Is titanium so bad?

MEDIUM-TERM OUTCOME OF CEMENTED TITANIUM STEMS

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Early failures have seen titanium fall from favour as a material for cemented femoral stems. Between 1989 and 1994, we performed a prospective review of a consecutive series of 122 cemented total hip replacements using the Ultima straight textured titanium stem, and report the five- to ten-year clinical and radiological outcomes. There were no revisions for loosening of the femoral stem. Revision surgery was undertaken for other reasons such as dislocation, infection and loosening of the cup in 7.3%. Of those patients without revision all but two were satisfied with their hip, with 74% graded good or excellent using a modified Harris hip score. Radiological assessment revealed probable loosening in two. Although slight vertical subsidence was found in one-third of patients it had not progressed to loosening. It is not clear whether this represents debonding. Non-progressive radiolucent lines (1 to 2 mm) were present in zone 1 at the cement-prosthesis interface in 14.7%. Calcar resorption and hypertrophy around the distal stem were not often seen. With 97% survival at a mean of 7.5 years, the medium-term results of this specific cemented titanium stem are reassuring so far, but we are concerned about debonding and future failure.

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Cemented titanium femoral stems are currently out of favour. A recent commercial list¹ of 82 available femoral components for cemented fixation includes only five made of titanium or titanium alloy. This fall from favour began before the controversy about the 3M Capital Hip,² but the

adverse publicity reinforced a lack of confidence in cemented titanium stems. Close follow-up of femoral components made of titanium alloy has been recommended³ in order to detect early loosening and femoral osteolysis. Reports on the clinical outcome of cemented titanium or titanium-alloy stems are varied⁴⁻⁷ and difficult to assess because of the numerous differences in the design of the stem.

The straight-stem Howse MkII femoral component (Johnson & Johnson, Leeds, UK) was first introduced in 1985 and renamed Ultima in 1990 (Fig. 1). Initially, it was a monoblock design with a 28 mm head, subsequently made in modular form with a 3° taper in 1986 to accept a titanium alloy head, and changed in 1990 to a 12/14 mm taper (Ultima) with a cobalt-chrome head. It is a straight, collarless stem made from titanium alloy (Ti6Al4V) and designed to be inserted with cement. In 1995, a cobalt-chrome version was produced and has now largely replaced the titanium implant owing to the general reluctance to use cemented titanium stems.

Fig. 1

The Ultima straight, collarless, titanium stem.

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The titanium version embodies six principles of design: 1) straight and collarless, to give a tight proximal fit, minimising varus tilt and simplifying adjustment of insertion length; 2) a broad proximal profile, producing greater torque and bending resistance with lower medial stress on the cement; 3) double tapered (6° mediolateral, 2° antero-posterior) for initial even cement pressurisation and subsequent uniform stress distribution and distal engagement; 4) a smooth, contoured cross-section to minimise the concentration of stress on the cement; 5) a textured surface finish for improved cement-stem adhesion; and 6) titanium alloy (Ti6Al4V), with material advantages in strength and biocompatibility associated with low stiffness to reduce proximal stress shielding. The prosthesis was marketed as having specific advantages over Charnley and Müller-type stems, particularly with respect to transmission of stress from bone to cement. Over 40 000 have been implanted since 1985 but its use has declined, as has that of other cemented titanium stems. To our knowledge, there are no published results of the clinical outcome of this cemented stem. We therefore report the prospective clinical and radiological follow-up of 122 cemented Howse MkII or Ultima straight femoral stems with a minimum follow-up of five years.

Patients and Methods

Between March 1989 and June 1994, 116 consecutive patients had 122 primary, elective total hip replacements. All procedures were undertaken by or under the supervision of the senior author (RV). The mean age of the patients was 55 years (26 to 81) with 40 (35%) being under 50 years. The preoperative diagnosis was osteoarthritis in 104, rheumatoid arthritis in seven, fracture in three, avascular necrosis in two, pigmented villonodular synovitis in two, ankylosing spondylitis in two and an arthrodesis in two.

The same type of cemented femoral stem, the Howse II/Ultima (DePuy, Leeds, UK), was used in all cases, with a posterolateral approach. There were 32 Howse MkII modular stems and 90 Ultima stems. The femur was prepared using circular hand reamers and broaches, supplied with the Howse II/Ultima instrumentation. Broaches of increasing size were used until an appropriate fit was achieved. A corresponding stem, 0.75 mm smaller than the last broach, was chosen. Contemporary cementing methods were used in each case according to the senior author's routine; brush, saline lavage, Hardinge-type cement restrictor, pack drying, Palacos R (Schering-Plough, Reading, UK) cement, retrograde insertion with cement gun, pressurisation and late implant insertion to a predetermined mark. Five different acetabular cups were used throughout the series; the Duraloc, Trilock and Mecring without cement, and the Ultima/Howse MkII and Elite with cement. Two types of femoral head of 28 mm were used: 31 titanium, used in the early years only, and 91 cobalt-chrome. All patients received three doses of a prophylactic antibiotic, flucloxacillin.

Standard thromboembolic prophylaxis comprised compression stockings, daily low-molecular-weight heparin as an inpatient, and early mobilisation.

Outcome assessment. Deaths, revisions and details of patients lost to follow-up were recorded. Prospective clinical follow-up was undertaken by postal questionnaire six months after operation and thereafter yearly, using a modified Harris hip (MHH) score.⁸ The modification removed the points awarded for range of movement and deformity, giving in a maximum score of 91: the clinical outcome was classified as either excellent (81 to 91), good (71 to 80), fair (61 to 70) or poor (<60). A simple evaluation of outcome at the study date was also undertaken by asking patients to grade their personal satisfaction.⁹

Radiological assessment. Standard two-plane radiographs were taken postoperatively, and during follow-up. Those at five to ten years were compared with the original postoperative films when available and assessed in a standard manner for cemented femoral stems.^{10,11} Vertical subsidence of the stem was measured, to the nearest millimetre, from the tip of the greater trochanter, or the most medial point of the lesser trochanter, to the superolateral shoulder of the prosthesis.¹² The location of the zones of Gruen, McNeice and Amstutz¹³ and the width (mm) of the radiolucent lines at both the cement-prosthesis (cp) and cement-bone (cb) interfaces were recorded, as well as the presence of fractures in the cement, endosteal resorption, or osteolysis. Distal cortical hypertrophy at the tip of the stem and the total thickness of the cement mantle especially in zone 7a proximomedially, were specifically assessed. The position of the stem was not accurately measured, but in none of the cases was significant varus or valgus present. Adjustments for magnification were undertaken.^{14,15} Loosening was described as 'possible' with cb radiolucency of 50% to 99%, 'probable' with cb radiolucency of 100% or more than 5 mm of subsidence,^{12,16,17} or both. The survival and wear of the acetabular cup were not assessed in this study. A life table and cumulative survival curves were prepared using 'all revisions', 'stem revision for loosening' and 'probable radiological stem loosening', as endpoints.¹⁸

Table I. Mean (range) modified Harris hip scores in 99 patients

	Pain	Function	Total
Preoperative	10 (0 to 44)	19 (0 to 47)	30 (0 to 68)
Last postoperative (5 to 10 yrs)	38 (0 to 44)	39 (0 to 47)	76 (20 to 91)

Table II. Magnitude of subsidence in 57 patients with full radiographic records

Subsidence (mm)	Number of stems
1	2
2	9
3	7
4	1
5+	1

Fig. 2a

Fig. 2b

Radiographs (posterior view) showing stem subsidence of 5 mm at (a) 3 months and (b) at 7 years.

Results

Eleven patients (13 hips) had died from unrelated causes, five more than five years after hip replacement. Their clinical and radiological outcome was assessed from radiographs and the last available hip score, and indicated that there were no significant problems with any of these stems. From the remaining group of 109 hips, eight (7.3%) had been revised, three (2.8%) for deep infection, three (2.8%) for recurrent dislocation and two (1.8%) for acetabular problems. One patient had gross loosening of the cup and the other, a 28-year-old woman, had asymptomatic, advanced wear of the liner. The femoral stems in those hips which were revised were radiologically and surgically secure. The three cases of infection were in hips which had not been implanted in a clean-air environment.

Of the 101 remaining hips, one 58-year-old patient was lost to follow-up after five years, and five refused to attend for radiography, one of whom also declined to complete any questionnaires. Each patient in this group, however, did confirm by telephone that they were satisfied with their hip. Hence, the clinical and radiological data were complete for 95 hips at a minimum follow-up of five years (mean 7.5 years; 5 to 10 years). Patients had been treated within the NHS and privately. The original postoperative radiographs for 38 NHS patients were not available.

Clinical outcome. The mean preoperative MHH score was 30 (maximum 91 points), rising by a mean of 46 points to a final mean score of 76 (Table I). At five or more years the scores were excellent in 61, good in 13, fair in 12 and poor in 13. Good or excellent results were found in 74%. Lower scores were affected by symptoms from the contralateral hip.

During clinical evaluation at follow-up 98% of patients stated that they were satisfied with their hip.

Radiological outcome. Vertical subsidence of the stem was found in 20 of 57 patients who had a full range of radiographs available. The magnitude of the subsidence is shown in Table II. Intermediate radiographs showed that

this had been present at two years and had not progressed. Only one prosthesis had moved 5 mm or more (Fig. 2).

Radiolucent lines at the cp interface were seen in 14/95 (14.7%). These were in zone 1 and, in one, extended into the proximal aspect of zone 2 (Fig. 3). In ten, the width of the lucent line was 1 mm and in four it was 2 mm. Some of these lines were present on early postoperative radiographs and others appeared by two years. With appropriate correction of magnification, the lucent lines had not progressed at the five- to ten-year follow-up. Radiolucent lines at the cb interface were present in two hips. In one this was confined to zone 1, but in the other it covered more than 50% of the interface (Fig. 4) and this stem was probably loose. The remainder had no radiolucent lines in zone 1 or elsewhere

Fig. 3a

Fig. 3b

Radiographs showing radiolucent lines at the cp interface in zone 1 and proximal portion of zone 2 a) after operation and b) at 6.5 years.

Fig. 4a

Fig. 4b

Radiographs showing radiolucent lines at the cb interface a) after operation and b) at eight years.

Fig. 5a

Fig. 5b

Fig. 5c

Radiographs showing preservation of radiological interface contact, with absence of radiolucent lines, in a) zone 1 after operation, b) in zone 1 at eight years and c) in all zones at seven years.

(Fig. 5). There were no obvious fractures of the cement.

Five of 95 stems (5.3%) had some calcar resorption (zone 7a) or osteolysis. There was one with a 15 mm endosteal cyst in zone 7b which appeared at six years but had not changed on review the following year (Fig. 6). The mean thickness of the proximomedial cement mantle, as measured from the postoperative radiographs, was 4 mm (2 to 10). The thickness of the cement mantle elsewhere was 2 to 3 mm. Seven of 57 patients (12.2%) showed mild distal cortical hypertrophy (1 to 3 mm). Overall, two hips were classified as 'probably' loose. Figure 7 shows the survival curves

using 'all revisions' and 'stem revision for loosening' or 'probable radiological loosening' as endpoints (Table III).

Discussion

We are encouraged by the absence of any femoral revisions, or definite indications to do so for aseptic loosening after a minimum of five years. This is an improvement on figures reported previously for cemented titanium stems^{6,7} and comparable to the best implants available at this stage of follow-up.^{17,19,20} Patient evaluation, pain and function

Fig. 6

Radiograph showing an endosteal cyst which appeared at five years but has remained static since.

scores are also comparable to those of other successful implant designs at this stage of follow-up. The difference in clinical outcome between the subjective assessment and the modified hip score is explained by variations in mobility not necessarily related to the patient's satisfaction with the hip. The mid-term radiological results of this stem may be interpreted in several ways, depending on the criteria for loosening.^{16,19,21} Although vertical subsidence of the stem was seen in a significant proportion of those with a full radiographic series, only one had subsidence of more than 5 mm. According to the margin of error in the measurement of subsidence,¹² only values of greater than 5 mm are usually considered to be true subsidence. We are of the opinion, however, that subsidence seen in others in the series also represents true subsidence, but the significance of this small degree of change is uncertain. Given the similarities in design to the Exeter and Müller straight stems, the observed subsidence may not predict early failure.^{19,22} It is possible that the subsidence in all except two

Table III. Life table for the Howse/Ultima cemented titanium stem using 'all revisions' and 'probable loosening' as endpoints

Years after operation	Number at start	Success within that year	Lost to all follow-up	Lost to radiological follow-up	Died	Cumulative survival (all revisions) %	Probable radiological loosening	Cumulative stem survival (%)
0 to 1	122	-	0	0	1	98.4	0	100.0
1 to 2	119	-	0	0	3	98.4	0	100.0
2 to 3	116	-	0	1	2	96.7	0	100.0
3 to 4	112	-	0	-	1	95.7	-	-
4 to 5	110	-	0	-	1	94.8	-	-
5 to 6	108	29	1	2	2	93.8	0	-
6 to 7	75	27	0	0	1	93.8	0	-
7 to 8	47	26	0	1	2	93.8	1	97.0
8 to 9	19	11	0	0	0	(87.2)	1	(89.5)
9 to 10	7	7	0	1	0	(87.2)	0	(89.5)

Fig. 7

Graphs of percentage survival rates using the endpoints of all revisions, stem revision for loosening, and radiological 'probable stem loosening'.

hips in our series is related to cementation and engagement of the double-tapered wedge, rather than to loosening. However, the Howse MkII/Ultima differs from the Exeter in both material and surface finish. Its textured finish and titanium composition are associated with less subsidence and engagement than polished stainless steel. Results for the Exeter prosthesis with a matt surface,^{17,19} perhaps similar to this stem, were not as good as those with a polished stem, possibly due to impediment of distal movement and continuous cement loading. The subsidence seen could represent debonding rather than engagement. If this is the case we are unable to explain why these stems have not progressed to loosening yet, but accept that they may do so in the near future.

Several papers reporting outcomes for cemented titanium stems, including the 3M Capital hip,³ describe the radiolucent gap at the cp interface in zone 1 as indicative of debonding of cement and prosthesis. Debonding is considered to be the first stage of failure of a cemented, non-polished, titanium-alloy stem, leading to accelerated loosening from abrasion debris, fretting and crevice corrosion.²³ The problems associated with the Capital hip were attributed to overload of a narrow, proximomedial cement mantle (1 mm) leading to fracture of the cement and loosening, preceding the production of wear debris.³ The mean proximomedial thickness of cement in our patients was 4 mm, within the optimum suggested range (2 to 5).²⁴ It is possible that the 15% of our cases with cp radiolucency in zones 1 and 2 are in the early stages of failure, but at a mean follow-up of 7.5 years there was no evidence of progression. The low rates of resorption of the calcar and distal cortical hypertrophy suggest that this implant achieved one of its original aims of its design in reducing proximal stress shielding.

We agree with the conclusion of a study of the BiContact, straight, polished, titanium stem at seven years⁴ that the design of the prosthesis is as important as the materials used. Our study has shown that this titanium stem is satisfactory so far, but we remain concerned about debonding and progression to loosening. Therefore, these patients will be kept under regular review and the ten-year results reported at a later date.

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