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ORIGINAL ARTICLE • HIP - ARTHROPLASTY

Mid-term clinical results of the cementless R3 cup and Polarstem total hip arthroplasty

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Abstract

Background There has been a shift from cemented to uncemented hip arthroplasty. One popular uncemented combination is the R3 acetabular cup with Polarstem, having the lowest revision rate in the UK National Joint Registry. However, there are no medium-term clinical outcomes on this combination in the literature. The aim of this study is to review our centre's outcomes with this combination using conventional bearings with a minimum of 7-year follow-up.

Methods Using our centre's arthroplasty database, we identified all patients that underwent a total hip arthroplasty using these implants from August 2009 to December 2010. One hundred and forty-four procedures were performed. The primary outcome was revision rate, and the secondary outcomes were clinical and radiological evaluation.

Results The mean cohort age at surgery was 68.3 years. There were three revisions, of which only one underwent a cup revision. The mean Oxford Hip Score at 7-year follow-up was 38. Radiological evaluation of both acetabular and stem component did not show any radiolucency at 7-year follow-up. Kaplan–Meier survivorship analysis showed an implant survival rate of 97.69% at 7 years using revision for all causes as endpoint. The risk of revision was 1.47% at 7 years.

Conclusion Our revision rates are comparable to the UK's National Joint Registry, with excellent clinical and radiological outcome. Our results correlate with the allocated rating of 7A* by the Orthopaedic Data Evaluation Panel for both R3 acetabular cup and Polarstem.

Keywords Total hip arthroplasty · Total hip replacement · R3 cup · Polar stem · Uncemented · Cementless

Introduction

Total hip arthroplasty (THA) has greatly evolved over the years in terms of stem and cup design, and fixation methods [1, 2]. Historically, the most common fixation method of primary THA was cemented. With the evolution of alternative methods such as cementless or hybrid fixation, there has been an increasing trend towards cementless THA since 2008, as demonstrated by the latest National Joint Registry (NJR) in the UK [3].

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The R3 modular metal-on-metal hips had reported high failure rate secondary to component corrosion due to the design of the metal shell and metal liner [4]. However, the R3 cementless acetabular cup when used in combination with the Polar cementless stem (both Smith & Nephew, Memphis, TN) with conventional bearings (ceramic-on-ceramic, ceramic-on-polyethylene, metal-on-polyethylene) is the best-performing cementless combination in the UK NJR with a 7-year revision rate of 0.98 (0.72–1.32), with the next best combination at 2.15 [3].

Registries have proven vital in monitoring new prostheses and bearing surfaces and to identify failing implants [3]. Registries help reduce the potential bias of design centre studies and those with conflicts of interests in the literature. However, they might not always tell the full picture. Registries require diligent reporting of all primary procedures, and there are concerns regarding interpretation of observational data, compliance with reporting revisions, lack of patient-reported outcome measures (PROMs) and timely feedback to support best practice. Surgeon

or institution-based outcomes provide close to real-time feedback that can alter practice.

The R3 cup was first marketed in Australia and Europe in 2007, while the Polarstem has been implanted since 2002. However, there have been no medium-term follow-up clinical studies published on this combination to date to the authors' knowledge. The aim of this study is to review our results of the R3 acetabular cup and the Polar femoral stem combination in conventional bearings with a minimum of 7-year follow-up in a non-designer centre, using revision rate as primary outcome measure and both Oxford Hip Score (OHS) and radiological evaluation, as secondary outcome measures.

Materials and Methods

Subjects

Using our centre's own arthroplasty database, we identified all patients who had a joint replacement with the cementless R3 acetabular cup and cementless Polarstem femoral component. Our centre started using this combination from 2009; therefore, we included patients from August 2009 to December 2010, thus producing a minimum follow-up of 7 years. Demographic data were recorded, and analysis was performed using SPSS Statistics Software 25.0 (IBM, Armonk, NY, USA). One hundred and forty-four consecutive THAs were performed in 143 patients. The main indication for arthroplasty was symptomatic hip osteoarthritis (OA) causing a reduction in activities of daily living in patients who had failed a trial of non-operative management. The indications for surgery are shown in Table 1.

Implants

All THAs were composed of cementless R3 three-hole cup (mean size 54 mm), with either ceramic ($n=109$, 75.7%) or XLPE liner ($n=35$, 24.3%), and ceramic ($n=137$, 95.1%) or oxinium ($n=7$, 4.9%) femoral head bearing. The distribution of cup sizes across our cohort is shown in Table 2. Seventeen cups required additional screw(s) to achieve a stable intraoperative fixation (1 screw, $n=6$; 2 screws, $n=7$; 3 screws, $n=4$). The bearing combinations used are shown in Table 3. The Polarstem sizes used are shown in Table 4. Only six lateralised offset Polarstems were used in our series.

Table 1 Indications for THA

Diagnosis	No.
OA	123 (86.0%)
Neck of femur fracture—revision of failed cannulated screw fixation	6 (4.2%)
Perthes disease	5 (3.5%)
Avascular necrosis	4 (3%)
Neck of femur fracture—primary THA	3 (2%)
Revision	3 (2%)

Table 2 Cup size distribution

Cup size	No.
48	9
50	15
52	41
54	23
56	28
58	19
60	5
62	2
64	2

Table 3 Bearing combination

Cup bearing*	Head bearing	No.
Ceramic	Ceramic	107 (74.3%)
XLPE	Ceramic	30 (20.8%)
XLPE	Oxinium	7 (4.9%)

*All liners used were neutral

Table 4 Polarstem size

Polarstem size	No.
0	13
1	11
2	23
3	38
4	24
5	11
6	9
7	6
8	7
9	0
10	1

Surgical procedure

All procedures were performed by one of four orthopaedic consultants or by their registrar under their direct supervision. The operations were performed in a laminar flow theatre, with patients positioned in the lateral decubitus position. They received the same surgical skin preparation and antibiotics on induction of anaesthesia. One hundred and thirty-nine operations were performed by posterior approach, while 5 were performed by direct lateral approach (Hardinge). The R3 acetabular component was inserted using the standard instruments provided by the company, and the three-hole

R3 cup was used for all cases. No screws were used in the majority of cases, but up to three screws were used in some patient. The acetabulum was either under-reamed by 1 millimetre or reamed line to line depending on the bone quality, and the component was impacted into final position. The Polar femoral stem was inserted after using the standard broaches provided by the company. All patients received T.E.D. antiembolism stockings (Covidien, Ireland) and foot pumps as thromboprophylaxis while an in-patient, as well as oral anticoagulation therapy post-operatively as per our hospital's protocol. All patients underwent a post-operative physiotherapy regime.

Patient follow-up

Patients were followed up at 6 weeks, 3 months and 1 year following surgery. Standardised anteroposterior pelvic and lateral hip radiographs were taken in the immediate post-operative period, and at each follow-up appointment. Following a satisfactory first-year follow-up, patients were enrolled into a virtual arthroplasty clinic where they were followed up at 3, 5, 7 and 10 years post-operative with repeat radiographs and completion of OHS questionnaire. The virtual clinic is a consultant arthroplasty surgeon led service at a local level. Patients are called back for a face-to-face follow-up clinic if they reported poor OHS or if their radiographs showed any concerning features.

Study outcomes

The primary outcome was to determine the revision rate of the R3/Polarstem combination in patients with a minimum of 7-year follow-up period. The secondary outcomes were to assess the PROMs using the OHS, along with evaluation of both preoperative and post-operative radiographs. The Dorr classification [5] was used to evaluate femoral canal type on preoperative radiographs, while the Brooker classification [6] was used to evaluate heterotopic ossification (HO) on serial post-operative anteroposterior pelvis radiographs. The radiographs were also reviewed for radiolucency in Gruen zones [7] for the femoral stem and DeLee and Charnley zones [8] for the acetabular cup by two independent surgeons who were not involved in the procedures. Osteolysis was defined as a lucent zone devoid of trabecular bone and usually with a sclerotic border not visible on the immediate post-operative radiograph [9]. The acetabular component was considered to be loose if there was migration of more than 3 mm in any direction over time or a circumferential radiolucent line in serial post-operative anteroposterior pelvis radiographs. Intraoperative and post-operative complications, such as periprosthetic fracture, dislocation, superficial wound infection, deep infection and venous thromboembolic events, were noted by reviewing the patients' operation notes and follow-up clinic letters using our electronic patient clinical portal system.

Results

Demographics

The mean age of the patients at the time of surgery was 68.3 years (range 37–86 years). This series consisted of 61 men and 82 women, with 70 left THAs and 74 right THAs.

Table 5 Review of patients with OHS less than 25 at 7-year follow-up

Reason for operation	Age at follow-up (years)	Post-operative complication	OHS at 7 years	Location of pain*	Stairs	Getting in/out of bed	Sitting on toilet	Overall satisfaction
OA	88	Nil	25	Nil	No issues	Discomfort	Nil	Yes
OA	82	Nil	18	H + LS	Restricted	Pain in LS	Pain	No
OA	70	Nil	10	H + LS	Restricted	Pain in LS	Pain	No
OA	54	Nil	21	H + K	Restricted	Discomfort	Pain	Yes
OA	82	Nil	22	H + LS	Restricted	Discomfort	Pain	No
OA	74	Nil	24	Nil	No issues	Discomfort	Nil	Yes
OA	64	Nil	19	LS	No issues	Discomfort	Pain	Yes
OA	83	Nil	23	LS	Restricted	Discomfort	Pain	Yes
OA	70	Nil	9	H + K	Restricted	Pain in H + K	Pain	No
OA	78	Fall (no fracture)	18	LS	Restricted	Discomfort	Pain	Yes
OA	53	Nil	21	H + K	Restricted	Discomfort	Pain	Yes
OA	79	Post-operative ACS	8	LS	Restricted	Pain in LS	Pain	No
OA	69	Nil	24	LS	Restricted	Discomfort	Pain	Yes

OA osteoarthritis, *ACS* acute coronary syndrome, *H* hip, *LS* lumbar spine, *K* knee

*All locations of pain were ipsilateral to index procedure

None of the patients included in this prospective study were lost to follow-up; however, 30 patients had died of unrelated causes (average time of implantation to death: 46.6 months, range 1–90 months) by the time of our study.

Clinical outcome

Out of the 114 THAs in our study, the final mean post-operative OHS at 7-year follow-up was 38 (range 8–48). All of the patients that had an OHS of <25 at 7-year follow-up ($n=13$) had a review to determine the reason(s) for the low score (location of pain, limitations in mobility or a combination of both) and whether they were satisfied with the overall outcome of their hip replacement. None of these patients had identifiable radiolucency around either the Polarstem or acetabular cup. The results of this review are shown in Table 5.

Radiographic outcome

Dorr classification of femoral canal showed 28 (19.4%) had a Dorr type A femoral canal, 109 (75.6%) a Dorr type B femoral canal and 7 (5%) a Dorr type C femoral canal. One hundred and fourteen patients, who had a 7-year follow-up, received a Brooker classification for HO. This analysis showed 92 (80.7%) joints had grade 0 HO, 19 (16.7%) had grade 1 HO, only 3 (2.6%) had grade 3 HO, and none had grade 4 HO. There was no radiolucency around the femoral stem, and none of the acetabular cups showed osteolysis at the final follow-up.

Revisions

There were three revisions in our series. There were no revisions of Polarstem, but there was one revision of R3 acetabular cup. The first patient had their initial THA for OA in November 2009 with a 58-mm cementless R3 cup (ceramic-on-ceramic bearings [Biolox® delta, 4th generation], 36 mm head). The patient had an uncomplicated first-year follow-up period, but sustained recurrent mechanical falls with no dislocations or periprosthetic fractures, and subsequently developed unresolving groin pain. He had unremarkable radiographs, with a mildly raised C-reactive protein (CRP) of 17 mg/L. His MRI was reported as a collection with pseudocapsule containing mixed signal intensity fluid and synovial debris. Aspiration of the affected joint was negative for infection. A revision was undertaken at 8 years from initial surgery where the intraoperative findings confirmed a chronic haematoma (secondary to concurrent warfarin use for atrial fibrillation). The appearance of the bearing surfaces looked unremarkable, and intraoperative samples were also negative for infection. The acetabular and head bearing were revised to XLPE and an oxinium head. The patient had been doing well at their latest follow-up.

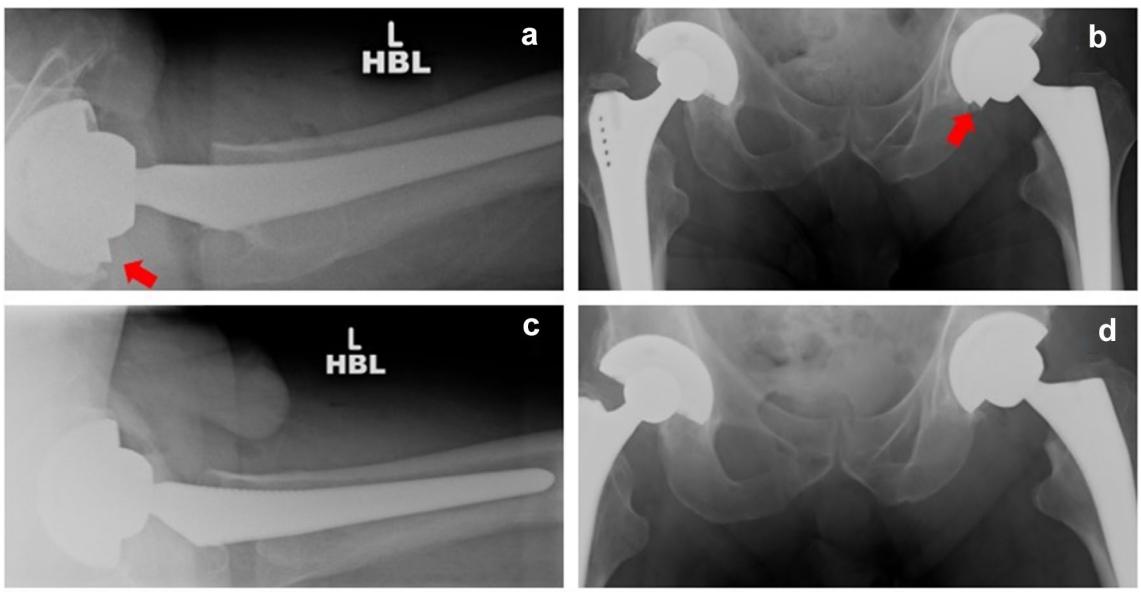

Figure showing lateral (a) and anteroposterior (b) immediate postoperative radiographs for patient 2. Note the malaligned liner (arrows). Lateral (c) and anteroposterior (d) radiographs of the revision surgery showing the acetabular cup in the same position, but the liner is flush to the acetabular cup.

Fig. 1 Pre and post-revision radiograph for patient two

The second patient had their initial THA for OA in July 2010 with a 58-mm cementless R3 cup (ceramic-on-ceramic bearings, Biolox® delta, 4th generation, 36 mm head). The acetabular liner was noted to be malaligned on the initial post-operative radiograph, and the patient underwent a revision of the liner on day 4 post-surgery. Intraoperatively, the R3 cup was well fixed and the cause of the malpositioned liner was due to soft tissue interposition (Fig. 1).

The third patient was initially a revision of a hip resurfacing (Durom Zimmer, Warsaw, IN, USA) due to metal hypersensitivity with a post-operative chromium level of 1150 nmol/L (chromium level interval in blood post-MoM replacement is 0.5–2.5 µg/L) [10] to a primary R3/Polarstem combination. A 52-mm R3 cup was used and fixed with two screws, with a 36-mm ceramic-on-ceramic bearing, Biolox® delta, 4th generation. The patient fell and sustained an anterior dislocation of the hip at 1 year post-operatively. This was reduced closed, but the patient continued to experience worsening squeaking and groin pain. Following thorough investigations for which no apparent cause was found, this was subsequently revised at 4.5 years from initial operation.

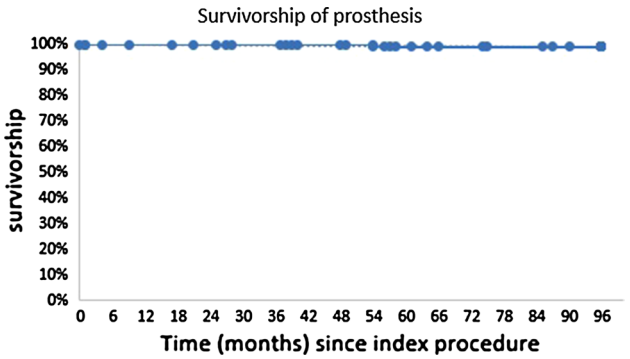

Fig. 2 Kaplan–Meier curve for implant survivorship

The acetabular cup was revised to a 56-mm trabecular metal shell (Zimmer Biomet, Warsaw, IN, USA), with a 36-mm acetabular XLPE liner and 36-mm oxinium head. The intraoperative findings suggest the combined anteversion was satisfactory at 10°, but there was evidence of posterior impingement with 1 mm wear to the posterior aspect of the femoral neck. Although this could not be reproduced on table, the senior surgeon decided that it was not acceptable and revised the cup to reduce the anteversion. The patient has been doing well at latest follow-up.

The Kaplan–Meier survivorship analysis of cumulative failure showed an implant survival rate of 99.20% at 7 years for revision of any component (cup or stem) as the end point and 97.69% at 7 years for revision for all cause as the end point (Fig. 2). The risk of revision at 7 years in our series is 1.47% (Table 6).

Complications

In addition to the three revisions, there were a further three patients that developed a stitch abscess, which in all cases was treated with oral antibiotics and resolved with no further complications. There were no cases of deep infection. Three patients sustained iatrogenic sciatic nerve injury: One had sensory loss which did not recover, while two developed a foot drop, one of which fully recovered. There were four patients who developed thromboembolic events: One had a deep venous thrombosis in the operated limb in the third week post-operatively, two patients had acute coronary syndromes at week two (one of which required a coronary angioplasty as an inpatient), and one patient developed a transient ischaemic attack during the fourth post-operative week. All four patients were receiving oral anticoagulation therapy as per hospital protocol.

Table 6 Survivorship analysis

Months after surgery	Number at start	Revision	Revision of stem	Revision of cup	Dead	Lost to follow-up	Number at risk	Interval failure rate (%)	Interval success rate (%)	Survival rate (%)
0–6	144	1	0	0	2	0	143	0.69	99.31	99.31
7–12	141	0	0	0	1	0	140	0.00	100.00	99.31
13–18	140	0	0	0	1	0	139	0.00	100.00	99.31
19–24	139	0	0	0	1	0	138	0.00	100.00	99.31
25–30	138	0	0	0	5	0	137	0.00	100.00	99.31
31–36	133	0	0	0	0	0	132	0.00	100.00	99.31
37–42	133	0	0	0	4	0	132	0.00	100.00	99.31
43–48	129	0	0	0	1	0	128	0.00	100.00	99.31
49–54	128	1	0	1	2	0	127	0.78	99.22	98.53
55–60	125	0	0	0	4	0	124	0.00	100.00	98.53
61–66	121	0	0	0	4	0	120	0.00	100.00	98.53

Discussion

To our knowledge, this is the first study reviewing the 7-year clinical results of the R3 acetabular cup and Polarstem combination with both PROMs (OHS) and radiological evaluation. Although this stem and cup combination is not the most commonly used in UK (Polarstem is fifth most popular cementless stem, and R3 cup is third most popular cementless cup in the most recent NJR report), it is the cementless combination with the lowest revision rate at all intervals measured in the UK NJR (cumulative percentage probability of revision (95% CI) at 1, 3, 5 and 7 years is 0.62%, 0.91%, 0.98% and 0.98%, respectively) [3]. The Australian Joint Replacement Registry (AJRR) cumulative percentage probability of revision at 5 years for this combination was 2.9% (2.4–3.9) in their 2017 report [11]. This significantly higher rate of revision (three times more than UK NJR) is due to infection rather than aseptic loosening. This is one of the limitations of joint registries with using revision as the primary outcome [12]. The R3 cup is the third most popular cementless acetabular cup after Trident (Stryker) and Pinnacle (Depuy Synthes) in Australia since 2013, while the Polarstem is also the third most popular after Corail (Depuy Synthes) and Quadra-H (Medacta) [11]. Our data show a revision rate of 1.47% for all causes at 7 years which compares favourably to both registries.

Our OHS had a mean of 38 which is comparable to a previous paper by Lau et al. [13], who evaluated PROMs in patients with ceramic-on-ceramic cementless THAs with a 10-year follow-up. The difference in OHS between our series and Lau et al.'s series (which showed a mean OHS of 39.8) is likely to be due to our series including more non-primary OA hips as the indication for arthroplasty, where our cohort included 14% of complex primary THA. Furthermore, patient age in their study was 39.6 years, compared to 68.3 years in ours.

Analysing the data from the patients that had OHS <25 at their 7-year follow-up ($n=13$, mean age 72.7 years with range 53–88), 61.5% ($n=8$) were overall satisfied with the outcomes of their procedure. The main cause of pain was not in the operated hip but in either their ipsilateral knee or lumbar spine, indicating that the problem may reside in antalgic posture. These patients generally acknowledged that they struggled with use of stairs and getting in and out of bed. This raises the question whether other scores should be used to assess outcomes [14]. Furthermore, consideration of responders burden must be taken into account when assessing PROMs, as this may skew data producing a lower result [15]. PROMs are valuable screening tools for those in need of face-to-face review, with a high sensitivity, although their specificity can be affected by associated pathologies [16]. Although Arden et al. identified a value of the OHS that predicts patient satisfaction 12–24 months following THR within a standard clinical setting, this threshold is markedly influenced by preoperative OHS and they suggested this should be stratified accordingly. Their data showed 91.9% of patients were satisfied with THR at 12 months (92.8% at 24 months). Using the ROC technique, the OHS at 12 months associated with patient satisfaction was 38 and at 24 months 33. The OHS at 24 months associated with satisfaction was higher in those with highest tertile of baseline OHS (30, 33, 43, respectively) and lowest tertile of BMI [17].

In a recent study by Buttaro et al. [18], it was suggested that patients with high BMIs and Dorr B-type femur are at risk of developing debonding of Corail stem (DePuy Synthes, Warsaw, Indiana). During revision of the affected cases, they found that the proximal part of the stem was not osseo-integrated, but remained distally fixed, allowing a 'wiper washer' type of movement. Although they are not the exact same implant, the Corail stem is very similar to Polarstem. The time to symptoms for their cohort of affected patients was 36 months (range 8–100 months). This phenomenon was not observed in our study, with a minimum of 7-year follow-up.

We used a virtual clinic system for the long-term follow-ups of our patients [19]. There are many different models used, and they vary depending on location, resources and consultant preferences. We have found that this system is a time and cost-effective system for long-term follow-ups and is useful to provide close to real-time feedback especially for newer prosthesis with no clinical results on the market.

One of the main limitations of our study is this being a single-centre case series (level 4 evidence). However, there are no current studies in the literature looking at the clinical results of this particular cementless combination which is far outperforming all other combination at every time point in the UK NJR. Our sample size is comparable to similar studies reporting medium- to long-term results of THA. Our results fall between the UK NJR and AJRR averages. OHS is the recommended PROMS in the UK to evaluate outcomes, but this has also limited our ability to compare our results to many other studies that use WOMAC as PROMs, and the Harris Hip Score to evaluate clinical outcomes [20]. Using the OHS by itself as a sole PROM may not reveal the full impact of the THA on all aspects of patients' activities of daily living [21].

Conclusion

This is the first clinical study that analyses the 7-year revision rates, radiological evaluation and PROMs for cementless R3 cup and cementless Polarstem. Our revision rates

compare favourably to both UK NJR and AJRR. Although joint registries provide valuable information, they do not capture long-term PROM data, making it difficult to compare clinical outcomes. The Orthopaedic Data Evaluation Panel (ODEP) has allocated a rating of 7A* for both cementless R3 acetabular cup and cementless Polarstem (ODEP 2018), which, along with this study, provides evidence that this combination is an excellent option for THA.

Compliance with ethical standards

Conflict of interest The authors declare no conflict of interest.

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