

■ HIP

The Exeter Universal cemented femoral stem at 20 to 25 years

A REPORT OF 382 HIPs

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Aims

We present a minimum 20-year follow-up study of 382 cemented Exeter Universal total hip arthroplasties (350 patients) operated on at a mean age of 66.3 years (17 to 94).

Patients and Methods

All patients received the same design of femoral component, regardless of the original diagnosis. Previous surgery had been undertaken for 33 hips (8.6%). During the study period 218 patients with 236 hips (62%) died, 42 hips (11%) were revised and 110 hips (29%) in 96 patients were available for review. The acetabular components were varied and some designs are now obsolete, however they were all cemented.

Results

With an endpoint of revision for aseptic loosening or lysis, survivorship of the stem at 22.8 years was 99.0% (95% confidence interval (CI) 97.0 to 100). One stem was revised 21 years post-operatively in a patient with Gaucher's disease and proximal femoral osteolysis. Survivorship with aseptic loosening or lysis of the acetabular component or stem as the endpoint at 22.8 years was 89.3% (95% CI 84.8 to 93.8). With an endpoint of revision for any reason, overall survivorship was 82.9% (95% CI 77.4 to 88.4) at 22.8 years.

Radiological review showed excellent preservation of bone stock at 20 to 25 years, and no impending failures of the stem.

Conclusion

The Exeter femoral stem continues to perform well beyond 20 years.

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The outcomes of the Exeter Universal stem (Stryker, Kalamazoo, Michigan) which was introduced in March 1988 (Fig. 1) have been published from our unit and others for up to 17 years of follow-up.¹⁻⁴ Apart from a minor change to the trunnion to the current 5°40' design, the Universal stem is identical to the contemporary Exeter V40 stem, which continues to perform well at medium-term follow-up in registries around the world.⁵⁻⁸ The National Joint Registry for England and Wales (NJREW) shows that for the Exeter V40 contemporary stem, the Kaplan-Meier estimate of probability of first revision at ten years is 3.15% (95% confidence interval (CI) 2.62 to 3.79).⁵ The long-term outcome of total hip arthroplasties (THAs) is increasingly important as the population ages.⁹

The aims of this study are to report the clinical, radiological and survivorship outcomes of the Exeter Universal stem at a minimum follow-up of 20 years.

Patients and Methods

Between March 1988 and December 1992, a consecutive series of 382 Exeter Universal stems were implanted into 350 patients, whose mean age was 66.3 years (17 to 94). A total of 203 patients (58%) were women. The operations were performed under the care of two specialist hip surgeons (R. S. Ling, G. A. Gie), although trainees performed the surgery in 134 hips (35%). The Exeter Universal was the only primary stem used at our institution during this period. It was used for simple and complex cases and no patients were excluded from this review.

Whilst most operations were undertaken for primary osteoarthritis (73%, Table I), a significant number were for more complex diagnoses and 9% of patients (33 hips) had undergone previous surgery. This study represents a new series of patients whose surgery was performed only by specialist hip surgeons and their teams, unlike previous publications reported by our unit which included THAs

Table I. Indications for arthroplasty

Primary diagnosis	Number of hips
Primary osteoarthritis (OA)	280
Protrusio	25
Rheumatoid arthritis	16
Dysplasia	15
Avascular necrosis	9
Post-traumatic OA	8
Failed osteotomy	5
Fracture of the proximal femur	5
Perthes' disease	4
Epiphysiolysis	4
Still's disease	3
Revision of hip fusion	3
Ankylosing spondylitis	3
Septic arthritis	1
Other	1
Total	382

Table II. Surgical details

Measure	Option	n (%)
Approach	Posterior	365 (95.5)
	Lateral	16 (4.2)
	Trochanteric osteotomy	1 (0.3)
Acetabular component	Exeter metal-backed	256 (67.0)
	Exeter Concentric	122 (31.9)
	Ogee	3 (0.8)
	Muller	1 (0.3)
Head size (all stainless steel)	22 mm	1 (0.3)
	26 mm	343 (89.8)
	30 mm	38 (9.9)

performed by general orthopaedic surgeons.^{1,2} Changing the inclusion criteria was necessary as many of those undertaken by general orthopaedic surgeons had been discharged, making their long-term follow-up impossible.

The details of the stem have been previously described.¹ Most stems were of 37.5 mm or 44 mm offset, but 11 35.5 mm offset stems and four 50 mm offset stems were used. The surgical details are shown in Table II. Simplex RO cement (Stryker) was used for fixation of the acetabular and femoral components, using techniques described by Williams et al.¹ The femoral canal was prepared with taper pin reamers and implant-specific broaches. Modern cementing techniques included a distal cement plug to occlude the canal, washing and drying the canal, and retrograde filling using a cement gun. Pressurisation was achieved using a proximal seal and the injection of further cement once the canal had been filled. This technique was consistent throughout the series. A hollow polymethylmethacrylate (PMMA) centraliser was placed on the tip of all the stems. A metal on polyethylene bearing was used in all cases.

Routine review of patients was undertaken one and five years post-operatively and every five years thereafter. All clinical and operative data were captured prospectively. Pre- and post-operative assessment was carried out using



Fig. 1

The Exeter Universal femoral stem.

the Charnley modification of the Merle D'Aubigne and Postel score,¹⁰ the Harris hip,¹¹ Oxford (0 to 48 worst to best),¹² and more latterly Euroqol EQ-5D scores.¹³ Of the 110 survivors, 76 were reviewed in clinic. The remaining surviving patients were contacted by telephone or post, and

Table III. Pre-operative and follow-up clinical scores and Charnley categories¹⁰

Score (possible range)	Pre-operative			Latest follow-up			p-value
	n	Median (IQR)	Range	n	Median (IQR)	Range	
HHS- pain (0 to 44)	-	-	-	101	44.0 (4)	0 to 44	
HHS- function (0 to 47)	-	-	-	101	34.0 (18)	0 to 47	
Oxford (0 to 48)	-	-	-	100	39.5 (16.5)	10 to 48	
Charnley – pain (0 to 6)	333	2.0 (1)	0 to 6	101	6.0 (1)	1 to 6	p < 0.001
Charnley – function (0 to 6)	337	2.0 (2)	0 to 6	102	4.0 (4)	0 to 6	p < 0.001
Charnley – ROM (0 to 6)	333	3.0 (1)	1 to 6	71	5.0 (1)	1 to 6	p < 0.001
Charnley categories (%)	A: 162 (42.4) B: 109 (28.5) C: 81 (21.2) Unrecorded: 30 (7.9)			A: 21 (19.7) B: 39 (35.5) C: 41 (37.3) Unrecorded: 9 (8.2)			p = 0.002
Euroqol (0 to 100)	-	-	-	78	77.5 (30)	30 to 100	

IQR, interquartile range; HHS, Harris hip score; ROM, range of movement

clinical scores completed where possible (Table III). Scoring was impossible for five patients, who had dementia, but it was confirmed that the hips had not been revised. The mean follow-up for the surviving patients was 22.4 years (20 to 26.6). The mean age at follow-up was 77.4 years (48 to 96).

Radiographs were reviewed by four authors (JRH, HK, MJW, TGP). For the initial post-operative radiographs, this included an assessment of the grade of cementing as described by Barrack, Mulroy and Harris¹⁴ and, on final follow-up, further assessment of radiolucent lines (RLLs), lysis at the cement-bone interface, changes at the calcar, diaphyseal hyperplasia and subsidence of the stem. Gruen zones¹⁵ were used to describe femoral changes. A total of 80 patients (91 hips) had 20-year radiographs available for review, 85 of which were performed during routine review. From those who were deceased, final radiographs were available for six hips at a minimum of 20 years post-operatively and were included in the radiological review. The mean time to the latest radiograph was 22.0 years (20 to 25). Subsidence at the stem-cement interface was assessed using the technique described by Fowler et al,¹⁶ or by measuring the reduction in distance from the tip of the stem to the bottom of the hollow centraliser. RLLs were defined as linear radiolucencies adjacent to a sclerotic line as described by Kobayashi et al.¹⁷

The outcome of patients who had died was reviewed to determine whether the hip had been revised prior to death. The date of the last review of deceased patients was confirmed and several strategies were used to complete data on all patients. In those patients who had not been seen clinically for more than five years prior to death (i.e. outside the standard review protocol), information was sought about any revision of the original THA, through a combination of contact with the General Practitioner, family, and a review of hospital notes and imaging for other purposes. In just two patients (three hips) the period of time between follow-up and death was greater than five years (6.8 years and 8.5 years), and these strategies were unable to exclude revision surgery on their hips. These cases were considered lost to follow-up in the construction of a worst case curve.¹⁸

Statistical analysis. Kaplan-Meier survival curves¹⁹ were calculated as described by Lettin, Ware and Morris,²⁰ with revision as the endpoint and data censored at the time of death, with a minimum of 40 hips remaining at risk. Statistical analysis was performed using SPSS version 18.0 (SPSS Inc, IBM Corporation, Armonk, New York), with a 5% significance level. Additional statistical analysis included the chi-squared test for association where appropriate.

Results

From the original 350 patients (382 hips), 218 had died before the final review (236 hips, 62%). The mean time between surgery and death was 10.6 years (0 to 24.0). The mean time from last contact to death in these patients was 2.0 years (0 to 8.5). A total of 42 hips (11.0%) were revised and 110 (28.8%) remained available for review, in 96 patients, for whom the mean follow-up was 22.4 years (20.0 to 26.6) (Fig. 2).

All scores remained significantly improved at the most recent follow-up compared with the pre-operative values (Table III). The mean age at operation of the surviving, unrevised group was 54.6 years (24 to 75), which was, as expected, statistically significantly lower than the mean age of the deceased group of 73.2 years (39 to 94), $p < 0.001$. The mean age of the revised group at the time of the primary procedure was 57.0 years (17 to 81).

The indications for the 42 revisions are shown in Table IV. Both the stem and acetabular component were revised in 36 (9.4%), the acetabular component alone in seven, although in one of these revisions the stem was revised later, using the cement-in-cement technique, for instability.

Only one of the 382 stems (0.3%) failed, due to proximal femoral lysis, 21.1 years post-operatively, in a patient with Gaucher's disease (Fig. 3). The mean time following surgery for all 36 revisions involving the stem was 12.9 years (0.1 to 21.2). The indications for revision related to the stem in 12 patients included lysis in one, periprosthetic fracture in three and instability in eight. A total of four stems were revised for infection. The remaining 20 were revised for access to allow acetabular revision, using a cement-in-

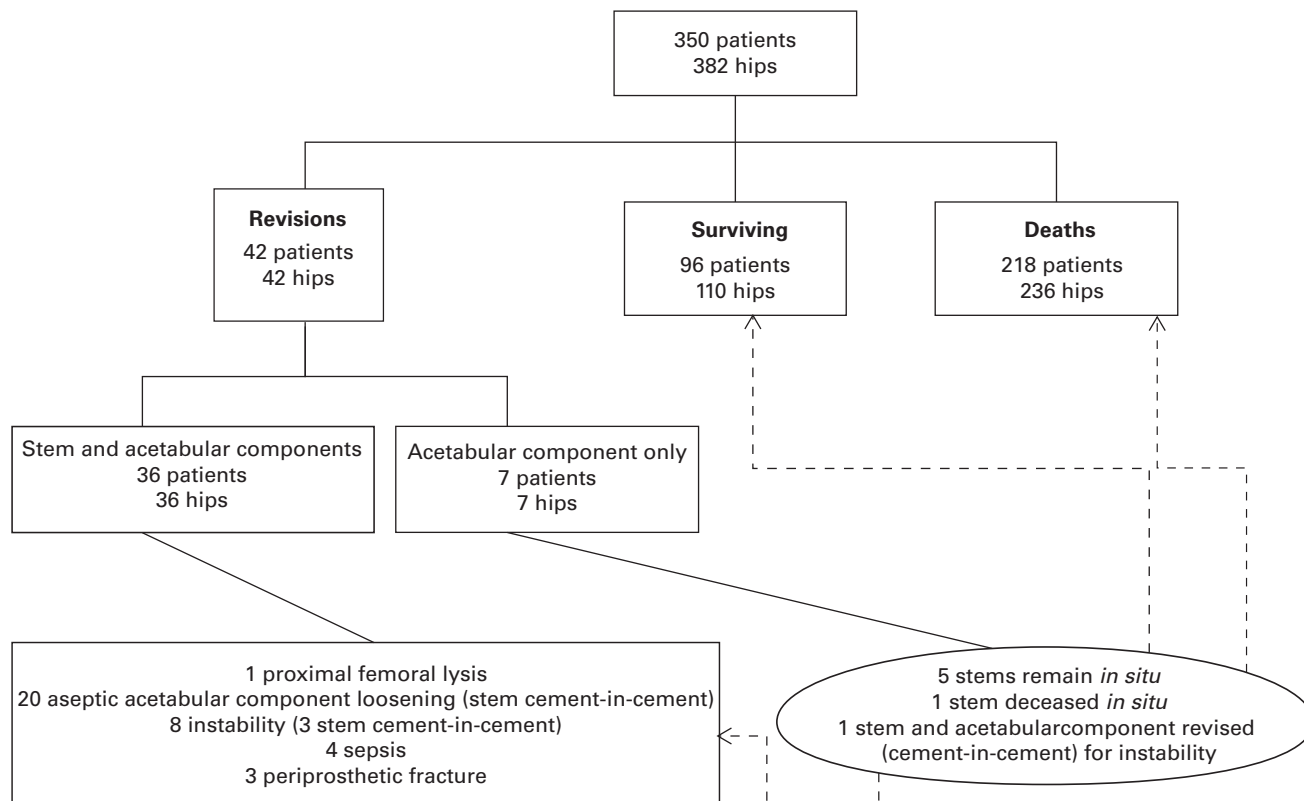


Fig. 2

Flowchart showing the outcome of 350 patients (382 hips).

Table IV. Indications for revision

Indication	Hips (n)
Aseptic loosening - acetabulum	20
Acetabular revision – stem retained (one stem and acetabular component subsequently revised for instability)	7
Dislocation	8
Infection	4
Periprosthetic fracture	3
Proximal femoral lysis	1
Total (N.B. one case appears twice)	42

cement technique. In seven cases, the acetabular component was revised with the stem remaining *in situ*; one of these was subsequently revised for instability and is included above; five remain *in situ* and one patient died with the stem *in situ*. Of the 42 acetabular components which were revised, 27 were Exeter metal-backed and 15 were Exeter concentric. These proportions were not statistically different to the proportions of these components which had been used initially (10.4% of the metal-backed, 12.1% of the concentric; $p = 0.40$).

Survivorship is reported at 22.8 years (Fig. 4). With an endpoint of revision for aseptic loosening or lysis, survivorship of the stem was 99.0% (95% CI 97.0 to 100). With revision for all causes including infection and periprosthetic fracture, survivorship was 95.6% (95% CI 92.3 to 98.9) and overall survivorship of the THAs, with revision of either

components for any reason as an endpoint at 22.8 years was 82.9% (95% CI 77.4 to 88.4). With an endpoint of revision for aseptic loosening or lysis of either component, survivorship was 89.3% (95% CI 84.8 to 93.8). For those with primary osteoarthritis, survivorship for all causes was 84.5% (95% CI 78.4 to 90.6). Finally, when considering those three stems in deceased patients with extended follow-up as lost to follow-up, calculation of the worst case scenario for aseptic loosening or lysis falls to 98.1% (95% CI 95.9 to 100), and overall survivorship with revision for all causes as the endpoint of 82.1% (95% CI 76.6 to 87.6).

Radiographs were available for 91 hips at a minimum of 20 years, and review showed no impending failures of the stem. A typical radiographic appearance is shown in Figure 5. Age-related cortical thinning/expansion was common (80%) and subsidence, whilst common (92%), was limited in mag-



Fig. 3a

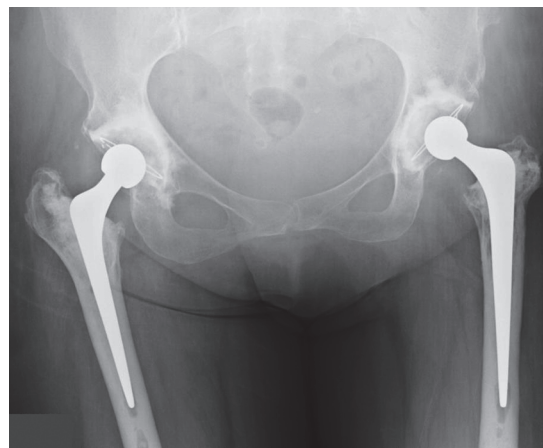


Fig. 3b



Fig. 3c

Progressive osteolysis of the proximal femur. Radiographs at a) one year showing satisfactory appearances; b) 15 years showing osteolytic changes. These appearances and the diagnosis of Gaucher's disease prompted closer monitoring of this patient; and c) prior to revision at 21 years.

nitude, with a median subsidence of 1 mm (0 to 3). Concerning features were much less common, with localised lysis in two hips (two zones in one and four in the other) and RLLs in four hips (one zone in two, and two zones in two). Rounding off of the calcar was seen in 36 (40%), and loss of calcar height in 44 (48%) (mean 2.7 mm, 0 to 15). Finally, cortical hypertrophy was identified in ten hips (11%), mainly in Zones 5 and 6.

Discussion

The results from our institution have previously shown that the Exeter Universal femoral stem has good survivorship and outcomes at both initial and medium-term reviews.^{1,2} This study describes the long-term survivorship of a different series of 382 hips, with survivors studied for a minimum of 20 years, with their clinical and radiological outcomes. This stem is identical to the current Exeter V40 stem in all but the trunnion taper. The load transmitting body that is in contact with the cement is common to both stems.

We found that 346 (89%) of the original 382 stems were still *in situ* at the time of death or latest follow-up. Only one stem needed revision for lysis, and the diagnosis of Gaucher's disease in this patient is likely to explain this failure. There was no evidence of significant polyethylene wear, and infection was excluded. THA has a high rate of failure in patients with Gaucher's, ranging from 13% to 54%.^{21,22} However, this stem survived until revision 21.1 years post-operatively.

The case-mix in this series shows the ability of the stem to cope with a variety of complex primary scenarios. Of 382 THAs, 73% were undertaken for primary osteoarthritis compared with 93% in the NJREW,⁵ and 9% of the patients had undergone previous surgery such as fixation of a fracture or osteotomy. The overall rate of revision was marginally higher for those who had undergone previous surgery; with five revisions from 33 THAs (15%) compared with 37 from 349 THAs (11%); these revisions were not, however, for loosening of the stem. The stem performed well in all circumstances. The survivorship of

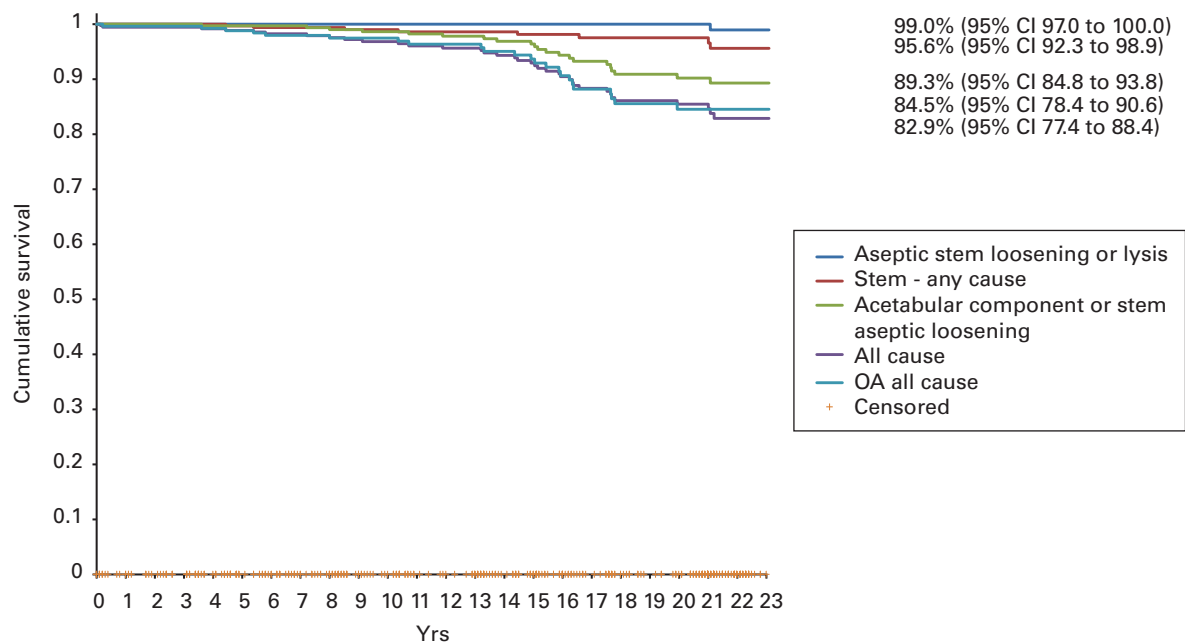


Fig. 4

Kaplan-Meier survivorship curves at 22.8 years (OA, osteoarthritis).

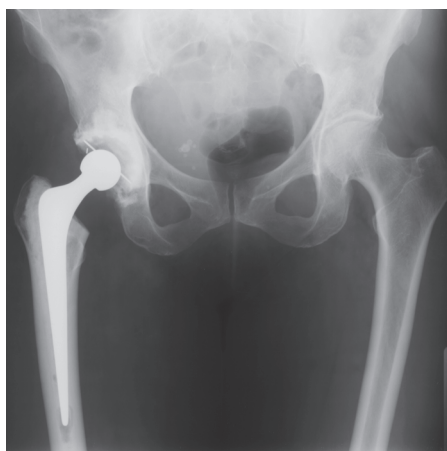


Fig. 5a



Fig. 5b

Typical radiograph a) immediately post-operatively and b) at 20-year final review.

straightforward primary THAs performed in the subgroup of 280 hips with a diagnosis of primary osteoarthritis was 100% for aseptic loosening of the stem at 22.8 years, and 82.1% for revision for all causes as the endpoint. Finally the patients in this series had a wide range of ages. A total of 62 THAs (16%) were used in patients aged < 55 years at the time of surgery and 44 (11.5%) in patients aged < 50 years; the youngest patient was aged 17 and the oldest was aged 94 years. Thus, the stem performs well in a variety of clinical settings, both routine and complex, and in all age ranges.

This series is from the originating centre and is thus open to potential bias, and all patients were under the care of two specialist hip surgeons. However, 35% of the operations were performed by trainees. This is not therefore a single expert surgeon series, as are many other reports of long-term survivorship (Table V),²³⁻³² and it is reasonable to conclude that these results could be replicated elsewhere.

Achieving follow-up of more than 20 years is not an easy task, especially as THA is usually undertaken in older patients. A significant proportion (218) had died since surgery (236 hips, 62%). It is not possible to improve on the

Table V. Published results of total hip arthroplasties with a minimum follow-up of 20 years²³⁻³²

Group	Implant	Hips (n)	Duration of survivorship	Method used	Survivorship stem aseptic loosening (%)	Survivorship hip all cause (%)	Single surgeon	Comment
Current	Exeter Universal (Stryker, Kalamazoo, Michigan)	382	22.4	K-M	99	82.9	Multiple	
Buckwalter et al ²³	Charnley (DePuy Synthes, Warsaw, Indiana)	357	25	K-M	93 to 95		Single	
Wroblewski et al ²⁴	Charnley (DePuy Synthes)	22 066	31	Not stated	80	30 at 30 yrs	Multiple	
Vidalain ²⁵	Corail (DePuy Synthes)	347	23	K-M	96.3 (all)	82.5	Single	29 lost to follow-up
Gerritsma-Bleeker et al ²⁶	Stanmore (Biomet, Warsaw, Indiana)	146	22	Cumulative (Dobbs)	91	85	Not stated	Cumulative survivorship
Al Muderis et al ²⁷	Spongiosa-I (ESKA Orthodynamics, Lubeck, Germany)	209	20	K-M	86 (all)		Not stated	13 lost to follow-up
Sandiford et al ²⁸	Furlong (JRI Orthopaedics, Sheffield, United Kingdom)	72	22.5	K-M	100	91.7	Multiple (single surgeon direct supervision)	Revisions and deaths beyond 20 years only reported
Kolb et al ²⁹	Zweimuller (Zimmer, Warsaw, IN, USA)	208	20	K-M	98	65	Multiple	13 lost to follow-up
Belmont et al ³⁰	AML (DePuy Synthes)	223	20	K-M	98	74.3	Single	12 lost to follow-up
Streit et al ³¹	CLS Spotorno (Zimmer Biomet)	354	22	K-M	93		Not stated	4 lost to follow-up
Meding and Ritter ³²	BiMetric (Zimmer, Biomet)	157	20	K-M	100		Not stated	9 lost to follow-up

K-M, Kaplan-Meier

final time of reviewing this subgroup of patients, and it may be that revision could have occurred between the time of final review and death. Many papers do not address this issue, but we felt it was important. We considered it reasonable to continue to use death as the endpoint for the analysis of survivorship where patients had attended for routine review, with the hip still *in situ*. Any patients falling outside the five-year interval were rigorously investigated. Only three stems in two patients eluded us in this regard, with a greater than five-year interval between last contact and death and separate analysis was performed to determine the 'worst case scenario'. One of these patients (two hips) died locally with an interval between the final contact and death of 6.8 years, and we can reasonably assume they would have presented to our unit if they had symptoms from the hip. The other, with an interval between the final contact and death of 8.5 years, had moved away. Another limitation is that despite knowing the fate of all patients, radiological analysis was not possible for all of them, recent radiographs having been performed in just 91 (82.7%) of the 110 surviving hips.

Whilst for the patient, the overall performance of the hip is of greatest importance, the acetabular components used in this series are now obsolete. Many of them were Exeter metal-backed components. These were discontinued in

1991 due to their poor performance. For these reasons we have not provided a more in-depth analysis or a radiological review of the acetabular components. Despite this, the rate of revision for loosening of the acetabular component was 7.1% at up to 25 years. Developments in the design of components and techniques such as flanges, iliac suction³³ and careful pressurisation, may improve the performance of all-polyethylene cemented components, which continue to be used in most THAs in our unit.³⁴ Promising results are appearing for the modern all-polyethylene cemented component, most commonly paired with the Exeter stem in the United Kingdom, the Contemporary flanged acetabular component (Stryker). Even in younger patients (< 50 years), survivorship for aseptic loosening at eight years has been shown to be 96.4% (95% CI 91.6 to 98.5) in a cohort of 152 THAs.³⁵

Our clinical outcomes reflect the changes that occur as follow-up lengthens and patients age. At 15 to 17 years follow-up, the mean Harris pain score was 38.6, and Harris function score 34.6.² In this series, at a mean follow-up of 22.4 years, the mean pain score remains good at 38.1, and the mean function score at 32.7. The relief from pain was maintained although function deteriorated; this may be explained by an increase in coexisting pathologies, rather than a problem with the hip. Within the surviving group of

patients, changes in the Charnley category over time (Table III) seem to support this hypothesis, with an increasing prevalence of Charnley category C patients, who have many other pathologies that affect function.¹⁰ This is in common with other reports with follow-up of > 20 years.^{26,28,36}

Radiological review showed few features of concern. The number of hips with lysis was small (2%). None of the areas of lysis totalled more than 15% of the mantle, and the depth was < 5 mm. These patients did not have pain, and none required revision. Similarly, radiolucent lines were limited to 4% of the radiographs, and were limited to one or two Gruen zones. Subsidence, as expected, was a median of 1 mm and did not appear to increase over time. The changes affecting the calcar potentially reflect some proximal stress shielding or reflect early proximal femoral lysis from polyethylene wear, as may be expected at > 20 years. The radiological findings reinforce the taper-slip theory of functioning of the stem, as described elsewhere.^{1,37} Overall, the key finding of the radiological review was that none of the surviving stems had impending failure.

There are few studies with a follow-up of THAs at > 20 years. Most involve outcomes of the Charnley THA. Buckwalter et al²³ reported a single surgeon series of 357 Charnley THAs followed up to a minimum of 25 years (mean 26.3 years) with 52 survivors. They found survivorship of 93% to 95% at 25 years with aseptic loosening of the stem as the endpoint, however eight of the 52 surviving hips had femoral loosening on radiographs at final follow-up; five requiring revision.

The second most commonly used stem currently in the NJREW is the Corail (DePuy Synthes, Warsaw, Indiana).⁵ Vidalain²⁵ described its results in a single-surgeon series of 347 THAs from its originating centre, at a mean follow-up of 20.9 years. He reported that 33 patients (9.5%) had cracks of the calcar, there were three fractures and two perforations at the time of the primary surgery. Revisions were performed in four THAs for aseptic loosening of the stem, eight other revisions of the stem were performed for other reasons including three for extensive proximal femoral granuloma during revision of the acetabular component, one for periprosthetic fracture, and four stable stems were removed for correction of leg length (n = 1) or to allow revision (n = 3). In all, 13 THAs were revised for dislocation. Kaplan-Meier survivorship with all-cause revision of the stem as the endpoint was 96.3% at 23 years, although it is unclear how deaths in this cohort were treated in the survivorship analysis, or the effective numbers remaining at risk. Global survivorship was reported to be 82.5% at 23 years. A significant number of patients (29; 9%) were lost to follow-up, and a worst-case scenario survivorship was not reported.

Other authors have reported survival at > 20 years, for other less-used designs (Table V). Comparison of survivorship requires careful interpretation, as different statistical

methods were used, and inclusion criteria and the nature of follow-up of the patients varied.

Overall, it is clear that the survivorship of our stem compares favourably with other available data and this series provides further evidence that the Exeter Universal stem continues to perform well beyond 20 years.



Take home message:

Long-term follow-up, beyond 20 years, shows that the Exeter stem performs well in all patients, regardless of age or diagnosis.

Author contributions:

T. G. Petheram: Data collection, Drafting of the manuscript, Editing of the manuscript, Data analysis, Radiology review.

S. L. Whitehouse: Data collection, Data analysis, Editing of the manuscript.

H. A. Kazi: Data collection, Editing of the manuscript.

M. J. W. Hubble: Editing of the manuscript, Basic concept

A. J. Timperley: Performed surgeries, Editing of the manuscript, Conceived the study.

M. J. Wilson: Editing of the manuscript, Basic concept, Radiology review.

J. R. Howell: Senior manuscript editor, Conceived the study, Radiology review.

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