Mid-term outcomes of 77 modular radial head prostheses

Aims
Radial head arthroplasty (RHA) may be used in the treatment of non-reconstructable radial head fractures. The aim of this study was to evaluate the mid-term clinical and radiographic results of RHA.

Patients and Methods
Between 2002 and 2014, 77 RHAs were implanted in 54 men and 23 women with either acute injuries (54) or with traumatic sequelae (23) of a fracture of the radial head. Four designs of RHA were used, including the Guepar (Small Bone Innovations (SBi)/Stryker; 36), Evolutive (Aston Medical; 24), Rhead RECON (SBi/Stryker; ten) or Rhead STANDARD (SBi/Stryker; 7) prostheses. The mean follow-up was 74.0 months (standard deviation (sd) 38.6; 24 to 141). The indication for further surgery, range of movement, mean Mayo Elbow Performance (MEP) score, quick Disabilities of the Arm, Shoulder and Hand (quickDASH) score, osteolysis and positioning of the implant were also assessed according to the design, and acute or delayed use.

Results
The mean MEP and quickDASH scores were 90.2 (sd 14; 45 to 100), and 14.0 points (sd 12; 1.2 to 52.5), respectively. There were no significant differences between RHA performed in acute or delayed fashion. There were 30 re-operations (19 with, and 11 without removal of the implant) during the first three post-operative years. Painful loosening was the primary indication for removal in 14 patients. Short-stemmed prostheses (16 mm to 22 mm in length) were also associated with an increased risk of painful loosening (odds ratio 3.54 (1.02 to 12.2), p = 0.045). Radiocapitellar instability was the primary indication for re-operation with retention of the implant (5). The overall survival of the RHA, free from re-operation, was 60.8% (sd 5.7%) at ten years.

Conclusion
Bipolar and press-fit RHA gives unsatisfactory mid-term outcomes in the treatment of acute fractures of the radial head or their sequelae. The outcome may vary according to the design of the implant. The rate of re-operation during the first three years is predictive of the long-term survival in tight-fitting RHAs.

Fractures of the proximal radius represent about one third of all fractures involving the elbow and are the most common fractures affecting this joint. Patients whose radial head cannot be reconstructed and who undergo excision of the radial head develop progressive varus instability, potential radial ascent, and secondary ulnocarpal symptoms with alteration in the kinematics of the elbow and forearm to a self-perpetuating cycle of degenerative changes. In the presence of associated ligamentous injury, good functional results have been reported with radial head arthroplasty (RHA). This procedure allows maintenance of the integrity of the four columns of the elbow in patients with very comminuted fractures of the radial head which cannot be treated by open reduction and internal fixation (ORIF). RHA produces satisfactory outcomes. However, it has recently been reported that a tight-fitting RHA may have inferior mid-term survival than a loose-fitting RHA. High rates of complications have also been reported after this procedure. There is limited information about the mid- and long-term outcomes comparing the functional results of different designs of RHA, due in part to the small effect sizes and varied indications for use in the available studies.
Between 2002 and 2014, four different models of tight-fitting RHA were used in our department to treat acute, non-reconstructable fractures of the radial head or their post-traumatic sequelae; the GUEPAR (Small Bone Innovations (SBi)/Stryker, Morrisville, Pennsylvania), the Evolutive (Aston Medical, Saint-Etienne, France), the rHead RECON and the rHead STANDARD prosthesis (both SBi/Stryker).

Our primary aim in this study was to investigate and compare the mid-term survivorships of press-fit and bipolar RHAs.

Patients and Methods
This is a retrospective, single-centre study performed at an academic department of orthopaedic surgery. Inclusion criteria were: patients undergoing surgery for a non-reconstructable fracture of the radial head or the sequelae of trauma, including malunion, pseudarthrosis, necrosis, failure of fixation, for whom a RHA was performed between 2002 and 2014 with a minimum follow-up of two years or follow-up until removal of the implant. Patients with follow-up of less than two years and patients aged < 16 years of age were excluded.

A total of 94 patients underwent RHA during this time; four were excluded due to a short follow-up and 13 were lost to follow-up. A total of 77 patients were included in the study. There were 54 men and 23 women. Their mean age was 52 years (20 to 82). The dominant hand was involved in 42 patients. 54 involved acute fractures and 23 the sequelae of trauma. There were 36 Guepar (Fig. 1), 24 Evolutive (Fig. 2), ten rHead RECON and seven rHead STANDARD prostheses (Fig. 3). The characteristics of these prostheses are shown in Table I. In our department, a call for tenders was performed for each model of RHA; one type was preselected to be used for all these procedures for a limited period of time. Our preference changed three times, giving a total of four different prostheses during this time. The RHA which was used in each patient was dependent on our preference at the time of surgery. No randomisation of the RHAs was performed, as only one choice was available at the time of surgery for each patient.

Initial evaluation of the fractures showed 65 Mason type III radial head fractures, two Mason type II fractures and ten radial neck fractures. There were 27 isolated fractures, 27 “terrible triad” fractures, four Essex-Lopresti injuries, four distal metaphyseal-epiphyseal fractures of the radius or ulna, and 11 patients had an associated transolecranon fracture-dislocation of the elbow.
A lateral approach to the elbow was used in 66 patients, and a posterolateral approach in 11, when there was an associated fracture of the olecranon. Particular attention was paid to preservation of the radial collateral ligament if it was intact. The annular ligament was incised longitudinally (i.e. transverse to its fibres). The capitellum was routinely carefully examined for the presence of cartilage lesions. Nine olecranon fractures were fixed with a plate and two by tension-band wiring. Four fractures of the coronoid process were fixed using retrograde screw fixation with intra-articular control of the reduction.

The radial neck was divided so as to preserve as much bone as possible. The radial neck was systematically conserved for all short-stemmed implants. The medullary canal of the radius was reamed and the prosthesis was introduced such that it did not pass the superior surface of the radial notch of the ulna. The elbow was then put through a full arc of flexion and the position was checked on extension and on anteroposterior (AP) and lateral fluoroscopic views.

Low-viscosity, antibiotic impregnated cement (Palacos Genta; Heraeus Medical, Wehrheim, Germany) was used for fixation of the 60 smooth-stemmed components. The 17 rough-stemmed components were either press-fitted (two) or fixed with cement (15) if the stability when press-fitted was felt to be insufficient according to the manufacturers’ specifications (Aston Medical and SBi/Stryker). The final radial head components were impacted onto the neck of long-stemmed prostheses, and directly onto the stem of rHead prostheses. The radial collateral ligament was reattached to the lateral epicondyle using trans-osseous sutures or suture anchors in 39 patients. In the remaining patients, the annular ligament and tendon layer were simply repaired. The stability of the elbow was then reassessed. The ulnar collateral ligament was re-attached to the medial epicondyle in three patients.

In 31 patients, in whom the lateral collateral ligament (LCL) was repaired, the elbow was immobilised in a long-arm dorsal-volar splint with the wrist in pronation, for 15 days post-operatively. The wrist was left free in 38 patients, in whom the LCL was not repaired. In eight patients, in whom the elbow remained unstable despite LCL reconstruction, a static external fixator was retained for two to three weeks. A hinged brace was used to allow extension up to -30° between the second and third post-operative week. Active mobilisation of the elbow and physiotherapy started about six weeks post-operatively.

All patients were assessed by an independent reviewer at the time of final review or at removal of the implant. The range of movement (ROM) of both elbows and wrists was recorded. AP and lateral radiographs of the elbow were undertaken in maximal extension and 90° of flexion for the 59 patients who retained the radial head prosthesis at the time of last follow-up. The pre- and post-operative clinical and radiographic data, and operative details were noted from the medical records for all 77 patients in the series. This information allowed analysis of the cause and timing of re-operation, with or without retention of the RHA.

**Clinical analysis.** Analysis was possible for 58 patients in whom the RHA was retained at the time of the final review. The maximum ROM was measured using a goniometer. The ratio, expressed as a percentage of the force of flexion and extension of both elbows, was measured using a Kinedyn dynamometer (Smith & Nephew, Memphis, Tennessee). Function was assessed using the Mayo Elbow Performance Score (MEPS) and the Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH) score.

**Radiographic analysis.** Radiographic results were available for all 77 patients. AP and lateral post-operative radiographs were used to assess alignment according to radiocapitellar congruence in both planes, overstuffing (associated or not associated with an asymmetry to the humero-ulnar interval, also called the river delta sign). Assessment included the position of the stem for the stemmed components which was considered to be valgus or varus when the distal extremity apposed the lateral or medial aspect of the radial cortex, respectively, signs of peri-prosthetic osteolysis (Fig. 2), heterotopic ossification according to the Brooker classification, and capitellar wear. These were noted at each post-operative review.

**Statistical analysis.** The primary objective was a descriptive analysis of the mid-term clinical and radiological outcomes. Results were described according to the mean, standard deviation (SD), maximum and minimum values. Fisher’s exact test and Kruskal-Wallis tests were used to compare
the clinical and radiographic outcomes according to the type of RHA. Fisher’s exact test was used to compare the rates of complications and re-operation according to four models for both acute and delayed use. The Mann-Whitney U test, also known as the Wilcoxon rank-sum test, was used to compare the quickDASH and MEPS, and the ROM and force with respect to the healthy contralateral side for both acute and delayed use. Odds ratios (OR) were used to assess the link between the size of the stem (short; rHead RECON and STANDARD and long; Guepar, Evolute), stemmed RHA and painful loosening. Survival analysis was performed using the Kaplan-Meier method, with failure including all causes of further surgery as the endpoint. Comparisons between survival rates were calculated using the log rank (Mantel Cox) method. Confidence intervals (CI) were fixed at 95%. Statistical significance was set at p < 0.05. The Bonferroni weighting system was used for sub-group comparisons.

Results
The mean follow-up for the entire cohort was 74.0 months (SD 38.6; 24 to 141). The mean follow-up for the different types of RHA was: 110.4 months (SD 28.5; 66 to 141) for the Guepar, 36.7 months (SD 17.9; 24 to 57) for the Evolute, 62.8 months (SD 11.8; 69 to 59) for the rHead RECON and 53.2 months (SD 8.1; 36 to 62) for the rHead STANDARD prostheses. The remaining patients were censored due to removal of the implant before this time.

Clinical results. The mean quickDASH score and MEPS are shown in Table II, as are the mean ROMs and the mean forces of flexion and extension of the elbows.

Radiographic results. The radiographic results are summarised in Table II. Grade 0 Brooker heterotopic ossification was found in 48 patients (62.33%), Grade I in 18 (23.38%), Grade II in four (5.19%) and Grade III in seven patients (9.09%).

Reasons for re-operations. A total of 40 complications were encountered and 30 patients (38.9%) required a re-operation at a mean follow-up of 14.75 months (SD 14.72; 0.2 to 36). A total of 11 patients (14.28%) had a re-operation at a mean follow-up of 14.75 months (SD 14; 0.2 to 36). A total of 19 implants (24.7%) were re-operated due to removal of the implant before this time.

Table II. Description of clinical and radiographic outcomes by design of radial head arthroplasty and acute or delayed use

<table>
<thead>
<tr>
<th>Clinical results, mean (sd)</th>
<th>Acute treatment</th>
<th>Delayed treatment</th>
<th>p-values</th>
<th>Guepar*</th>
<th>Evolute*</th>
<th>rHead RECON*</th>
<th>rHead STANDARD*</th>
<th>p-values according to the implants</th>
</tr>
</thead>
<tbody>
<tr>
<td>QuickDASH score (points)</td>
<td>n = 42</td>
<td>n = 16</td>
<td>p-values</td>
<td></td>
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<tr>
<td>13.1 (10.24)</td>
<td>12.3 (11.16)</td>
<td>0.06</td>
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<tr>
<td>MEPS (points)</td>
<td>n = 26</td>
<td>n = 21</td>
<td></td>
<td></td>
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<tr>
<td>91.5 (12)</td>
<td>88 (15.2)</td>
<td>0.06</td>
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<tr>
<td>Range of movement (°)</td>
<td>n = 26</td>
<td>n = 21</td>
<td>p-values</td>
<td></td>
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<tr>
<td>Flexion</td>
<td>132.1* (16.49*)</td>
<td>126.1* (18.93*)</td>
<td>0.37</td>
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<tr>
<td>Extension</td>
<td>- 12.9* (11.03*)</td>
<td>- 16.9* (13.88*)</td>
<td>0.28</td>
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<tr>
<td>Supination</td>
<td>67.8* (7.66*)</td>
<td>65* (9.97*)</td>
<td>0.30</td>
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<tr>
<td>Pronation</td>
<td>76* (7.71*)</td>
<td>75* (9.12*)</td>
<td>0.74</td>
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<tr>
<td>Force compared with contralateral side (%)</td>
<td>n = 54</td>
<td>n = 23</td>
<td>p-values</td>
<td></td>
<td></td>
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<tr>
<td>Flexion</td>
<td>87.2 (19.25)</td>
<td>90 (19.35)</td>
<td>0.41</td>
<td></td>
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<tr>
<td>Extension</td>
<td>93.6 (15.79)</td>
<td>95.1 (14.72)</td>
<td>0.94</td>
<td></td>
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<td></td>
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<tr>
<td>Radiographic results, n (%)</td>
<td>n = 54</td>
<td>n = 23</td>
<td></td>
<td></td>
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<tr>
<td>Osteolysis</td>
<td>22 (40.7)</td>
<td>16 (69.5)</td>
<td>0.22</td>
<td></td>
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<tr>
<td>Around the stem*</td>
<td>14 (36.1)</td>
<td>12 (50)</td>
<td>0.80</td>
<td></td>
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<tr>
<td>Under the head (collar)*</td>
<td>21 (38.9)</td>
<td>13 (56.5)</td>
<td>0.76</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Malposition</td>
<td>25 (46.3)</td>
<td>20 (55.6)</td>
<td>0.46</td>
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<tr>
<td>Overstuffing</td>
<td>23 (42.6)</td>
<td>20 (43.5)</td>
<td>0.60</td>
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<tr>
<td>Stem position</td>
<td>Centered*</td>
<td>25 (46.3)</td>
<td>17 (47.2)</td>
<td></td>
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<tr>
<td>Varus</td>
<td>20 (37)</td>
<td>17 (42.9)</td>
<td>0.40</td>
<td></td>
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<tr>
<td>Valgus*</td>
<td>9 (16.7)</td>
<td>7 (29.1)</td>
<td>0.04</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Capitellar erosion*</td>
<td>19 (35.2)</td>
<td>10 (43.5)</td>
<td>0.88</td>
<td></td>
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</table>

*Guepar/rHead RECON/rHead STANDARD (Small Bone Innovations (SBI)/Stryker, Morrisville, Pennsylvania); Evolutive (Aston Medical, Saint-Etienne, France)
†Statistically significant result (p < 0.05)

p-values were calculated using Fisher’s exact test, Kruskal-Wallis tests, and the Mann-Whitney U test.

QuickDASH, Quick Disabilities of the Arm, Shoulder and Hand; MEPS, Mayo Elbow Performance Score
Table III. Description of complications and re-operations by the type of radial head arthroplasty and acute or delayed use

<table>
<thead>
<tr>
<th>Complications, n (%)</th>
<th>Acute treat.</th>
<th>Delayed treat.</th>
<th>p-values</th>
<th>Guepar*</th>
<th>Evolutive*</th>
<th>rHead RECON*</th>
<th>rHead STANDARD*</th>
<th>p-values according to the implants</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 54</td>
<td>n = 23</td>
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<tr>
<td>Painful loosening1</td>
<td>8 (14.8)</td>
<td>6 (26.1)</td>
<td>0.33</td>
<td>7 (19.4)</td>
<td>1 (4.2)</td>
<td>5 (50)</td>
<td>1 (14.2)</td>
<td>0.017</td>
</tr>
<tr>
<td>Radiohumeral conflict</td>
<td>4 (7.4)</td>
<td>3 (13)</td>
<td>0.40</td>
<td>3 (8.3)</td>
<td>2 (8.3)</td>
<td>1 (10)</td>
<td>1 (14.2)</td>
<td>0.77</td>
</tr>
<tr>
<td>Radialcapellar insta-</td>
<td>3 (5.6)</td>
<td>4 (17.4)</td>
<td>0.18</td>
<td>4 (11.1)</td>
<td>2 (8.3)</td>
<td>1 (10)</td>
<td>0</td>
<td>0.82</td>
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<td>bility</td>
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<tr>
<td>Component disassocia-</td>
<td>0</td>
<td>1 (4.3)</td>
<td>0.28</td>
<td>1 (27)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.77</td>
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<td>tion</td>
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<tr>
<td>Ulnar nerve palsy</td>
<td>5 (9.2)</td>
<td>1 (4.3)</td>
<td>0.66</td>
<td>4 (12.2)</td>
<td>2 (6.3)</td>
<td>0</td>
<td>0</td>
<td></td>
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<tr>
<td>Complex regional pain</td>
<td>4 (7.4)</td>
<td>1 (4.3)</td>
<td>1</td>
<td>3 (8.3)</td>
<td>1 (4.2)</td>
<td>1 (10)</td>
<td>0</td>
<td>0.77</td>
</tr>
<tr>
<td>syndrome</td>
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</tbody>
</table>

Surgical re-interventions

| Implant removal      | 12 (22.2)  | 7 (30.4)       | 0.56     | 10 (27.8)| 3 (12.6)  | 5 (50)      | 1 (14.2)      | 0.11                              |
| No implant removal   | 6 (11.1)   | 5 (21.7)       | 0.28     | 5 (12.8)| 5 (20.8) | 1 (10)      | 0             | 0.63                              |

*Guepar/Head RECON/rHead STANDARD (Small Bone Innovations [SBi]/Stryker, Morrisville, Pennsylvania); Evolutive (Aston Medical, Saint-Etienne, France)

p-values were calculated using Fisher's exact test

1Statistically significant result (p < 0.05)

Discussion

This study shows unsatisfactory mid-term results, and does not corroborate excellent outcomes of RHAs published recently in the literature.16,18,19,21

We speculate that outcomes in the present series would have been worse if ORIF had been performed, as conservative treatment of comminuted radial head fractures leads to an increased risk of early failure of fixation and pseudarthrosis.38 Despite good mean quickDASH scores and MEPs of 14.0 and 90.2 points respectively, we report a
high rate of re-operation of 38.9%, including 11 (14.3%) with retention of the implant and 19 revisions (24.67%).

The rate of complications and failures of RHA performed in a delayed fashion were high. We confirmed that, when performed acutely, RHA results in improved clinical and radiographic outcomes compared with those performed in a delayed fashion, although the difference was not statistically significant due to the small sample size. The three primary reasons for failure were painful loosening (14; 18.2%), radiocapitellar instability (six; 7.5 %), and humeroradial conflict (five; 17.5%). Painful loosening was the most common indication for removal of the implant, although its rate varied significantly among the different designs of RHA (p = 0.017) (Fig. 4). Short-stemmed implants (rHead RECON and STANDARD) were significantly more prone to loosening compared with those with a long stem (Guepar, Evolutive) (OR 3.54; 1.02 to 12.2; p = 0.045). The rHead prostheses have shorter stems than Guepar or Evolutive designs, but their acetabular components are of identical height to the two others in the series (Table I). According to Shukla et al the risk of instability is dependent on the ratio of the length of the radial head of the RHA divided by the total length of the implant. When this ratio is > 0.4, the risk of instability is significantly higher due to increased micromotion of the stem. The increased ratio in rHead short-stemmed RHAs could explain the significantly increased rate of loosening and osteolysis that we found. For all short-stemmed implants, intra-operative press-fit was found to be insufficient, and cement was required, except in two patients, to obtain a satisfactory fixation. Since a layer of cement could be added, it follows that the diameter of these prostheses was smaller than the maximal and sub-maximal diameter needed. Moon et al found that implants of sub-maximal size had micromotion (> 250 micrometers) that exceeded the threshold needed for bone ingrowth and initial stability.

Lastly, the level of comfort with the surgical technique could play a role in the high failure rate. Malpositioning (overstuffing) theoretically contributes to the risk of micromotion of the stem by increasing the extramedullary portion of the implant. The rate of capitellar wear in our series varied with the design of the implant (p = 0.04). The rates of early capitellar wear for the Guepar and monopolar rHead STANDARD designs were > 40%. This could be explained by hypermobility of the acetabular component and repeated posterolateral subluxation of Guepar RHAs, and higher radiocapitellar contact pressures with rHead STANDARD RHAs. It has recently been reported that monopolar implants are preferable to bipolar implants in patients with associated ligamentous injury because they allow for superior radiocapitellar stability. The implant selected for each patient did not depend on the integrity of the soft tissues. Only one design of RHA was available at the time of each operation for all the patients in this series. We recognise that this is a weakness of the study as the bipolar implant is clearly recommended only when there is malalignment of the proximal radius with respect to the capitellum.

Our study identified two distinct follow-up periods after RHA. Within the first three years there was early drop in survival and during this time re-operations with and without removal of the implant were undertaken at a mean of 15.4 months post-operatively. Subsequent survival rates stabilised with an increased life expectancy of the implants which survived for more than three years (Fig. 4).

The limitations of this study relate to its retrospective, single-centre nature and sample size. The retrospective design inherently leads to more loss of data and bias. The small sample size did not allow us to find a statistically significant difference in outcome between the different types of design. We considered only tight-fitting RHAs and did not include loose-fitting designs. We analysed a heterogeneous set of uni- and bipolar prostheses and a variety of associated lesions that were not accounted for by comparative analysis in the follow-up period. The differences in the sizes of the groups, with, for instance, seven with a monopolar design and 70 with a bipolar design, did not allow for reliable comparative sub-group analysis. Surgeon training in elbow surgery, particularly in RHA was variable; we speculate that this may have also influenced the results. The analysis of the position of the stem on AP radiographs may have depended on the ROM of the elbow; 16 radiographic analyses were performed in patients with incomplete supination or extension. Follow-up was < 30 months in eight patients with the Evolutive design. These patients were therefore only included in analyses of outcome during the first three post-operative years and the true rate of complications may have been lower. Similarly, the true overall survival (mean time 14.75 months, SD 11; 0.2 to 36 and mean time to removal 21 months, SD 9; 6 to 36) may be higher.

In conclusion, the mid-term outcomes of bipolar and press-fit RHAs are unsatisfactory, with a high rate of re-operation during the first three post-operative years. Fixed RHAs may be prone to painful loosening, especially those implants with short stems. A comparative study would be necessary to further assess the risk of painful loosening in loose- compared with tight-fitting RHAs.

Take home message:
- There were high rates of re-operation during the first three years after implantation.
- Fixed RHAs may be prone to painful loosening.
- Short-stemmed implants may be prone to painful loosening.

Author contributions:
P. Laumonerie: Conception and design, Acquisition, analysis and interpretation of data, Critically revising the article, Reviewed submitted version of manuscript, Statistical analysis.
References


