiographic changes (loosening, stress shielding, and implant tilting) can be expected in a substantial portion of elbows at long-term follow-up.

Key Words: radial head replacement, radial head fracture, stress shielding, outcomes

Level of Evidence: Therapeutic Level III. See Instructions for Authors for a complete description of levels of evidence.

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INTRODUCTION

Radial head replacement (RHR) is frequently considered for nonreconstructible radial head fractures in the acute setting.[1] Multiple radial head prostheses have been developed, with differences in geometry, modularity, materials, and methods of fixation. Despite a highly successful track record for the use of cement for fixation of arthroplasty components in other locations, many implants designed for RHR use uncemented stems with either press-fit ingrowth or a smooth loose fitting stem.[2–4]

Loosening is a common indication for revision or removal of radial head arthroplasty.[5] Reports of radial head loosening have been associated with forearm pain, cortical expansion of the radial neck, and bone loss, regardless of the type of fixation.[6–8] Implant-related issues may create situations that are challenging to salvage.

Currently, there is a paucity of studies reporting on the long-term outcome of various implant designs. Most reported studies include only one implant design, oftentimes combining RHR in the acute setting with RHR used for reconstruction of the sequels of trauma, and follow-up times are relatively short. The purpose of this study is to compare the long-term survivorship of 3 implant designs used for acute radial head fractures. Our hypothesis was that different implant designs would be associated with different survivorship and that cemented radial head implants would have better survivorship overall.

MATERIALS AND METHODS

Patients

Between 2001 and 2015, 116 consecutive monopolar RHRs were performed at our institution for acute, nonreconstructible radial head fractures. Two patients refused authorization for their medical records to be used for research, leaving 114 elbows for the retrospective review. There were 64 women

(56%) and 50 (44%) men with an mean age at the time of operation of 53 years (range 20–84 years) and an average body mass index of 32 (range 20–52). There were no patients with bilateral RHR.

Implants

All surgeries were performed at a single tertiary care referral hospital by 14 different surgeons. Three monopolar radial head designs were used during the study period, including a nonanatomic design with a smooth stem (Evolve; Wright Medical, Bloomington, MN, n = 60; 5% cemented), a nonanatomic design with a grit-blasted, ingrowth curved stem [Sbi/Avanta/Stryker (S/A/S), Mahwah, NJ, n = 21; 66% cemented], and an anatomic design with a grit-blasted, ingrowth straight stem (Anatomic, Acumed, Portland, OR n = 33; 35% cemented). In total, there were 85 uncemented implants (75%) and 29 cemented implants (25%). The implant design and the use of cement were based on surgeon's preference.

Evaluation

At our institution, all patients receiving any type of arthroplasty, including RHR, are enrolled in a Joint Registry Database at the time their implant is placed and prospectively followed at regular intervals after the index procedure. Patients either return to our institution for a physical examination and radiographs or they are offered to fill out a written or telephone questionnaire and send radiographs. Information collected prospectively include pain, motion, Mayo Elbow Performance Score (MEPS), complications, and reoperations. Because all RHRs were performed for acute trauma, there were no preoperative clinical data available for postoperative comparison.

Of the 114 patients identified for this study, 2 died and 12 were lost to follow-up within in the first 2 years after the index procedure. Fourteen RHR were removed (8) or revised (6) during follow-up, leaving 86 elbows with clinical or radiographic follow-up greater than 2 years. Of these 86 elbows, 79 elbows had greater than 2-year clinical follow-up (orthopedic examination n = 17 and joint registry questionnaire n = 62), and 61 elbows had greater than 2 years radiographic follow-up, and there was no statistical difference in demographics between these groups. Of these 86 patients, 54 patients had both clinical and radiographic follow-up. The duration of follow-up was determined by the most recent clinical contact (including clinic visit, joint registry questionnaire, and telephone encounter) or radiograph confirming that the original implant was still in place.

The primary outcome of the study was implant survivorship free of implant revision or removal for any reason. This included revision to another RHR, revision to another form of elbow arthroplasty (interposition, radiocapitellar, or total elbow arthroplasty), or removal of the implant. For elbows with greater than 2 years clinical follow-up, medical records were retrospectively reviewed to extract information for pain, range or motion, MEPS, and reoperations/complications.

Radiographic outcomes are reported only for the 61 elbows with a minimum 2 years radiographic follow-up. Radiographs were reviewed by 2 experienced fellowship-trained shoulder and elbow surgeons and 2 orthopaedists currently completing a shoulder and elbow fellowship. Injury films were evaluated to confirm that the reason for replacement was an acute radial head fracture. All follow-up radiographs were evaluated for loosening, stress shielding, changes in component position, and posttraumatic osteoarthritis. Radiographic loosening was defined as a change in the implant position associated with endosteal erosions, canal expansion, or progressive radiolucent lines in sequential radiographs. For smooth stem RHR, loose fitting implants without progressive radiolucent lines, a change in implant position, or canal expansion/erosions were not considered grossly loose. Stress shielding was defined as bone resorption and remodeling around the proximal stem of the implant in the absence of loosening. It was associated with thinning and tapering of the proximal cortical bone to the implant stem and could progress to expose a portion of the implant stem. Stress shielding was graded as mild (proximal cortical thinning with $<1/3$ of the stem length exposed), moderate (between $>1/3$ and $<2/3$ of the stem length exposed), or severe ($>2/3$ of the stem length exposed). Implant tilt was a term used to describe a progressive angulation of the implant stem alignment on sequential radiographs. The term adverse bone reaction will be used to discuss radiographs with bone changes associated with either loosening or stress shielding.

Statistics Analysis

Survivorship free of removal or revision was estimated using the Kaplan–Meier method, and the risk of revision was evaluated using Cox regression. Range of motion measurements and MEPS scores were compared between the 3 implant types using analysis of variance and between cemented and uncemented implants using 2-sample *t*-tests. Pain categories were compared using χ^2 tests.

RESULTS

Implant Removal/Revision

Of the 114 RHRs included in this study, 14 implants (12%) had been revised or removed at most recent follow-up [Evolve, 5 elbows (8%), cemented n = 0 (0%), uncemented n = 5 (9%); S/A/S, 7 elbows (33%), cemented n = 3 (21%), uncemented n = 4 (57%); and Acumed, 2 elbows (6%), cemented n = 1 (8%), uncemented n = 1 (5%)]. Reasons for removal included symptomatic loosening (10 elbows), pain without loosening (2 elbows), instability (1 elbow), periprosthetic fracture (1 elbow), and stiffness (1 elbow) (Table 1).

Survivorship Analysis

Implant survivorship free of revision or removal was calculated for the following 3 different scenarios: (1) all implants, (2) individual implants (Evolve, S/A/S, and Acumed), and (3) cemented or uncemented implants.

The rates of survivorship free of revision or removal for any reason for all implants were 92% [95% (confidence interval) CI = 87%–98%] at 2 years, 90% (95% CI = 84%–96%) at 5 years, and 84% (95% CI = 75%–94%) at 10 years.

Survivorship rates for the anatomic implant (Acumed) were 100% (95% CI = 100%–100%) at 2 years, 95% (95% CI = 86%–100%) at 5 years, and 86% (95% CI = 68%–100%) at 10 years. Survivorship rates for the nonanatomic grit-

TABLE 1. Summary of Implants Removed/Revised

	Age	Gender	Side	Implant	Cement	Revision or Removal	Time to Revision (y)	Reason for Revision	Comments Operative Findings
1	32	M	L	S/A/S		Revision RHR	1.5	Pain and stiffness	Grossly loose, revised to smaller head size
2	59	F	R	S/A/S		Revised to anconeus interposition	11.3	Pain	Grossly loose
3	25	M	L	E		Removed	0.8	Pain	Grossly loose, impinging on humerus
4	62	F	R	E		Removed	1.5	Pain	Grossly loose, capitellar arthritis
5	62	M	R	S/A/S	x	Removed	0.8	Stiffness	Decreased ROM with impingement
6	24	M	L	S/A/S		Revision to RC arthroplasty	12.4	Pain	Stem well fixed, capitellar arthritis
7	53	F	R	S/A/S		Removed	8.1	Pain	Grossly loose, capitellar arthritis
8	67	F	R	A		Removed	6.5	Periprosthetic fracture	Fracture in the setting of severe stress shielding
9	52	M	L	E		Removed	2.0	Pain	Grossly loose
10	76	F	L	E		Removed	1.8	Pain	Metallosis from RH articulating with a screw
11	32	M	L	A	x	Revision to TEA	3.0	Pain	Grossly loose, severe posttrauma OA
12	52	M	R	E		Revision RHR	1.8	Pain	Grossly loose
13	54	F	R	S/A/S	x	Revision RHR	0.3	Transverse instability/pain	Lateral dissociation, change head size, stem stayed
14	56	M	R	S/A/S	x	Removed	0.4	Pain	Grossly loose

A, anatomic, Acumed; E, Evolve, Wright Medical; RC, radiocapitellar; RHR, radial head revision; TEA, total elbow arthroplasty.

blasted curved stem (S/A/S) were 79% (95% CI = 63%–100%) at 2 years, 79% (95% CI = 63%–100%) at 5 years, and 70% (95% CI = 51%–98%) at 10 years. Survivorship rates for the nonanatomic smooth stem (Evolve) were 92% (95% CI = 86%–100%) at 2 years, 90% (95% CI = 83%–99%) at 5 years, and 90% (95% CI = 83%–99%) at 10 years.

Survivorship rates for the anatomic (Acumed, Hillsboro, OR) implants were used as the reference for comparison with the other implants, and provided a hazard ratio (HR) of 4.6 (95% CI = 0.9%–23%, $P = 0.063$) for the S/A/S implant and had a HR of 1.4 (95% CI = 0.3–7.3, $P = 0.687$) for the Evolve implant.

Survivorship rates for all uncemented stems were 93% (95% CI = 88%–99%) at 2 years, 92% (95% CI = 86%–98%) at 5 years, and 85% (95% CI = 74%–97%) at 10 years. Survivorship rates for cemented stems were 89% (95% CI = 79%–100%) at 2 years, 82% (95% CI = 67%–100%) at 5 years, and 82% (95% CI = 67%–100%) at 10 years. With the numbers available, differences in survivorship between cemented and cementless fixation did not reach statistical significance ($P = 0.879$) (Figs. 1A–C).

Clinical Outcomes

There were 79 elbows with surviving RHR implants and clinical follow-up greater than 2 years. For these elbows, the average follow-up time was 6.5 years (range 2–16 years). There were complete data available for range of motion and pain scores in all patients, whereas 68 patients had complete data for calculation of the MEPS. At most recent follow-up, pain was rated as none in 48%, mild in 42%, moderate in 8%, and severe in 3%. The mean motion included 14 degrees (range 0–90 degrees) for extension, 133 degrees (range 60–150 degrees) for flexion, 78 degrees (range 0–90 degrees) for pronation, and 66 degrees (0–90 degrees) for supination. The average MEPS score was 87 (range 25–100).

Pain, range of motion, and MEPS were compared for the 3 different implant groups. With the numbers available, differences in these outcome measurements did not reach statistical significance (P values ranged between 0.2 and 0.8).

Complications and Reoperations

As mentioned, 14 elbows required RHR revision or removal. For the remaining 100 elbows without an implant revision or removal, 11 had other complications (11%). These included wound-healing issues or infection (n = 5), instability (n = 3), painful retained implants other than RHR (n = 2), and fracture (n = 1). Twenty elbows with retained RHR implants underwent reoperation due to the complications summarized above; 14 had more than one reoperation (range, 2–10). Thus, including the 14 elbows that required RHR removal, the overall reoperation rate was 30% (34/114).

Radiographic Outcomes

There were 61 elbows with radiographic follow-up greater than 2 years; the average radiographic follow-up for these elbows was 6 years (range 2–15 years). Radiographs

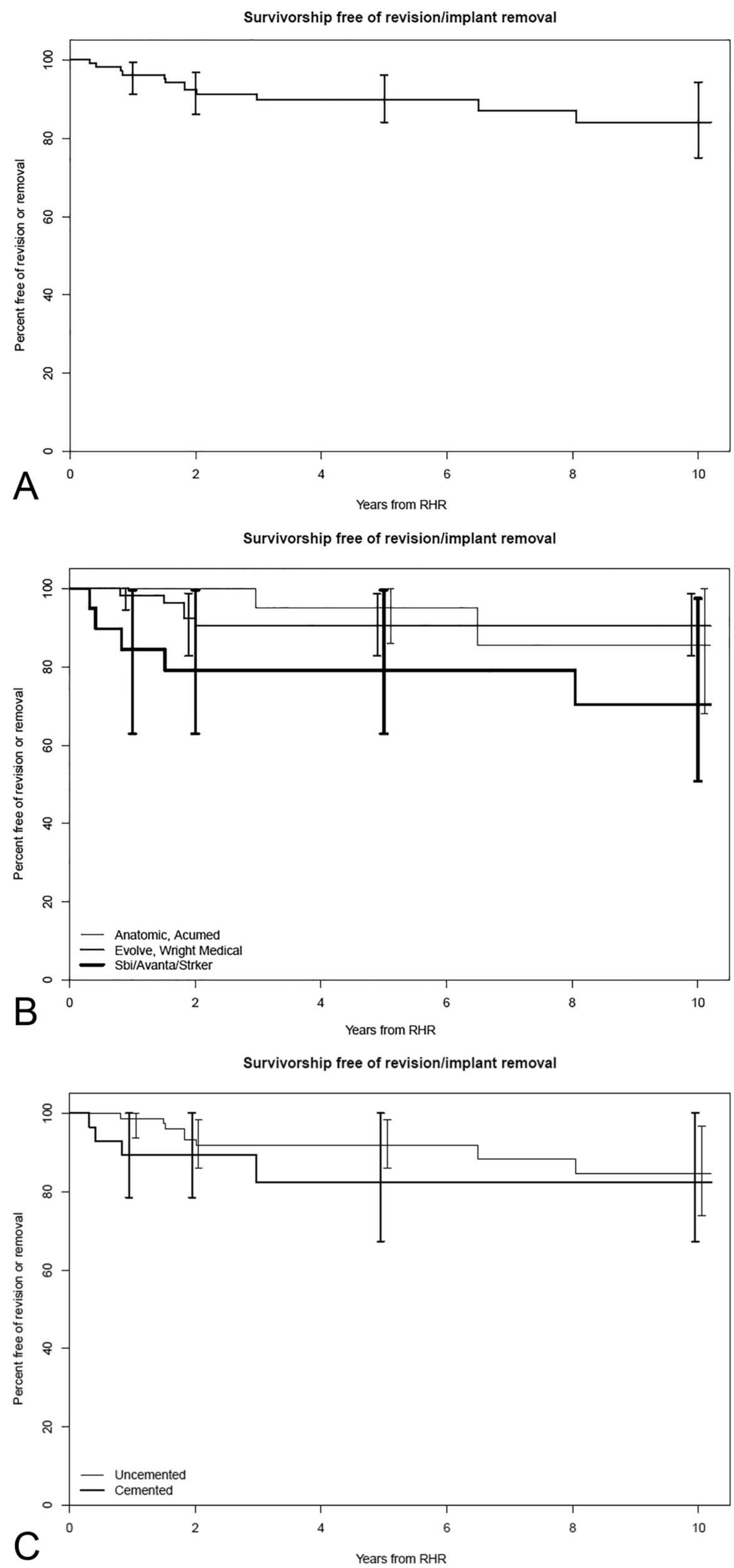

FIGURE 1. A–C, Survivorship curves.

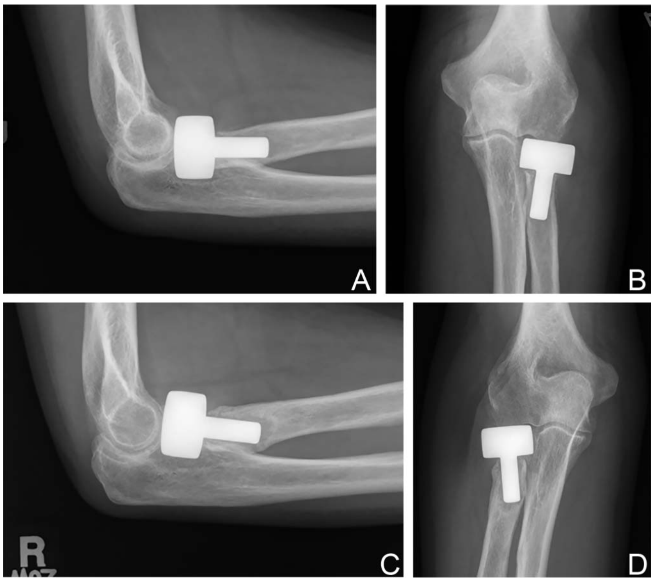

FIGURE 2. A–D, A second example of the smooth stem (Evolve; Wright Medical) RHRs with implant tilting over time. A, B, the first postoperative radiographs and (C, D) are at 2 years postoperatively. Similar finds as previous figure with implant tilt causing thinning of the cortex near the tip of the stem.

showed substantial implant tilt, with posterior and ulnar deviation, in 10 elbows, all Evolve prosthesis (30%) (Figs. 2A–D). Findings concerning for radiographic loosening were present in 16 of the 61 elbows (26%). Three of the 17 implants with cement fixation (18%) and 13 of the 44 uncemented implants (30%) were considered radiographically loose. Of the loose uncemented stems, 10 were smooth (Evolve) and 3 were ingrowth (2 S/A/S and 1 Anatomic, Acumed). Of the loose cemented stems, 1 was smooth (Evolve) and 2 were ingrowth (1 S/A/S and 1 Anatomic, Acumed). Of the remaining 45 implants without evidence of loosening, stress shielding was seen in 19 implants [3 Evolve (14%), 0 S/A/S, and 16 Anatomic, Acumed (89%)] and rated as mild (11), moderate (7), or severe (1) (Fig. 3). These adverse bone reactions were not associated with an increase in pain or worse MEPS scores (P = 0.83 and 0.44, respectively). Furthermore, the use of cement was not a statistically significant factor in stress shielding with this population (P = 0.48). Moderate-to-severe radiographic posttraumatic osteoarthritis was observed in 15 elbows (25%). Despite the radiographic presence of arthrosis, there were no associated differences in pain or worse MEPS scores (P = 0.26 and 0.46, respectively).

DISCUSSION

RHR is commonly considered for the surgical management of acute nonreconstructible radial head fractures. Although several studies have reported on relatively small series of RHR using a single implant, there is limited information about the long-term outcome of various implants designs used by the same surgeons and followed over time. The results of our study seem to indicate that using one of the 3 implants included, the expected 10-year survivorship free of revision or removal can be expected to be approximately 85%. Although there was a clear trend for worse long-term survivorship with a grit-blasted curved stem, with a HR of 4.6 in reference to the Anatomic Acumed implant, with the numbers available, differences in survivorship did not reach statistical significance based on either implant design or cemented versus cementless fixation.

The management of comminuted radial head fractures continues to be controversial. Surgical options include radial head excision, open reduction and internal fixation, and RHR. Antuna et al reported successful long-term outcomes with radial head excision.[9] However, the radial head is considered to be an important stabilizer of the elbow and it is estimated to bear 60% of the forearm load in the pronated position with axial loads, such as pushing open a door.[10] Consequently, excision can lead to poor outcomes in selected patients.[11] Therefore, many surgeons prefer to attempt internal fixation or RHR in the acute setting. A recent meta-analysis performed by Vannabouathong et al[12] demonstrated better outcomes and reduced complications in patients treated with a RHR compared with open reduction and internal fixation for displaced radial head fractures.

Currently, there is a wide variety of implant options available for RHRs, with differences in stem fixation (smooth loose fitting vs. press-fit stems), monopolar or bipolar articulations between the stem and the head, head geometry (nonanatomic vs. anatomic), and others. Several other studies have attempted to compare RHR implants. Agyeman et al[13] evaluated the implant fixation method using a systematic review and meta-analysis and found no difference in outcomes for implants rigidly fixed (ingrowth or cemented) versus those loose fitting (loose smooth stems), although there was a higher relative risk of revision and complications with the fixed cohort. Berschback et al compared a smooth-stemmed bipolar implant and an ingrowth monopolar press-fit design, showing similar short-term and mid-term outcomes between the 2 groups. They cautioned that if a press-fit stem loosens, it can cause significant osteolysis and proximal radius bone loss.[14] We reviewed the same ingrowth stem (Anatomic; Acumed) as Berschback et al and did not identify similar rates of loosening and osteolysis. On the other hand, the press-fit ingrowth curved stem (S/A/S) reviewed in our study did demonstrate higher rates of loosening when used uncemented, with some of the adverse bone reactions reported by Berschback.

A possible explanation for the different rates of failure reported by various investigators using the same press-fit stem may have to do with the ability to achieve adequate primary stability at the time of surgery. To minimize micromotion, cementless ingrowth prostheses must be implanted with a very tight fit, and some surgeons may fail to achieve adequate primary stability at the time of surgery for fear of creating an iatrogenic intraoperative fracture of the radial neck. Cemented fixation or use of a loose-fitting prosthesis reduces the risk of intraoperative fracture.

As previously shown by van Riet et al,[5] loosening is a common indication for reoperation after RHR. In our study, 65% of the implants revised or removed were found to be

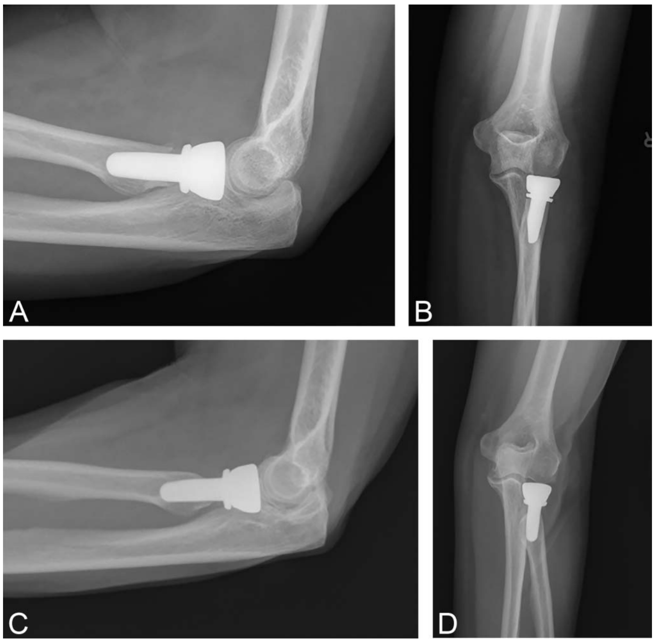

FIGURE 3. Example of the anatomic design with a grit-blasted ingrowth straight stem (Anatomic, Acumed) RHRs stress shielding over time. A, B, the first postoperative radiographs and (C, D) are at 6 years postoperatively. Graded as moderate.

grossly loose at the time of reoperation. As mentioned before, cemented fixation is an attractive option because it provides immediate stabilization and has an excellent track record for arthroplasty in other anatomic regions.[2–4] In this study, differences in implant survival did not reach statistical significance when comparing cemented and uncemented stems, although the rate of loosening was decreased with cemented fixation (18% vs. 30%). Cementing seemed to particularly improve the performance of the S/A/S, but our sample size was too small to allow for statistical significance. Also, when comparing loosening in the cement group to the uncemented group as a whole, there was a lower rate of loosening in the cemented group but were unable to show statistical significance.

Radiographic findings of stress shielding were common in patients with greater than 2 years radiographic follow-up. Most commonly, stress shielding was seen in the press-fit grit-blasted, ingrowth straight stem (Anatomic; Acumed), and implant tilting was seen in the smooth stem design (Evolve; Wright Medical). Stress shielding is a known phenomenon that occurs with well-fixed implants. Chanlalit et al[15] described stress shielding occurring commonly in well-fixed radial head implants. There was stress shielding present in 80% of the press-fit, ingrowth straight stems with anatomic radial heads in our study.

The smooth stem implants are designed to be loose in the intramedullary canal, and radiographic evidence of loosening is not "unexpected." Marsh et al[16] reported a 45% rate of stem radiolucency using smooth stem implants. In our study, the rate of radiographic loosening was slightly less, at 30% for the same smooth stem implant. One finding we did notice that was unique to the loose-fitting smooth stem implant was a tendency for the implant to tilt over time and the long axis of the radius to migrate in a posterior and ulnar direction. The migration of the radius is similar to that seen after a radial head excision. We do not have insights into the long-term effect of this tilting, but it was a recurring radiographic finding. This was often associated with a loose implant with concomitant canal expansion and cortical thinning near the tip of the stem. Nevertheless, with these data, adverse bone reactions were not associated with an increase in pain or worse MEPS scores ($P = 0.83$ and 0.44, respectively). Other radiographic findings included arthrosis in 25% of patients; however, interestingly, this also did not correlate with worse clinical outcomes.

Our study has several limitations. RHR was implanted for the management of traumatic elbow injuries with various degrees of associated pathology. Implant selection and surgical technique were completely dependent on the surgeon responsible for the procedure, with no standard method for bone preparation or component fixation. Furthermore, RHR from 14 different surgeons were included in this study that does create a degree of variability in technique and individual surgeon outcome was not evaluated. Nevertheless, we decided to include all surgeons because these results more faithfully recapitulate the reality that multiple surgeons with varied training treat these patients and this increases the sample size to evaluate survivorship. Finally, several of the elbows with adequate clinical follow-up did not have adequate radiographic follow-up. The strengths of this study include the relatively large sample size allowing the examination of different RHRs over a long-term follow-up period.

In conclusion, RHR for the surgical management of acute radial head fracture with 3 different implant designs was associated with an 85% survivorship free of revision or removal at 10 years. Although there were trends indicating worse survivorship with one particular implant (curved grit-blasted stem) and cementless fixation, the differences in survivorship based on implant design or fixation did not reach statistical significance. Adverse bone reactions were commonly observed in implants functioning clinically well, including progressive tilt and endosteal expansion with the loose cemented prosthesis and stress shielding with the cementless anatomic prosthesis. Further studies are required to continue to elucidate the ideal implant design and fixation method for RHR in the acute setting. Forgiveness of implant placement and the relatively benign clinical consequences of adverse bone reactions must be balanced against the need to provide these typically young patients with a reconstruction that will perform well for decades.

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