Long-term survival of a cemented titanium-aluminium-vanadium alloy straight-stem femoral component

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We present a retrospective series of 170 cemented titanium straight-stem femoral components combined with two types of femoral head: cobalt-chromium (CoCr) alloy (114 heads) and alumina ceramic (50 heads). Of the study group, 55 patients (55 stems) had died and six (six stems) were lost to follow-up. At a mean of 13.1 years (3 to 15.3) 26 stems had been revised for aseptic loosening. The mean follow-up time for stable stems was 15.1 years (12.1 to 16.6).

Survival of the stem at 15 years was 75.4% (95% confidence interval (CI) 67.3 to 83.5) with aseptic failure (including radiological failure) as the end-point, irrespective of the nature of the head and the quality of the cement mantle. Survival of the stem at 15 years was 79.1% (95% CI 69.8 to 88.4) and 67.1% (95% CI 51.3 to 82.9) with the CoCr alloy and ceramic heads, respectively. The quality of the cement mantle was graded as a function of stem coverage: stems with complete tip coverage (type 1) had an 84.9% (95% CI 77.6 to 92.2) survival at 15 years, compared with those with a poor tip coverage (type 2) which had a survival of only 22.4% (95% CI 2.4 to 42.4). The poor quality of the cement mantle and the implantation of an alumina head substantially lowered the survival of the stem.

In our opinion, further use of the cemented titanium alloy straight-stem femoral components used in our series is undesirable.

Titanium alloys are widely used for the manufacture of orthopaedic implants in total hip replacement (THR), for both cemented and cementless prostheses. The properties of titanium alloys include good biocompatibility, low modulus of elasticity and resistance to fatigue and corrosion.1 The ability to accept bone on-growth makes titanium alloy favourable for cementless fixation. According to the literature, cementless stems produce less osteolysis and suffer fewer mechanical failures than similar cemented stems.2-4 However, the use of titanium for articulating surfaces is not recommended because of their low wear resistance.5

Cemented titanium alloy monoblock stems were introduced in the 1970s4 and initial results proved encouraging. Sarmiento and Gruen7 reported good short-term radiological results for cemented titanium alloy straight stems. Additional reports for other cemented titanium alloy stems with cobalt-chromium (CoCr) heads quote survival rates of 97% at 7.5 years and 10 years.8

Straight Müller stems (Proteck, Freiburg, Germany) made of titanium-aluminium-niobium (TiAl16V4) with a ceramic head had a revision rate of 2.5% at a mean of six years’ follow-up.10 The patient’s weight was considered to be a factor affecting loosening. Good long-term results with 87.3% survival at 20 years were reported with 89 Ceraver Osteal (Ceraver Osteal, Roissy, France) polished titanium-aluminium-vanadium (TiAl16V4) cemented stems when combined with an alumina-on-alumina coupling.11

Maurer et al12 reported increased loosening of cemented straight Müller stems made of titanium alloy compared with cobalt-nickel-chromium (CoNiCr) alloy stems at a median follow-up of 7.7 years, and noted that smaller titanium stem sizes, male gender and increased physical activity were associated with an increased risk of failure. Failure rates of 4.5%,13 and 9%14 at five years and 11.5% at 5.5 years,15 have been reported for titanium alloy cemented stems. The report from Jacobsson et al14 found that most failures occurred with smaller stems, especially in heavier patients, implicating the influence of the modulus of elasticity. The results of the Capital modular titanium alloy stems (3M, Loughborough, United Kingdom) with either CoCr or nitride-coated titanium heads were poor.
with loosening of 16% of the femoral components at a mean follow-up of 26 months.16

The cemented modular Müller self-locking titanium alloy straight stem was introduced in 1984.12 We have retrospectively examined the outcome of 164 self-locking titanium alloy straight stems combined with either a CoCr alloy or an alumina head, implanted in patients between June 1986 and June 1988.

Patients and Methods
During the study period 386 THRs were performed in our hospital, of which 170 consecutive cemented titanium alloy straight Müller-style stems were implanted. Although 62 patients had bilateral THRs during this period, none had self-locking stems bilaterally. Six patients were lost to follow-up, leaving a final study group of 164 patients (164 hips).

The mean age of the patients was 64.9 years (48 to 80), with three less than 50 years old at the time of operation. There were 114 women and 50 men. The pre-operative diagnosis was primary osteoarthritis in 139 hips, rheumatoid arthritis in six, avascular necrosis in eight, osteoarthritis secondary to dysplasia in four, and post-traumatic osteoarthritis in seven. There were 80 left and 84 right THRs.

The self-locking stem (Lima-Lto, Udine, Italy) is a Müller-style cemented straight stem made of a titanium alloy (TiAl6V4) which relies on a biomechanical self-locking mechanism. The surface of the stem is roughened by grit-blasting. The surface roughness of retrieved components was measured at three sites on the surface with a diamond stylus profilometer using a 2 mm evaluation length and a 0.25 mm cut-off length (Taylor-Hobson Form Talysurf Series 2; Leicester, United Kingdom). The mean surface roughness (Ra) was 1.72 µm (1.30 to 2.5). The tapered stem is flattened anteroposteriorly and primary stability is achieved by impaction into the broached femoral canal. Introduction of the stem and the extrusion of excess cement is facilitated by a groove on the anterior and posterior surfaces (Fig. 1). The stem is available in seven different sizes, with a 14/16 morse taper and can be coupled with a 32 mm diameter cobalt-based alloy (CoCr) or an alumina (Al2O3) ceramic head. The polyethylene cemented acetabular components obtained from the same manufacturer were sterilised in ethyleneoxide.

All the size options were used in various patients. The 7.5 mm stem was used in four patients, the 10 mm in 42, the 11.5 mm in six, the 12.5 mm in 44, the 13.5 mm in 16, the 15 mm in 40 and the 17.5 mm in 12. CoCr alloy heads were used in 114 and alumina heads in 50 patients. Cementing was performed using Palacos R cement (Schering Plough, Luzern, Switzerland) without antibiotic, using a distal bone plug and retrograde filling without pulsatile
lavage. The operations were performed by five surgeons using either a lateral or an anterolateral approach.\textsuperscript{17,18}

The standard peri-operative prophylactic antibiotic regimen consisted of three 1 g doses of intravenous cefuroxime, and 5000 international units of heparin were administered twice daily for post-operative antithrombotic prophylaxis until the time of discharge. Post-operative rehabilitation consisted of range of movement and isometric exercises on the first to the third post-operative days, and partial weight-bearing with two crutches on the fourth post-operative day. Full weight-bearing was allowed three months after the operation. None of the surgeons originally involved in implanting the prostheses were involved in the final follow-up evaluation.

Clinical evaluation. The patients had periodic two- to three-year follow-up examinations. Patients who had been absent from review were traced via the Health Service Central Register.

All patients were invited for a final examination performed by one of the authors (SK). Pre- and post-operative pain, function, and range of movement were graded using the Harris Hip score (HHS).\textsuperscript{19} Patients unwilling to attend the examination were evaluated by their personal physicians to obtain information about the status of their implant and to calculate the HHS. For these patients, the date of the last radiological examination in our institution was used for survival analysis. For patients who underwent re-operation elsewhere we collected data concerning the revision operation from the performing institution.

Radiological evaluation. An anteroposterior radiograph of the hip was made immediately after the operation and at each subsequent visit to the hospital. The first post-operative radiograph was used to grade the quality of the cement mantle. The self-locking philosophy (close fit of the stem to the lateral and medial cortical bone in the frontal plane) rendered the cement mantle non-circumferential,\textsuperscript{20} and so the grading system of Barrack, Mulroy and Harris\textsuperscript{21} could not be applied. We divided the stems into two groups according to the cement mantle around the tip: type 1, the cement covers the entire tip of the prosthesis and type 2, a part or the whole tip remains uncovered. We also recorded the position of the stem. If more than a 5° difference was measured between the axis of the stem and the femoral canal, we graded the stem either varus or valgus. Otherwise the stem was graded as neutral.

Anteroposterior radiographs taken at the last follow-up evaluation were examined for signs of stem loosening. Loosening was defined as subsidence or tilting of the femoral component, fracture of the cement or the stem, or the appearance in serial radiographs of a progressive radiolucent line at the bone-cement interface. A continuous radiolucent line along the entire interface was considered definitely loose, whereas possible loosening was indicated by a radiolucent line that encompassed between 50% and 100% of the circumference of the stem on the anteroposterior radiograph.\textsuperscript{22} We considered definite and probable loosening as failures of the arthroplasty and these were used as the end point in survival analysis.

The extent of osteolysis was graded according to the classification system by Goetz, Smith and Harris\textsuperscript{23} and recorded according to the seven zones around the stem delineated by Gruen, McNeice and Amstutz.\textsuperscript{24} Heterotopic ossifications were classified using the method of Brooker et al.\textsuperscript{25}

Statistical analysis. The survival analysis of the stems was estimated using the method of Kaplan and Meier.\textsuperscript{26} Revision for aseptic loosening and aseptic radiological failure of the stem (definite and probable loosening) according to
Harris\textsuperscript{19} were defined as the end-points. Age at the time of operation, diagnosis, body mass index, size of the stem, type of head and type of cement mantle were analysed to evaluate the revision rate using the log rank test.\textsuperscript{27} The association of continuous and ordinal variables with survival was also estimated using the Cox proportional hazards model.\textsuperscript{28} A p-value of < 0.05 was considered to be significant.

Results
Clinical results and complications. Septic loosening occurred in three of the 164 hips (1.8%), leaving 161 to be analysed for aseptic loosening. All deep infections were treated by removal of the components. A total of 55 patients had died before either revision or the latest follow-up examination. The surviving 106 patients have been followed for a mean of 15.1 years (12.1 to 16.6). The mean pre-operative HHS was 34 points (10 to 48), and the mean post-operative HHS for non-revised hips was 89 points (68 to 100). Clinical assessment was performed on five patients by their personal physicians. These patients were reported to be asymptomatic.

All patients with stable prostheses were sedentary, with low levels of physical activity. However, three were bedridden, two because of senile dementia and one because of a cerebrovascular accident.

There was one transient femoral nerve palsy and one permanent peroneal nerve palsy. In one patient a fatal pulmonary embolism occurred in the fourth post-operative week. Six deep-vein thromboses were diagnosed clinically.

Re-operations. Revision for aseptic loosening of the stem was undertaken in 26 patients, four in another institution. The mean time to revision of the femoral component was 13.1 years (3 to 15.3). Spontaneous breakage of an alumina head resulted in the first revision, 36 months after the index operation, requiring exchange of the whole prosthesis owing to damage to the trunnion.

Radiographical analysis. Based on the first post-operative radiograph, 140 hips had a type 1 cement mantle (87%) and 21 (13%) had type 2. The stem was in valgus in 11 hips (7%), in neutral in 145 hips (90%), and in varus in five (3%).

At the time of the final follow-up, of a total 106 patients (106 stems) who were alive, 30 (28.3%) had stems which were definitely loose. Five patients without symptoms with stable stems refused to attend for radiological examination and the remaining 71 were available for radiological examination. Osteolyses were observed in 40 (56.3%), and was extensive in one (1.4%), of intermediate severity in five (7%) and mild in 34 (47.9%). The incidence of osteolysis was highest in Gruen zones VII (36 stems; 50.7%) and I (14 stems; 19.7%).

Of the 106 patients, heterotopic ossification was found in 29 (27.4%) of which 18 (17%) were rated as Brooker\textsuperscript{25} grade I, four (3.8%) as grade II, six (5.7%) as grade III and one (0.9%) as a grade IV. No evidence of heterotopic ossification was present in 77 hips (72.6%).

Survival analysis. Cumulative survival for the aseptic failure of the stem was 93.5% (95% confidence interval (CI) 89.5 to 97.5) at ten years and 75.4% (95% CI 67.3 to 83.5) at 15 years (Fig. 2). All stems graded as definitely loose according to Harris\textsuperscript{19} were included as failures. One of the stems was revised for progressive osteolysis in zone IV with severe cortical thinning, even though it remained well fixed.

The survival of the 111 stems with a CoCr head at ten years was 96.8% (95% CI 93.3 to 100) and 79.1% (95% CI 69.8 to 88.4) at 15 years, whereas survival of the 50 stems using alumina heads was 85.9% (95% CI 74.4 to 96.4) at ten years and 67.1% (95% CI 51.3 to 82.9) at 15 years (Fig. 3). The difference in survival between the two groups was statistically significant (log rank test, p < 0.05).

Stems with an adequate cement mantle (type 1) yielded better results than those with an inadequately cemented tip (type 2). A difference in survival did not appear until the tenth post-operative year, after which the survival of those stems with a type 2 cement mantle declined rapidly (Fig. 4). Stems with a type 1 cement mantle had a 95.3% (95% CI 91.2 to 99.4) and 84.9% (95% CI 77.6 to 92.2) survival rate at ten and 15 years, respectively, whereas stems with a type 2 cement mantle had only an 83.5% (95% CI 66.4 to 100) and 22.4% (95% CI 2.4 to 42.4) survival rate at ten and 15 years, respectively (log rank test, p < 0.005) (Fig. 4).

Further analysis revealed that adequately cemented stems with CoCr heads had the best survival (Table I). The lowest survival was observed for poorly cemented stems with alumina heads. All stems with a type 2 cement mantle and alumina heads failed after 15 years.

Age at the time of operation, diagnosis, body mass index, size of the stem, type of head and type of cement mantle were analysed using the Cox proportional hazards model. A statistical correlation was found between the grade of cement mantle (p < 0.005) and the type of femoral head (p < 0.05), and revision of the stem. Other factors did not affect the survival of the stem.

Discussion
The first Müller straight stem made of titanium alloy was introduced in 1984. Shortly afterwards, reports of poor results of the titanium alloy stems, particularly the titanium monoblock stems, began to appear in the literature.\textsuperscript{7,15,29} However, the many designs of cemented titanium stems makes comparison of survival rates difficult, albeit some good long-term results for cemented titanium alloy stems have been published\textsuperscript{8,30} one of which showed survival of stems with CoCr heads was 97% at 11 years.\textsuperscript{9} Coupling of one titanium alloy stem with an alumina head had a 96% survival probability at nine years, but the same stem with a zirconium head had a survival rate of only 63% at eight years.\textsuperscript{30} Polished and titanium oxide-coated cemented stems with alumina-on-alumina coupling achieved excellent results, with almost 98% survival at eight years\textsuperscript{31,12} and 87.3% survival at 20 years, comparable with the results of Charnley stems used in the 1980s.\textsuperscript{11} When
alumina-on-alumina coupling is used there is virtually no osteolysis or wear present.\textsuperscript{11,31} The same stem with an alumina-on-polyethylene coupling had excellent (97.9\%) survival at ten years, but with femoral osteolysis present in 35\% of cases.\textsuperscript{32} To the best of our knowledge there are no previously published results regarding the long-term survival of cemented grit-blasted titanium-alloy stems with alumina or CoCr-alloy heads and polyethylene acetabular components.

In our series the cumulative survival of the stem at 15 years was 75.4\%. Two factors were correlated with a higher rate of loosening, namely a poor cement mantle and a ceramic head. A combination of a well-cemented stem with a CoCr-alloy head achieved the best results (88.8\% at 15 years).

Poor cementing has been reported elsewhere to adversely affect long-term survival of the stem,\textsuperscript{20,33,34} and it has been stated that maximal stability of the stem requires an ideal thickness of 3 mm to 4 mm of cement.\textsuperscript{35} A tapered straight stem design prevents such cement thickness, particularly laterally and medially in the frontal plane where the prosthesis is in close contact with the femur. Under these circumstances the cement mantle is neither uniform nor circumferential,\textsuperscript{20} as is the case in other successful implants. Also, an abnormally high micromovement occurs when the cement mantle is thinner than 2 mm and the stem is made of a titanium alloy.\textsuperscript{35} In the absence of in vitro studies on the stability of the straight stem, we can only speculate that an uneven cement mantle and the lack of cement at the tip of the stem further diminishes its stability. This can lead to a faster debonding of the stem at the stem-cement interface and cause accelerated development of the loosening cascade, as described by Willert et al.\textsuperscript{36} Straight stems without a centraliser show the highest risk of having a thin cement mantle in Gruen zone XII.\textsuperscript{37}

Stems with an alumina head showed a significantly lower survival probability than those with a CoCr femoral head. This was not in accord with accepted theory.\textsuperscript{38} However, not all clinical data have shown the superiority of ceramic heads.\textsuperscript{38,39} Hasegawa et al\textsuperscript{39} published a survival at 15 years of only 65\% for a stem with an alumina head. Scanning electron microscopy revealed wear debris stuck to the gaps on the bearing surfaces of the heads, which may induce third-body wear of polyethylene.\textsuperscript{39}

Titanium alloys are among the most biocompatible of materials, but can be susceptible to abrasion and fretting wear. The surface finish of the titanium alloy is known to have an important effect on the performance of the prosthesis. In reports comparing rough and smooth or polished but otherwise similar stems, the outcome has been poorer in the rough finished components.\textsuperscript{12,40,41} The titanium alloy stems with a roughened surface may have contributed to greater fretting wear at the cement interface than smoother titanium alloy surfaces and hence the debris released might promote aseptic loosening.\textsuperscript{5,29,42,43} Less tolerance of micromovement and high generation of metal, cement and polyethylene particles has been observed for a number of titanium alloy stems with roughened surfaces.\textsuperscript{2,15,16,44-46} This must be compared with the good results published for a smooth TiAl\textsubscript{6}V\textsubscript{4} stem combined with a CoCr-alloy head,\textsuperscript{8} and a polished TiAl\textsubscript{6}V\textsubscript{4} stem covered with TiO\textsubscript{2} and combined with an alumina head.\textsuperscript{30,32}

Micromovement because of inappropriate contact between the taper lock and the hard ceramic head can cause fretting wear in the modular prostheses and produce additional metallic debris.\textsuperscript{47} Although not observed in our series, excessive wear of the neck in the same titanium stem design coupled with an alumina head has been described and the phenomenon attributed to a slight mismatch between the size and cone angle of the femoral head and taper lock.\textsuperscript{43} Titanium particles deposited on an alumina ceramic head can cause high polyethylene wear.\textsuperscript{48} When using titanium alloy stems, the stiffer alumina ceramic head may cause more damage to the femoral neck than the softer CoCr alloy head, and produce more metallic debris. We assume that all these observations could provoke enhanced third-body wear when an alumina head was used, leading to excessive polyethylene wear and premature loosening.

Moreover, the quality of alumina ceramics used in our series from 1986 to 1988 was lower than that of contemporary ceramics. One of the important characteristics which has changed significantly since then is the grain size. At that time alumina ceramic with a grain size of 7 \(\mu\)m or less was used.\textsuperscript{49} In the 1990s changes in the manufacturing process produced smaller grain sizes with a maximum of 4.5 \(\mu\)m.\textsuperscript{50} Reductions in grain size achieved with contemporary alumina ceramics is, therefore, desirable in order to reduce the size of the gaps between the grains into which debris might lodge and cause third-body wear.

The clinical results of the cemented titanium alloy straight stem used in our series are dependent on the quality of the cement mantle and the type of femoral head used. In cases where the tip of the stem is not fully covered with

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**Table I. Survival of the stem (with 95% confidence intervals (CI)) at ten and 15 years post-operatively as a function of the head material and quality of the cement mantle**

<table>
<thead>
<tr>
<th>Stem Type</th>
<th>Cement Mantle</th>
<th>Survival (%)</th>
<th>Survival (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10 yrs</td>
<td>15 yrs</td>
<td>10 yrs</td>
</tr>
<tr>
<td>CoCr head</td>
<td>Type 1</td>
<td>97.5 (95.8 to 99.2)</td>
<td>88.8 (84.7 to 92.9)</td>
</tr>
<tr>
<td></td>
<td>Type 2</td>
<td>92.3 (84.9 to 99.7)</td>
<td>28.3 (15.3 to 41.3)</td>
</tr>
<tr>
<td>Alumina</td>
<td>Type 1</td>
<td>97.5 (95.8 to 99.2)</td>
<td>88.8 (84.7 to 92.9)</td>
</tr>
<tr>
<td></td>
<td>Type 2</td>
<td>92.3 (84.9 to 99.7)</td>
<td>28.3 (15.3 to 41.3)</td>
</tr>
</tbody>
</table>

* CoCr, cobalt chromium
Recent studies demonstrated superior results of CoCr-alloy cemented stems with the same stem design over titanium alloy stems, while better results were obtained with cementless stems than with cemented titanium stems of the same design. The cumulative survival of 75.4% for the stem used in our series is unacceptable low. Therefore, it is our belief that further use of the cemented titanium alloy grit-blasted stems is undesirable. Since 1996, in our institution titanium-based stems have only been used for cementless fixation.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References


