


# Tight-fitting radial head prosthesis: does stem size help prevent painful loosening?

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Received: 23 June 2017 / Accepted: 10 September 2017 / Published online: 21 September 2017  
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## Abstract

**Introduction** The most common reason for removal of well-fixed radial head prostheses is painful loosening. We hypothesised that short-stemmed prostheses, used for radial head arthroplasty, are not associated with an increased risk of implant loosening.

**Methods** From 2002 to 2014, 65 patients were enrolled in a retrospective single-centre study. The radial head prostheses were classified as having either a long (30-mm) or short (16- to 22-mm) stem. The long-stemmed implants comprised 30 GUEPAR<sup>®</sup> DePuy Synthes (West Chester, PA, USA) and 20 Evolutive<sup>®</sup> Aston Medical (Saint-Etienne, France) devices; the short-stemmed implants comprised nine RECON and six STANDARD rHead<sup>®</sup> SBI-Stryker (Morrisville, PA, USA) devices. At last follow-up, clinical (range of motion, Disabilities of the Arm, Shoulder, and Hand score, Mayo Elbow Performance score) and radiographic (osteolysis) outcomes were assessed.

**Results** At a mean follow-up of 76.78 months (24–141), the rate of painful loosening [6 (40%) vs 8 (16%),  $p = 0.047$ ] and osteolysis [12 (80%) vs 23 (46%),  $p = 0.02$ ] were significantly higher in patients with short-stemmed versus long-stemmed implants. Despite the significant difference in loosening

between stems as groups, individual stem length was not determined.

**Conclusions** Tight-fitting implants with short stems are more prone to painful loosening.

**Keywords** Arthroplasty · Failure · Loosening · Radial head prosthesis · Stem

## Introduction

Fractures of the proximal radius account for 1.7–5.4% of all fractures and approximately one third of elbow fractures [1]. This becomes important when one considers that the proximal radius is a major contributor to elbow and forearm stability [2–4]. Radial head arthroplasty (RHA) has satisfactory outcomes according to recent literature [5–8]; however, tight-fitting radial head prostheses (RHP) may have inferior mid-term survival than loose-fitting implants [5–14]. High complication rates have been reported after this procedure, and the most common cause of RHP removal is painful prosthetic loosening [15–19]. O’Driscoll and colleagues [20, 21] identified several mechanical rules to follow to obtain a well-fixed implant while minimising micromotion, with stem diameter and length being the most important factors.

Between 2002 and 2014, four different RHP designs were used in the Department of Orthopaedic Surgery at this institution to treat non-reconstructable acute radial head fractures or their post-traumatic sequela: GUEPAR<sup>®</sup> prosthesis (Depuy-Synthes, West Chester, PA, USA), Evolutive<sup>®</sup> prosthesis (Aston Medical, Saint-Etienne, France), rHead<sup>®</sup> RECON prosthesis or rHead<sup>®</sup> STANDARD prosthesis (Stryker-Small Bone Innovation). The primary aim in this study was to investigate and compare the risk of painful loosening of tight-fitting RHPs with short and long stems.

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## Materials and methods

This was a single-centre comparative retrospective study conducted in an academic department of orthopaedic surgery. Inclusion criteria were patients undergoing surgery for non-reconstructable fracture of the radial head fracture or sequela of trauma (including malunion, pseudarthrosis, necrosis, failure of fixation) for which an RHA was performed between 2002 and 2014, with a minimum follow-up of two years or until implant removal. Patients with follow-up of < two years, aged <18 years and prosthesis removal not due to loosening were excluded. The study was approved by the local institutional review board.

### Patients

A total of 94 patients underwent RHA during this time. Sixteen patients were excluded due to: short follow-up (4 cases), removal for a reason other than painful loosening [5 cases: posterolateral instability (1); radiohumeral conflict (4)] and re-operation with implant retention [7 cases: persistent lateral posterior instabilities (5), radiohumeral conflict (1), prosthesis head dislocated from stem (1)]. Thirteen patients were lost to follow-up, and 65 were assessed [44 men, 21 women; mean age 52.46 years (20–82)]. Forty-five RHAs were performed for acute fractures and 20 for sequelae of trauma. Injury mechanisms comprised 25 falls from standing height, 17 a roof or a ladder, nine down stairs, nine traffic accidents and five sports accidents. Initial fracture evaluation showed 57 Mason type III, two Mason type II and six radial neck; 26 were isolated proximal radius fractures, 27 terrible triad, three Essex–Lopresti, four distal ulna or radius metaphyseal–epiphyseal and 11 associated transolecranon. Population details are reported in the Table 1.

Sixty-five tight-fitting RHAs were reviewed retrospectively using four different prosthetic models: 30 GUEPAR® (bipolar implant), 20 Evolutive® (bipolar implant) six rHead® STANDARD (monopolar implant) and nine rHead® RECON prostheses (e.g. bipolar RHP) (Fig. 1). The long-stemmed implants [50 long, smooth stems (30 mm)] were GUEPAR® and Evolutive® designs, and the short-stemmed implants (15 short, roughened stems (16–22 mm)) were rHead®. A call for tenders was performed for each RHA model; one type was preselected to be used for all procedure for a limited period. Our preference changed three times for a total of four different prostheses during this time. The RHA used for each patient was dependent on our preference at the time of surgery. No RHA randomisation was performed, as only one choice was available at the time of surgery for each patient.

## Surgical approach and technique

A lateral approach to the elbow was used in 58 cases, and a posterolateral approach was preferable in seven cases when there was an associated fracture of the olecranon. Particular attention was paid to preserving the radial collateral ligament if it was intact. The annular ligament (AL) was incised longitudinally (incision transverse to AL fibres). The capitellum was routinely carefully examined for the presence of cartilage lesions. Seven olecranon fractures were fixed with a plate. Four fractures of the coronoid process were fixed using retrograde screw fixation with intra-articular control of the reduction. The radial neck was divided to preserve as much bone as possible; short-stemmed components were used if it was possible to conserve radial neck length. The radial medullary canal was reamed and the prosthesis introduced such that it did not surpass 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 (PalacosGenta®) was used for fixation of all RHPs; the press-fit stability of stems with roughened surfaces was felt to be insufficient, and the short-stemmed prostheses were anchored with cement according to the manufacturers' specifications. The final radial head components were impacted onto the neck of long-stemmed prostheses and directly onto the stem of Stryker prostheses. The radial collateral ligament was reattached to the lateral epicondyles using transosseous sutures or suture anchors in 29 patients; in the remaining patients, only the annular ligament was repaired, followed by the tendon layer. Elbow stability was then assessed. The ulnar collateral ligament was re-attached to the medial epicondyle in three patients.

### Post-operative procedure

In 29 patients in whom the lateral collateral ligament (LCL) was repaired, the elbow was immobilised for 15 days in a long-arm dorsal-volar splint with the wrist in pronation. The wrist was left free in 36 patients in whom the LCL was not repaired. In five patients in whom the elbow remained unstable despite LCL reconstruction, a static external fixator was retained for two to three weeks. Between post-operative days 15 and 21, a hinged brace was used to permit extension up to –30°. By postoperative day 45, active mobilisation and physiotherapy were initiated, including active range of motion (ROM) exercises to encourage articular coaptation.

### Evaluation methods

All patients were assessed by an independent reviewer at the aforementioned time points or until removal for painful loosening. Comparative clinical examination of both upper

**Table 1** Characteristics of the study population: long- or short-stemmed prostheses used for radial head arthroplasty

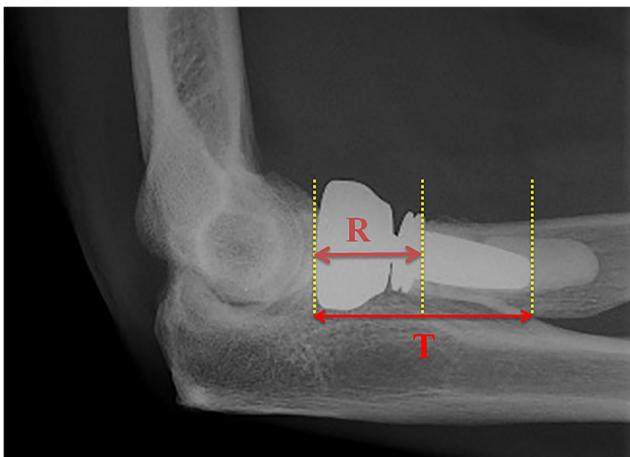
	Long-stemmed prosthesis ( <i>N</i> = 50)	Short-stemmed prosthesis ( <i>N</i> = 15)	<i>P</i> values
Sex			0.47
Male	35 (70%)	9 (60%)	
Female	15 (30%)	6 (40%)	
Age (years)	52.20 (range, 20–79)	53.33 (range, 35–82)	0.75
Lesions			0.38
Acute	36 (72%)	9 (60%)	
Chronic	14 (28%)	6 (40%)	
Radial head injuries			
Mason II	2 (4.00%)	0	
Mason III	44 (88.00%)	13 (86.67%)	
Radial neck fracture	4 (8.00%)	2 (13.33%)	
Associated Upper Limb injuries	34 (68.00%)	11 (73.33%)	0.69
Terrible triad	21 (42.00%)	6 (40.00%)	
Essex–Lopresti injury	2 (4.00%)	1 (6.67%)	
Distal ulna or radius fracture (metaepiphyseal)	3 (6.00%)	1 (6.67%)	
Olecranon fracture	8 (16.00%)	3 (20.00%)	

\*Statistically significant ( $p < 0.05$ )

extremities (wrist and elbow) was performed. Anteroposterior and lateral radiographs were taken with the elbow in maximum extension and 90° of flexion for the 51 patients who retained the radial head prosthesis at the time of last follow-up. Pre- and post-operative clinical and radiographic data and operative details were noted from the medical records for all patients.

#### Primary endpoint

We reviewed pre-operative physical exams (proximal radial forearm pain reported according to O’Driscoll’s definition [18]) and operative reports (loose implant confirmed by the

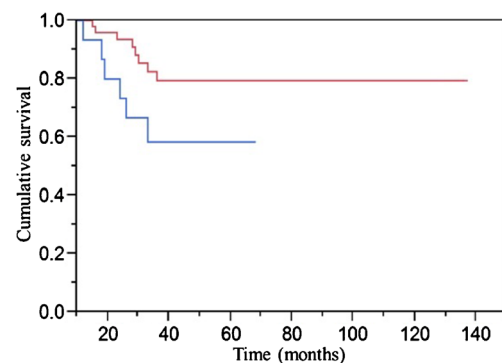


**Fig. 1** Ratio describing head length (R) divided by total implant length (T) of a short-stemmed prosthesis (rHead® RECON, Stryker-Small Bone Innovation)

quality of the prosthetic sealing) to identify whether painful loosening was the cause for re-operation for each patient.

#### Secondary endpoint

Clinical analysis was possible for 51 patients in whom the RHP was retained at the time of the final review. Maximum ROM was measured using a goniometer. The ratio (expressed as %) of operative to non-operative elbow flexion and extension force was measured using a Kinedyn® dynamometer (Smith & Nephew, Memphis, TN, USA). Function was assessed using the Mayo Elbow Performance Score (MEPS) and the Quick Disabilities of the Arm, Shoulder, and Hand (QuickDASH) score [22, 23].



**Fig. 2** Kaplan–Meier curves for short- and long-stemmed radial head prostheses (RHPs). Prostheses with short and long stems are represented by blue and red curves, respectively. Event (removal of painful loosened implant) = 1

For all cases, radiographic analysis of the elbow (lateral/AP views) was used to assess for signs of periprosthetic osteolysis, overstuffing (on lateral radiograph according to the method described by Van Riet et al. [24]) and presence or absence of river delta sign (asymmetric humero-ulnar joint space, wider on the radial side according to Gauci et al. [9]). Assessment included heterotopic ossification according to Brooker classification and capitellar wear. These were noted at each post-operative review.

### Statistical analysis

A single-sample chi-square analysis was used to compare sex, associated lesions, prosthesis use in an acute or delayed fashion, osteolysis and overstuffing between long- and short-stemmed prostheses. The Mann–Whitney U test, also known as the Wilcoxon rank-sum test, was used to compare age, QuickDASH, MEPS, ROM and force with the healthy contralateral side. Odds ratios (OR) were used to analyse the predictive link between stem size (long or short) and loosening, the predictive link between overstuffing, and loosening or capitellar wear. The survival rate of long- versus short-stemmed prostheses was determined according to the Kaplan–Meier method. Comparative analysis between survival curves of long and short stems was performed using the log-rank test (Mantel–Cox). Confidence intervals (CI) were fixed at 95% and statistical significance at  $p < 0.05$ . Results are described according to their mean or percentage (with absolute number) and range. Normality of data was assessed, and all data was determined to be non-normally distributed ( $P < 0.01$ , Kolmogorov–Smirnov test) requiring the use of non-parametric tests.

### Results

Mean follow-up was 76.78 months (24–141) for 51 patients. At the time of data collection, mean follow-up for the short-stemmed implants was 58.01 (44–69) and 82.42 (24–141) months for long-stemmed implants. The remaining patients were censored due to prosthesis removal prior to this time point. Clinical and radiographic results are reported in Table 2.

### Primary endpoint

A total of 14 cases of painful aseptic loosening were reported in ten men and four women, mean age 51.1 years, with seven GUEPAR<sup>®</sup>, one Evolutive<sup>®</sup>, five rHead<sup>®</sup> RECON and one rHead<sup>®</sup> STANDARD. There was a statistically significant difference in loosening between short- and long-stemmed implants [6 (40%) vs 8 (16%), respectively;  $p = 0.047$ ] (Table 2). Despite the significant difference in loosening between stems as groups, individual stem length was not determined [OR 3.5

(0.9–12.59);  $p = 0.055$ ]. The loosened implants were removed at a mean of 23.28 months (6–36) postoperatively, with no significant difference between groups (24.7 versus 23.1 months;  $p = 0.75$ ). Comparative analysis demonstrated greater survival for long stems, though this difference was not significant [log-rank (Mantel–Cox);  $p = 0.0506$ ] (Fig. 2).

### Secondary endpoint

Secondary endpoints of clinical and radiological results are shown in Table 2.

#### Clinical results

No significant difference in results between short- and long-stemmed implants was found. The average reported MEP score was 87.4 points (92 versus 86.8, respectively;  $p = 0.35$ ), and mean quickDASH score was 16.57 points (12.8 versus 17.7, respectively;  $p = 0.38$ ).

#### Radiological results

Periprosthetic osteolysis was noted in 35 cases; it was located around the neck of the radius in 11 cases, circumferentially around the stem in 27 cases and limited to the lateral or medial side of the stem in four and three cases, respectively. Overstuffing was identified in 30 cases at a frequency of 47% (7) for short and 46% (23) for long stems; ( $p = 0.96$ ). A river delta sign [9] was reported in 11 cases (3 short and 8 long). There was no significant association between implant overstuffing and loosening [OR 0.96 (0.28–3.27);  $p = 0.95$ ] or osteolysis [OR 0.78 (0.30–2.02);  $p = 0.62$ ]. Additionally, overstuffing was not associated with negative radiographic findings, such as osteolysis [OR 0.78 (0.30–2.02);  $p = 0.62$ ], capitellar wear [OR 0.76 (0.27–2.08);  $p = 0.59$ ] or painful loosening [OR 0.96 (0.28–3.27);  $p = 0.95$ ]. Analysis of humeroulnar joint space narrowing revealed capitellar wear in 27 prostheses. Heterotopic periprosthetic ossification was found in 24 cases and classified according to Brooker: grade 0 in 41, grade 1 in 15, grade 2 in four, and grade three in five cases.

### Discussion

This study shows that the rate of painful loosening was significantly higher in tight-fitting RHPs with short stems ( $p < 0.05$ ). Despite satisfactory mid- to long-term outcomes (mean quickDASH and MEP scores of 16.57 and 87.4, respectively), tight-fitting RHP may have inferior mid-term survival than loose-fitting implants according to recent literature [5–15]. Painful loosening of tight-fitting implants is the most common cause of RHA failure [15–19, 25, 26]. Our

**Table 2** Description of clinical and radiological outcomes after tight-fitting radial head arthroplasty with short and long stem

Radiological/clinical results	Short-stemmed implant ( <i>N</i> = 15)	Long-stemmed implant ( <i>N</i> = 50)	<i>P</i> value
Radiological ( <i>N</i> = 15 short-stemmed implants; 50 long-stemmed implants)			
Painful loosening*	6 (40%)	8 (16%)	0.047
Osteolysis*	12 (80%)	23 (46%)	0.02
Overstuffing	7 (47%)	23 (46%)	0.96
Capitellar Wear	9 (64%)	18 (36%)	0.07
Clinical ( <i>N</i> = 9 short-stemmed implants; 42 long-stemmed implants)			
QuickDash score (points)	12.8	17.7	0.38
MEP score (points)	92	86.8	0.35
Subjective utilization elbow (%)	80	75.5	0.52
Range of Motion (°)			
- flexion	123	133.6	0.06
- extension	-11	-16.8	0.68
- supination	67.5	66.3	0.76
- pronation	81	74.5	0.41
Force compared with contralateral side (%)			
- flexion	85.8	90.8	0.43
- extension	96.4	95.2	0.99

\*Statistically significant ( $p < 0.05$ )

study did find a decreased implant survival time for short-versus long-stemmed implants (Fig. 2); however, demonstrating a cumulative survival difference ( $p = 0.0506$ ) and an increased risk of loosening ( $p = 0.055$ ) according to stem length would have required larger sample size. According to Shukla et al. [21], the risk of instability is dependent on the ratio of RHP length divided by total implant length (Fig. 1). When this ratio is  $>0.4$ , the risk of instability is significantly higher due to increased stem micromotion. The increased ratio in short-stemmed RHAs could explain the significantly increased rate of loosening ( $p = 0.047$ ) and osteolysis ( $p = 0.02$ ) found in our study. For all short-stemmed implants, intra-operative press-fit was insufficient, and cement was required 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 submaximal diameter needed to fill the canal. Moon et al. [20], found that implants of submaximal size had micromotion ( $>250 \mu\text{m}$ ) 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. We speculate that the increased rate of overstuffing [30 (46%), regardless of stem length; ( $p = 0.96$ )] was due to difficulties in obtaining stable fixation. This may predispose the surgeon to favour stability over implant position. We speculate overstuffing could theoretically contribute to the risk of stem micromotion by increasing the extramedullary portion of the prosthesis. However, our study did not show that overstuffing was a risk factor for painful loosening ( $p = 0.95$ ) or osteolysis ( $p = 0.62$ ) [21, 27–29].

The rate of early capitellar wear in our series was high ( $>30\%$ ) and did not vary with stem length ( $p = 0.07$ ); overstuffing was not a predictive factor of capitellar wear ( $p = 0.59$ ). We speculate that cup hypermobility and repeated episodes of posterolateral subluxation of bipolar implants, as well as higher radiocapitellar contact pressures with monopolar implants, could explain the high rate of early capitellar wear [30–32].

The implant selected for each patient did not depend on soft tissue integrity. Only one RHA design was available at the time of each operation for all patients in this series. We recognize 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. Other limitations of our study relate to its retrospective, single-centre nature and small sample size. The retrospective design inherently leads to more data loss and bias. The rate of loss to follow-up was elevated, at (13.9%); however, this rate is justified in light of the retrospective design and the requirement of a midterm clinical visit dedicated specifically to the study. The small sample size of short-stemmed implants did not allow us to find statistically significant risk factors for painful loosening. We considered only tight-fitting RHAs and did not include loose-fitting RHAs or designs. We analysed RHPs with a variety of associated lesions that were not accounted for by comparative analysis in the follow-up period. However, characteristics of the study population were not significantly different between implant groups (Table 1); most importantly, the rates of associated lesions ( $p = 0.69$ ) and use of the



prosthesis in a delayed or acute fashion ( $p > 0.38$ ) were not different. Surgeon training in elbow surgery, particularly in RHA, was variable; which may influence results [17]. Since the mean follow-up for short-stemmed implants was less than for long-stemmed implants, the true rate of painful loosening and negative radiographic outcomes may have been lower in the short-stemmed implant group.

## Conclusions

Tight-fitting RHPs with short stems are more prone to painful loosening. An additional study with a larger cohort of patients focused on fixed RHP malpositioning and sequential painful loosening will be necessary to further understand this association.

**Funding** All the authors (Pierre Laumonerie, Nicolas Reina, Claudia Gutierrez, Stephanie Delclaux, Meagan E Tibbo, Nicolas Bonneville, Pierre Mansat) and their immediate family, and any research foundation with which they are affiliated, did not receive any financial payments or other benefits from any commercial entity related to the subject of this article.

## Compliance with ethical standards

**Disclaimer** Not applicable.

**Conflict of interest** All the authors (Pierre Laumonerie, Nicolas Reina, Claudia Gutierrez, Stephanie Delclaux, Meagan E Tibbo, Nicolas Bonneville, Pierre Mansat) report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

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