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ORIGINAL ARTICLE

Radial head replacement with unipolar and bipolar SBi system: a clinical and radiographic analysis after a 2-year mean follow-up

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Abstract Radial head prosthetic replacement is indicated in case of comminuted fracture not amenable to internal fixation, especially when the radial head fracture is part of a pattern of lesions configuring a complex instability of the elbow. Thirty-one SBi radial head prostheses were implanted in 30 patients (one bilateral simultaneous fracture) over a 2 years period. In 10 patients, the mean time from trauma to surgical treatment was 2.4 days, while the remaining 20 patients were treated as "second opinion" cases presenting with elbow stiffness or instability after an average of 19 days from trauma. The implants were monopolar in 12 cases and bipolar in 19. The clinical results were evaluated through the Mayo Elbow performance scoring system. At an average follow-up of 2 years (range 13–36 months), the mean MEPS was 90 points (range 65–100). At late radiographic analysis, radiolucent lines around the stem were found in 11 of the 31 cases. Heterotopic ossifications were found in 14 cases. Bone resorption was observed in 9 cases. Two of the 31 prostheses were removed after 16 and 20 months, in one case to correct stiffness in pronation/supination, in the other one for asymptomatic aseptic mobilization. These short-term results are satisfactory, especially when considering that they were obtained in complex elbow lesions treated in many cases at a delayed stage. Our preference over time went more and more to bipolar implants, but from a comparison of the results we could find no evidence of a superiority of bipolar or monopolar implants. The evolution of these prostheses needs to be evaluated with further studies to assess mid-term and long-term follow-up results.

Keywords Radial head prosthesis · SBi prosthesis · Radial head fracture · Complex instability of the elbow

Introduction

A wide consensus exists in literature about the implant of a radial head prosthesis in case of comminuted unreconstructible fracture of the proximal radius. Moreover, this approach is mandatory when the radial head fracture is accompanied by other bone lesions (coronoid and olecranon fractures) and ligament ruptures (lateral and medial collateral) in the setting of so-called "Complex Instabilities of the Elbow" [1–5]. Radial head substitution in complex instability of the elbow is necessary in order to avoid worsening of the instability that would be caused by excision of the radial head both on the horizontal (valgus instability) and on the longitudinal (Essex-Lopresti) planes. Such type of instability once established results difficult and sometimes impossible to treat even by a new surgical approach. In the years, a great variety of implants have been developed to replace the radial head [6]. The prostheses currently in use are manufactured in metallic materials and nowadays more than 10 prosthetic models are available that, basing on the design of the proximal component, can be divided into three different categories: unipolar, with a fixed cylindrical head; anatomical, with a fixed and anatomically designed head; and bipolar, with cylindrical mobile head. Following the development of these different prosthetic models and after trying prostheses of the different described categories, the Authors have

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elected in the last 3 years to use the unipolar or bipolar SBi system. This system appears nowadays to be the most versatile, as it allows the possibility to chose during the surgical procedure between a unipolar and a bipolar implant and to modify the height of the prosthesis, basing on the actual bone loss. Another important feature of this kind of implant is the anatomical shape of the cementless textured stem, designed with the aims of making introduction in the medullary canal easier, if compared with the straight stems, and of increasing prosthesis stability. The Authors preference has gradually gone to the bipolar SBi system on the belief that, given the impossibility to reconstruct the anatomical shape of the radio-humeral and of the radio-ulnar joints, a bipolar design may offer the best possible contact in the whole range of movement in both the articular surfaces of the prosthesis, thanks to its self-alignment to the capitellum and to the proximal ulna [7]. The Co–Cr radial head brings an internal polyethylene coating that gets firmly held with a snapping mechanism in the spherical head of the anatomical metallic stem allowing a movement of 10°, searching for the best compromise between congruency and stability of the elbow. The polyethylene coating may, however, theoretically become the origin of debris production.

Aims of this study are first to verify the ability in correct implant positioning (head size, stem orientation and fit), second to verify the occurrence of heterotopic ossifications, radiolucency lines, bone resorption and arthrosis; and third, to analyze the quality of clinical results looking for possible differences between unipolar and bipolar implants.

Materials and methods

Study population

A retrospective review of institutional database was performed and allowed us to find 31 consecutive cases in which a radial head prosthesis was implanted (30 patients, one case of bilateral contemporary replacement) for unfixable fractures with elbow or forearm instability in the period January 2009–December 2010. There were 19 men and 11 women, in 16 cases the right elbow was involved, and in 15 cases the left one. The mean age was 44 years (range 22–73) and the mean follow-up was 24 months (range 13–36).

To define a mean delay between the time of the injury and the surgical treatment, we have to divide the patients in two groups. The first group includes 10 patients who had their first medical care in the emergency ward of our Institute. In these cases, the average time from injury to surgical treatment was 2.4 days (range 1–6); the delay was less than 48 h in 6 cases. The other 20 patients came to our attention as "second opinion" cases because of elbow stiffness or instability, after nonsurgical treatment (19 cases) or after previous surgical treatments at outside Institutions (1 case, patient nr. 22, had a transolecranon elbow dislocation with radial head and coronoid fractures, surgically treated only with ulna fixation 17 days before). For these reasons, these data suffer from a great heterogeneity (mean interval 19 days, range 5–130).

Classification of the lesions

Every patient was studied at the time of admission in our Unit with a 2D-3D CT scan to better analyze the pattern of the lesion that was defined following the Van Riet-Morrey classification [8, 9] of radial head fractures and associated injuries. After that, the 31 cases were assigned to one of five categories. Group 1—2 cases of isolated unfixable radial head fracture (Van Riet-Morrey III). Group 2—7 cases of radial head fracture with lesion of the collateral ligaments (4 cases of Van Riet-Morrey III M L, 2 cases III L, and 1 case of III M). Group 3—15 cases of radial head fracture with coronoid fracture and lesion of both collateral ligaments (Van Riet-Morrey III C M L). Group 4—5 cases of transolecranon dislocation with radial head fracture (4 cases of Van Riet-Morrey III O and 1 case III O M L). Group 5—2 cases of transolecranon dislocation with radial head and coronoid fractures (Van Riet-Morrey III O C M L).

Operative treatment and postoperative care

After a blended locoregional and soft general anesthesia with a laryngeal mask, the stability of the elbow was tested before starting surgery. Every patient was placed in a supine position with the arm lying on the chest. Ischemia was induced by a sterile pneumatic tourniquet. The surgical approach in every case of group 1 (isolated unfixable radial head fracture), group 2 (unfixable radial head fracture with lesion of the collateral ligaments), and group 3 (unfixable radial head fracture with coronoid fracture and lesion of both collateral ligaments) was based on a lateral skin incision, identification, and entrance of the Kocher interval between Anconeus and Extensor Carpi Ulnaris muscles (except when the trauma had determined a wide lesion in the context of the extensor muscles that was used to reach the joint). The procedure was performed with the forearm held in pronation to protect the posterior interosseous nerve (PIN). In group 4 (transolecranon dislocation) and group 5 (transolecranic dislocation and coronoid fractures) patients, a posterior skin incision was preferred allowing to perform a Boyd approach for radial head substitution and coronoid fixation as well as ORIF of the olecranon with a pre-contoured plate and screws.

The first surgical step, both in cases of lateral and posterior approach, has always been the approach to the joint with the aim to evaluate the real status of the radial head that appeared unfixable in each case. Once the radial head and its fragments have been removed, the coronoid was examined: in one case, the coronoid was not dislocated and was not surgically treated; in two cases (Regan-Morrey type III coronoid fractures [10]), the large size of the fragment allowed its fixation with one 3.5 mm screw and one K wire to neutralize the rotational forces; in five cases (Regan-Morrey type II), the coronoid fragment was fixed with two K wires following an out-in technique under fluoroscopic control (handling the ulnar nerve to avoid any injury); in nine cases (Regan-Morrey type I), the coronoid and the anterior capsule were fixed by two high-performance braided sutures, passing through two tunnels from the ulnar crest. After obtaining a satisfactory fixation of the coronoid, the following steps were the implant of the radial head prosthesis, the collateral ligaments repair, the olecranon ORIF when required and a final fluoroscopic control of the implants. The stability and the range of movement in flexion, extension, pronation and supination were always verified.

The implanted prostheses were 12 monopolar and 19 bipolar SBi radial head prostheses (Radial Head Implant, Small Bone innovations, Morrisville, Pennsylvania, USA). This prosthesis is a modular implant with a Co–Cr stem coated with a textured surface and head in Co–Cr (four stem sizes and three head sizes are currently available), created with the aim to give the surgeon the possibility to choose during the operation the type of head, fixed or mobile. All the stems were implanted without use of cement. Every elbow was placed in a splint in flexion, allowing a self-assisted mobilization starting the day after surgery.

Follow-up evaluation

During the second day after surgery, the drainage was removed and an X-ray study in antero-posterior and lateral views was performed to evaluate the implant positioning. Three parameters were taken into account: the size of the head, the orientation of the stem and its fit. To evaluate the correct sizing of the head, we considered as correct a head whose profile did not exceed a line tangent to the lateral humeral condyle and a line tangent to the radio-humeral joint (Fig. 1). The correct orientation of the stem, according to the surgical technique, is defined by the correspondence of the stem concavity with the "concavity" drawn by the biceps tuberosity of the radius (Fig. 1). The third parameter was the fit of the stem: this kind of prosthesis, if implanted un-cemented as usual, must be press-fitted, obtaining a circumferential contact between the anatomic stem and the bone. To define the quality of the fit on an X-ray examination in two projections, we chose the following definitions: fit 4 means the contact of the stem with both cortical walls in both planes of the X-ray; fit 3 means the lack of contact between the stem and one cortex in the two planes (Fig. 2a, b); fit 2 the lack of contact between the stem and two cortices in the two planes; fit 1 the contact between the stem and one only cortex in the two planes (Fig. 3a, b); fit 0 is a circumferential lack of contact with the cortical bone.

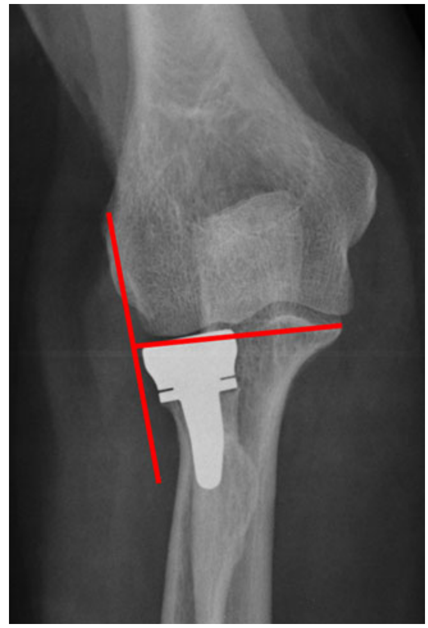

Fig. 1 Correct radial head sizing and stem orientation

The patients were then followed up clinically and radiographically. The clinical assessment was analyzed by the Mayo elbow performance score (MEPS), that is, an objective and subjective scoring system evaluating pain, range of motion, stability and daily function [11] and classifying as excellent the results greater than 90 points, good the results between 75 and 89 points, fair the results between 60 and 74 points and poor the results lower than 60 points. The radiographical evaluation was done at 2 weeks, 4 weeks, 3 months, 6 months, 12 months after surgical treatment and then twice a year. In the radiographic examination, four parameters were assessed: ulnohumeral joint arthrosis, radiolucency around the stem, radiohumeral ossifications and bone resorption around the stem. The ulnohumeral arthrosis was defined based on the Broberg–Morrey definition [12]: grade 0, normal elbow; grade 1, slight joint space narrowing with minimum osteophyte formation; grade 2, moderate joint space narrowing with moderate osteophyte formation (Fig. 4a, b); grade 3, severe degenerative change with gross destruction of the joint. Three categories of lucency around the stem were defined: absent, less than 2 mm, and greater than 2 mm, measured in the deepest lucency point (Fig. 5a, b). The

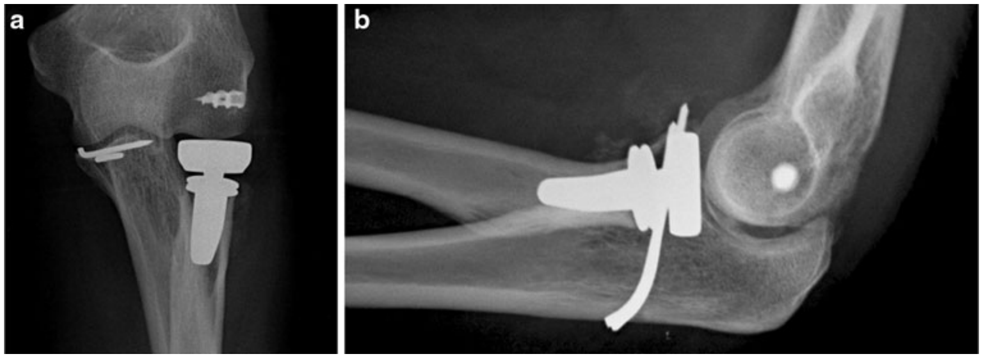

Fig. 2 Example of fit 3 between stem and bone. **a** One cortical fit in antero-posterior view, **b** two cortical fits in lateral view

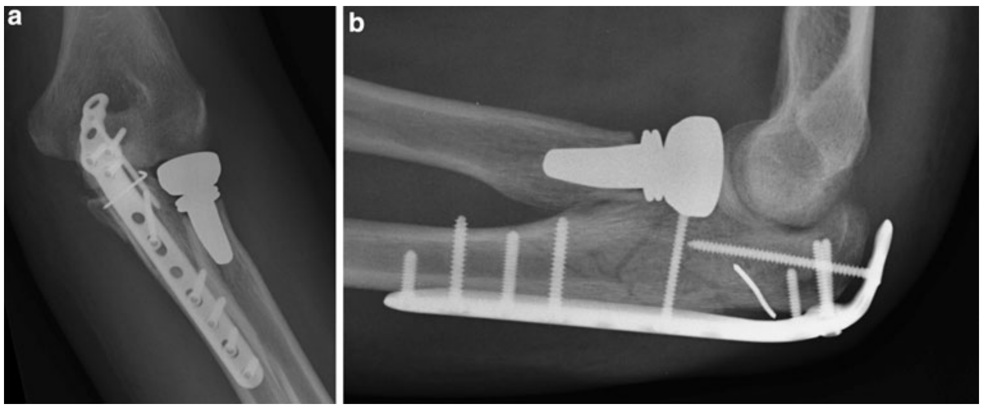

Fig. 3 Example of fit 1 between stem and bone. **a** One cortical fit in antero-posterior view, **b** no cortical fit in lateral view. The largest available stem was used

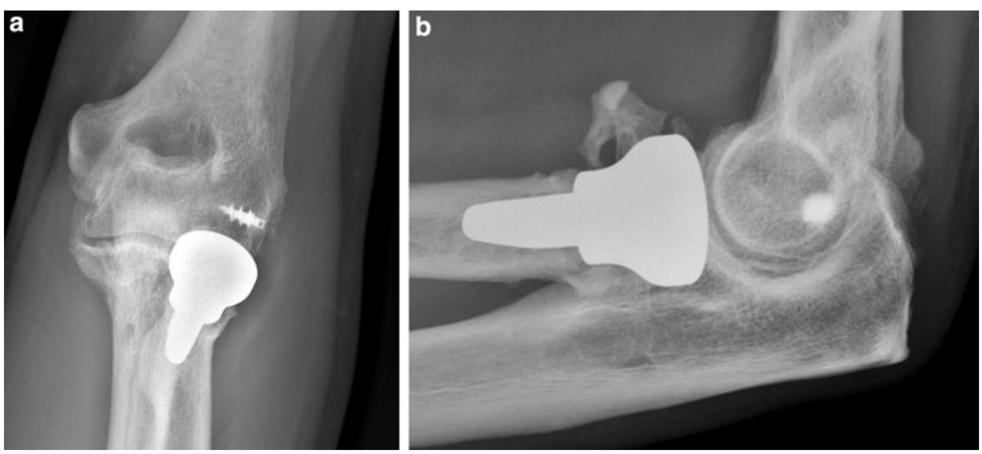

Fig. 4 Ulnohumeral arthrosis, grade 2 according to Broberg–Morrey classification at 31 months follow-up

heterotopic ossifications of the elbow were defined following the Ilahi-Gabel classification [13, 14], considering the angle subtended by the largest piece of ectopic bone, measured from the center of the capitellum on the lateral radiograph: grade 0, absence of ossifications; grade I, ossification subtending less than 30°; grade II, ossification subtending an angle between 30° and 60°; grade III, ossification subtending an angle greater than 60° (Fig. 6); grade IV bridging ulnohumeral or radiohumeral ectopic bone on any radiographic view. We defined bone resorption around the stem in three grades: grade 0, absent resorption; grade 1: resorption less than 3 mm in the deepest point; grade 2, resorption greater than 3 mm in the deepest point (Fig. 7a, b).

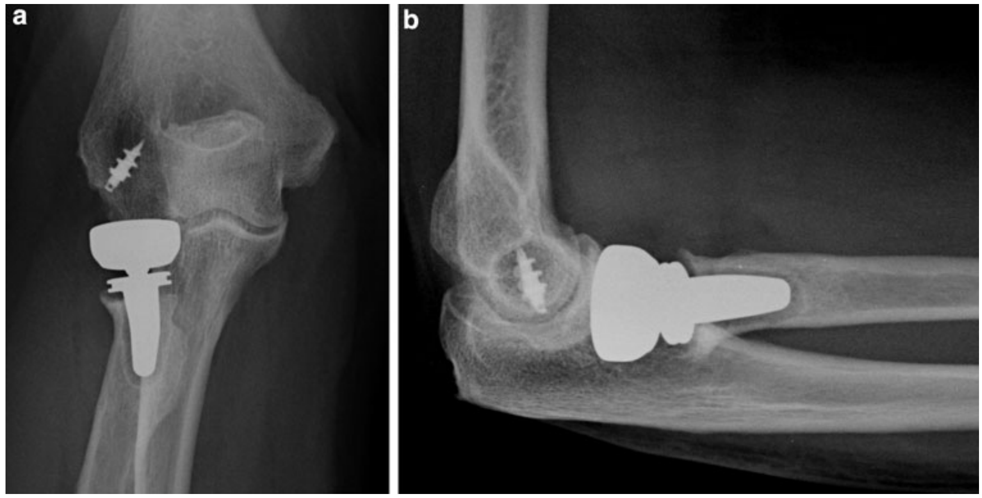

Fig. 5 Stem radiolucency greater than 2 mm

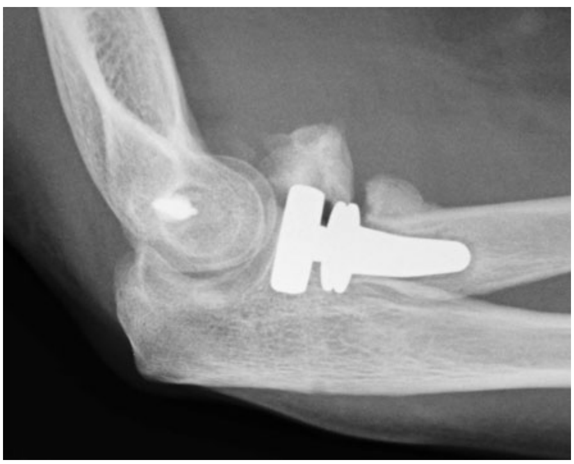

Fig. 6 Heterotopic ossification, grade 3 according to Ilahi-Gabel classification, in lateral view. A periosteal bone reaction of the antero-lateral neck cortical is visible

Data analysis

A Fisher's exact test has been performed to check whether any correlation could be found between ten series of couples of parameters of our study (stem fit and resorption; stem fit and radiolucencies; timing and heterotopic ossifications; ROM in f/e and heterotopic ossifications; ROM in p/s and heterotopic ossifications; type of implant and resorption; ROM in f/e and type of implant; ROM in p/s and type of implant; type of lesion and arthrosis; type of implant and arthrosis).

Results

Postoperative radiographic evaluation

Analyzing the "early" radiographic study, carried out 48 h after the surgical treatment for every patients, 4 heads out of 31 (12.8 %, patients nr. 2, 3, 10 monopolar and 12 bipolar) were evaluated as oversized. In two cases out of 31 (6.4 %, patient nr. 1 and patient nr. 7), the stem did not result to be in the correct position, defined by the correspondence of the stem concavity with the "concavity" drawn by the biceps tuberosity of the radius. One of these was the first implant in the Authors' experience. Dealing with the fit, 4 cases (12.9 %) had a type 4 fit, 7 cases (22.6 %) had a type 3 fit, 12 cases (38.7 %) had a type 2 fit, 8 cases (25.8 %) had a type 1 fit, no case was find to have a type 0 fit. Based on these data, in 20 cases, (64.5 %) there was a postoperative fit with less than three cortical walls.

Clinical and functional results

The clinical results at last follow-up (average 24 months, range 13–36 months) evaluated through the MEPS system were excellent in 21 cases (67.7 %), good in 8 (25.8 %), and fair in 2 (6.5 %). The mean value of 90 points (minimum 65–maximum 100) depicts a satisfactory clinical result (93.5 % excellent and good results), even more if we take into account the pattern of severity of the lesion. One of the two cases with a fair result is a 56-year-old woman (patient nr. 8), which was one of the two cases of Van Riet-Morrey III O C M L, surgically treated 11 days after the trauma (the patient was transferred from another Institution to our ward) with a unipolar radial head prosthesis and fixation of olecranon and coronoid. She was offered the opportunity of a hardware removal with the goal of improving range of movement, but she refused. The second case with a fair result is a 65-year-old woman with a Van Riet-Morrey type III lesion (patient nr. 18) who underwent the implant of a bipolar prosthesis 27 days after the injury and the conservative treatment decided elsewhere. She achieved a range of movement of 100° in flexion–extension

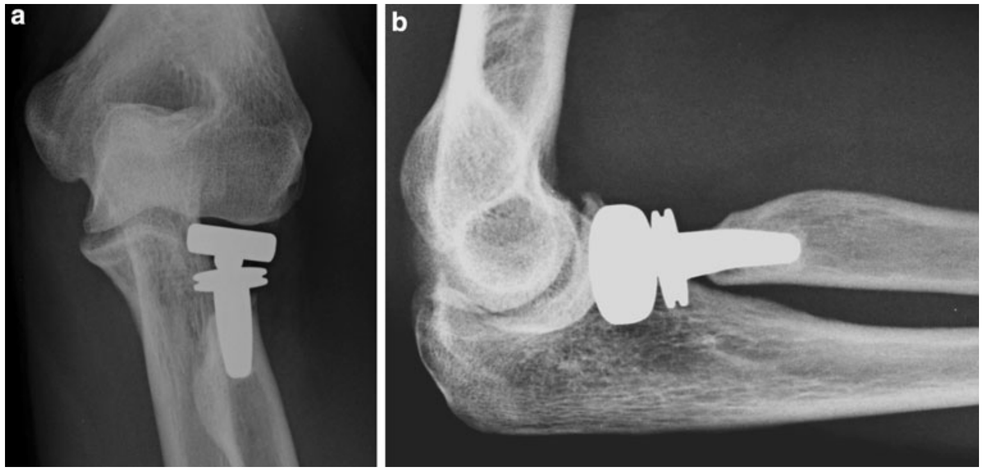

Fig. 7 Bone resorption (stress-shielding) grade 2

and of 130° in pronation–supination, but complained about pain and functional limitation in daily activities.

Late radiographic evaluation

The data obtained at the late radiographic study are summarized in Table 1. Two patients (6.4 %) developed a Broberg–Morrey grade 2 (moderate) arthrosis of the ulnohumeral joint. They were a 52-year-old woman (patient nr. 30), that had suffered from a III C M L Van Riet-Morrey injury, and the right elbow of the 43-year-old male patient who underwent a simultaneous bilateral implant (patient nr. 12). About the development of arthrosis, all the other patients were classified as grade 0 or 1, according to Broberg–Morrey. No significant correlation was found between group of pathology and development of arthrosis ($p = 0.41$).

Just one case (3.2 %) showed a significant lucency around the stem (patient nr. 11) without radiological signs of implant mobilization, with a range of movement of 140° in flexion and extension and 160° in pronation and supination and with a MEPS of 90 points 29 months after the treatment. Ten cases (32.2 %) showed a lucency less than 2 mm and 20 cases (64.6 %) showed no lucency, with a good contact between the stem and the bone.

Three patients (9.7 %, patients nr. 22, 27 and 30) developed periarticular ossifications grade 3 according to the Ilahi-Gabel classification. Two of them showed a limitation in pronation and supination (20 and 30°, respectively), the third achieved 120° in pronation and supination, but all of them had a good movement in flexion and extension. Six patients (19.4 %) developed grade 2 periarticular ossifications: two of them (patient nr. 16 and patient nr. 28) recovered a full range of movement, two (patent nr. 4 and the left elbow of the patient nr. 12) had no limitation in pronation and supination with a slight limitation in extension, one (patient nr. 19) obtained 140° in pronation and supination and 85° in flexion–extension and the last (patient nr. 19) showed a limitation in pronation and supination (60°) and in flexion–extension (85°). Five patient (16.1 %) developed grade I periarticular ossifications: three of them had a wide recovery of movement (patients nr. 3, 10 and 26), the other two (the right elbow of the patient nr 12 and patient nr. 17) showed a good recovery of flexion and extension and limitation in pronation and supination; 17 patients (54.8 %) did not develop any kind of ossifications and in this group and there was no significant limitation in the range of movement. The statistical analysis put into evidence a significant correlation between ROM in flexion and extension and ossifications ($p = 0.0046$) and ROM in pronation and supination and ossifications ($p = 0.0027$).

The analysis of bone resorption showed three patients (9.7 %) with a rate greater than 3 mm. along the entire circumference of the radius: The first case is the woman (patient nr. 9) with a circumferential bone resorption greater than 7 mm., who underwent the prosthesis removal at 20 months, because of aseptic loosening (Fig. 8a, b); the other two cases (patient nr. 15 and 23), despite the resorption, showed on radiographs a bone–distal stem integration with complete recovery of the movement and very good clinical results (90 and 100 MEPS, respectively). Six patients (19.3 %) showed a resorption inferior to 3 mm.; four of them (patient nr. 1, 11, 14, and 28) had no limitation of movement and excellent clinical results, one (patient nr. 13) had a slight limitation in the flexion–extension range (30–140°) with a MEPS of 100 points and the last (patient nr. 19) had a lack of 40° in extension and of 25° in flexion, but pronation and supination were satisfactory (140°) and the clinical result was excellent (MEPS 95 points). In 22 cases (71 %), no resorption was found. On a statistical basis, there was no correlation between type of prosthesis and resorption ($p = 0.6035$).

Re-operation rate

Analyzing the re-operation rate, the cases of ulnar hardware removal (complex instability of the elbow in which a

Table 1 Data of the patients

Nr.		Sex	Age	Van Riet	Group	Side	Implant	Head length	Stem orientation	Fit	MEPS	Ext–flex	Pron–sup	Arthrosis	Lucency	Ossifications	Resorption
1	U. P.	F	50	III O	4	Right	Monopolar	Corr	Wrong	2	95	0–140	80–0–80	0	0	0*	1
2	C. V.	M	33	III O	4	Right	Monopolar	Over	Corr	2	95	10–120	70–0–70	0	0	0	0
3	M. M.	M	26	III C M L	3	Right	Monopolar	Over	Corr	1	100	10–140	75–0–85	0	0	1	0
4	B. D.	M	48	III C M L	3	Left	Monopolar	Corr	Corr	2	90	45–130	75–0–85	1	0	2	0
5	M. D.	M	22	III M L	2	Left	Bipolar	Corr	Corr	2	100	0–140	80–0–80	0	1	0	0
6	C. M. A.	F	33	III M L	2	Left	Monopolar	Corr	Corr	3	100	10–150	80–0–80	0	0	0	0
7	P. V.	M	42	III C M L	3	Right	Monopolar	Corr	Wrong	1	85	30–130	60–0–80	1	1	0	0
8	R. M. G.	F	56	III O C M L	5	Left	Monopolar	Corr	Corr	2	65	45–130	60–0–70	1	0	0	0
9	B. L.	F	56	III	1	Right	Monopolar	Corr	Corr	3	85	10–120	60–0–70	0	1	0*	2
10	P. T.	F	73	III C M L	3	Left	Monopolar	Over	Corr	4	95	0–140	60–0–60	1	0	1*	0
11	T. T.	F	52	III M L	2	Right	Bipolar	Corr	Corr	3	90	0–140	80–0–80	0	2	0	1
12	G. A.	M	43	III C M L	3	Right	Bipolar	Over	Corr	2	80	30–110	0–0–20	2	1	1	0
				III CM L	3	Left	Monopolar	Corr	Corr	1	80	30–120	80–0–70	1	0	2	0
13	B. C.	M	33	III M	2	Right	Bipolar	Corr	Corr	2	100	30–140	75–0–85	0	0	0	1
14	P. C.	M	40	III O	4	Right	Bipolar	Corr	Corr	2	100	10–140	70–0–70	1	0	0	1
15	M. S.	F	47	III C M L	3	Right	Bipolar	Corr	Corr	3	100	0–140	80–0–80	0	0	0*	2
16	M. M.	M	57	III L	2	Left	Monopolar	Corr	Corr	1	85	15–130	70–0–70	1	1	2	0
17	R. M. T.	F	53	III M L	2	Left	Bipolar	Corr	Corr	2	85	20–130	30–0–10	0	0	1	0
18	G. M. R.	F	65	III	1	Right	Bipolar	Corr	Corr	1	70	20–120	60–0–70	1	1	0	0
19	C. G.	M	47	III C M L	3	Left	Bipolar	Corr	Corr	4	90	40–115	70–0–70	0	0	2	1
20	Sd'A. A.	M	53	III C M L	3	Right	Bipolar	Corr	Corr	1	95	10–140	60–0–60	0	0	0	0
21	R. G. M.	M	41	III C M L	3	Left	Bipolar	Corr	Corr	2	100	0–140	75–0–85	0	0	0	0
22	F. A. D.	M	24	III O C M L	5	Right	Bipolar	Corr	Corr	3	82	45–120	10–0–10	1	0	3	0
23	A. M.	F	32	III C M L	3	Right	Bipolar	Corr	Corr	3	90	10–140	75–0–85	0	0	0*	2
24	F. S. F.	M	53	III C M L	3	Left	Monopolar	Corr	Corr	4	100	10–140	75–0–85	0	1	0*	0
25	G. G.	M	39	III C M L	3	Left	Bipolar	Corr	Corr	3	80	25–110	40–0–20	0	1	2	0
26	G. A.	M	45	III L	2	Left	Bipolar	Corr	Corr	2	95	10–140	60–0–40	0	0	1	0
27	D. L. A.	M	46	III O M L	4	Right	Bipolar	Corr	Corr	4	78	25–130	30–0–0	0	0	3	0
28	A. M.	M	33	III C M L	3	Left	Bipolar	Corr	Corr	2	95	0–140	75–0–85	1	0	2	1
29	M. A.	M	40	III O	4	Left	Bipolar	Corr	Corr	1	90	10–140	50–0–50	0	1	0	0
30	S. G.	F	52	III C M L	3	Right	Bipolar	Corr	Corr	1	90	35–125	60–0–60	2	1	3	0

The asterisks in the column regarding the ossifications underline the six patients treated within 48 h from the trauma

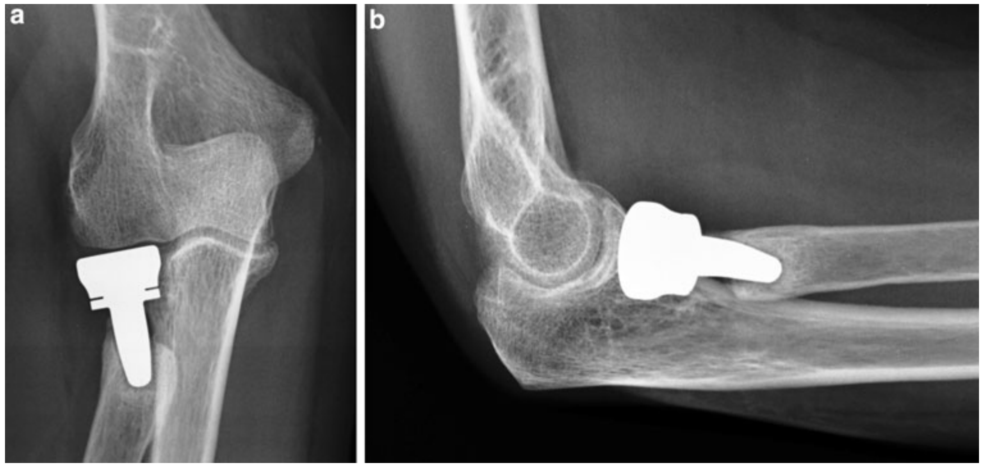

Fig. 8 Aseptic loosening with bone resorption

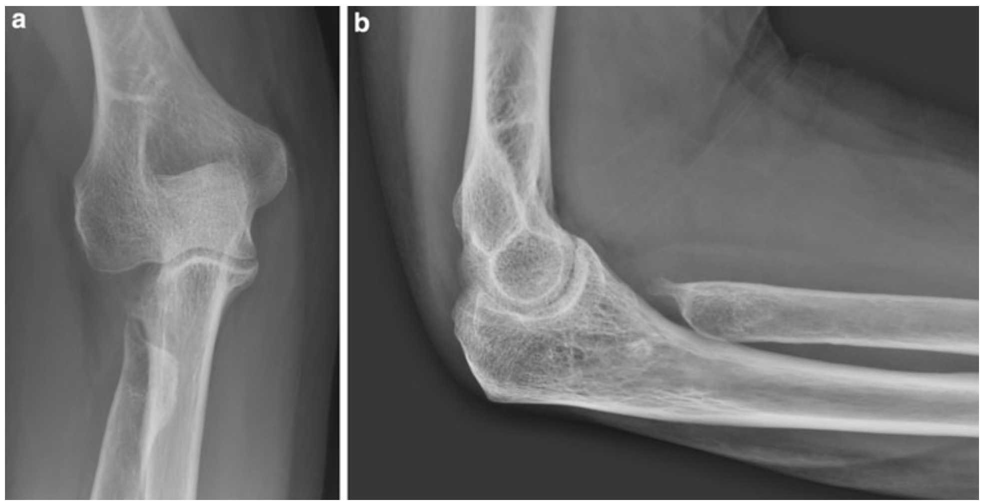

Fig. 9 X-ray evaluation after implant removal

synthesis of the coronoid and/or of the olecranon had been performed) were excluded, with the aim of analyzing the complications strictly related to the radial head prosthesis. In this series, there are two cases of prosthesis removal (6.4 %). The first patient (nr. 9), who had a Van Riet-Morrey type III lesion surgically treated with a monopolar prosthesis 48 h from the injury, underwent removal because of aseptic mobilization 20 months after the implant, despite a good clinical result (MEPS 85). Eight months after the removal the patient had a complete recovery of flexion, extension, pronation, and supination and a completely stable elbow (Fig. 9a, b), with the persistence of a slight forearm weakness (final MEPS 90). The second one (patient nr. 27), a Van Riet-Morrey type III O M L lesion surgically treated 11 days after the trauma with a bipolar radial head implant, underwent the removal of the prosthesis 16 months later because of persistent stiffness in pronation (30°) and supination (0°) with MEPS 75 pts. One month after re-operation he obtained a 70° pronation and a 40° supination with a completely stable elbow (final MEPS 90).

Monopolar and bipolar implants (12 and 19, respectively) were evenly distributed, although no randomization had been done, among the different groups of lesions (Group 1: 1 monopolar and 1 bipolar; group 2: 2 monopolar and 5 bipolar; group 3: 6 monopolar and 9 bipolar; group 4: 2 monopolar and 3 bipolar; group 5: 1 monopolar and 1 bipolar). This uniform distribution is statistically confirmed by the Fisher's exact test, demonstrating the absence of correlation between type of implant and group of pathology ($p = 0.97$). No differences were found relative to resorption rate, ROM in f/e, ROM in p/s and development of arthrosis.

One patient (nr. 7) showed persisting wrist pain during his hard handwork, without radiological signs of Essex-Lopresti lesion.

A correlation was noticed between the appearance, within 3–6 months from treatment, of an antero-lateral ossification and a lower rate of bone resorption. This ossification, probably originated and sustained by the periosteum, seems to give support to the base of the stem, apparently representing a positive factor in improving the implant stability and survival (Fig. 10a, b).

No cases of neurological injury were detected after surgery. Each elbow at follow-up showed a complete

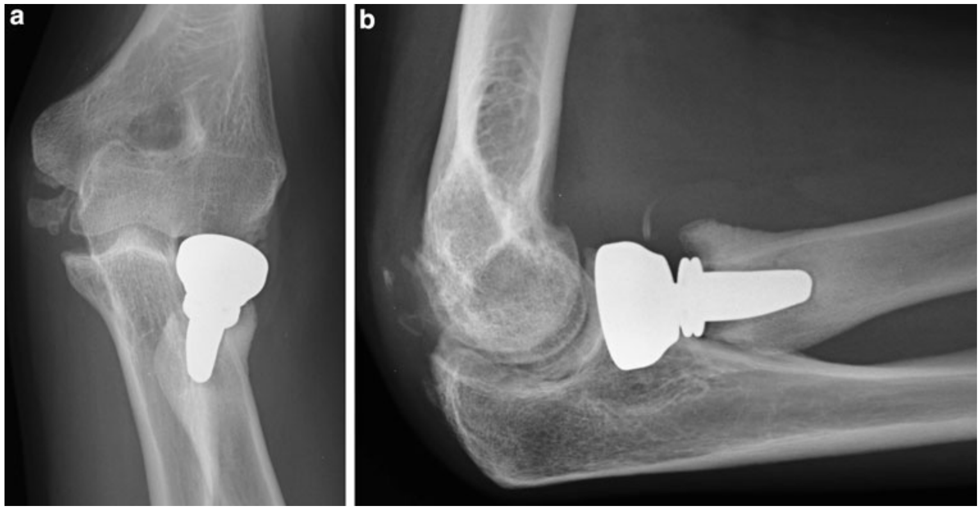

Fig. 10 Periosteal bone reaction of the antero-lateral neck cortical. This radiographic sign has been found to be associated with implant stability and survival

stability. There were no cases of early or late septic complications. On the basis of the radiological examinations of all cases and of the direct inspection during the two reoperations for prosthesis removal, no case of capitellar necrosis has been observed.

Discussion

The head of the radius is considered a secondary stabilizer, when the elbow is intact. If one of the primary constraints is injured (fracture of the coronoid, lesion of the medial and/or of the lateral collateral ligament) or if the longitudinal stability of the forearm is compromised (interosseous membrane lesion), the role of the radial head becomes of primary importance. In these situations, if a nonreconstructible fracture of the radial head occurs, the use of a prosthesis is indicated. These implants have been developed, in the last years, both in the materials and designs, with the aim of avoiding the complications caused by excision of the radial head: valgus instability, that leads to an early ulnar nerve neuropathy and to a delayed ulnohumeral arthrosis; and longitudinal instability, with impairment of the wrist (typical of the Essex-Lopresti syndrome). For the surgeon, these conditions once established are very difficult to treat, and therefore, the correct treatment of the radial head in the acute setting is fundamental for the future function of the upper limb of the patient.

The recent years have seen the diffusion of several modular radial head prosthetic devices, differing for head features (unipolar or bipolar, anatomic or nonanatomic), for stem characteristics (right or curved, smooth and polished or surface textured) and for type of fixation (cemented or cementless).

To our knowledge, our case series is the first one in literature dealing with the results obtained with the SBi prosthesis, which is a modular unipolar or bipolar prosthesis with a curved textured cementless stem.

In designing this study, we decided to evaluate a series of radiological and clinical criteria. On the radiological point of view, our aim was to define a series of parameters and criteria for a radiographic assessment of the correct positioning of the prosthesis and its evolution in time. At the postoperative radiographic evaluation, we checked the stem orientation, the fit between stem and cortical bone and the sizing of the head in height and width. On average, we observed that the instrumentation of the SBi prosthesis allows an adequate stem orientation (93 % correct). The stem-bone fit proved suboptimal (contact with less than 3 cortices) in 64.5 % of cases, but this did not seem to condition the appearance of radiolucent lines or bone resorption or prosthesis mobilization. In two male patients, the larger stem available (size nr. 4) did not perfectly fit the broad medullary canal of the radius (Fig. 3). Since biomechanical studies [15] put into evidence the importance of a correct press-fit for bone ingrowth and stem stability, the availability of a bigger stem could be useful. About the head size, it is our opinion that the specific cutting-guide of the instrumentation with intraoperative reference point of lesser sigmoid notch allows for the correct choice.

Although the limitations of a radiographic evaluation of the correct sizing of the radial head are well known [16, 17], we elected to study the size of the implanted head in both height and width. Based on the criteria preliminarly defined, we found that the height of the head resulted to be correct in 100 % of cases, while the width of the head was correct in 87 % of cases (27/31). The clinical evaluation of the four patients with an oversized head evidenced, however, a good result (average MEPS >90) with no sign of capitellar necrosis and in three of them no sign of arthrosis up to the last follow-up.

The development of heterotopic ossifications has been a limited problem. Of the seven patients who were operated before 48 h, six have grade 0 ossifications and one grade 1 ossifications, in line with the data reported in literature [13, 14, 18].

On a clinical view point, the results of our patients also look in line with the mid-term and long-term results obtained with other prosthetic models, both monopolar and unipolar [19–24].

The re-operation rate (2/31) can be considered low. Moreover, the two patients who underwent the removal of the implant at 20 and 16 months, respectively, obtained an improvement in motion and clinical results with a final MEPS of 90. Both showed a stable elbow, because the prosthesis, acting as a spacer, had allowed the correct healing of the elbow constrainers.

In our study, we did not observe any evidence of a superiority of bipolar or monopolar implants, but the number of cases that we treated is probably too limited in order to draw definitive conclusions. With both types of implant, the rate of arthrosis, lucency, ossifications or resorption is reasonably low.

In our opinion, it is strongly advisable to follow the patients with a radial head prosthesis in time and search for the possible appearance of lateral forearm pain, which O'Driscoll [25] demonstrated to be a sensible marker of implant mobilization. Another reason for which periodical radiographic controls are necessary is the possible evolution of bone resorption that can take place, as we have seen, in completely asymptomatic patients.

Recent research stresses the interest in a better comprehension of the biomechanics of the radial head, of the forces that it has to withstand and of the features that a prosthetic stem should have [26]. From such studies, further indications hopefully may come on how to improve the implant fixation and consequently reduce the occurrence of prosthesis mobilization.

Considering the severity of the patterns of lesion and the unfavorable condition that 20 out of 31 cases were treated as second opinion patients some weeks after trauma, the short-term results that we have recorded look encouraging. It is quite evident that these gratifying short-term results need to be verified by further studies in which the behavior of these prostheses will be evaluated at mid-term and long-term follow-up, especially considering the young age of most of the patients who receive a radial head prosthesis.

Conflict of interest None.

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