Failure of a Unipolar Radial Head Prosthesis Due to Component Dissociation

Roger E. Wiltfong, MD; Raymond K. Wurapa, MD; James C. Cassandra, DO

Abstract
Radial head implant arthroplasty is a consideration for the treatment of comminuted, unreconstructable fractures of the radial head. Many prosthetic designs exist and can be unipolar or bipolar, each of which can be cemented or noncemented. For most unipolar designs, a prosthetic stem is first implanted into the proximal radius. The prosthetic radial head is then impacted onto a morse taper on the stem or secured with a set screw. There is little information published on the mechanisms of failure for radial head implants, regardless of design. The authors found 2 individual case reports that describe component dissociation in bipolar implants. They could find no individual case reports of implant failure due to component dissociation of a unipolar implant related to failure of the set screw. The authors describe such a case 5 years after unipolar radial head implant arthroplasty. The system used employs a set screw to secure the prosthetic head onto the stem. The patient subsequently had a successful outcome after implant removal without reimplantation. Orthopedic surgeons have many options when considering radial head replacement implants and should be aware of the potential complications of each. The authors present this case to show one potential complication of unipolar prosthetic radial head implant arthroplasty. [Orthopedics. 2016; 39(4):e771-e774.]

Surgical treatment for fractures of the radial head generally falls into 1 of 3 categories: radial head resection, open reduction and internal fixation, and prosthetic replacement. Prosthetic replacement is an appropriate treatment option for comminuted fractures involving more than one-third of the radial head that are not amenable to internal fixation, especially those with concomitant ligamentous injury or dislocation.1-3 When choosing a particular implant for radial head arthroplasty, orthopedic surgeons should be aware of the potential complications of each design. The literature suggests that component dissociation is an uncommon reason for implant failure4 and has been described in a small number of case reports.5,6 The mechanisms for dissociation in those reports were thought to be related to instability. The current authors describe a case of implant failure due to prosthetic radial head dissociation from the prosthetic stem after unipolar radial head implant arthroplasty using a system that employs a set screw.

Case Report
An otherwise healthy 71-year-old right-hand–dominant woman presented after sustaining a fall onto her right elbow. She had no focal neurologic deficits and her vascular status was intact. Radiographs and a computed tomography scan confirmed significant displacement and comminution of the radial head and neck. Open reduction and internal fixation of the fracture vs radial head implant arthroplasty was recommended.

The authors are from Mount Carmel Health System (REW) and Orthopedic One (RKW), Columbus, and OhioHealth Orthopedic Surgeons (JCC), Hilliard, Ohio.

The authors have no relevant financial relationships to disclose.

Correspondence should be addressed to: Roger E. Wiltfong, MD, Mount Carmel Health System, 793 W State St, MSB 3rd Fl, Columbus, OH 43222 (roger.wiltfong@gmail.com).

Received: November 7, 2014; Accepted: September 9, 2015.

doi: 10.3928/01477447-20160513-01
At the time of surgery, the radiocapitellar joint was exposed through a standard Kocher approach. Extensive comminution was confirmed, and the fracture was determined not to be amenable to fixation. Radial head implant arthroplasty was performed using the ExploR Modular Radial Head (Biomet, Warsaw, Indiana) system (Figure 1). The system design includes a prosthetic radial stem and a modular radial head, which are secured together by a set screw. The prosthesis may be press-fit or cemented, and in this particular case, the prosthesis was not cemented. At 3 months postoperatively, she had no complaints and was released from follow-up.

Nearly 5 years postoperatively, she presented with a 1-month history of right lateral elbow pain and occasional “catching.” Her elbow range of motion was maintained but associated with mild pain at terminal flexion and extension. No elbow instability was noted on examination. Radiographs showed dissociation of the prosthetic radial head from the stem (Figure 2). The set screw had completely disengaged and migrated. Also noted was bony resorption of the proximal radius from stress shielding. Treatment options included replacement of the implant vs implant removal if the longitudinal forearm axis was stable. The previous lateral surgical approach was used. Extensive metallosis was encountered. The implant was removed and a synovectomy was performed. She also had significant erosion of the capitellum cartilage. There was no preoperative or intraoperative concern for infection, and no cultures were obtained. After the removal and synovectomy, there was no instability noted. Given that implant removal was 5 years from the time of the original injury, it was assumed that ligamentous injury to the forearm leading to longitudinal instability of the radius would have resolved. Therefore, no new implant was thought to be necessary. Standard closure of her wound followed.

One year after implant removal, the patient was doing well. She noted only occasional mild discomfort, which is well controlled with over-the-counter anti-inflammatory therapy. She demonstrated an elbow range of motion from 20° to 130°, with full forearm pronation and supination. Radiographs obtained at the 1-year follow-up visit showed mild diffuse arthritic changes (Figure 3). There have been no subsequent wrist complaints, and therefore no follow-up wrist radiographs were scheduled.
**Discussion**

Radial head arthroplasty is an appropriate treatment option for comminuted fractures involving more than one-third of the radial head that are not amenable to internal fixation, especially those with concomitant ligamentous injury or dislocation.\(^1\)\(^-\)\(^3\) There is little information on the mechanisms of failure for metallic radial head replacement, but in 2010, van Riet et al\(^4\) published a report on these mechanisms. During a 10-year period from 1998 to 2008, they examined 44 consecutive patients (47 elbows) who underwent removal of a failed metallic radial head replacement. The most common reason for revision was painful loosening, which occurred in 31 elbows. In 3 patients, however, there was dissociation of the radial head from the prosthetic stem. Two of the dissociations were from fixed-stem bipolar implants, and 1 was from a loose-stem unipolar implant. None of the implants in the study were the ExploR system, and none of the unipolar implants employed a set screw to secure the head to the stem.

Two individual case reports in the literature have shown component dissociation as a mode of failure for bipolar radial head replacement implants.\(^5\)\(^,\)\(^6\) The first, by Herald and O’Driscoll,\(^5\) describes a 60-year-old woman who sustained an elbow fracture dislocation treated originally with radial head internal fixation and lateral collateral ligament repair. Fixation failure occurred as well as recurrent elbow instability. The construct was revised to a Judet bipolar radial head replacement (Tornier SAS, Saint-Ismier, France), re-repair of the lateral collateral ligament, and placement of a hinged external fixator. The external fixator was removed at 2 weeks because of pin site infection, and dissociation of the radial head prosthesis followed. The dissociation was thought to be related to instability, which can cause pistoning between the radial stem and the radial head components.

The second case report, by Muñoz-Mahamud and Fernández-Valencia,\(^6\) describes a 72-year-old woman who sustained comminuted radial head and neck fractures. Intraoperative radiographs showed widening of the medial joint space, suggesting injury to the ulnar collateral ligament. The GUEPAR (DePuy France SAS, Saint-Priest, France) bipolar radial head replacement was implanted, followed by repair of the annular ligament. The elbow was immobilized for 3 weeks because of persistent instability, and postoperative radiographs indicated signs of radiocapitellar joint overstiffing. Dynamic splinting was instituted, and at week 5, radiographs showed component dissociation and ulnohumeral joint subluxation. Like the case described by Herald and O’Driscoll,\(^5\) instability was thought to be a contributor to the component dissociation, as well as the overstiffing. It is an important fact that, in both case reports,\(^5\)\(^,\)\(^6\) the radial head replacement systems were bipolar.

The current authors do note significant radiographic changes to their patient’s elbow that occurred over time. They first note stress shielding of the proximal radius, which is known to occur after radial head arthroplasty. Chanlalit et al\(^7\) retrospectively reviewed the radiographs of 26 patients who had either insertion, removal, or revision of a radial head arthroplasty unrelated to infection or loosening. They excluded patients who may have had bone resorption from complex regional pain syndrome or particle-induced bony resorption. At an average follow-up of 33 months (range, 13-70 months), they found stress shielding in 63% of the patients. No cases involved the biceps tuberosity. The current patient’s biceps tuberosity is visualized in *Figure 1*, *Figure 2*, and *Figure 3*. In addition to the stress shielding, the authors note mild, diffuse arthritic change. This is not unexpected, as in a study by Yalcinkaya et al,\(^8\) osteoarthritic changes in the elbow were frequent findings after primary resection arthroplasty for comminuted radial head fractures, but were without pronounced functional impairment. That study examined long-term results in 14 comminuted radial head fractures without associated injuries. Five elbows had excellent results and 9 had good results. Eight elbows and 4 wrists had degenerative changes. In the current case,
the patient’s elbow arthritis causes only occasional, mild pain adequately treated with oral anti-inflammatory medications. Because she has no wrist complaints, no wrist radiographs have been ordered.

**CONCLUSION**

To the authors’ knowledge, this is the first case report of in vivo component dissociation after unipolar prosthetic replacement of the radial head secondary to failure of the set screw. The cause of failure is unclear because the primary procedure was performed precisely per the manufacturer’s recommendations and there were no difficulties during the case. The failure may be related to micromotion of the screw during elbow and forearm motion and loading. The authors think this is a reasonable assertion because the failure occurred 5 years after the index procedure. They believe that if the failure had been from instability, as in the case reports by Herald and O’Driscoll and Muñoz-Mahamud and Fernández-Valencia, or from set screw micromotion, it would have occurred much earlier after the index procedure. A search of the Manufacturer and User Facility Device Experience (MAUDE) from the Food and Drug Administration’s website indicates medical device reports of similar dissociations of the ExploR system, although none of these reports, to the authors’ knowledge, have been published in the orthopedic literature.

As opposed to the radial head replacement system described in this case report, many other prosthetic radial head systems use a morse taper instead of a set screw, with the prosthetic radial head impacted onto the stem. Orthopedic surgeons have many options when considering radial head replacement implants and should be aware of the potential complications of each. The authors present this case to show one potential complication of a unipolar prosthetic radial head implant where the components are secured with a set screw.

**REFERENCES**