Midterm Results with a Bipolar Radial Head Prosthesis: Radiographic Evidence of Loosening at the Bone-Cement Interface

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Background: Metal prostheses are useful for restoring elbow and forearm stability when the radial head cannot be fixed after a fracture. Because the anatomy of the radial head is difficult to reproduce with a prosthesis, two different options have been proposed: a bipolar prosthesis with a fixed stem and a mobile head, and a monoblock prosthesis with a smooth stem that is intentionally fixed loosely in the neck of the radius. One concern with a fixed-stem implant with a mobile head has been the risk of osteolysis. The purpose of this study was to evaluate radiographic changes reflecting or suggesting progressive osteolysis in patients with a bipolar radial head prosthesis.

Methods: The functional and radiographic outcomes following treatment of fifty-one comminuted fractures of the radial head with a bipolar radial head prosthesis in fifty-one consecutive patients were evaluated at a mean of 8.4 years postoperatively. There were eleven isolated comminuted fractures involving the entire radial head. Thirty-four fractures were associated with a posterior elbow dislocation, and six patients had a posterior Monteggia lesion.

Results: According to the Mayo Elbow Performance Index, fourteen elbows were graded as excellent; twenty-five, as good; nine, as fair; and three, as poor. Radiographic changes reflecting or suggesting progressive osteolysis were present in thirty-seven patients. Complications occurred in ten patients, but only one underwent surgical treatment, for an ulnar neuropathy.

Conclusions: Although satisfactory midterm functional results were achieved in thirty-nine of the fifty-one patients, the high prevalence of adverse radiographic changes suggesting periprosthetic osteolysis should alert clinicians to this possible drawback of the use of bipolar radial head prostheses, especially in young and/or active patients.

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

It is well recognized that the radial head is an important secondary stabilizer of the elbow and forearm, and the importance of preserving it after a complex elbow fracture has been well documented. Open reduction and internal fixation of comminuted and severely displaced radial head fractures may be technically very difficult to achieve. Metal radial head prostheses were developed to restore elbow stability and permit early joint mobility, and the short-term clinical results following use of these implants have generally been promising. There are two different types of metal radial head prostheses, based on different concepts: a loose monoblock prosthesis and a bipolar prosthesis.

Most monoblock metal radial head prostheses have an axisymmetric head with a smooth stem. They are not fixed with cement. The designers believe that a small amount of movement of the stem within the radial neck may compensate for the lack of head asymmetry and improve the congruency of the articular surface of the implant with the capitellum and...
the proximal part of the ulna\textsuperscript{12}. However, this intentionally loose intramedullary fixation may have been an important factor in the development of radiolucencies surrounding the uncemented stem that was reported by Moro et al.\textsuperscript{13}, who noted that the lucencies tend to develop early and remain stable over time.

Bipolar radial head prostheses have a symmetric head that articulates in a semiconstrained fashion with a cemented stem\textsuperscript{20}. The rationale for the design of this prosthesis is that the additional freedom of movement may reduce stress at the implant-bone interface and increase the contact area at the radio-capitellar joint\textsuperscript{14}. However, generation of wear debris and osteolysis could be a disadvantage. To our knowledge, this has not yet been reported in the literature, perhaps because the number of patients available for study has been limited and follow-up has been relatively short\textsuperscript{11,13,14,18}. The purpose of this study was to evaluate the midterm radiographic outcomes of the use of a bipolar radial head prosthesis in a consecutive group of patients presenting with a comminuted fracture of the radial head associated with other destabilizing injuries of the elbow.

**Materials and Methods**

A retrospective study was undertaken to evaluate fifty-five consecutive patients who had been admitted to our hospital between January 1994 and December 2001 with an acute radial head fracture associated with other destabilizing elbow injuries. The associated elbow injuries included elbow dislocation, ligamentous injuries, and fractures. The radial head was excised because open reduction and internal fixation was not considered to be feasible, and a bipolar radial head prosthesis (Tornier, Saint Ismier, France) was implanted. The prosthesis is available with two radial head diameters: 19 and 22 mm. The radial stem is available in two sizes: a diameter of 8 mm with a length of 60 mm and a diameter of 6.5 mm with a length of 55 mm. These components are interchangeable and allow four different combinations of the head and stem (Fig. 1).

Our institutional review board approved this review. The physical and radiographic examinations, including the assessment protocol, were carried out after the patients gave informed consent to participate in the study. The outcomes of fifty-one arthroplasties in fifty-one patients were reviewed. Four patients were lost to follow-up after two years. The dominant arm of forty-one patients and the nondominant arm of ten patients were involved. There were thirty-two men and nineteen women with a mean age of fifty-one years (range, twenty-two to sixty-nine years). Thirty-two patients were injured in a ground-level fall on the outstretched hand; six, in a fall on stairs; five, in a fall from a roof; and eight, in a motor-vehicle accident. All patients had a closed elbow injury.

Preoperative anteroposterior and lateral radiographs were made of each elbow to identify the radial head fracture and whether there was an elbow dislocation. Plain anteroposterior and lateral radiographs of the forearm and wrist were made as well. Computed tomographic evaluation was performed routinely for all patients to identify any other osseous injury that was not identified during the initial radiographic evaluation.

The fractures of the radial head were classified according to Mason’s system\textsuperscript{19}. Nine fractures involved part of the radial head (Mason type II), and forty-two involved the entire head (Mason type III). Eight patients had a simple fracture of the entire neck with the head completely displaced from the shaft, sixteen had a fracture of the entire head with more than two large displaced fragments, and eighteen had a fracture with a tilted and impacted articular fragment and small, comminuted markedly displaced fragments. All fractures were subclassified with regard to the absence or presence of a dislocation of the elbow. Eighteen patients had a posterior elbow dislocation with an isolated radial head fracture, and sixteen other patients had a posterior elbow dislocation associated with fractures of the coronoid process and radial head. The fractures of the coronoid process were categorized into three types according to the system of Regan and Morrey\textsuperscript{20}. There were ten type-I B fractures, five type-IB fractures, and one type-IIIIB fracture. Two patients had an associated fracture of the proximal part of the ipsilateral humerus. Six patients had both a radial head fracture and a posterior fracture-dislocation of the elbow (a posterior Monteggia lesion). The mean time from the injury to surgery was 4.1 days (range, two to seven days).

The surgical technique has been previously described\textsuperscript{20}. The patient was placed in the supine position on the operating table with the arm on a side arm-table for the entire procedure. A Kocher exposure was used with the forearm pronated.
to protect the posterior interosseous branch of the radial nerve. The interval between the anconeus and the extensor carpi ulnaris was developed. In patients with an elbow dislocation, the lateral collateral ligament was already avulsed from its proximal attachment, facilitating surgical exposure. In some patients, the lateral collateral ligament was carefully released and then repaired at the end of the operation. The medial collateral ligament and the interosseous radioulnar membrane\(^a\) were assessed for stability during the surgery. With the forearm placed in pronation and the elbow in 30° of flexion, the stability of the medial collateral ligament was assessed by exerting a valgus stress on the elbow. A decrease in the distance between the radial neck and the capitellum of >2 mm was considered abnormal. A Kocher clamp was placed on the radial neck and the radius was axially loaded to assess the competence of the interosseous membrane. A change in the distance between the radial neck and the capitellum of >2 mm was considered abnormal. Lateral ligament injuries were assessed during the surgical approach.

The medullary canal was prepared with small rasps of 6.5 or 8 mm in diameter sized with trial stems. All of the stems were cemented. The canal was plugged distally with bone fragments from the fractured radial head. With use of a syringe, cement was inserted in an antegrade manner, and the corresponding radial shaft component was inserted manually. The inclination of the neck was set in the same plane as that of the thumb positioned in abduction and forward flexion\(^b\). Radial head templates (19 and 22 mm) were used to assess stability and the head dimensions and to avoid impingement against the humerus while allowing a clearance of 1 mm. Particular attention was paid to the surgical repair of the lesions of the lateral ligament complex to prevent posterolateral rotatory instability of the elbow. The ulnar attachment of the lateral ulnar collateral ligament was palpated at the tubercle of the supinator crest and was dissected. On the humeral side, the supracondylar ridge was exposed posteriorly and anteriorly. We reattached the lateral collateral ligament with interrupted transosseous number-1 nonabsorbable braided sutures after insertion of the prosthesis in thirty-three patients.

The torn medial collateral ligament was repaired in seven patients because the elbow was unstable following radial head replacement. The ligament was exposed through a medial incision centered over the medial epicondyly, and the ulnar nerve was identified. In four patients, a muscle-splitting approach was made in the flexor-pronator mass extending from the medial humeral epicondyly to a point distal to the tubercle of the ulna. In three patients, to provide additional exposure, the common flexor-pronator mass and the pronator teres were released from the medial epicondyly in such a way that reinsertion was possible. Mobilization and subcutaneous transposition of the ulnar nerve was performed in these patients. The medial epicondyly was exposed completely. The medial collateral ligament was found to be disrupted from its insertion on the medial epicondyly. The proximal point of isometry was determined, and the medial collateral ligament was reattached with 5.0-mm FastinRC suture anchors with number-2 Ethibond (DePuy-Mitek Products, Raynham, Massachusetts). The suture in the medial collateral ligament was tied after the radial head was inserted.

The mean duration of follow-up was 8.4 years (range, four to thirteen years). All patients were examined by us clinically and radiographically two and six months after the operation and then annually with plain radiographs of the elbow and wrist. All fifty-one patients were evaluated by one of us (N.P.) at the time of the last follow-up.

Anteroposterior, lateral, and radiocapitellar radiographs of the elbow were made with the patient sitting on a stool and the upper extremity resting on a table. For the anterior radiograph, the shoulder was flexed forward and the elbow was extended as much as possible with the forearm supinated. The beam was centered perpendicular to the elbow on the midpoint of the antecubital crease. The lateral radiograph was made with the elbow flexed to 90°, the forearm in neutral rotation, and the shoulder internally rotated. The radiocapitellar radiograph was made with the elbow positioned as it was for the lateral radiograph but with the beam angled 45° anteriorly. Our radiographic system used phosphorus crystal plates and an analogue-to-digital converter system (ADC; Agfa, Mortsel, Belgium) for development. This allowed zooming of the digital image on a screen and provided more accurate measurements.

Assessment of the patients included measurement of the range of motion of the elbow and forearm as well as evaluation of pain and grip strength. Flexion and extension of the elbow were measured with a handheld goniometer held along the lateral aspect of the arm with the forearm in neutral rotation. Pronation and supination were measured at the extremes of active motion with the elbow in 90° of flexion. One arm of the goniometer was held along the patient’s arm and the second was placed parallel to the dorsal or volar aspect of the wrist. Pain was graded as absent, mild, moderate, or severe, and the need for pain medication was recorded. The isometric strength in flexion, extension, supination, and pronation was measured with a tensiometer (Pesola, Paris, France) at 90° of elbow flexion. All patients were evaluated with use of the Mayo Elbow Performance Index\(^c\).

Radiographic evaluation consisted of assessment and quantification of changes in the elbow joint and around the stem of the prosthesis in the proximal part of the radius. Degenerative changes in the elbow joint were classified according to the system of Broberg and Morrey\(^d\) and heterotopic ossification was graded according to the system of Hastings and Graham\(^e\) on the postoperative and most recent radiographs. The presence or absence of overstuffing of the radial head prosthesis was determined on follow-up radiographs by comparing the medial ulnohumeral joint space of the operatively treated and untreated elbows. If the medial ulnohumeral joint surfaces were parallel and the joint space was equal to that of the contralateral elbow, it was deemed that there was no overstuffing.

Changes in the proximal part of the radius, including radiolucent lines, osteolysis, and proximal resorption of the radial neck, were recorded. Resorption sites and lengths were assessed on standard anteroposterior radiographs with use of
the method developed by Gruen et al.\textsuperscript{24} for the hip. The proximal part of the radius was divided into seven zones (Fig. 2). The width of the radiolucent zones was measured at their widest point with a ruler. Progression was deemed to have occurred when the resorption had either extended into an additional zone or had widened by at least 1 mm between consecutive assessments\textsuperscript{25}.

Complete or incomplete radiolucent lines were defined by the presence of an adjacent layer of reactive bone sclerosis appearing as a radiopaque line no more than 1 mm thick. Osteolysis was identified as balloon-shaped radiolucent zones around the stem or as isolated proximal bone resorption at the radial neck, without any reactive bone sclerosis.

Migration of the stem of the prosthesis relative to the bone was evaluated with use of the Imagika image analysis system (GreyStone, Paris, France). An analysis model (a custom-made program built with the Imagika software) was created in order to evaluate the reliability of several possible landmarks on the proximal part of the radius and on the stem and to assess the possibility of using a correction factor to improve the comparability of successive radiographs made under nonstandardized conditions. The Imagika method can be applied to marked reference points on scanned radiographs. On the basis of two points determined manually on the contour of the prosthetic head, the software identifies the largest diameter of the head with use of automatic edge detection. The known diameter of the prosthetic head is used for calibration. For assessment of migration, a reference point on the prosthesis is determined at the intersection of the longitudinal axis of the stem and the transverse axis of the collar of the prosthesis. The reference point on the radius is the most distal point of the radial tuberosity; from this point, a line is drawn perpendicular to the longitudinal axis of the stem, and a second reference point is marked at the intersection. The distance between these two points is compared on consecutive radiographs, and any reduction in the distance indicates subsidence of the stem (Fig. 3).

The stability of the implant in the coronal plan was evaluated by measuring valgus laxity with stress radiography. Stress radiographs were made with the aid of a Telos GA-II/E stress device (Telos, Weiterstadt, Germany) for all fifty-one patients. The Telos stress device was used to provide consistent extremity positioning and a valgus stress. The reliability of the Telos stress device was tested in a previous study, in which bilateral radiographs of the elbows of fifty normal individuals were made.
were made with use of an identical procedure. The intraclass correlation coefficient was found to be 0.95. The Telos device can provide medial joint space widths that can be reliably measured on anteroposterior radiographs when the radiographs are interpreted by one radiologist. The elbow was flexed 30° with the forearm in neutral rotation. The elbow flexion position was verified with use of a standard universal goniometer. The patient was seated on a stool with the Telos device placed on the radiography table and the shoulder abducted 65° and externally rotated. The arm was placed within the Telos apparatus with a proximal stabilizing pad just distal to the axilla and a distal stabilizing pad at the hand and the wrist. This was accomplished by having the patient grasp a handle on the Telos device with the forearm in neutral rotation. Anteroposterior radiographs of both elbows were then made with 0 and 150 N of applied valgus force. The medial joint space was measured before and after application of the valgus stress. A dependent t test was used to identify differences in medial laxity between the operatively treated and contralateral arms, with significance set at the 0.05 level. All radiographs were made by one technician with the assistance of the senior author (N.P.), and they were interpreted by one independent senior radiologist.

**Results**

**Clinical Results**

At the time of follow-up, the average Mayo Elbow Performance Index was 83 points (range, 59 to 95 points). Elbow flexion averaged 130°; extension, 14°; supination, 71°; and pronation, 68°. The mean functional arc of motion was 116° (range, 50° to 135°). A correlation (r = 0.84) was noted between restriction of elbow mobility and the severity of the initial injury. Twenty-three patients had complete pain relief; eighteen patients had mild elbow pain after strenuous daily activities; eight patients had moderate pain, requiring some form of medication, with daily activities; and two patients, both with overstuffing of the radial head prosthesis, had severe pain. The mean grip strength on the injured side (29 kg) was significantly reduced compared with that of the contralateral extremity (34 kg) (p = 0.017). One patient, in whom the initial injury was a comminuted radial head fracture associated with elbow dislocation and proximal detachment of the lateral collateral ligament, had persistent ligamentous laxity. The lateral ulnar collateral ligament had been inadequately restored. At six months, the patient reported mild pain. During the pivot shift maneuver, a clunk as a result of spontaneous radial head reduction was noted. A subcutaneous dimple was present just proximal to the radial head as the prosthesis subluxated posteriorly, and it disappeared with reduction of the radial head. The patient deferred operative intervention. None of the patients had any symptoms related to the radiocarpal or distal radioulnar joint.

**Radiographic Assessment**

Twenty-seven patients (53%) had radiographic evidence of periprosthetic lucency within the medullary canal of the radius. Progressive loss of bone in the radial neck region, adjacent to the area beneath the collar of the implant (zones 1 and 7), was observed in sixteen patients (31%) (Fig. 4). Five patients (10%) had progressive balloon-shaped osteolysis in the midstem region (zones 2, 3, 5, and 6) with important changes in cortical wall thickness (Fig. 5). The stem of the prosthesis had migrated more than 1 mm in these five patients.

Six patients were seen to have a reduction in the thickness of the articular cartilage of the capitellum on the radiocapitellar radiograph, and marked flattening of the capitellum was noted in two patients. Compared with the contralateral elbow, thirty involved elbows had radiographic evidence of posttraumatic osteoarthritis according to the classification system of Broberg and Morrey. The posttraumatic ulnornueral osteoarthritis was graded as mild in twenty-one patients, moderate in seven, and severe in two. An increase in pain after daily activities could be attributed to degenerative arthritis of the elbow in these patients. Heterotopic ossification was observed in twenty-one patients at the time of final follow-up. According to the Hastings-Graham classification, thirteen had class-I ossification, six had class-II (three had class-Ila, two had class-Iib, and one had class-IIC), and two had class-III. There were no fractures of any of the prosthetic components.

With no stress applied, the radiographic measurements of the medial joint space widths did not show a significant difference between the operatively treated elbows (mean and standard deviation, 3.5 ± 0.5 mm) and those that had not been operated on (3.4 ± 0.5 mm) (p = 0.36). Application of
the valgus stress (150 N) resulted in a significant increase in the medial ulnohumeral distance in both elbows as compared with the values under the unstressed condition (p = 0.018); on the average, the operatively treated extremities had 0.3 ± 0.1-mm greater increase in the medial joint space width with the application of 150 N of valgus stress (p = 0.06). There was no significant difference in the amount of valgus stress opening between the operatively treated and contralateral elbows.

Complications
There were ten complications. Complex regional pain syndrome developed in one patient. Four patients sustained a posterior interosseous nerve palsy related to exposure that resolved spontaneously four months postoperatively. In these four patients, a more anterior interval through the extensor digitorum communis had been used and retractors had been placed around the radial neck. We believe that these factors were responsible for the transient neurological complications. A progressive ulnar neuropathy developed in one patient who had had a comminuted radial head fracture associated with a posterior elbow dislocation and a type-IB coronoid fracture; nerve decompression was performed at eight months, with a satisfactory result. A complete proximal radioulnar synostosis developed in another patient. Two patients had early persistent pain and early degenerative changes, which were attributed to overstuffing of the radial head replacement. One patient had posterolateral subluxation of the prosthesis. There were no infections. At the time of writing, no implant has been permanently removed.

Discussion
Overall, the short-term results following treatment with the bipolar radial head prosthesis have been promising, so that this implant appeared to be a safe and effective option. The clinical results in the present study are largely comparable with those in other studies on metal radial head replacement. They suggest that the bipolar radial head prosthesis provides an overall satisfactory clinical outcome with respect to the four most important functional parameters: stability, motion, pain, and strength. Our observation that the severity of the initial elbow injury influenced the functional outcomes, especially elbow mobility, is in agreement with the findings of others.

Previous reports on the short-term results of treatment with a bipolar radial prosthesis did not mention progressive radiographic changes at the elbow—i.e., the authors did not note lucencies surrounding the cemented stems, progressive joint space narrowing, stem loosening, or osteoporosis of the humeral condyle. To our knowledge, only Smets et al. reported progression of degenerative changes in a few patients. These excellent short-term radiographic results were attributed to automatic (self-correcting) positioning of the prosthetic head against the capitellum and the radial notch of the ulna, reducing the possibility of aseptic loosening secondary to the complex movements of the elbow. However, in our midterm study, we observed three different types of radiographic changes around the prosthetic stem: complete or incomplete radiolucent lines, balloon-shaped radiolucent zones, and proximal bone resorption at the radial neck.

Radiolucent lines surrounding the stem of the bipolar radial head prosthesis were observed in twenty-seven patients. In eleven of these patients, incomplete radiolucent lines developed early in the first postoperative year and remained stable over time. It is our impression that the lucencies in these eleven patients can be attributed to suboptimal initial fixation as a result of suboptimal cementing technique because of the small diameter of the medullary canal of the proximal part of the radius. Progressive radiolucent lines were observed in the other sixteen patients. They may reflect progressive stem loosening as a result of mechanical factors, possibly in conjunction with progressive osteolysis.

Sixteen of our fifty-one patients had partial or complete loss of proximal bone support at the neck of the radius, whereas...
the distal end of the prosthesis remained rigidly fixed in the cement. Proximal bone resorption could result from osteolysis secondary to wear debris from the bipolar device or from altered load transmission to the osteotomized neck of the radius. A possible indication for operative intervention is local pain with radiographic evidence of complete loosening and bone destruction around the stem with a danger of cortical fracture. If intervention is necessary, removal of the prosthesis is the only procedure that we would currently recommend, considering our limited experience with failed radial head prostheses. As we have not reintervened to date and therefore have no histologic studies, we can only speculate that the bone destruction may have been related to tissue reaction to wear particles, a process that has been studied extensively at the hip joint. Whether stress-shielding played any role in the bone loss at the radial neck is difficult to say, although one would expect that it would result first in cortical atrophy, which we did not observe. Longer follow-up is needed to assess whether the proximal resorption is a continuous process. We did observe progressive ballooning osteolysis with bone destruction in the midstem region and radiographic evidence of complete loosening in five patients.

A possible explanation for the high prevalence of radiographic changes reflecting or suggesting osteolysis in our patients is that the bipolar radial head prosthesis consists of two parts. The radial head is made of high-density polyethylene enclosed in a cobalt-chromium cup that articulates in a semi-constrained manner with the spherical end of a cemented stem21. Biomechanical studies have shown that the radiocapitellar joint carries considerable loads22,23 and that the contact area of a metal head is reduced by approximately two-thirds as compared with the native radiocapitellar joint24. We hypothesize that there is likely an excess of contact stresses between the small spherical metal head and the thin (3-mm-thick) polyethylene insert. Previous studies on hip arthroplasty have suggested that the yield strength of ultra-high molecular weight polyethylene inlays of <8 mm in thickness is exceeded by the joint contact stresses, which may result in catastrophic wear25. However, this finding may not be applicable to the elbow joint, where the biomechanical conditions are different, or to the particular design concept of the bipolar radial head prosthesis. It is well established that polyethylene wear can lead to osteolysis and bone loss as a result of a macrophage response to particulate debris26. Osteolysis is often silent, and it is common for patients not to experience pain until the bone loss is advanced, as was the case in five of our patients. In our series, stem migration was observed only in the patients with obvious balloon-shaped osteolysis and not in the patients with radiolucent lines or radial neck resorption. The results of this study confirm that, despite midterm satisfactory clinical results with the bipolar radial head prosthesis, radiographic changes occur over time, possibly reflecting osteolysis at the bone-cement interface in a number of patients. It also appears that the fixed cemented stem of a bipolar radial head prosthesis can loosen over time and that osteolysis secondary to wear debris from the bipolar interface may be one of the contributing factors. Clinicians should be aware that one possible long-term drawback of use of the bipolar radial head prosthesis is major loss of bone in the area of the stem, which warrants caution regarding the use of this prosthesis in young and active individuals. A longer duration of follow-up and studies of larger series of patients will be required before definitive treatment recommendations can be made.

References

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