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Original article

Outcomes of bipolar radial head prosthesis to treat complex radial head fractures in 22 patients with a mean follow-up of 50 months

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ABSTRACT

Background: Radial head replacement is indicated to treat complex proximal radial fractures that are not amenable to internal fixation.
Hypothesis: Implantation of a bipolar radial head prosthesis after radial head excision ensures stability of the elbow and forearm, thereby promoting ligament healing and restoring elbow function.
Material and methods: Twenty-two patients managed with implantation of a bipolar radial head prosthesis (Guepar®) were evaluated after a mean follow-up of 50 months. The procedure was performed in the acute setting in 16 patients, including 13 with associated injuries; and at the stage of sequelae in 6 patients.
Results: Prosthesis removal was required in 4 patients. Of the remaining 18 patients, 14 (77%) had satisfactory Mayo Elbow Performance Score values, 14 (77%) little or no functional impairment, and 11 (61%) little or no pain. Mean motion arcs were 100° in flexion-extension and 143° in pronation-supination. Mean elbow strength in flexion and mean wrist strength were 67% and 86%, respectively, of those on the contralateral normal side. Radio-lucent lines were visible around the prosthesis in 5 patients, radial neck osteolysis in 10 patients, and capitellar erosion in 7 patients. Seven patients each experienced a complication. Early revision surgery to treat elbow instability was required in 6 patients.
Discussion: Outcomes after Guepar® bipolar radial head prosthesis implantation were disappointing in patients with complex radial head fractures seen in the acute or chronic setting. The associated injuries to bones and ligaments and the measures taken to repair them influence the prognosis. The complication rate is non-negligible and seems to increase over time.
Level of evidence: IV, retrospective study.

1. Introduction

Comminuted radial head fractures can jeopardise the stability of the elbow and forearm. When internal fixation is not feasible, the surgeon must choose between radial head excision alone or followed by radial head replacement [1,2]. Given that associated ligament injuries are common, elbow instability in the coronal plane and forearm instability may become apparent after excision of the radial head [3–5].

Implantation of a radial head prosthesis restores the lateral column and ensures both elbow stability in the coronal plane and vertical stability of the forearm [6]. Silicone prostheses have been reported to induce complications, and most of the currently available radial prostheses are metallic, although pyrocarbon is used in some cases. Mono-block and modular options are available, with a fixed or bipolar head, according to the design described by Judet et al. in 1996 [7].

Since 2002, the modular bipolar radial head prosthesis Guepar® (DePuy Orthopaedics, Johnson & Johnson; Warsaw, IN, USA) has been used in our department to treat radial head fractures that are not amenable to internal fixation. For the present study, our hypothesis was that this prosthesis stabilised the radial head and forearm after radial head resection, thereby restoring elbow function.

2. Material and methods

A retrospective non-comparative study of consecutive patients treated at a single orthopaedics and trauma surgery centre in a university hospital was performed. All patients managed with a Guepar® radial head prosthesis between 2002 and 2008 then re-evaluated after a follow-up of at least 24 months or at implant removal were included in this study. Patients with follow-up

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Fig. 1. The Guepar® bipolar radial head prosthesis.
DePuy Orthopaedics, Johnson & Johnson; Warsaw, IN, USA.

durations of less than 24 months after prosthesis implantation were excluded.

2.1. Patients

Twenty-two patients, 7 women and 15 men, with a mean age of 44 years (range, 22–65 years) were included in this study. The dominant arm was involved in 10 patients. The mechanism of injury was a fall on the hand in 5 patients, a fall from a ladder or roof in 9 patients, a motor vehicle accident in 4 patients, a fall on stairs in 2 patients, and a sports-related injury in 2 patients.

In the Mason classification [8], 16 fractures were type III and 6 fractures involved the radial neck. Associated injuries included elbow dislocation in 14 patients, ulnar ligament injury in 4 patients, coronoid process fracture in 4 patients, distant fractures in 8 patients (distal radius, $n = 1$; ulna, $n = 4$; and contralateral upper limb, $n = 3$), and Essex-Lopresti injury in 3 patients.

The radial head prosthesis was implanted in the acute setting in 16 patients (mean time since injury, 4 days) and at a distance from the injury in 6 patients (mean time since injury, 14 months).

2.2. The Guepar® radial head prosthesis

The Guepar® radial head prosthesis is an intermediate modular bipolar implant featuring a retentive cylindrical radial cup whose upwards-facing concave surface is made of metal. The intermediate couple linking the metallic stem to the polyethylene of the inner part of the head allows a 40° motion arc. Two head diameters and two stem lengths are available. Production of this prosthesis has been discontinued by the manufacturer (Fig. 1).

2.3. Operative technique

A lateral approach was used in 19 patients and a postero-lateral approach in 3 patients with associated olecranon fractures. During this approach, the radial collateral ligament was preserved if it was intact. After incision of the annular ligament, the elbow was explored to determine the full extent of the injuries. Coronoid process fractures were managed by retrograde screw fixation with intra-articular verification of the quality of reduction. Olecranon fractures were treated by plate fixation. For the radial head prosthesis, only two head diameters were available, 14 and 16 mm, and the diameter closest to that of the native head was chosen. The radial notch of the ulna served as a landmark to determine the optimal position of the prosthetic radial head, which was not to extend beyond the edge of the notch [9]. After implantation of the prosthesis, the elbow was tested in flexion and extension. Persistence of an interval of a few millimetres between the capitulum and prosthesis in both flexion and extension was sought; contact was taken to indicate an excessively high prosthesis position requiring the use of a shorter head or a re-cut of the neck. The final stem was then cemented into the radial shaft using low-viscosity antibiotic-impregnated cement (PalacosGenta®), and the final head was press-fit onto the stem. The radial collateral ligaments were re-attached to the lateral epicondyle using trans-osseous sutures or anchors in 11 patients; in the remaining 11 patients, only the annular ligament was closed, followed by the tendon plane. Elbow stability was then evaluated; in the 3 patients with persistent valgus laxity, the ulnar collateral ligament was approached and re-attached to the medial epicondyle.

2.4. Postoperative management

A posterior long-arm splint was used, with the wrist pronated if radial ligament re-attachment was performed and in the neutral position otherwise. Between the 15th and 20th postoperative day, the patients were switched to an articulated splint that limited extension to 30°; the wrist was protected in the event of ligament re-attachment and left free otherwise. Associated injuries required 6 weeks of complete immobilisation in 6 patients. On the 45th postoperative day, the splint was removed and rehabilitation started, with emphasis on active elbow movements to promote joint coaptation.

2.5. Assessment methods

All patients were re-evaluated by an independent assessor at least 24 months after radial head replacement. The physical examination included comparison of the elbow and wrist to the contralateral side, patient report of the visual analogue scale (VAS) pain score, goniometric determination of motion ranges, and symmetrical muscle strength measurement comparatively with the contralateral normal side using a Kinedyn®-type dynamometer for the elbow and a Jamar®-type dynamometer for the wrist. The Mayo Elbow Performance Score (MEPS) was used to categorise the results [10]. Function was also evaluated using the QuickDASH score [11]. Antero-posterior and lateral radiographs of the elbow were obtained to assess the quality of prosthesis fixation and to look for peri-articular ossifications, degenerative elbow lesions, evidence of implant wear, and peri-prosthetic lucencies.

2.6. Statistical analysis

The statistical analysis was performed using Excel and PASW® Statistics 17.0. The objectives were to compare outcomes in the patients managed in the acute versus chronic setting and to compare patients with and without associated injuries. Qualitative variables were described as n (%) and quantitative variables as means (range). Given the small sample sizes, the non-parametric Mann–Whitney test was chosen to compare means. Values of $P < 0.05$ were considered significant.

3. Results

The reported results were recorded after a mean follow-up of 50 months and a minimum follow-up of 24 months (Table 1).

Table 1
Lesions and outcomes in the overall population of 22 patients.

Patient	Fracture (Mason)	Type of lesion	Associated injuries	F/E	P/S	MEPS	Q-DASH	Complications
1	III	Acute	Bifocal ulnar fr.	110/−60	60/60	80	11.3	Post.-lat. instab.
2	III	Chronic	Elbow disl.	140/−10	90/90	85	20.5	CRPS I
3	III	Acute	Elbow disl.	115/−30	80/90	60	31.8	Ulnar nerve
4	III	Acute	Elbow disl.	80/−20	60/60	90	–	0
5	III	Acute	Essex-Lopresti	135/−30	70/70	85	18	Post.-lat. instab.+Ulnar nerve
6	Neck	Chronic	None	150/+10	90/90	100	9	0
7	III	Acute	Elbow disl.	100/−30	70/60	80	22.7	Ulnar nerve
8	III	Chronic	Coronoid fr.	100/−50	30/0	95	9	0
9	III	Acute	Coronoid fr.	140/−20	80/90	85	22.7	Ulnar nerve
10	Neck	Acute	Elbow disl. and ulnar fr.	140/−20	80/80	85	2.3	0
11	III	Acute	Elbow disl.	140/−25	90/90	85	2.2	0
12	III	Chronic	None	145/−50	90/90	80	15.9	Ulnar nerve
13	III	Acute	None	120/−30	80/80	80	15.9	0
14	III	Acute	None	90/−20	45/50	60	59	CRPS I
15	III	Acute	Trans-olec.disl.	130/−15	90/90	100	4.5	Disassembly of prosthesis
16	III	Acute	Trans-olec.disl.	125/−20	30/30	60	45.5	0
17	Neck	Acute	Trans-olec.disl.	140/−40	75/80	30	50	Post.-lat. instab.
18	III	Acute	None	140/−25	90/85	75	15.9	0
19	III	Chronic	Essex-Lopresti	–	–	–	–	Pros. removal
20	Neck	Acute	Elbow disl.	–	–	–	–	Pros. removal
21	Neck	Chronic	None	–	–	–	–	Pros. removal
22	III	Acute	Essex-Lopresti	–	–	–	–	Pros. removal
Global	–	–	–	126/−26	72/72	79	21	

F/E: flexion-extension in degrees; P/S: pronation/supination in degrees; MEPS: Mayo Elbow Performance Score in points; Q-DASH: shortened version of the Disabilities of the Arm, Shoulder, and Hand score (DASH); Fr.: fracture; disl.: dislocation; olec.: olecranon; post.-lat.: postero-lateral; instab.: instability; CRPS I: complex regional pain syndrome type I; pros.: prosthesis.

3.1. Complications and revisions

Of the 22 patients, 6 (27%) experienced early postero-lateral subluxation of the elbow, which was consistently managed with revision surgery; 3 patients required re-attachment of the radial capsule and ligaments, combined in 1 patient with external fixation to stabilise the elbow; 2 other patients were managed with external fixation alone; and the remaining patient had elbow instability related to prosthetic head disassembly with ulnar non-union and was managed with revision surgery of the ulnar internal fixation, press-fit implantation of a new radial head prosthesis, and repair of the radial collateral ligament.

Delayed complications consisted of complex regional pain syndrome type I in 2 patients and sensory ulnar nerve dysfunction in 5 patients, all of whom had complex elbow injuries with other lesions in addition to the radial head fracture.

The radial head prosthesis was removed in 4 (18%) patients. In 3 patients, removal occurred after 6, 14, and 28 months, respectively, because of lateral elbow pain with radiographic evidence of impingement of the prosthesis on the humeral condyle. The remaining patient had the prosthesis removed after 42 months because of symptomatic loosening. Of these 4 patients, 3 were pain-free at last follow-up after prosthesis removal and 1 had persistent pain with evidence of humero-ulnar osteoarthritis.

3.2. Clinical and functional outcomes

The clinical outcomes were analysed in the 18 patients who still had their initial radial head prosthesis at last follow-up. Their main features are listed in Table 1. Among them, 11 had little or no pain, 6 had pain during weather changes or exertion, and 1 had permanent elbow pain. The elbow was clinically stable in 17 patients; the remaining patient was a woman with progression to osteoarthritis and postero-lateral elbow subluxation. Motion ranges were within the functional range, with a 100° flexion-extension arc and a 143° rotation arc. Compared to the contralateral upper limb, mean strength with the elbow flexed was 67% (range, 16–97%) and mean wrist strength was 86% (range, 12.5–118%). Mean MEPS was 79 points (range, 30–100 points) and 3 patients had excellent results, 11 good results, 3 fair results, and 1 poor results. Mean QuickDASH was 21 points (range, 2–59 points).

3.3. Radiographic outcomes

The radiographic outcomes were analysed in all 22 patients, after 50 months of follow-up in the 18 patients who still had their original implant and 22 months in the 4 patients who required early implant removal (Fig. 2). On the antero-posterior radiograph of the elbow, the prosthetic stem was well centred in 11 patients, tilted in varus in 7 patients, and tilted in valgus in 4 patients. On the lateral radiograph of the elbow, the stem was well centred in 16 patients and tilted in flexion in 6 patients. Centring on both the antero-posterior and the lateral radiographs was noted for only 8 of the 22 implants. The cement mantle around the prosthetic stem was at the same level as the stem in 3 patients and extended beyond the stem in 19 patients. When viewed on the antero-posterior radiograph, the proximal edge of the prosthetic head was flush with the proximal edge of the radial notch of the ulna in 9 patients; it was

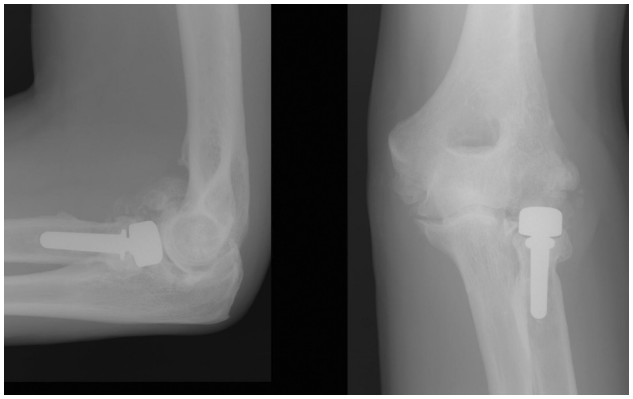

Fig. 2. Radiographs taken 10 years after implantation of a Guepar® bipolar radial head prosthesis.

Fig. 3. Radiograph showing progressive peri-prosthetic lucencies in an asymptomatic patient.

above and below this landmarkin 11 and 2 patients, respectively. Osteolysis was visible under the prosthetic stem in 8 patients. In 4 patients, the radiographs showed lucencies around the stem (Fig. 3), which were limited in 2 patients and circumferential in 2 patients. One prosthesis was considered loosened. Evaluation of the joint space showed narrowing in 5 patients, advanced osteoarthritis in 1 patient, and capitellar erosions in 6 patients (Fig. 4). Finally, ossifications were visible anterior to the radial head in 4 patients.

3.4. Statistical analysis

The statistical analysis showed no significant differences in clinical outcomes between the patients managed in the acute setting and those managed at a distance from the injury. Neither were any significant differences found between the subgroup with isolated radial head fracture and the subgroup with associated injures. Of the 8 prostheses considered well centred, 2 had to be removed, whereas only 2 of the remaining 14 prostheses required removal. Of the 11 prostheses whose position was considered too high, 3 were removed, compared to only 1 of the remaining 11 prostheses. Importantly, all 6 patients with capitellar erosions had an excessively high position of the implant. No correlation was noted between implant position and clinical outcomes other than the development of capitellar erosions.

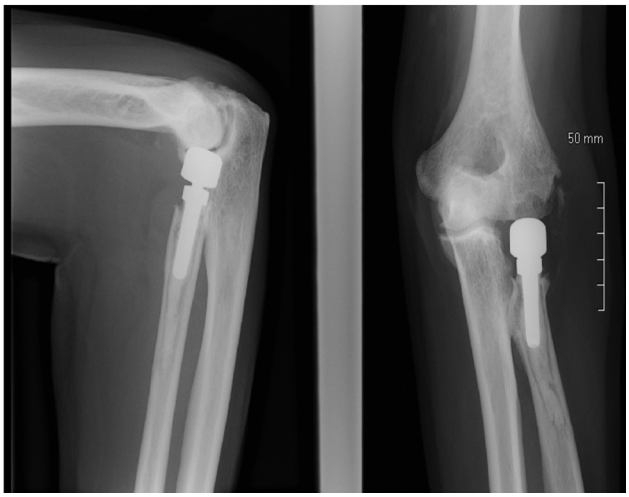

Fig. 4. Radiograph showing a capitellar erosion opposite a radial head prosthesis implanted in an excessively high position.

4. Discussion

Comminuted fractures of the radial head constitute a therapeutic challenge. When internal fixation is not feasible, the treatment options are simple radial head excision in the absence of other injuries and radial head replacement otherwise. Radial head fractures are rarely isolated: most patients also have injuries to the humero-ulnar collateral ligaments or inter-osseous membrane [12–14]. In a case-series study of 333 adults with radial head fractures, van Riet et al. [15] found other fractures or damage to the peri-articular tissues in 88 (26%) cases overall. The probability of having associated injuries correlated with the type of radial head fracture; thus, 75% of patients with Mason III fractures had other injuries. These data suggest that greater degrees of fracture displacement and comminution may be accompanied with a higher probability of associated injuries.

Biomechanical studies have established that radial head excision alters elbow joint kinematics and stability, even when the collateral ligaments are intact [3,16]. The instability becomes severe when the ligaments are damaged [17]. Metallic radial head prostheses seem to restore near-normal elbow joint kinematics and stability [18] and also limit proximal migration of the radius [19]. Several groups have established that internal fixation is superior over radial head excision in patients with Mason III fractures in terms of motion range, strength, and function [20,21]. However, routine internal fixation of fractures having more than three fragments can result in early failure with breakage of the material, non-union, and loss of forearm rotation [22,23]. In this situation, radial head replacement by a metallic prosthesis may be the best option.

Most of the currently used radial head prostheses are metallic mono-block implants that are not consistently adaptable and raise technical challenges since their implantation requires lateral elbow subluxation [24–32]. Metallic modular radial head implants available in various head and stem sizes have been developed to improve adaptability and facilitate implantation [32–34]. Accurate positioning of these prostheses is crucial to ensure proper tracking of the prosthetic head on the capitulum and to avoid a cam effect during forearm rotation. Abnormal tracking can cause accelerated wear of the capitulum with loosening of the stem due to increased shear stresses applied to the bone-cement interface [35]. Bipolar radial head prostheses were developed to improve tracking on the capitulum [7,36–42]. An example is the Guepar® radial head used in the present study. However, this design is theoretically associated with a risk of wear of the bipolar joint with production of polyethylene debris [42], and the stabilising effect may be inadequate in patients with elbow instability and damage to the ligaments [43]. Erosion of the capitulum may be related to prosthesis malalignment or to excessive pressure by the prosthesis placed in an excessively high position. The treatment rests on removal of the prosthesis. In some cases, implantation of a lateral condylar prosthesis may also provide a solution [44]. A study by van Riet et al. [45] demonstrated that preoperative capitellar osteoporosis was associated with an increased risk of erosion by the prosthetic radial head.

Previously published studies do not allow comparisons across implants, as no comparative studies are available and indications vary with each type of implant. A meta-analysis of the most recently published case-series studies suggests that the outcomes are satisfactory in 88% of patients managed in the acute setting and 66% of those managed at the stage of sequelae, after a mean follow-up of 3–4 years (Table 2). The outcomes do not seem to differ significantly for mono-block prostheses (66%to 94% of satisfactory

Table 2
Outcomes of radial prosthesis implantation for acute or chronic abnormalities in previous studies and in our study.

Authors	Year	Type	N acute cases (% satisf.)	N chronic cases (% satisf.)	Total N(% satisf.)	FU (years)
Knight et al. [24]	1993	Mono	31 (94)	–	31 (94)	4.5
Judet et al. [7]	1996	Bipol	7 (100)	7 (72)	14 (86)	4
Wick et al. [25]	1998	Mono	–	–	30 (73)	–
Smets et al. [36]	2000	Bipol	13 (77)	2 (0)	17 (67)	2
Popovic et al. [37]	2000	Bipol	11 (83)	–	11 (83)	2.5
Harrington et al. [26]	2001	Mono	–	–	20 (80)	12
Moro et al. [27]	2001	Mono	25 (68)	–	25 (68)	3.25
Holmenschlager et al. [38]	2002	Bipol	10 (100)	6 (67)	16 (81)	1.5
Alnot et al. [39]	2003	Bipol	18 (100)	4 (0)	22 (82)	1.5
Ashwood et al. [28]	2004	Mono	10 (100)	6 (50)	16 (75)	2.8
Brinkman et al. [40]	2005	Bipol	–	11 (81)	11 (81)	2
Gabrion et al. [46]	2005	Bipol	10 (50)	–	10 (50)	2.5
Chapman et al. [29]	2006	Mono	8 (100)	8 (87)	16 (93)	2.75
Dotzis et al. [41]	2006	Bipol	12 (83)	–	12 (83)	5
Grewal et al. [33]	2006	Modul/non bipol	26 (61)	–	26 (61)	2
Wretenberg et al. [30]	2006	Mono	18 (72)	–	18 (72)	3.7
Doornberg et al. [34]	2007	Modul non bipol	27 (82)	–	27 (82)	3.5
Popovic et al. [42]	2007	Bipol	51 (76)	–	51 (76)	8.4
Lim and Chan [31]	2008	Mono	6 (66)	–	6 (66)	2.4
Shore et al. [32]	2008	Mono (22) Modul non bipol (10)	–	32 (66)	32 (66)	8
Chien et al. [47]	2010	Modul non Bipol	10 (90)	3 (66)	13 (84)	3
Celli et al. [48]	2010	Bipol	16 (87.5)	–	16 (87.5)	3.5
Burkhart et al. [49]	2010	Bipol	9 (100)	7 (85)	17 (94)	8.8
Lamas et al. [50]	2011	Modul non bipol	47 (89)	–	47 (89)	4
Zunkiewicz et al. [51]	2012	Bipol	23	7	30 (92 pts)	3
Sarris et al. [52]	2012	Modul non bipol	30	2	32 (97)	2
Rotini et al. [53]	2012	Mono (12) Bipol (19)	31 (93)	–	31 (93)	2
Flinkkilä et al. [54]	2012	Modul non bipol	42 (62)	–	42 (62)	4
Chanlalit et al. [55]	2012	Modul non bipol	–	–	26	2.7
Katthagen et al. [56]	2013	Modul non bipol	16 (–)	15 (–)	31 (84)	2
Our study	2013	Bipol	14 (71)	4 (100)	18 (77)	4
Total (% satisfy.)			438 (88)	86 (66)	670 (75)	4

N: number; satisfy.: satisfied; FU: follow-up; mono: mono-block; bipol: bipolar; modul non bipol: modular non bipolar; pts: patients.
The totals were determined based only on the case-series studies that reported the percentage of satisfactory outcomes.

outcomes), modular mono-polar prostheses (61%to 82% of satisfactory outcomes), and bipolar prostheses (67%to 86% of satisfactory outcomes). A single study evaluated outcomes after treatment with the bipolar Guepar® radial head implant [39]. This single-centre retrospective study included 22 patients, of whom 18 were treated for a recent fracture and 4 for an old fracture of the radial head. Follow-up was short, with a mean of only 18 months (range, 11–59 months). Outcomes were better in the subgroup managed in the acute setting than in the subgroup with sequelae. Peri-prosthetic lucencies did not develop in any of the patients. Narrowing of the humero-ulnar joint space was found in a single patient. The prosthesis was too high in 1 patient, who had a fair result. Elbow instability was noted in another patient. Secondary arthrolysis was required in 4 patients. The complication rate seems to increase over time: thus, in our case-series, peri-prosthetic lucencies were visible in 18% of patients, osteolysis of the neck distal to the stem in 36% of patients, and capitellar wear in 27% of cases. Osteoarthritis developed in 27% of our patients. These complications have been found by others after a similar follow-up duration [54–56] or after more than 5 years [26,32,41,42,49]. Radial cup disassembly has been reported by Alnot et al. [39] and Winter et al. [57]. This complication seems related to persistent postero-lateral elbow instability, in which the bipolar head lodges under the capitulum, producing a cam effect responsible for implant disassembly. This complication also occurred in our study (Fig. 5). It has been reported with other mono-polar [50] and bipolar [58] cup designs.

The main limitations of our study are the retrospective design and small number of patients in each of the two groups. In addition, the variability of the associated lesions across patients may have adversely affected the quality of the results. However, the use of the same prosthesis in all patients and the mean follow-up of 50 months allowed an evaluation of the effectiveness of this implant in complex elbow injuries and a comparison with previously published data.

Fig. 5. Disassembly of a radial head prosthesis.

5. Conclusion

The clinical outcomes obtained with the bipolar radial head prosthesis Guepar® were satisfactory in 77% of cases, with a stable elbow and good function. However, this prosthesis was not always sufficient to ensure elbow stability, and re-attachment of the postero-lateral ligaments combined with appropriate post-operative care was clearly crucial. The complication rate is not negligible and is influenced by the implantation technique, management of associated injuries, and duration of follow-up.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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