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Mixed manufacturer dual mobility bearing and the Exeter V40 Stem: is it safe? Short-term results in primary and revision hip replacement

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The aim is to review clinical and radiological outcomes for all cases of primary and revision THA, combining a cemented stem (Exeter V40) with a dual mobility component from a different manufacturer (SERF Novae), to evaluate whether concerns regarding mixing components from different manufacturers are justified. We identified 72 hip replacements performed between May 2010 and December 2015 using the SERF Novae dual mobility cup with an Exeter V40 stem, the majority of which were cemented (90%) and revisions (58%). Patients were evaluated clinically and radiologically at a minimum of two years. There were five (6.9%) dislocations; three (4.2%) requiring revision – one of which was an intra-prosthetic disarticulation and two infections. No cases were lost to follow-up and 49 surviving cases were reviewed at a mean of 4.0 (range 1.8-8.1) years following surgery. Pain and functional outcome scores all improved. There were no radiological failures and no revisions for aseptic loosening of stem or cup. The combination of Exeter cemented stem with a dual mobility bearing from a different manufacturer results in acceptable short-term outcomes in terms of hip stability, revision rates and patient-reported measures.

Keywords: total hip arthroplasty, Exeter stem, dual mobility cup, primary, revision, SERF, safety.

INTRODUCTION

Dislocation is one of the most common causes of failure of primary and revision total hip arthroplasty (THA) affecting up to 29% of cases in some series[1-4]. Recurrent dislocation is challenging to treat, often requiring further surgical intervention in a population that is typically older or multiply comorbid. To mitigate this risk, there has been increased use of dual-mobility components (DM)[5]. Originally described by Bousquet and Rambert in France in 1974[6], DM components comprise an intermediate polyethylene (PE) bearing, within which is a captured but mobile femoral head, whilst the outer convex surface of the PE articulates within a polished metal acetabular liner. Most movement in the functional range occurs between the metal head and polyethylene, the polyethylene-on-metal bearing moving towards the limits of range[7]. This results in an effective increase in head size, greater jump-distance and increased head:neck ratio, thus improving stability[6]. Dual-mobility bearings have been shown to reduce dislocation in both primary and revision arthroplasty, avoiding some issues seen with large-diameter or fully constrained bearings[8,9]. Indications for use include patients with pre-existing comorbidities such as neuromuscular disorders, seizures and substance misuse, along with patients undergoing revision surgery where there can be loss of the usual soft-tissue or bony stabilisers[10].

Dual mobility bearings can suffer the unique complication of intra-prosthetic dislocation[11], which may occur during attempted closed reduction and will require open reduction to revise the dual-mobility head. The risk of this has decreased with improved design and better capture mechanisms in the latest implant designs[7]. There are concerns regarding the rate of volumetric PE wear, particularly the large-diameter convex outer surface. However, retrieval and wear analyses have not shown this to be borne out[12].

Concerns have been raised through the UK Medicines and Healthcare products Regulatory Agency (MHRA), reporting an issue identified by the England and Wales National Joint Registry (NJR), with a cemented DM bearing from one manufacturer (Novae Stick, SERF, Décines-Charpieu, France) when inserted with a different manufacturer's stem (CPT, Zimmer-

Biomet, Indiana, US). Specific details of the issue were not made available by the NJR, but SERF published the MHRA field safety notice to surgeons, reporting a revision rate of 10/332 cases, and reiterated guidance that "mix-and-match" use of component brands was against the manufacturer's recommendations[13]. It is unclear whether the issue resulting in revision lies with the femoral or acetabular component, the articulation, or a combination of these.

Although several manufacturers produce DM bearings, this does not cover all stem brands, and few offer a cemented option for their DM components. It has been commonplace amongst a variety of arthroplasty units and surgeons to mix manufacturers, for a number of potential reasons including preference to a familiar stem, retention of a well-fixed stem or cement-in-cement revision[14,15], these stems may not have a matched-brand DM option.

There are several long-term studies looking at the outcomes of cementless DM components, but very few for cemented[16-19]. There is a potential concern around the use of a cemented metal shell; concerns have been raised around the use of cemented metal-backed polyethylene sockets[20,21] and early loosening and excess polyethylene wear, but no equivalent long-term study has been performed, to the authors' knowledge, for cemented all-metal DM shells. Short-term reports of comparative stability between cemented and uncemented components are encouraging, with superior stability for cemented cups up to 24 months[22].

The manufacturer of the femoral stem used in our unit does not currently offer a cemented DM option and as a result the Novae Stick (Figure 1) has been used where cemented DM is indicated. Following the notice published by SERF, we reviewed all cases performed at our unit with a Novae DM bearing coupled with the Exeter V40 cemented collarless taper-slip stem (Stryker Orthopaedics, Mahwah, NJ).

PATIENTS AND METHODS

A retrospective review of prospectively-collected data was performed, identifying all primary and revision THA procedures carried out at our unit using DM bearings between May 2010 and December 2015, in order to ensure a minimum follow-up of two years for surviving patients. This work is part of ongoing routine review of a cohort of patients and so is exempt from IRB approval. Operation notes were reviewed for component brands and a consecutive series of Exeter V40 highly-polished taper-slip cemented stems and Novae dual mobility cups (cemented or cementless) were included. Cases in which other stems or DM components had been inserted were excluded.

Figure 1. — The cemented SERF Novae Stick dual mobility cup.

Each case was reviewed for demographic information, the indications for surgery and for using DM, along with the operating surgeon grade, surgical approach and whether it was a primary or revision procedure. All post-operative complications, including dislocations, infection and fracture, and details of any further surgical intervention such as reduction of dislocation or revision were recorded.

All surviving patients were followed-up clinically and radiographically for a minimum of two years. Two patients had x-rays at 1.85 and 1.9 years, which were accepted with confirmation by telephone of the hip status. Pre- and post-operative scores were collected, including Oxford Hip Score[23], Harris Hip Score[24] and Charnley scores[25]. Reviews were completed in clinic, by telephone or by postal completion through our virtual clinic protocol. Carers were contacted for patients unable to communicate themselves. If patients had moved from the local area, radiographs were arranged by their General Practitioner and transferred electronically for review, or confirmation of hip status was obtained where radiographs were not possible. Radiographs were reviewed for the presence of radiolucent lines around the acetabular component in the DeLee and Charnley zones[26], and around the femoral component in Gruen's zones[27].

Statistical analysis was undertaken using SPSS version 25 (SPSS Inc, IBM Corp, Armonk, NY) and NCSS version 10 (NCSS 10 Statistical Software (2015). NCSS, LLC. Kaysville, Utah, USA, ncss.com/

software/ncss). Frequencies (with percentages), means, medians and ranges are presented as appropriate. As scores were not normally distributed, they are presented as median and range, and Wilcoxon signed rank test for non-parametric paired data used for comparison of change between pre-operative and latest time points. Age at death was compared using the Mann-Whitney U test for non-parametric data.

RESULTS

A total of 156 cases were identified as having received DM components between May 2010 and December 2015. Seventy-one were excluded due to having a non-SERF DM component, and 13 cases were excluded due to non-Exeter stem types: three primary cases (two for femoral neck fracture requiring uncemented cone-conical stems, one for proximal femoral replacement for metastatic disease) and the remaining ten were revisions where either a well-fixed stem was retained or an uncemented stem was inserted, leaving 72 hips (70 patients). Twenty patients (20 hips) had died by the time of the review and three cases were revised, leaving 49 (68.1%) cases with an Exeter/SERF Novae THA surviving with a mean follow up 4.0 (range 1.8-8.1) years.

The average age at surgery was 74.7 years (range 40-93 years). Fifty-three cases (74%) were female. Thirty-three (46%) were left-sided, 39 (54%) right. Thirty cases (42%) were primary THAs and 42 (58%) were revisions: 30 first-time revisions; five second-time, seven third or greater. The surgical scenarios for which DM bearings were utilised are shown for primaries (Table I) and revisions (Table II).

All operations were performed by either a consultant within the hip unit or a senior hip fellow under consultant supervision. Seventy-one (99%) were performed through a posterior approach, one by transgluteal (1%) – a primary THA for a femoral neck fracture. Sixty-five (90%) used a cemented acetabular component, of which 28 were primary procedures and 37 were revisions, including 14 cement-in-cement revisions; seven (10%) were cementless (two primary and five revision procedures). In all cases the smaller head for the dual mobility bearing was a Stryker stainless steel head with a V40 taper to match the Exeter stem's trunnion. Thirteen heads were 22.2mm diameter, 59 were 28mm.

No cases were lost to follow-up. Twenty cases (20 patients) died during the follow-up period but none of the deaths were related to the arthroplasty procedure or complications thereof. The average age of those who died was significantly higher (79.7 years compared with 72.6, p=0.005 Mann-Whitney U test). Average time between surgery and death was 3.0 years (0.02-6.0); earlier deaths affected patients with metastatic malignancy and pathological fractures, in whom surgery was being performed for prophylactic and/or pain-relieving purposes.

Five hips (three patients) dislocated (6.9%). Of these, three hips (two patients, 4.2%) subsequently underwent revision THA for instability – one of which was an intra-prosthetic disarticulation (Figure 2). The remaining

Table I. — Surgical scenario of dual mobility bearing cases (some patients had more than one indication for DM use) for primary cases.

Scenario	Number of cases
Within Acetabular Cage	7
Fractured Neck of Femur	7
Age / Frailty	5
Metastatic Acetabular Malignancy	5
Cognitive Impairment	3
Neurological Disease	3
Alcohol Abuse	3
Femoral Head Avascular Necrosis	3
Acetabular / Pelvic Fracture	1
Previous Contralateral THA instability	2
Soft Tissue Contracture	1
Paget's Disease & Per-operative Instability	1
Poor Compliance	1

Table II. — Surgical scenario of dual mobility bearing cases (some patients had more than one indication for DM use) for revision cases.

Scenario	Number of cases
Recurrent Dislocation	28
Peri-prosthetic Femoral Fracture	5
Multiple Revisions	4
Trabecular Metal Revision Shell	3
Acetabular Cage	3
Infection	3
Abductor Insufficiency	2
Pelvic Discontinuity	2
Metastatic Acetabular Malignancy, Into Cage	2
Age / Frailty	1
Disarticulated Constrained Liner	1
For Intra-operative Instability	1
Into Custom Acetabular Component	1
Chronic Dislocation	1

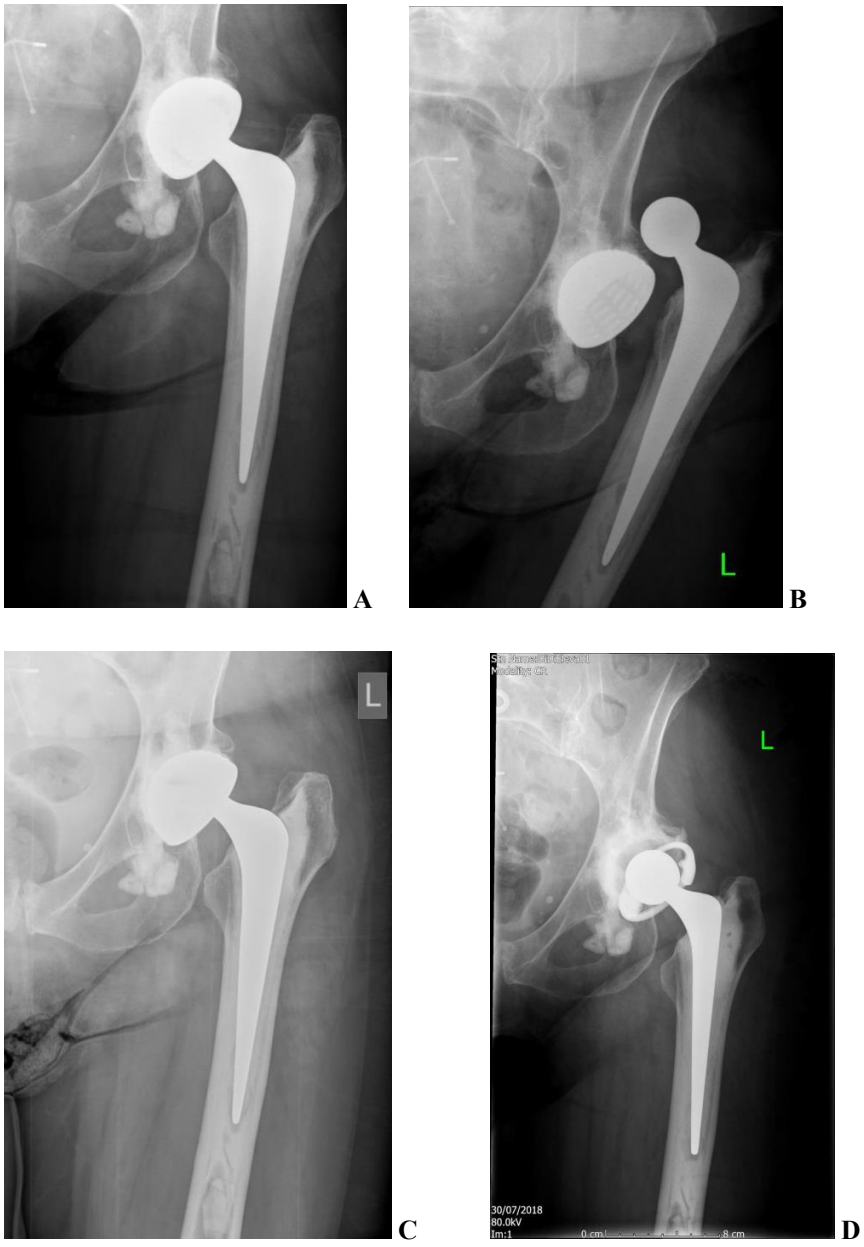

Figure 2. — Intra-prosthetic disarticulation at 3 years following left revision SERF cemented Novae Stick dual mobility cup (A – before dislocation episode) – The hip before (B) and after (C) closed reduction under sedation had been performed in the Emergency Department. Note the asymmetric reduction, indicating that the polyethylene component (not easily seen on this radiograph) had become detached from the metal head of the femoral prosthesis. This was revised using the cement-in-cement technique to a constrained liner (D).

two were managed with closed reduction, one in the emergency department, the second in theatre under anaesthetic. Neither suffered further dislocations. One dislocation followed a primary THA (1/30 primaries, 3.3%), four were revisions (4/42 revisions, 9.5%).

Two cases (2.8%) developed a deep infection; both were revision procedures; one a conversion from failed hip fracture fixation and, due to patient comorbidity, was managed with long-term antibiotic suppression. The second underwent staged revision. There was one Vancouver type-C peri-prosthetic femoral fracture, managed with open reduction and internal fixation – the arthroplasty was retained. No cases were revised for aseptic loosening.

Radiographs were reviewed for lucency. Fifty-five cases had no lucent lines; nine have lucency in a single

Table III. — Outcome scores presented as median (range), overall and split for primary and revision cases. Comparisons made using the Wilcoxon signed rank test for non-parametric paired data.

Score	Timepoint	Overall	Primaries	Revisions
Oxford (0-48 worst to best)	Pre Post p-value	17.0 (5-46) 31.5 (6-48) p=0.009*	9 (5-46) 37 (20-48) p<0.001*	23 (5-46) 29.5 (6-48) p=0.13
HHS pain (0-44 worst to best)	Pre Post p-value	20.0 (0-44) 40.0 (10-44) p=0.002*	10 (0-40) 40 (20-44) p=0.013*	20 (10-44) 30 (10-44) p=0.055
HHS function (0-47 worst to best)	Pre Post p-value	15.5 (2-45) 24.0 (4-47) p=0.009*	15 (5-37) 30.5 (7-47) p=0.052	20 (2-45) 22 (4-47) p=0.141
Charnley pain (0-6 worst to best)	Pre Post p-value	2 (0-6) 6 (1-6) p<0.001*	1 (0-5) 6 (2-6) p=0.006*	1.5 (0-6) 5 (0-6) p=0.002*
Charnley function (0-6 worst to best)	Pre Post p-value	1 (0-6) 5 (1-6) p<0.001*	1 (0-5) 5 (2-6) p=0.001*	1.5 (0-6) 4 (0-6) p=0.004*
Charnley ROM (0-6 worst to best)	Pre Post p-value	4 (1-6) 5 (0-6) p=0.422	3 (1-5) 4 (4-6) p=0.102	4.5 (1-6) 5 (4-6) p=0.836

HHS – Harris Hip Score; ROM – range of motion; *significant at 5% level.

acetabular zone, three cases have lucency affecting two acetabular zones. These are non-progressive and not felt to represent loosening. Five cases do not have two-year radiographs but due to comorbidity have declined further follow-up imaging; none had lucency on latest images.

Across the whole cohort, all scores other than Charnley ROM demonstrated significant improvement. Subdividing into primary and revision cases reduced this, with fewer scores achieving significant improvements, particularly in the revision cohort (Table III).

DISCUSSION

The safety notice released by the Medicines and Healthcare products Regulatory Agency (MHRA) in April 2017 followed the identification by the NJR of an issue regarding the combination of cemented SERF Novae Stick cups with cemented Zimmer CPT stems. SERF's MHRA report[13] stated that the "Patient Time Incidence Rate was more than twice that of their device group," with a revision rate of 10/332 procedures (3.0%). However, only one case required revision of the Novae cup, implying the DM bearing was retained in 90%. No further information was given regarding the cases, such as the timeframe over which these were performed, the indication for surgery, whether they were primary or revision procedures, the indication for using DM, or the mode of failure requiring revision. It is unknown if there was an issue with instability of the bearing or loosening of the DM component.

The 14th Annual Report of prostheses used in the NJR[28] shows that SERF Novae cups were used in 543/97,705 (0.6%) THA procedures in 2016 (321/92,143 primary (187 cemented, 134 cementless), 222/5562 revision (199 cemented, 23 cementless) THAs), most commonly with the Exeter V40 (94 cemented, 55 cementless) followed by CPT (37 cemented, 32 cementless) stems in primary cases. None were paired with a SERF stem. The report identifies a single SERF stem (a Sagitta uncemented component) was implanted in a revision procedure; although it does not identify with which cup it was paired. Furthermore, the originator institution for the SERF cup, who have published widely on its use, typically pair it with an unmatched Depuy Corail stem[29]. Therefore, there seems to be very little evidence to suggest that matching SERF cups with SERF stems would have a positive effect on survivorship or to support the conclusions in the published safety notice.

Following the safety notice released by the MHRA that focused on a polished, taper-slip cemented stem (the CPT), we felt it important to review the combination of SERF DM bearing with the Exeter stem used in our unit. There is a growing body of literature on the use of dual-mobility bearings in arthroplasty, the majority of which concentrates on the bearing itself with less attention on the stem with which it is coupled; many

either do not comment on the stem type or collate multiple stems.

A systematic review by Darrith et al confirmed DM improved stability with a 0.46% dislocation rate in primary and 2.2% in revision THA, which compare favourably with published dislocation rates for single-bearing THA of 3.9% in primary and 28% in revision surgery[7,30]. These excluded intra-prosthetic dislocations (IPD), affecting a further 1.1% of primaries and 0.3% of revisions. The primary THA group had an overall dislocation rate including IPD of 1.7%. Another systematic review identified a 0.9% dislocation rate and 0.7% IPD in primary THA[31]. Neither review included assessment of patient case-mix, complexity, dislocation risk or component manufacturer.

Registry-level data demonstrated the efficacy of DM bearings in managing instability; from the Swedish Hip Arthroplasty Register, DM bearings in first-time revisions due to dislocation gave a significant improvement in implant survival compared with standard bearings (96% ± 3.0% vs 92% ± 3.3%; p=0.001[32]. Registry data has limitations; in particular that it presents revision rates not dislocation rates.

As previously outlined, there are limited reports on the long-term outcomes of cemented all-metal DM acetabular components such as the SERF Novae Stick. A systematic review on modes of failure for DM components did not look at the method of fixation (cemented or not)[33]. In a minimum 5-year follow up study, two of 51 patients (3.9%) had undergone revision for aseptic loosening of a cemented DM acetabulum.[19] Although there have previously been many reports of issues around cemented metal-backed PE components, the majority of these conclude the rigidity of the metal backing leads to excess PE wear rates compared with all-PE socket. As such this mode of failure is unlikely to be extrapolatable to an all-metal socket. Further long-term studies are needed into the outcomes of cemented all-metal DM components.

The DM bearings in our consecutive series were used in high-risk patients, with significant comorbidities. Due to a lack of granularity in published and registry data it is difficult to make a direct comparison between these and our own results. The NJR collects American Society of Anesthesiologist (ASA) scores for patients as a crude reflector of general health and comorbidity, but there are concerns over the accuracy of scoring and recording of ASA[34]. This may underestimate the true extent of patients' comorbidities and, although related[35], ASA provides little practical information on dislocation risk.

Our study identified five dislocations from seventy-two cases. Three cases (in two patients), one primary and two revisions, required further revision for instability. Although this is a higher proportion than is seen in some larger cohorts, this could result from the small patient number in our series and our restriction of DM component use to those patients who were at significantly increased risk of dislocation.

The practice of mixing components from different manufacturers is routinely stipulated in manufacturer documentation as being off-license, as described by the SERF Safety Notice. The literature supplied with Stryker components advises that mixing manufacturers "will negate the responsibility [of Stryker] for the performance of the implant[36]." However, a study of THA component types in the England & Wales NJR demonstrated increased revision rates were only seen when heads and stems from different brands were used, potentially resulting from differences in taper geometry. In contrast, when stem and head were matched but the acetabular component was from an alternate manufacturer, revision rates were significantly lower than with matched implants (eight year cumulative revision rate 1.9% vs 2.4%, p=0.001)[37].

There are limitations to our study; it is a single centre, non-randomised study with relatively short follow-up. However, as the primary mode of failure is dislocation, this should be sufficient because dislocation is predominantly an early complication. Woo and Morrey[38] reported 59% occur in the first three months after THA, 77% within twelve months, whilst more recently, Berry et al.[39] found a cumulative risk of first dislocation of 1% at one month, 1.9% at one year, rising approximately 1% every five years[30].

Another shortcoming of our study is the relatively small sample size and the lack of a control group. Although we have performed several cases using an alternative dual mobility bearing with the same manufacturer as the stem (Trident MDM, Stryker Orthopaedics, Mahwah, NJ), there is such a high degree of heterogeneity between the two cohorts that direct comparisons are very difficult to make and conclusions from the data would be open to significant doubt.

Despite these limitations, we have shown SERF Novae dual mobility bearings can be used successfully for various indications, mixing with the cemented Exeter stem, in a higher-risk group. They improve pain and function and have low rates of radiological lucency. We will continue their use in high risk patients, accepting that there can still be complications for a number of reasons other than the component manufacturer. We feel the risk of complications and re-revision reflects

the nature of the patient group rather than a limitation of the implant or a result of its combination with a proven stem. We conclude that the issued safety notice is not fully justified in deterring surgeons from these mixed combinations, either in terms of the data presented or in its interpretation of that data. Furthermore, we have highlighted a potential over-interpretation of registry data that may lack the necessary detail on patients' comorbidities and risk profile to support some of the conclusions being drawn from it.

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