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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**

No benefits or funds were received in support of the study.

13 **Abstract**

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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.

17

18 At endpoint, only one stem revision was performed for aseptic loosening, and two were

19 planned due to subsidence superior to 5 millimetres. Non-progressive radiolucencies in zones

20 1 and 7 were observed in 16 hips at the cement-interface, without osteolysis. Median serum

21 titanium concentrations were below the detection limit (30 nmol/l) except in patients with

22 failed stems.

23 The overall stem survival rate was 97.7% at a mean follow-up of 9 years, which is

24 comparable to other series of cemented stems. The protective layer of titanium oxide coating

25 the stem and a thick cement mantle may help resist aseptic loosening.

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

30

31 **Introduction**

32

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

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

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

49 **1 Materials and methods**

50

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

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

61

62 The average follow up was 9 years, with follow up ranging from 7 to 11 years. The age at the
63 time of arthroplasty ranged from 30 to 60 years (mean age: 54 years). Fifty-three females and
64 56 males were included. Sixty eight right hips were treated, and 66 left hips. Etiologies were
65 essentially symptomatic stage of osteonecrosis or primary arthritis. Patients were evaluated
66 preoperatively and followed-up with clinical and radiological examinations at regular
67 intervals. Hip function results were rated according to the Harris Hip Score grading system in
68 the preoperative period and latest follow up [16].

69

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

75 This modular stem was combined with a 28 millimeter (mm) Metasul® femoral head
76 (Centerpulse-Zimmer, Warsaw, Indiana, U.S.) using a 12 – 14, 5°43 taper.
77 Tapers were inspected individually before micro threading, using an electro pneumatic
78 system (HIGH PRESSURE ELECTRONIC PNEUMO TRANSDUCER 150015, Solex Metrologie, La
79 Boisse, France) for the taper angle (precision, 1 minute), the diameter at the base, and the
80 diameter at the summit (precision, 1 micron). This inspection was counter-checked by a unit
81 control on a tridimensional machine with 1-micron precision. The micro threading was
82 inspected using a projected side view with a 20x enlargement for the pace, profile, and
83 dimension of the threading (Pexit 14 VS Profile Profector, Pixit Dorsey Gage, Cambridge,
84 UK). Compatibility between cones and heads were controlled and guaranteed by the
85 manufacturers. All of the sockets were “sandwich” cemented Metasul® cups (Weber cups,
86 Centerpulse-Zimmer, Warsaw, Indiana, U.S.). Palacos Genta® cement (Scherring Plough,
87 Brussels, Belgium) was used to cement both components in all cases.

88
89 ***Surgical technique:*** All procedures were performed following the standard procedure
90 at our institution via an antero-lateral approach on a Judet orthopaedic table [19]. In order to
91 obtain a complete and thick cement mantle, the canal was over-reamed by 2 mm. Then the
92 femoral canal was washed, brushed, and distally occluded by a resorbable femoral plug
93 (Synplug®, Zimmer, Warsaw, Indiana, U.S). The cement was inserted retrogradely using a
94 gun.

95 ***Radiological evaluation and clinical assessment:*** Anteroposterior (AP) and lateral
96 radiographs of each hip were available before and immediately after surgery, 6 weeks after
97 discharge from the hospital, and at 3 months, 6 months, 1 year, and then yearly thereafter.
98 We defined radiographic loosening of the cup as the presence of radiolucent lines measuring
99 at least two millimeters according to DeLee-Charnley zones, axial cup migration of > 5 mm,
100 or > 5° of change in cup inclination on the AP radiographs of the pelvis [20].

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

106

107

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

113 To avoid metallic contamination, blood samples were drawn using a sampling kit specifically
114 dedicated to trace element determination: a needle for S-Monovette® (ref. 85.1162.400) and
115 7.5 mL S-Monovette® Lithium Heparin for Trace Metal analysis (ref. 01.1604.400) from
116 Sarstedt (Marnay, France). Two Monovettes were sampled and numbered in sampling order.
117 After centrifugation, aliquots of plasma were placed in metal-free plastic tubes (2
118 tubes/sample) and frozen at – 20°C. All metal measurements were performed on two samples
119 in order to control for any contamination.

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

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

125 Cobalt and chromium were determined by Electrothermal Atomic Absorption Spectrometry
126 on a simultaneous SIMAA 5100 spectrometer® UNTIL 2004, and then 6100 (Perkin Elmer,

127 Courtabœuf, France). The detection limits were 3 nmol/L for cobalt and 1 nmol/L for
128 chromium. Seronorm Levels I and II (Sero, distributed by Ingen, Rungis, France) were
129 analyzed in each analytical run as internal quality controls. The serum titanium level was
130 expressed in nmol/L (1 nmol/L = 47.9 ng/L=0.0479 µg/L =0.0479 ppb).

131 **Statistical analysis**

132

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

139 In order to test for any difference between small stems and larger ones regarding subsidences
140 or radiolucencies, we selected two subgroups of stems within the unilateral hip replacement
141 group. The first subgroup was composed of stems with a size of 1 to 3. In the second
142 subgroup, the sizes of the stems ranged from 4 to 6. A non-parametric Wilcoxon test was
143 performed to detect any difference in these 2 subgroups. Statistical significance was set at p
144 <0.05.

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

147 **Results**

148

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

151

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

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

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

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

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

169 One prosthesis was revised due to persistent and unexplained pain. At the time of the
170 revision, we found no abnormalities apart from a massive and macroscopic metallosis of the
171 joint. The cobalt serum level was increased more than 20-fold compared with the detection

172 limit. The implants were changed, and new metal-on-metal bearing surfaces were again
173 implanted, but did not resolve the symptoms.

174

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

177

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

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

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

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

190 Periarticular ossification, according to the method of Broecker et al. [22], was observed in
191 30% of the hips. Eight percent were type III and IV.

192

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

196 Failed stems, as shown in Table 3, caused the highest titanium serum levels at their end-point
197 in the series, and titanium levels were much higher than the detection limit ranging from 196
198 to 1274 nmol/l.
199 Titanium serum levels remained below the detection limit in cases with loosened cups.

200 Discussion

201

202 Use of cemented titanium alloy stems remains extremely controversial and has caused
203 some surgeons to renounce them [3-5]. Some series showed a large rate of early aseptic
204 loosening, usually when the stem was rough and cemented [4-6,23-25]. Jergesen reported an
205 11.5% aseptic loosening rate in a series of 118 total hip replacements at a mean follow-up of
206 66 months [6]. In the Scholl E series, the revision rate was 88% at a mean of 6.6 years due to
207 loosened stems, and 30% of cases showed a significant osteolysis of the proximal femur [26].
208 Two factors are suggested that explain the early stem failure for the cemented titanium
209 solutions. Firstly, the high elasticity of titanium and the excessive stresses in the mantle of the
210 cement could lead to micromotion and debonding of the stem [4]. Micro-movements at the
211 cement-stem interface may be responsible for cement mantle breakage and titanium-debris
212 generation inducing necrosis and osteolysis [23]. The failure risk could be higher for smaller
213 stems due to their greater elasticity, and in males who are physically active [26], while larger
214 diameter titanium stems may be more successful [6]. In our series, we did not observe this
215 relationship.

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

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

234 The present study demonstrated that good results could be achieved with a different
235 design and a different concept. In this cohort, the alloyed femoral stems were smooth,
236 anodized, collarless, oval in section proximally, and circular for the distal 2/3 to reduce stress
237 contact areas around the implants. Collarless implants have been associated with an increase
238 in the frequency and width of radiolucent areas in zones 2 and 7 [31]. Nevertheless, we
239 did not find such radiographic results and the rate of radiolucent lines was low in our study
240 (14/119) at a mean follow-up of 9 years. Moreover, Meding et al. performed a prospective
241 randomized study of collared versus collarless femoral prosthesis and reported that there was
242 no difference in stem subsidence or functional scores [32]. Irrespective of their design or
243 surface coating, all stems have been shown to move inside of their cement mantle in the first
244 years after implantation [33]. Obviously, a polished surface limits the abrasion due to
245 micromotion and ipso facto reduces production of active biological debris. On the contrary, it
246 is established that the roughness of the stem directly influences the amount of debris
247 produced and the rate of femoral loosening [23,34,35]. Better results have been obtained after
248 implantation of titanium alloy stems with a polished surface compared with a rough surface
249 with regard to the aseptic loosening rate [36]. Resistance to abrasion and corrosion of
250 titanium implants depends on a thin and highly protective surface of oxide film [37]. The

251 protective, passive, titanium oxide film (TiO₂) is obtained by anodization during the
252 manufacturing process. This titanium oxide surface protects against exposure to air or other
253 oxidizing elements. If scratches occur, this passive layer is supposed to heal and restore itself.
254 In our series, we experienced 3 femoral subsidences that could be clearly explained by a poor
255 cementing technique. The cementing technique did not follow the “French paradox”
256 guidelines; our cement mantle had to be complete and superior to 2 millimeters thickness
257 using a pressurized cementing technique. Studies focused on stress at the interfaces
258 demonstrated minimal micromotion of the stem when the cement mantle was 3 to 4
259 millimeter thick around either a titanium or a more rigid, cobalt-chromium implant [38,39].
260 Moreover, in these studies, high micromovement occurred when the cement was thinner than
261 2 mm and there was no difference in micromotion or debonding between a titanium and a
262 cobalt-chromium stem [38,39]. A finite-element analysis study identified factors
263 influencing cement strains of the femoral component [40]. The authors of this study
264 found that mantle thickness had the greatest effect on cement strains and suggested that a
265 cement mantle thickness of 2.5 to 5.0 mm was optimal.

266
267 In addition to the clinical assessment, we measured the serum titanium levels at each
268 patient follow-up. The only source of titanium particles and ions in this study was the femoral
269 stem. The aim was to monitor the behaviour of the implant as previously performed with
270 chromium or cobalt [8,41]. Regarding titanium, several previous reports have shown
271 significantly increased levels in case of failure in arthroplasty [13,42,43]. Buly reported a
272 series of failed cemented all-titanium alloy femoral stems with high titanium levels in either
273 dry tissues or synovial fluid [13]. Leopold and von Schroeder reported a failed patellar
274 component in total knee arthroplasty, with elevated serum titanium at least 20 times higher
275 than normal values [43,44].

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

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

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

298
299 In conclusion, this series shows that satisfactory results can be achieved using
300 cemented, smooth, and oval in section titanium alloy stems. In addition, these results are
301 consistent with series using other cemented implants [28]. A thick cement mantle combined

302 with a polished, anodized surface may play a major role in minimizing the debris source and
303 the stress at the interfaces.

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

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311

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430 **Figures**

431

432 Fig 1: Survivorship of loosened stems as the end point

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

436

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

438

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

440

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

442