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ARTHROPLASTY

Outcomes of the Exeter V40 cemented femoral stem at a minimum of ten years in a non-designer centre

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Aims

The Exeter V40 cemented femoral stem was first introduced in 2000. The largest single-centre analysis of this implant to date was published in 2018 by Westerman et al. Excellent results were reported at a minimum of ten years for the first 540 cases performed at the designer centre in the Exeter NHS Trust, with stem survivorship of 96.8%. The aim of this current study is to report long-term outcomes and survivorship for the Exeter V40 stem in a non-designer centre.

Methods

All patients undergoing primary total hip arthroplasty using the Exeter V40 femoral stem between 1 January 2005 and 31 January 2010 were eligible for inclusion. Data were collected prospectively, with routine follow-up at six to 12 months, two years, five years, and ten years. Functional outcomes were assessed using Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores. Outcome measures included data on all components in situ beyond ten years, death occurring within ten years with components in situ, and all-cause revision surgery.

Results

A total of 829 stems in 745 patients were included in the dataset; 155 patients (20.8%) died within ten years, and of the remaining 664 stems, 648 stems (97.6%) remained in situ beyond ten years. For the 21 patients (2.5%) undergoing revision surgery, 16 femoral stems (1.9%) were revised and 18 acetabular components (2.2%) were revised. Indications for revision in order of decreasing frequency were infection (n = 6), pain (n = 6), aseptic component loosening (n = 3), periprosthetic fracture (n = 3), recurrent dislocation (n = 2), and noise production (ceramic-on-ceramic squeak) (n = 1). One patient was revised for aseptic stem loosening. The mean preoperative WOMAC score was 61 (SD 15.9) with a mean postoperative score of 20.4 (SD 19.3) (n = 732; 88.3%).

Conclusion

The Exeter V40 cemented femoral stem demonstrates excellent functional outcomes and survival when used in a high volume non-designer centre. Outcomes are comparable to those of its serially validated predecessor, the Exeter Universal stem.

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Keywords: Hip, Arthroplasty, Cement, Registry, Stem, Survivorship

Introduction

The Exeter V40 cemented femoral stem (Stryker Orthopaedics, Mahwah, New Jersey, USA) was first introduced in 2000 as an advancement of the Exeter Universal stem.[1] The development of the Universal stem in 1988 was an evolutionary milestone in the Exeter stem lineage, which began with the monoblock Original in 1970. The Universal stem featured a 5°40’ trunnion which combined with a range of Orthinox stainless steel femoral heads and gave surgeons greater intraoperative freedom.[2-4] Both the original polished Exeter stem and the Exeter Universal stem have been widely studied since their introduction and have repeatedly been shown to have excellent performance and survivorship.[2-7]

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Table I. Head size by year of insertion.

Head size, mm (%)	Total (n = 829)	2005 (n = 126)	2006 (n = 152)	2007 (n = 168)	2008 (n = 177)	2009 (n = 206)
22.225	27 (3.3)	13 (10.3)	8 (5.3)	1 (0.6)	4 (2.3)	1 (0.5)
26	108 (13)	32 (25.4)	32 (21)	22 (13)	11 (6.2)	11 (5.3)
28	352 (42.5)	61 (48.4)	81 (53.3)	69 (41)	60 (33.9)	80 (38.8)
32	190 (22.9)	10 (7.9)	20 (13.2)	51 (30.4)	53 (29.9)	55 (26.7)
36	138 (16.6)	10 (7.9)	11 (7.2)	20 (11.9)	43 (24.3)	53 (25.7)
40	14 (1.7)	0 (0)	0 (0)	4 (2.4)	5 (2.8)	5 (2.4)
52	3 (0.4)	0 (0)	0 (0)	1 (0.6)	1 (0.6)	1 (0.5)

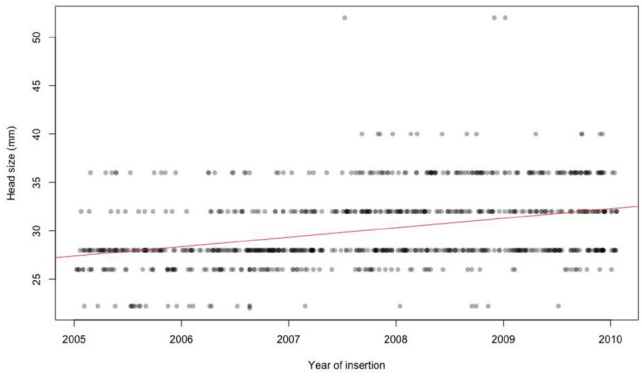

Fig. 1
Scatterplot of head diameter by date of insertion with regression line.

The Exeter V40 stem features the same double-tapered stem geometry and highly polished Orthinox composition. In addition, a tapered neck and reduced starting diameter of the 5°40' trunnion provides greater modularity across a range of head size and bearing options with a nominally increased range of motion.[1]

The Exeter V40 is one of the most widely used arthroplasty components in current practice – it is the current market leader in the UK National Joint Registry (NJR), accounting for 60% of all stems, and has demonstrated a statistically and clinically significant survival advantage over all other stems in previous registry-based analysis.[8,9]

The largest single-study analysis of this implant conducted to date was published in 2018 by Westerman et al[1] with a minimum ten year follow-up of the first 540 cases performed in the designer centre in the Exeter NHS Trust. This study demonstrated excellent long-term survival.

The aim of this current study is to report mid- to long-term outcomes and survivorship for the Exeter V40 stem in the experience of a non-designer centre.

Methods

This was a retrospective review of prospectively collected registry data conducted in a national orthopaedic hospital (NOH) with full ethical approval. We retrospectively reviewed the joint registry for patients undergoing primary total hip arthroplasty (THA) between 1 January 2005 and 31 January 2010. All patients that received the Exeter V40 stem were eligible for inclusion. Exclusion criteria were a follow-up of less than ten years and THA for malignancy and fracture.

The primary outcomes were defined as the number of components in situ beyond ten years, death occurring before ten years with components in situ, and all-cause revision surgery. Secondary outcomes were pre- and postoperative functional outcome scores such as Harris Hip Score[10] (HHS) and the Western Ontario and McMaster Universities Osteoarthritis Index[11] (WOMAC). Perioperative information collected included patient body mass index (BMI), American Society of Anesthesiologists grade[12] (ASA), implant details, operating time, blood loss, use of surgical drains, length of stay, and consultant surgeon. Data collection was conducted by review of patient and operative records. Implant details were available from the joint registry.

In total, 829 stems were implanted in 745 patients, of whom 297 (39.9%) were male. Bilateral THAs were performed in 84 patients (11.3%). The mean patient age was 67.8 years (25 to 89; σ = 11.1), with 50 patients (6.7%) aged under 50 years. Of the total cohort, 451 hips (54.4%) were right-sided. Mean BMI was 28.8 (15 to 49; σ = 5.55) and modal ASA was 2 (67.5%) (1 to 4). Mean operating time was 95.3 minutes (45 to 330; σ = 25.9) , and mean estimated blood loss was 457 ml (30 to 2,830; σ = 321.3). In 636 (76.7%) cases, one or more drains were left in situ postoperatively. The mean length of stay was 9.6 bed days (2 to 96; σ = 4.9). Our dataset featured a total of 22 consultant surgeons.

Statistical analysis. All statistical analysis and graphic generation was performed using RStudio computer software (RStudio, Boston, Massachusetts, USA), Microsoft Office Excel (Microsoft Corporation, Redmond, Washington, USA), and Stata (StataCorp, College Station, Texas, USA). Data were normality tested using the Shapiro-Wilk test with construction of Q-Q plots. Box plots were generated to illustrate functional outcome scores. Kaplan-Meier curves were used to illustrate the overall survivorship of the Exeter V40 stem and a scatterplot with regression line was generated to express the change in pattern of femoral head size between 2005 and 2010.

Table II. Stem outcomes.

Outcome	n (%)	Mean yrs (range)	95% CI
In situ beyond 10 yrs	648 (78.1)	12.3 (10.0 to 15.1)	12.2 to 12.4
In situ at death before 10 yrs	165 (19.9)	4.9 (0.4 to 9.8)	4.8 to 5.1
Stem revised	16 (1.9)	4.8 (0.1 to 12.0)	2.7 to 7.0
During acetabular revision	2 (0.2)	11.7 (11.3 to 12.0)	10.9 to 12.4
Pain	2 (0.2)	1.2 (0.1 to 2.3)	0.0 to 3.3
Infection	6 (0.7)	2.5 (0.6 to 5.8)	0.7 to 4.3
Recurrent dislocation	1 (0.1)	1.3 (N/A)	N/A
Squeak	1 (0.1)	11.6 (N/A)	N/A
Aseptic loosening	1 (0.1)	2.5 (N/A)	N/A
Periprosthetic fracture	3 (0.4)	6.9 (4.5 to 11.5)	4.6 to 9.2
Revised acetabular component only	5 (0.6)	4.6 (1.3 to 7.0)	2.6 to 6.5
Aseptic loosening	2 (0.2)	11.7 (11.3 to 12.0)	10.9 to 12.4
Pain	3 (0.4)	5.9 (4.7 to 7.0)	4.6 to 7.3
Recurrent dislocation	1 (0.1)	1.3 (N/A)	N/A

CI, confidence interval; N/A, not applicable

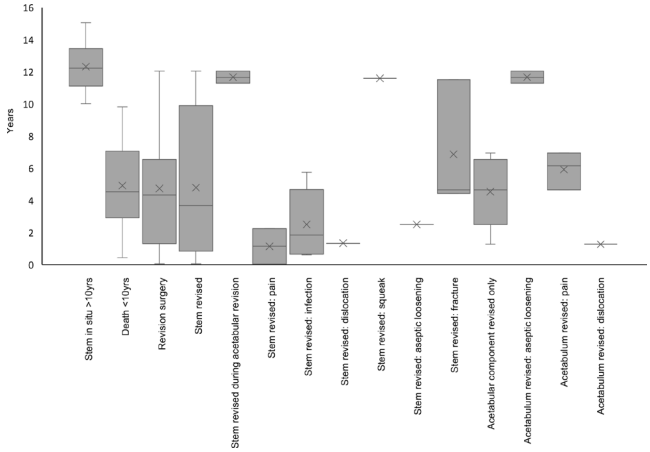

Fig. 2

Boxplot of time to each endpoint. Whiskers denote the outlier range/whole range outside of the upper and lower quartiles. The × denotes the mean, and the transverse line represents the median value.

Results

Implant details. There were 520 cemented acetabular components (63%) and 309 uncemented components (37%). Three types of cemented cup were used; 380 Contemporary (45.8%) (Stryker, Newbury, UK), 131 Ogee (15.8%) (DePuy, Leeds, UK), and nine Marathon cups (1.1%) (DePuy UK). Four types of cementless cup were used in hybrid constructs; 260 Trident cups (31.4%) (Stryker UK), 37 ABG II (4.5%) (Stryker UK), nine Pinnacle (1.1%) (DePuy UK) and three Mitch TRH systems (0.4%) (Stryker, Montreux, Switzerland/Finsbury Orthopaedics, Leeds, UK). Stem offset ranged from 30 mm to 50 mm with a mode of 44 mm (n = 665).

Head size ranged from 22.2 mm to 52 mm with a mode of 28 mm (351) (Table I). The mean value of femoral head size increased over time up to 32 mm in 2010 (Figure 1). Head materials consisted of stainless steel (n = 476; 57%), alumina ceramic (n = 269; 32%), and cobalt chrome (n = 80; 9.6%). Metal-on-polyethylene (MoP) was the most common bearing surface (551 hips, 66.5%) followed by ceramic-on-ceramic (CoC) (171 hips, 20.6%), and ceramic-on-polyethylene (CoP) (99; 11.9%). There were three metal-on-metal (MoM) hips in this series (0.3%).

Stem results. The fate of every stem is known and all patients remain under review. Mean follow-up was 12.34 years (10.03 to 15.07 years; σ = 1.44). A total of 155 patients (20.8%), representing 165 stems (19.9%), died before ten years. Of the remaining 664 stems, 648 stems (97.6%) remain in situ (Table II). A total of 21 patients (3.1%) underwent revision surgery; 16 stems (2.4%) were revised and 18 cups (2.7%) were revised. Indications for revision consisted of infection (n = 6), pain (n = 6), aseptic component loosening (n = 3), fracture (n = 3), recurrent dislocation (n = 2), and noise production (n = 1). Time to each endpoint is illustrated in Figure 2.

Indications for stem revision were infection (n = 6); pain (n = 2); fracture (n = 3); dislocation with revision of the stem and head (n = 1); aseptic stem loosening (n = 1); and noise production with revision of the ceramic articulation and stem (n = 1). Two well-fixed stems were revised during revision of acetabular components for aseptic loosening to facilitate intraoperative access. One patient underwent open reduction internal fixation of a periprosthetic fracture in an alternative site, with subsequent revision and ensuing follow-up under their care – the patient remains under review.

Figure 3 demonstrates the Kaplan-Meier curve illustrating excellent survivorship at a minimum of ten years.

The mean preoperative HHS was 48.8 (SD 14.3) and the mean preoperative WOMAC was 61 (SD 15.9). At six to 12 months postoperatively, the mean WOMAC was 22.2 (SD 18.7) (n = 661; 79.7%). At two years it was 21.4 (SD 19.6) (n = 463; 55.9%), at five years 20.8 (SD 20.3) (n = 501; 60.4%), and at ten years 17.5 (SD 18.4) (n = 231; 34.8%) (Figure 4).

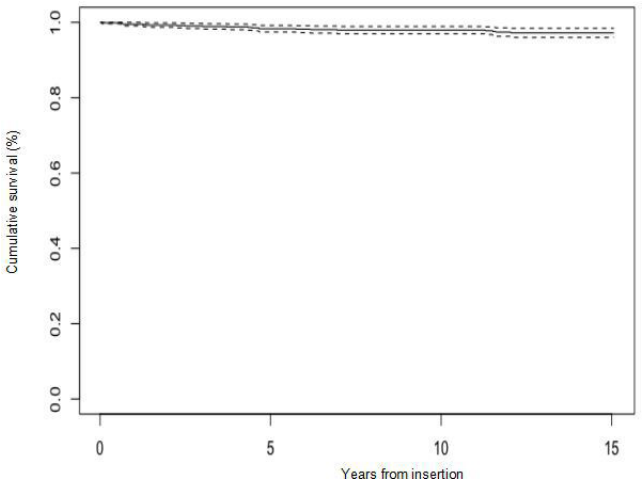

Fig. 3

Kaplan Meier Survival curve for 829 hips. Dashed lines represent 95% confidence intervals.true

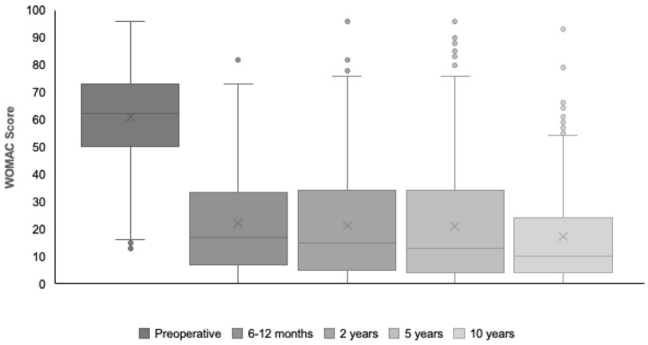

Fig. 4

Boxplot of Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores.

Discussion

The Exeter V40 is one of the most widely used arthroplasty components in current practice, accounting for 60% of current market share in the UK.[8] Previous registry-based analysis has demonstrated a statistically and clinically significant survival advantage over all other stems.[9]

In the designer centre at 13.5 years, the survival rate for aseptic stem loosening was 100%, all-cause stem survivorship was 96.8%, and all-cause survivorship was 91.2%.[1] In comparison, this current study reports an aseptic stem survivorship of 99.85%, an all-cause stem survivorship of 97.6%, and an all-cause survivorship of 96.9%. This demonstrates the reproducibility of the outstanding Exeter V40 stem results outside of the designer centre setting.

Data from the UK NJR report a cumulative probability of revision at ten years of 2.42% for Exeter V40 stems in combination with a Contemporary Flanged cup, and 2.59% when used with a Trident cup.[8] These implant combinations were used in 640 hips in our cohort, constituting 77.2% of the total number (45.8% and 31.4% respectively).

Comparison of outcomes of the Exeter Universal stem from designer and non-designer centres demonstrates a trend of slightly superior survivorship in the designer centre. Long-term survivorship of the Universal stem for all-cause revision stands at 78.4% to 81.1% in reported non-designer centres, and 82.9% in the designer centre. With an endpoint of revision for aseptic stem loosening, survivorship has been quoted as 96.77% to 100% in non-designer centres and 99% in the designer centre.[2-7] Superior results in a designer centre may be due to a variety of factors influencing outcomes, such as greater familiarity with the implant, more precise sizing, and intraoperative technique.[13–15]

The data from our joint registry demonstrate that the Exeter V40 continues to exhibit excellent performance and survivorship at ten years and beyond in a non-designer centre. Outcomes in our centre were comparable to those of the designer centre, and correlate with the performance of the Exeter V40 stem in the UK NJR, suggesting that these outcomes are reproducible.[1,8]

Our data show excellent functional outcomes based on our patient-reported outcome measure (PROM) scores – mean preoperative HHS and WOMAC scores were suggestive of advanced pathology, and postoperative WOMAC scores demonstrate significant improvement. The most commonly used instruments for evaluating functional outcomes in the literature are the HHS and the Oxford Hip Score.[16,17] Previous research from Söderman et al[18] has shown that, when transformed to identical scales, the HHS and WOMAC index correlate well and exhibit high levels of internal consistency. It is reasonable to contextualize our outcomes in terms of the percentage change in discrete PROM scores, which are comparable to those of the designer centre.[1]

Based upon the demographics of our patient cohort, the findings of this paper should be broadly generalizable. The age and sex characteristics were grossly commensurate with those described by Westermann et al[1] and previous follow-up of the Universal stem in both designer and non-designer centres.[5,7] Mean BMI was 28.8 (15 to 49; $\sigma = 5.55$) in our cohort, higher than previously reported non-designer centres, but similar to that of the UK NJR at 28.7.[5,8] ASA 2 was the most common grade in our cohort and accounted for 67.5% of patients, while in the NJR 67.6% of patients were ASA 2.[8]

The principal limitations of this paper are the differences in practice which have evolved in the intervening years, affecting the generalizability of the data. These are inherent limitations to this form of long-term registry review.

National joint registry data currently represent the best standard of practice in arthroplasty, with long-term follow-up of large numbers of patients from a broad

variety of surgeons allowing for increased generalizability while limiting bias.[19]

Technological development plays a significant role in shaping the face of orthopaedic practice, particularly in the field of THA. Outcomes from our dataset potentially underestimate survivorship of more recently implanted Exeter V40 stems, which make use of evidence-based advancements in applied biomechanics and materials technology, specifically regarding implant choice and fixation, femoral head sizing and materials, and bearing surfaces.

Cemented acetabular components are overrepresented in our data compared with current trends favouring hybrid THA, with rates of hybrid fixation continuing to rise as those of cemented and uncemented fixation decline.[8] In the case of the Exeter Universal stem, long-term follow-up demonstrated cemented acetabular component survivorship was significantly inferior to stem survivorship.[20] The use of uncemented acetabular fixation with the Universal stem showed improved survivorship at all ages for revision for aseptic loosening, wear, and osteolysis; and for all-cause revision in patients less than 70 years.[21]

The most commonly used head size in our dataset was 28 mm, accounting for 42.3% of all heads. However, as shown in Figure 1, there was a trend toward the use of larger head sizes over time with 32 mm being the mode head size in 2010. This is reflective of trends within arthroplasty as a whole, with head sizes increasing from 2003 onwards in NJR reports – as of 2018, 51% of all THA in the UK used a 32 mm head.[8]

Regarding bearing surfaces, MoP and CoC are overrepresented in our data compared with current practice, accounting for 66.5% (n = 551) and 20.6% (n = 171) respectively, in comparison to 55.3% and 7.2% in the most recent NJR.[8]

MoP remains the most common choice of articulation in the UK; however, at head sizes of 36 mm and greater, it exhibits unfavourable wear characteristics compared with head sizes of 32 mm and below.[22,23] Projected estimates of cumulative revision from the UK NJR show that 32 mm heads represent the lowest achieved rates of revision when used in cemented or hybrid CoP constructs, but the highest failure rates in cemented MoP constructs.[8]

Although CoC bearings confer certain favourable biomechanical properties and allow for the use of larger head sizes, there exist causes of revision which are almost uniquely seen in CoC such as noise production (i.e. squeak) and ceramic fracture. The rate of revision for squeak has been quoted as 2.4% and that of ceramic fracture in CoC THA as 0.16% versus < 0.01% for that of zirconia-toughened alumina ceramic head fracture alone.[24,25]

This has contributed to increased usage of CoP with larger head sizes as an alternative for better biomechanical properties and greater jump distance leading to lower dislocation rates, especially in younger or larger patients.[26] CoP articulations are underrepresented in our dataset at 11.9% (n = 99). However, their use has been steadily rising since 2010, accounting for 35% of all THA in the UK in 2018.[8]

It should be noted that our data feature 77 Low Friction Ion-Treatment (LFIT) CoCr femoral heads (9.3%) and three Mitch TRH CoCr MoM systems (0.3%). The use of CoCr is associated with an increased risk of taper fretting corrosion, an increasingly topical discussion point in modular THA stems.[27]

To date, outcomes of the Exeter V40 in the designer centre do not appear to have been adversely affected by the reduction in trunnion size. This was hypothesized to be due to the use of smaller femoral head sizes and elimination of titanium and CoCr from the taper interface.[1] Our current study was not specifically designed to assess for taper corrosion; however, no excess burden of morbidity is apparent from our data, which do feature CoCr and larger head sizes, although this may be due to these elements being present in only a small number of cases.

This dataset represents the largest curated arthroplasty registry in Ireland prior to the formation of the Irish National Orthopaedic Registry under the National Office of Clinical Audit in 2016. As such, the NOH joint registry is uniquely poised to provide the closest available alternative to a pooled Irish joint registry for follow-up beyond five years. Due to the large throughput of the NOH, this data can be viewed as representative of the Irish arthroplasty experience.

In conclusion, the Exeter V40 cemented femoral stem demonstrates excellent functional outcomes and survivorship when used in a high volume non-designer centre. Outcomes are comparable to those of its serially validated predecessor, the Exeter Universal stem.

Supplementary material

Sunburst plot of implants, bearing surfaces, and acetabular fixation. Graphical representation of all implants used, including interfaces between components (concentricity) and material composition (colour).

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Author contributions:
- J. Mahon: Collected the data, Performed the statistical analysis, Reviewed the literature.
- C. J. McCarthy: Collected the data, Reviewed the literature.
- G. A. Sheridan: Reviewed and revised the draft, Collected the data, Performed the statistical analysis, Reviewed the literature.
- J. P. Cashman: Reviewed and revised the draft.
- J. M. O'Byrne: Reviewed and revised the draft.
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