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ORIGINAL STUDY

Long-term follow-up of a cemented titanium stem

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We present the outcome of 270 cemented titanium alloy femoral stems. These patients were followed up annually both clinically and radiologically, and were included up until their last follow-up. 120 patients completed a 10-year follow-up. The 10-year survival of the Ultima Straight Stem cemented femoral component (defined by revision of the femoral stem) was 90.1% (95% CI = 84.0-94.0%), with aseptic loosening being the major reason for failure. The preoperative Harris Hip Score improved from 35.3 to 79.3 at 10 years. There were 17 cases of stem subsidence, radiolucent lines in 11 hips, 5 cases of cement fracture and 18 hips had osteolysis in 2 adjacent Gruen zones. This is the largest study in the English literature of this implant, and reflects UK district general hospital practice with surgery performed by a variety of surgical grades and via different surgical approaches. Although the outcome of this implant was within the previous standard set by the National Institute for Health and Clinical Excellence and is comparable to other series of titanium stems, it is inferior to that of more modern cemented and uncemented implants, and falls outside the new NICE recommendation of <5% revision rate at ten year. As a result this implant is no longer used in our institution, and it has also now been withdrawn from the market. We suggest that patients with this implant should be followed up radiologically due to the relatively high rate of stem subsidence and lucency between the cement and prosthesis, to identify those who may be at risk of failure.

Keywords : hip ; arthroplasty ; titanium ; surgery ; survival ; prothesis.

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INTRODUCTION

Titanium alloy has fallen out of favour recently as a material for cemented femoral stems in total hip arthroplasty, but it has traditionally been extensively used due to its excellent biological and mechanical properties, including biocompatibility and low toxicity and decreased stress shielding due to its low modulus of elasticity. It also has good fatigue strength, allowing for a smaller implant to be placed within a thick cement mantle (*20*). These properties also allow titanium to be used as a material for uncemented components (*11*).

Titanium implants carry mixed reports in the orthopaedic literature. Bowditch and Villar (*4*) reported encouraging early results with the Ultima Straight Stem implant, while Boyer (*5*) and

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Eingartner (*6*) also published good long-term results using different stem designs. However, Kovac (*14*) reported poor long term results of a different cemented titanium-aluminium-vanadium stem, and there remain concerns over corrosion (*9,23,24*), aseptic loosening and osteolysis (*22*) and calcar resorption (*20*) with the use of titanium implants. Following problems with the Capital hip arthroplasty (3M Healthcare Ltd, Loughborough, UK), it was recommended that patients with titanium stems be followed up closely to look for signs of failure (*17*).

The Ultima Straight Stem total hip replacement (Johnson & Johnson, Leeds, UK) is a straight-stem, titanium-aluminium-vanadium alloy (Ti6Al4V), designed for cemented fixation. It is a modular system, with a 12/14 Morse taper and was used with a 28mm cobalt-chrome head. The design specifics include a double taper designed to allow even cement pressurisation, a textured surface for cement-implant bonding and low stiffness allowing for reduced proximal stress-shielding. The stem design was identical to the monoblock Howse II Straight Stem, as reviewed by Wood and Gibson (*27*). The matt stem has a surface roughness ($R_a$value) of 0.51, and the finish was achieved by a 2-stage process of first grit-blasting with angular shaped grit and then blasting with spherical ceramic beads to smooth the surface down. The aim was to create a smooth matt surface but with a texture to allow better grip by the bone cement. The broach was line-to-line, with the implant allowing for a 2 mm cement mantle.

Although there are many studies looking at short, medium and long-term outcomes of titanium cemented stems, there are few examining the long term outcome of the Ultima Straight Stem in particular. There are also many different stem designs on the market with differing design rationales, alloys and bearing surfaces, thus making it difficult to extrapolate outcomes from one implant onto another. We report the prospectively studied 10-year outcomes of the Ultima Straight Stem from a single centre.

PATIENTS AND METHODS

Between July 1995 and July 2001, 287 hips (in 270 patients) were enrolled into a prospective randomised controlled trial with either a cemented all-polyethylene acetabular component (Ultima ; Johnson & Johnson-DePuy, Leeds, United Kingdom) or a cementless porous-coated cobalt chromium acetabular component with polyethylene liner (PFC ; Johnson & Johnson-DePuy) (*2*). Among the 287 hips in the study, 270 hips (in 255 patients) received the same cemented femoral component, the Ultima Straight Stem (Johnson & Johnson, Leeds, UK), referred to here as the Ultima Straight Stem cohort (USC). Of the 270 hips in the USC, 175 (64.8%) received the cemented all-polyethylene acetabular component, while 95 (35.2%) received the uncemented acetabular component with a polyethylene bearing.

Exclusion criteria for the study were age under 55, a history of either septic arthritis or radiation therapy to the affected joint, metabolic bone disorders and an inability to participate in the follow-up protocol. In the USC, 157/270 (58.1%) of hips were in females and 113/270 (41.9%) were in males ; the average age at surgery was 70.8 years (range 55-89) ; 255/270 (94.8%) of arthroplasties were performed for osteoarthritis and 11/270 (4.1%) for rheumatoid arthritis, with the remainder being for other causes such as avascular necrosis or trauma.

The surgery was carried out by a range of grades of surgeon and via different surgical approaches, as shown in table I. The same cemented femoral component, the Ultima Straight Stem was implanted in all cases using Palacos cement with gentamicin (Schering-Plough, Reading, UK) following standard preparation of the femoral canal by sequential broaching, pulsed lavage and insertion of a Hardinge cement restrictor (Corin, Cirencester, UK). Standard cementing technique was used in all cases. Our routine prophylaxis against infection with 3 doses of cefuroxime and thromboprophylaxis with enoxaparin and TED stockings was used in all cases. Early mobilisation was encouraged.

Outcome assessment : Patients who had died or been lost to follow-up as well as revisions for any reason were recorded. The Harris hip score (HHS) (*10*) was used as a tool to assess outcome at each annual visit, along with clinical examination by an independent research nurse (SB). The last recorded HHS was used in patients who had been lost to follow-up. The primary outcome of this paper was revision of the femoral component for any reason.

Radiological assessment : Standard AP and lateral radiographs were taken postoperatively and at each subsequent follow-up appointment, and examined by two of the authors (DSA and SB), with consensus on the reported findings. At each attendance, loosening was recorded according to the zones described by Gruen (*8*) and

Table I. — Grade of surgeon and surgical approach

Grade of surgeon		Surgical approach	
Consultant	174 (64%)	posterior	145 (54%)
Trainee	94 (35%)	anterolateral/lateral	106 (39%)
Not Recorded	2 (1%)	other	19 (7%)

subsidence of the stem was recorded as well as any incidence of cement fracture or osteolysis. In patients who had died or been lost to follow up the last available radiographs were used. The average length of follow up was 7.6 years (range 0.4 to 15.0).

Survivorship was calculated using the Kaplan-Meier method, using PROC LIFETEST in SAS version 9.3 (SAS Institute Inc., Cary, NC, USA). The 95% confidence intervals were calculated using the method known as the log cumulative hazard transformation method.

RESULTS

Of the 255 patients who received an Ultima Straight Stem component, 68 (27%) subsequently died, including 3 patients with bilateral THRs (26% of all femoral stems). For those 68, the average time from surgery to death was 7.1 years (0-14.5). A further 77 (30% ; 29% of all femoral stems) patients had withdrawn from the study, usually due to increasing frailty and an inability to attend for annual review, or had been lost to follow-up, but these patients had attended follow-up for a mean of 4.7 years (0.1-11.9). Two of these patients had bilateral THRs. In all these cases, patients were included up until their last annual follow up appointment (including 10 years where possible), and attempts were made to contact patients who had been lost to follow up as well as their general practitioners in order to ensure our data regarding both revisions as well as symptoms from the hip was as complete as possible. 101 patients (37%) completed a formal face-to-face 10 year review, with a further 19 (7%) having a telephone review.

There were a total of 26 revisions, 17 of which involved revision of the femoral stem. In 12 cases both stem and cup were revised and in 5 cases only the stem was revised. Three stem revisions were due to infection ; all of these were late infections, at 1.2, 7.2 and 12 years post-op. The intention was to treat all of these with 2-stage revisions, although one patient declined the second stage and simply had an excision arthroplasty. Of the remaining 14 subjects with revised stems, 11 were revised for aseptic loosening (mean = 7.5, range 3.6 to 10.8), 1 for recurrent dislocations, 1 for lucency and periprosthetic fracture of the femur, and 1 for osteolysis around the stem. A further 7 hips had acetabular cup revisions (2 loosening, 1 eccentric cup wear, 3 recurrent dislocations/subluxation, and 1 slipped cup), but at surgery the stem was examined and found to be well-fixed and therefore not revised. Two hips had femoral head and acetabular liner exchange (at 3.8 & 7.7 years post-op, for liner fracture and recurrent dislocations, respectively). One subject had a posterior augmentation of a cemented acetabular component during a stem revision procedure (4.9 years post-op). The mean time to stem revision was 7.0 years (range 1.2-12.0). The 10-year Kaplan-Meier survival estimate with failure = revision of the femoral stem was 90.1% (95% CI 84.0% to 94.0%), with 87 unrevised stems remaining at risk (having further follow-up) at 10 years post-op ; at 12 years the estimate was 88.9% (95% CI 82.2% to 93.2%) with 48 unrevised stems remaining at risk at 12 years post-op. Figure 1b presents stem survivorship (failure = revision of the stem) graphically. The 10 year Kaplan-Meier survival estimate for failure = revision of any THA component (stem, shell, head or liner) was 87.4% (95% CI 80.9% to 91.8%), with 87 unrevised hips remaining at risk at 10 years post-op.

The survival tables for revisions of the femoral stem alone and revision of any component for any reason are shown in table II & III below :

Clinical outcomes : The average pre-operative Harris hip score was 35.3 out of a maximum 100 (range 9-76). At 6 months, it was 79.1 (258 patients,

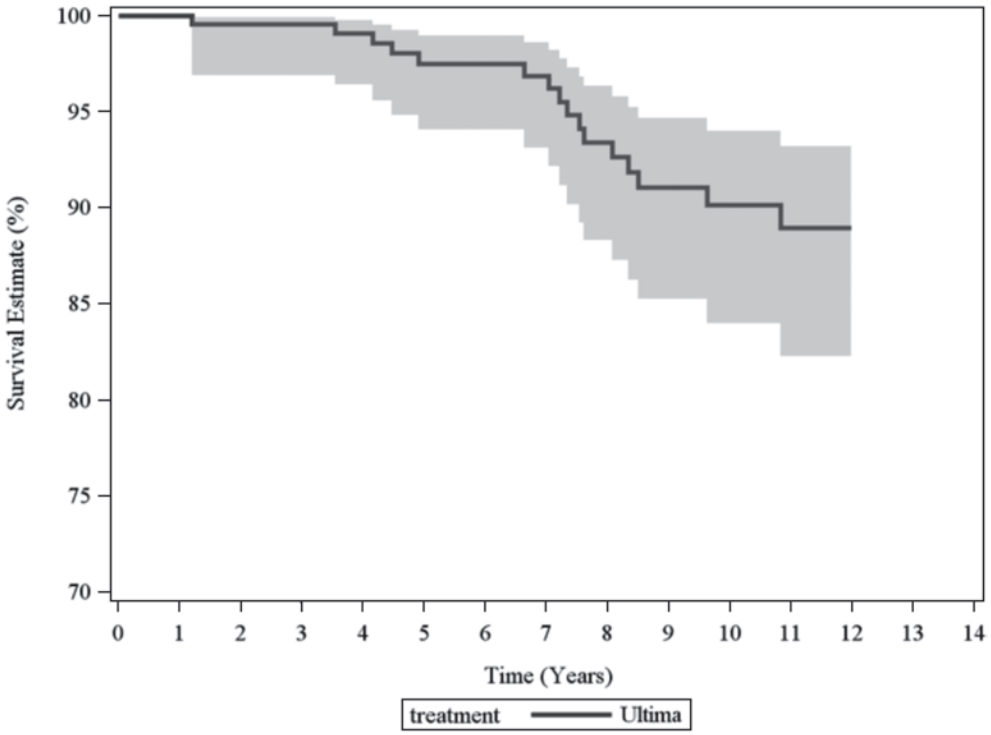

Fig. 1a. — Kaplan-Meier survivorship analysis for survivorship of the Ultima Straight Stem

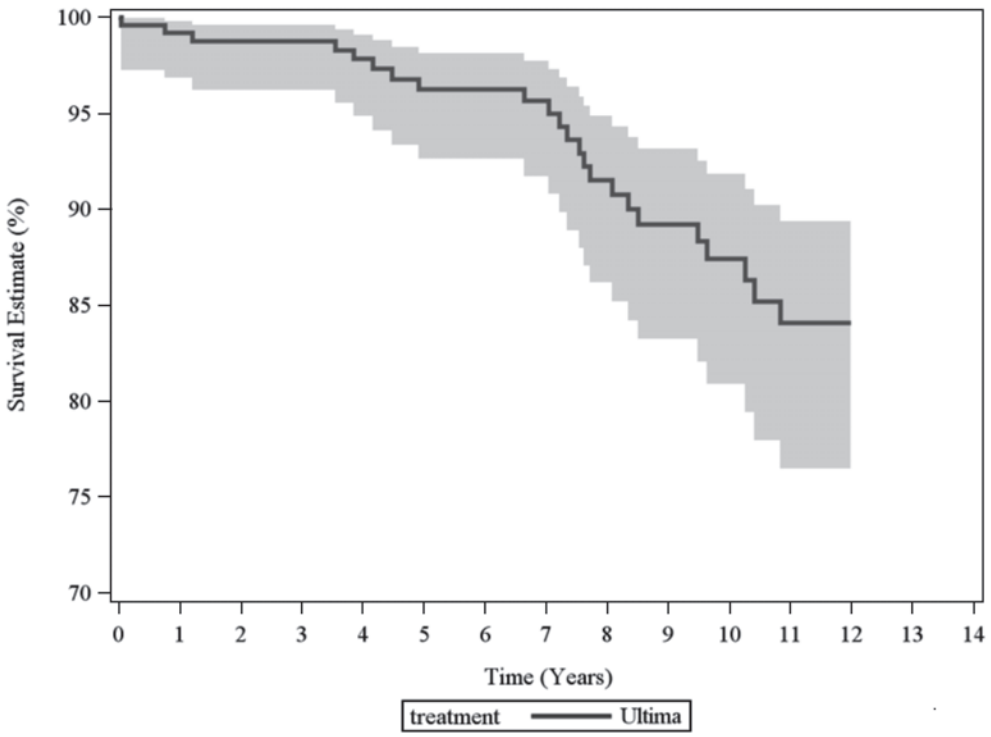

Fig. 1b. — Kaplan-Meier survivorship analysis with the endpoint of revision for any cause (includes acetabular revisions where the stem was retained).

Table II. — Survival table up to 12 years for Ultima Straight Stems with revision as the endpoint. Please note that one stem was revised after 12 years

	Years post-op											
	1	2	3	4	5	6	7	8	9	10	11	12
Survival estimate (stems)	100.0	99.6	99.6	99.1	97.5	97.5	96.9	93.4	91.1	90.1	88.9	88.9
Lower 95% confidence limit	100.0	96.9	96.9	96.4	94.1	94.1	93.1	88.3	85.2	84.0	82.2	82.2
Upper 95% confidence limit	100.0	99.9	99.9	99.8	99.0	99.0	98.6	96.3	94.7	94.0	93.2	93.2
Hips remaining (with further follow-up)	242	224	222	197	176	164	149	124	105	87	65	48
Cumulative number of stems revised	0	1	1	2	5	5	6	11	14	15	16	16

Table III. — Survival table up to 12 years for Ultima Straight Stems with revision of any component for any reason as the endpoint. Please note that three hips were revised after 12 years

	Years post-op											
	1	2	3	4	5	6	7	8	9	10	11	12
Survival estimate (any component for any reason)	99.2	98.8	98.8	97.8	96.3	96.3	95.6	91.5	89.2	87.4	84.1	84.1
Lower 95% confidence limit	96.9	96.2	96.2	94.9	92.6	92.6	91.7	86.2	83.3	80.9	76.5	76.5
Upper 95% confidence limit	99.8	99.6	99.6	99.1	98.1	98.1	97.7	94.9	93.2	91.8	89.4	89.4
Hips remaining (with further follow-up)	242	224	222	197	176	164	149	124	105	87	65	48
Cumulative number of revisions	2	3	3	5	8	8	9	15	18	20	23	23

range 13-100). At the 10 year follow up it was 79.3 (101 patients, range 25-100).

Radiological outcomes : Stem subsidence greater than or equal to 3 mm was seen in 17 hips (7%). This subsidence was greater than 5 mm in 4 stems ; 3 of these 4 stems were revised (2 for aseptic loosening, 1 for loosening with infection). Radiolucent lines greater than or equal to 2 mm in at least one zone (around the stem) were seen at last follow-up in 11 hips (4.5%). The stems were revised in three of these 11 hips for loosening (2 aseptic loosening, 1 loosening with infection). There were 5 cases of cement fracture, 2 of which were among those which exhibited stem subsidence of 3 mm or more (4 mm, and 5mm respectively). One of these 5 subjects was revised for aseptic loosening (the subject with 5 mm stem subsidence). There were 18 hips with lysis in 2 adjacent zones at latest follow-up ; the mean time to the first visit in which lysis was observed in these 18 hips was 7.4 years (range 2.9 to 14.0 years). 9 of these 18 hips had a revision of the stem for loosening (6 for aseptic loosening, 1 for loosening with infection, 1 for lucency and periprosthetic fracture of the femur, and 1 for osteolysis around the stem). There were 7 further stems which did not have lysis in 2 adjacent zones at latest follow-up, but were revised for loosening (5 aseptic, 2 with infection) ; 5 of these 7 had evidence of lysis in at least one zone at last follow-up, and the mean time to the first visit in which lysis was observed in these 5 hips was 5.7 years (range 2.6 to 8.2 years). In all, there were 42 cases with one or more of the following : subsidence (≥ 3 mm), radiolucent lines (≥2mm in at least one zone at last follow-up), cement fracture, lysis (in 2 adjacent zones at last follow-up), or revised, as presented in Table IV.

Table IV. — Radiographic outcomes and stem revisions

Case	Subs.	Rad. lines	Cem. frac.	Lysis	Revision
1	× (4 × mm)				
2	× (3 × mm)				
3					Aseptic loosening (7.6 yrs)
4		×			
5				×	
6		×			loosening with infection (1.2 yrs)
7	× (12 × mm)			×	Aseptic loosening (6.6 yrs)
8				×	
9			×		
10	× (13 × mm)			×	
11					Aseptic loosening (8.5 yrs)
12	× (3 × mm)			×	
13		×			
14		×			
15	× (5 × mm)			×	Aseptic loosening (7.3 yrs)
16				×	
17	× (6 × mm)			×	loosening with infection (12.0 yrs)
18	× (4 × mm)			×	
19		×			Aseptic loosening (10.8 yrs)
20	× (3 × mm)				
21	× (3 × mm)				
22				×	
23					loosening with infection (7.2 yrs)
24		×			
25	× (4 × mm)		×		
26	× (3 × mm)			×	
27				×	Aseptic loosening (8.1 yrs)
28					Aseptic loosening (9.6 yrs)
29		×			
30					Recurrent dislocations (4.9 yrs)
31		×			
32		×			
33	× (22 × mm)	×		×	Aseptic loosening (4.5 yrs)
34	× (3 × mm)				Aseptic loosening (8.3 yrs)
35				×	Lucency & periprosthetic fracture (4.2 yrs)
36	× (4 × mm)				
37			×		
38				×	Osteolysis (7.5 yrs)
39	× (3 × mm)				
40		×	×	×	
41				×	Aseptic loosening (3.6 yrs)
42	× (5 × mm)		×	×	Aseptic loosening (7.0 yrs)
Subs : Subsidence ≥ 3 mm in at least one follow-up visit					
Rad. Lines : Radiolucent Lines ≥ 2 mm in at least one zone at latest follow-up					
Cem. Frac. : Cement fracture in a post-op radiograph					
Lysis : Lysis in 2 adjacent zones at latest follow-up					
Revision : Reason for revision and time (post-op) is noted for all stem revisions					

DISCUSSION

The use of titanium alloy femoral implants has mixed reports, but interpretation of these reports can be difficult due to the different stem designs, titanium alloys and bearing surfaces used. As far as we are aware, this is the largest single-centre cohort of patients with an Ultima Straight Stem total hip arthroplasty in the literature so far, and it also reflects true UK district general hospital practice with operations being carried out by several consultants as well as registrars in training and other staff-grade surgeons, through a variety of surgical approaches. We have shown that aseptic loosening is the predominant cause of failure, and that these revisions are relatively early at a mean of 7.5 years.

Our results are similar to other studies in terms of the revision rate for the Ultima Straight Stem ; a previous study demonstrated a 92% survival rate at 8 years for aseptic loosening (*18*). We have also demonstrated that the Ultima Straight Stem has near-equivalent revision rates to other implants with a proven track record such as the Charnley. Allami (*1*) showed that this system had a ten-year survival rate of 93.1% across a wide range of hospitals in the Trent region including both district general and teaching hospitals. Our results are superior to some other types of titanium alloy prosthesis, including the Triad (Johnson & Johnson, New Brunswick, NJ, USA) (*24*) which reported a 4.3% revision rate at a mean of 4.8 years and the DF-80 (Zimmer, Warsaw, Indiana, USA) (*13*) which reported failure or impending failure rates of 11% at 2 years. Both of these studies identified calcar resorption, osteolysis and aseptic loosening as a reason for early revision. Our results are however worse than some others including the monobloc STH stem (Zimmer, Warsaw, Indiana, USA) (*20*), although it should be pointed out that this is a report of a single surgeon's series. Polished titanium stems such as the Ceraver Osteal (Ceraver Osteal, Roissy, France) have better outcomes with stem survival of 99% at 10 years (*15*). It would appear that implant design including surface finish, offset, cement mantle thickness and cementation technique (*3*) are of paramount importance as well as the material used for the prosthesis (*17,18*). It should be noted that with the updated NICE guidance (*19*) requiring a revision rate of less than 5% at 10 years, the Ultima Straight Stem no longer meets this benchmark.

Our study also shows that the long-term results of the Ultima Straight Stem do not match those published with the use of cemented collarless polished tapered stems such as the Exeter (Stryker Howmedica Osteonics, Mahwah, NJ, USA), which has reported results at 33 years from the designing centre (*16*) and 2.2% all-cause revision rates at 12 years from an independent centre (*12*) ; the C-stem (DePuy International, Leeds, UK) which shows no revisions for aseptic loosening at a mean of 3 years (range :1-7) when performed in a specialist hospital (*28*) ; or the CPT (Zimmer, Warsaw, Indiana, USA) which has all-cause survival of 95.9% at a minimum of ten years, although again this is from a specialist hospital (*29*). It should be noted that all of these are polished cemented stems and this, as well as the shape of the stem, is likely to be of importance in terms of stem survival (*21*). None of these systems use titanium alloy as the basis for their femoral stem, and this study adds to the evidence that titanium is perhaps better restricted to use in uncemented implants. Our results also do not match those of modern uncemented total hip replacements such as the Corail (DePuy International, Leeds, UK) which showed no revisions for aseptic loosening at a minimum of ten years (*7*) and has recently shown good results at 20 years (*25*). Although the Ultima Straight Stem femoral component is no longer commercially available, there are likely to be many patients who have previously had this system implanted who are no longer under routine follow-up. Given the fairly high rate of radiological changes in terms of stem subsidence and radiolucent lines at the cement-bone interface, and that these are likely to loosen and require revision more than 4 years post-implantation, we would recommend continuing long term clinical and radiological surveillance of patients with this implant to identify those potentially at risk of failure.

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