# Clinical and biological assessment of cemented titanium femoral stems: an 11-year experience.

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# Clinical and biological assessment of cemented titanium femoral stems: an 11-year experience

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**Abstract**

This study prospectively assessed the outcome of 134 cemented titanium stems and serum ion levels. The stems were smooth and collarless with circular cross-sections.

At endpoint, only one stem revision was performed for aseptic loosening, and two were planned due to subsidence superior to 5 millimetres. Non-progressive radiolucencies in zones 1 and 7 were observed in 16 hips at the cement-interface, without osteolysis. Median serum titanium concentrations were below the detection limit (30 nmol/l) except in patients with failed stems.

The overall stem survival rate was 97.7% at a mean follow-up of 9 years, which is comparable to other series of cemented stems. The protective layer of titanium oxide coating the stem and a thick cement mantle may help resist aseptic loosening.

**Key words:** titanium, total hip prosthesis, corrosion, osteolysis, femoral stem

## Introduction

Titanium and its alloys are commonly used for orthopaedic implants such as screws, plates, and spinal implants. This success is explained by the mechanical and biological properties of these materials such as resistance to fatigue, low elasticity modulus to reduce stress shielding, and bio inertness in a physiological environment [1,2]. Despite these properties, the use of polished cemented titanium stems is still debated [3-5]. Titanium stems are thought to be highly sensitive to corrosion and micromotion leading to early aseptic loosening [4,5,6].

Like other metallic orthopaedic implants, titanium stems can release metal debris and ions from their coated surface that may also contribute to titanium stem failure [7-11]. Several previous studies investigated ion and particle release into the biological fluid from joint replacement, but to the best of our knowledge no series concerning cemented titanium stems are available [12-15].

In this prospective study, we hypothesized that satisfactory results could be reached with cemented smooth titanium stems that are oval in section. In addition, the titanium ions released into the serum from the stems was measured up to the last time-point, in both unilateral and bilateral hip replacements, to monitor the behaviour of the stems.

## 1 Materials and methods

***Demographic data*****:** From January 1997 to December 2000, we prospectively followed a consecutive series of 109 patients who underwent primary total hip replacements performed at our institution (134 joint replacements/ 25 bilateral). All patients provided informed consent for the long duration of this prospective clinical and biological study. They received complete information, including the goals and procedures for blood sampling.

The inclusion criteria were strict; patients with orthopaedic titanium implants other than their hip stem, professional or dental exposure to titanium, previous hip conservative surgical procedures, or renal disease were excluded. Additionally, all patients enrolled were under 60 years of age at the time of surgery. In our practice, this represented less than 20% of all primary total hip arthroplasty performed during the study period.

The average follow up was 9 years, with follow up ranging from 7 to 11 years. The age at the time of arthroplasty ranged from 30 to 60 years (mean age: 54 years). Fifty-three females and 56 males were included. Sixty eight right hips were treated, and 66 left hips. Etiologies were essentially symptomatic stage of osteonecrosis or primary arthritis. Patients were evaluated preoperatively and followed-up with clinical and radiological examinations at regular intervals. Hip function results were rated according to the Harris Hip Score grading system in the preoperative period and latest follow up [16].

***Prostheses****:* The cemented femoral stem was collarless, oval in cross section, and straight (Alizé® Fournitures Hospitalières, Quimper, France). The implant was made of titanium alloy (TiA16V4) with a polished surface coated with titanium oxide (TiO2) obtained by anodization [17,18]. The thickness of the titanium oxide layer was 1/10000 micron. Six different sized stems were available.

This modular stem was combined with a 28 millimeter (mm) Metasul® femoral head (Centerpulse-Zimmer, Warsaw, Indiana, U.S.) using a 12 – 14, 5°43 taper.

Tapers were inspected individually before micro threading, using an electro pneumatic system (HIGH PRESSURE ELECTRONIC PNEUMO TRANSDUCER 150015, Solex Metrologie, La Boisse, France) for the taper angle (precision, 1 minute), the diameter at the base, and the diameter at the summit (precision, 1 micron). This inspection was counter-checked by a unit control on a tridimensional machine with 1-micron precision. The micro threading was inspected using a projected side view with a 20x enlargement for the pace, profile, and dimension of the threading (Pexit 14 VS Profile Profector, Pixit Dorsey Gage, Cambridge, UK). Compatibility between cones and heads were controlled and guaranteed by the manufacturers. All of the sockets were "sandwich" cemented Metasul® cups (Weber cups, Centerpulse-Zimmer, Warsaw, Indiana, U.S.). Palacos Genta® cement (Scherring Plough, Brussels, Belgium) was used to cement both components in all cases.

***Surgical technique:*** All procedures were performed following the standard procedure at our institution via an antero-lateral approach on a Judet orthopaedic table [19]. In order to obtain a complete and thick cement mantle, the canal was over-reamed by 2 mm. Then the femoral canal was washed, brushed, and distally occluded by a resorbable femoral plug (Synplug®, Zimmer, Warsaw, Indiana, U.S). The cement was inserted retrogradedly using a gun.

***Radiological evaluation and clinical assessment***: Anteroposterior (AP) and lateral radiographs of each hip were available before and immediately after surgery, 6 weeks after discharge from the hospital, and at 3 months, 6 months, 1 year, and then yearly thereafter.

We defined radiographic loosening of the cup as the presence of radiolucent lines measuring at least two millimeters according to DeLee-Charnley zones, axial cup migration of > 5 mm, or > 5° of change in cup inclination on the AP radiographs of the pelvis [20].

Parameters investigated on the femoral side included presence and progression of radiolucent lines according to Gruen et al, calcar resorption or atrophy, subsidence, periprosthetic osteolysis, and cortical hypertrophy [21]. Loosening of the stem was defined as a migration exceeding 3 mm or a continuous radiolucent line greater than 2 mm. Heterotopic ossifications, if present, were graded according to Brooker et al. [22].

***Titanium serum level determination*****:** In order to determine titanium release from the femoral stem, dosages were determined in two patient groups: those with unilateral replacements and those with bilateral replacements. Blood samples were taken just before implantation and at 3 months, 6 months, 1 year, and then yearly thereafter until the last end point was reached.

To avoid metallic contamination, blood samples were drawn using a sampling kit specifically dedicated to trace element determination: a needle for S-Monovette® (ref. 85.1162.400) and 7.5 mL S-Monovette® Lithium Heparin for Trace Metal analysis (ref. 01.1604.400) from Sarstedt (Marnay, France). Two Monovettes were sampled and numbered in sampling order. After centrifugation, aliquots of plasma were placed in metal-free plastic tubes (2 tubes/sample) and frozen at – 20°C. All metal measurements were performed on two samples in order to control for any contamination.

Titanium was measured in blood plasma diluted by Inductively Coupled Optical Emission Spectrometry (ICP-OES) on a JY24 spectrometer® (Jobin Yvon, Longjumeau, France). The detection limit (DL) was 30 nmol/L of plasma. Concentrations under the DL were set at half the DL value (15 nmol/L) to allow for statistical calculation by convention.

Meanwhile, chromium and cobalt were also determined in the serum from the same samples.

Cobalt and chromium were determined by Electrothermal Atomic Absorption Spectrometry on a simultaneous SIMAA 5100 spectrometer® UNTIL 2004, and then 6100 (Perkin Elmer, Courtabœuf, France). The detection limits were 3 nmol/L for cobalt and 1 nmol/L for cromium. Seronorm Levels I and II (Sero, distributed by Ingen, Rungis, France) were analyzed in each analytical run as internal quality controls. The serum titanium level was expressed in nmol/L (1 nmol/L = 47.9 ng/L=0.0479 µg/L =0.0479 ppb).

**Statistical analysis**

Survival analyses were calculated according to the Kaplan-Meier method. Loosened stems (revised or not) were considered as end points. For each time-point, the median as well as the twenty-fifth and seventy-fifth percentiles of serum titanium concentrations were calculated in the unilateral and the bilateral replacement groups. Continuous data were tested for normal distribution using the Kolmogorov-Smirnov test. Normally distributed data were analysed with t-tests.

In order to test for any difference between small stems and larger ones regarding subsidences or radiolucencies, we selected two subgroups of stems within the unilateral hip replacement group. The first subgroup was composed of stems with a size of 1 to 3. In the second subgroup, the sizes of the stems ranged from 4 to 6. A non-parametric Wilcoxon test was performed to detect any difference in these 2 subgroups. Statistical significance was set at $p < 0.05$.

All statistical analyses were carried out with PRISM 3 **(**GraphPad Software, Inc,San Diego, U.S.).

## Results

***Survival rate*** (Fig 1): Overall stem survival (loosened, revised or not) was 97.7% at a mean follow-up of 9 years (95% CI, 95.4%–99.5%).

***Complications:*** Two recurrent dislocations required revisions due to impingement between the titanium femoral neck and the edge of the chromium-cobalt insert of the cup, 1 month and 6 months, respectively, after the implantation. At the time of revision, the components were not loosened; black staining of the joint space was observed due to titanium release from femoral neck notches. In both cases, the patient's serum titanium levels were high due to the release of titanium from the femoral neck lesions. All of the components were revised with the same polished cemented stem and a cemented polyethylene cup.

Eight revisions were performed for loosened Metasul® cemented cups with radiolucencies superior to 2 millimeters and osteolysis.

In the first 3 cases, hips were revised using new metal-on-metal or polyethylene cups with respect to the femur.

Considering the high cobalt-chromium serum levels and the local conditions in 2 revision cases, the bearing surfaces were converted to alumina-on-alumina using a new cementless stem. In last three cases, the hips were revised using alumina-on-alumina with sleeved femoral heads (Ceramtec, Plochingen, Germany) as the taper and the stem fixation was intact.

One case of progressive subsidence due to poor cement technique required a unipolar femoral revision using a cementless stem, 5 years after implantation.

One prosthesis was revised due to persistent and unexplained pain. At the time of the revision, we found no abnormalities apart from a massive and macroscopic metallosis of the joint. The cobalt serum level was increased more than 20-fold compared with the detection limit. The implants were changed, and new metal-on-metal bearing surfaces were again implanted, but did not resolve the symptoms.

***Clinical results:*** The mean Harris Hip Score improved significantly ($p<0.05$) from 39 (range 15-68) preoperatively to 91 (range 83-97) at the ultimate follow-up.

***Radiological results:*** We observed 4 cases with osteolysis and 16 cases with evolutive radiolucencies at the cement-bone interface on the acetabular side.

Three stem subsidences due to poor cement technique were identified on the early postoperative radiographs. Two were inferior to 10 mm and slowly evolutive with time requiring potential revision in the future (Fig 2). The third was of more concern (subsidence superior to 10 mm) and was revised, as mentioned previously. It was associated with osteolysis in zone 6 of Delee and Charnley [20].

Non-progressive femoral radiolucent lines were present in zone 1 at the cement-prosthesis interface in 10 hips, and had spread into zone 7 in six more hips. We did not observe femoral hypertrophic reaction around the distal stem or calcar resorption.

No statistically significant difference ($p > 0.05$) was observed between small and large titanium stems regarding subsidences ($p=0.74$) and radiolucency frequencies ($p=0.96$).

Periarticular ossification, according to the method of Broocker et al. [22], was observed in 30% of the hips. Eight percent were type III and IV.

***Serum titanium concentration:*** In both the unilateral and bilateral replacement groups, the median titanium concentration was constant and within range, and always below the detection limit of 15 nmol/l (Tables 1 and 2).

Failed stems, as shown in Table 3, caused the highest titanium serum levels at their end-point in the series, and titanium levels were much higher than the detection limit ranging from 196 to 1274 nmol/l.

Titanium serum levels remained below the detection limit in cases with loosened cups.

**Discussion**

Use of cemented titanium alloy stems remains extremely controversial and has caused some surgeons to renounce them [3-5]. Some series showed a large rate of early aseptic loosening, usually when the stem was rough and cemented [4-6,23-25]. Jergesen reported an 11.5% aseptic loosening rate in a series of 118 total hip replacements at a mean follow-up of 66 months [6]. In the Scholl E series, the revision rate was 88% at a mean of 6.6 years due to loosened stems, and 30% of cases showed a significant osteolysis of the proximal femur [26]. Two factors are suggested that explain the early stem failure for the cemented titanium solutions. Firstly, the high elasticity of titanium and the excessive stresses in the mantle of the cement could lead to micromotion and debonding of the stem [4]. Micro-movements at the cement-stem interface may be responsible for cement mantle breakage and titanium-debris generation inducing necrosis and osteolysis [23]. The failure risk could be higher for smaller stems due to their greater elasticity, and in males who are physically active [26], while larger diameter titanium stems may be more successful [6]. In our series, we did not observe this relationship.

The second factor in early stem failure for the cemented titanium implants could be corrosion affecting the cemented, titanium alloy, stem surface. The implant could be deeply damaged by micromotion at the cement-stem interface leading to a progressive abrasion, which later induces a surface corrosion. Retrieval studies on loosened titanium alloy cemented stems report severe corrosion with associated typical crevices [5,27]. Scholl found such abrasions in corroded areas in all stem revisions with radiographic osteolysis at the same location [26]. Tissues were stained black with granuloma, including titanium wear particles. These findings suggest that corrosion could initiate an inflammatory foreign-body reaction that is responsible for the osteolysis of the adjacent bone, and aseptic loosening as seen with polyethylene wear particles.

The results of this prospective series are not in accordance with these observations. The overall survival rate of the stems was 97.7% at a mean of 9 years, which makes the failure rate consistent with the survival rate at 10 years of other cemented stems as reported in the Swedish Hip registry |28]. In the past, satisfactory results have been reported in the literature with cemented titanium stems. Known as the “French paradox”, the stems were rectangular in cross section, filling the medullary canal of the femur as much as possible with the largest implant associated with a thin cement mantle [29]. Survivorship at ten years ranged from 97% to 99% in these series [30,18].

The present study demonstrated that good results could be achieved with a different design and a different concept. In this cohort, the alloyed femoral stems were smooth, anodized, collarless, oval in section proximally, and circular for the distal 2/3 to reduce stress contact areas around the implants. Collarless implants have been associated with an increase in the frequency and width of radiolucent areas in zones 2 and 7 [31]. Nevertheless, we did not find such radiographic results and the rate of radiolucent lines was low in our study (14/119) at a mean follow-up of 9 years. Moreover, Meding et al. performed a prospective randomized study of collared versus collarless femoral prosthesis and reported that there was no difference in stem subsidence or functional scores [32]. Irrespective of their design or surface coating, all stems have been shown to move inside of their cement mantle in the first years after implantation [33]. Obviously, a polished surface limits the abrasion due to micromotion and ipso facto reduces production of active biological debris. On the contrary, it is established that the roughness of the stem directly influences the amount of debris produced and the rate of femoral loosening [23,34,35]. Better results have been obtained after implantation of titanium alloy stems with a polished surface compared with a rough surface with regard to the aseptic loosening rate [36]. Resistance to abrasion and corrosion of titanium implants depends on a thin and highly protective surface of oxide film [37]. The protective, passive, titanium oxide film (TiO2) is obtained by anodization during the manufacturing process. This titanium oxide surface protects against exposure to air or other oxidizing elements. If scratches occur, this passive layer is supposed to heal and restore itself. In our series, we experienced 3 femoral subsidences that could be clearly explained by a poor cementing technique. The cementing technique did not follow the “French paradox” guidelines; our cement mantle had to be complete and superior to 2 millimiters thickness using a pressurized cementing technique. Studies focused on stress at the interfaces demonstrated minimal micromotion of the stem when the cement mantle was 3 to 4 millimeter thick around either a titanium or a more rigid, cobalt-chromium implant [38,39]. Moreover, in these studies, high micromovement occurred when the cement was thinner than 2 mm and there was no difference in micromotion or debonding between a titanium and a cobalt-chromium stem [38,39]. A finite-element analysis study identified factors influencing cement strains of the femoral component [40]. The authors of this study found that mantle thickness had the greatest effect on cement strains and suggested that a cement mantle thickness of 2.5 to 5.0 mm was optimal.

In addition to the clinical assessment, we measured the serum titanium levels at each patient follow-up. The only source of titanium particles and ions in this study was the femoral stem. The aim was to monitor the behaviour of the implant as previously performed with chromium or cobalt [8,41]. Regarding titanium, several previous reports have shown significantly increased levels in case of failure in arthroplasty [13,42,43]**.** Buly reported a series of failed cemented all-titanium alloy femoral stems with high titanium levels in either dry tissues or synovial fluid [13]. Leopold and von Schroeder reported a failed patellar component in total knee arthroplasty, with elevated serum titanium at least 20 times higher than normal values [43,44].

Although a few studies have analysed titanium release from femoral stems previously, it is difficult to compare their results with ours because of differences in the type of stems (design, coating, etc), mean follow-up, and units [12-15]. In the present study, medians were constant in range up to a mean follow-up of 9 years in both unilateral and bilateral hip replacement groups, and were always under the detection limit. The low serum concentrations observed are reassuring with regard to some concerns about potential titanium toxicity [44]. Although titanium is considered safe except for its potential osteolytic activity, it circulates throughout the body and particles have been found in hair, lungs, brain, urine, and serum [44,45].

The highest titanium serum concentrations were found in cases of mechanical complications such as stem fixation (subsidences) or neck impingement. These findings are in accordance with previous studies that monitored metal release. They could also emphasize the ability of polished and titanium oxide coated surfaces to resist against corrosion and micromotion.

Another potential source of titanium particle release could be the junction between the cobalt-chromium femoral head and the softer femoral taper due to fretting and corrosion. In all of our revision cases, we carefully studied the femoral taper. In the 2 revisions with an exchange of the femoral stem, both the head and taper were under the specifications and we did not observe significant lesions in the contact areas. Our interpretation of higher serum titanium levels in a few patients is the unusual fretting and corrosion of the stem against the cement mantle. In the revision cases without femoral stem exchange, an inspection of the taper did not show significant alteration of the implant, allowing us to use sleeved revision femoral heads according to the recommendations.

In conclusion, this series shows that satisfactory results can be achieved using cemented, smooth, and oval in section titanium alloy stems. In addition, these results are consistent with series using other cemented implants [28]. A thick cement mantle combined with a polished, anodized surface may play a major role in minimizing the debris source and the stress at the interfaces.

The high rate of acetabular loosening in this series of cemented cups questions the potential role of titanium debris. We could not find an argument for this hypothesis. We did not observe relationships between acetabular loosening and high titanium serum levels; head-neck modularity did not seem responsible. Moreover, all the tapers were intact at the time of the revision. In addition, titanium serum levels found in this study showed satisfactory monitoring of the stems.

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**Figures**

Fig 1: Survivorship of loosened stems as the end point

Fig 2: After 10 years of follow-up, typical evolution of the stem could be seen in this series showing controlled subsidence

Table 1 : Serum titanium levels in the unilateral hip replacement group

Table 2 : Serum titanium levels in the bilateral hip replacement group

Table 3 : Serum titanium levels in the group with failed stems