Original article

Titanium-titanium modular neck for primary THA. Result of a prospective series of 170 cemented THA with a minimum follow-up of 5 years

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** ABSTRACT **

Background: Although they have been in use since the end of the 1980s, modular titanium neck components are associated with a risk of wear or fracture, and their safety has recently become a subject of debate and has never been evaluated in a consecutive series of patients. The goal of this study was to evaluate: revision-free survival of these implants after a minimum follow-up of 5 years; clinical and radiographic results; and the potential complications associated with the use of modular titanium neck components.

Hypothesis: The use of titanium modular neck on cemented titanium THA is safe at a minimum follow-up of 5 years.

Patients and methods: Between January 2006 and December 2008, we prospectively followed 170 patients (170 hips) who underwent primary anatomical THA with a modular cemented titanium stem design implant. The indications were unilateral THA for primary (n = 160) or secondary (n = 10) hip osteoarthritis (aseptic osteonecrosis of the femoral head or hip dysplasia). Mean age of patients was 75.4 ± 5.8 years old (52–85), and mean BMI was 26.1 ± 4.5 kg/m² (16.6–42.1). Patients were operated on by a modified Watson-Jones anterolateral approach based on preoperative 2D planning. All patients underwent annual clinical and radiological follow-up by an independent observer.

Results: At a mean follow-up of 71 ± 8 months (60–84), 5 patients died and 7 were lost to follow-up. There was no revision of THA after a minimum follow-up of 84 months. The Harris score improved significantly from 50.4 ± 11.3 (0–76) preoperatively to 84.5 ± 15.2 (14–100) at the final follow-up. There was no difference in postoperative femoral offset or the position of the center of rotation compared to the opposite side. On the other hand, the neck-shaft angle (NSA) and limb length were corrected (2 ± 5° [−11 to +14°] and 2.16 ± 3.6 mm [−7.4 to +12.7 mm]) respectively. Fifteen patients (9%) had limb length discrepancies of more than 5 mm and 4 patients (2%) of more than 10 mm. There were no complications due to the modular implant design.

Discussion: Our study suggests that the use of cemented titanium implants with a modular titanium stem is safe at a follow-up of 5 years. The modular design does not prevent limb length discrepancies but restores femoral offset.

Level of evidence: IV: prospective, non-comparative study.

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1. Introduction

Total hip arthroplasty is a reliable procedure to relieve pain and improve patient function with implant survivorship of more than 95% at 10 years [1]. Significant anatomical variations of the proximal femur have been described (femoral anteversion, femoral offset, and neck-shaft angle [NSA]) [2–4]. Modular total hip arthroplasty (THA) implants have been designed to optimally restore the normal biomechanics of the hip including correction on three planes of femoral offset, leg length, femoral anteversion and NSA.
[5,6] particularly in case of anatomical abnormalities [7–9]. The development of these new designs has been associated with concerns about the risk of corrosion and wear, which are inherent to all modular systems due to rubbing of the modular interfaces [10–13], as well as the risks of dislocation or fracture of the modular neck [14–17]. Titanium alloys used in certain modular components help prevent corrosion of the interface observed with modular cobalt-chromium necks because the interface surfaces are made of the same material [11]. Fractures of the femoral neck have, however, been observed in first generation titanium neck components [18]. Nevertheless, to our knowledge there is no consecutive study in the literature analyzing the efficacy and safety of these implants. It was our hypothesis that the use of modular cemented titanium THA was safe at a minimum follow-up of 5 years. Thus, the goal of our study was to perform a prospective study of modular cemented titanium THA to analyze:

- revision-free survival at a minimum follow-up of 5 years;
- clinical and radiographic results;
- the potential complications associated with the use of modular titanium alloy neck components.

2. Materials and methods

2.1. Patients

In this prospective, single center, non-randomized consecutive study, all patients who underwent primary total hip arthroplasty between January 2006 and December 2008, using an anatomical cemented femoral stem including a modular femoral neck on three planes (valgus/varus, anteversion/retroversion, length) were included. Inclusion criteria were: primary THA, patients operated on for primary or secondary osteoarthritis (avascular necrosis of the femoral head, Crowe’s 1, 2 dysplasia), age between 18 and 85 years old and acceptance of the follow-up protocol. All patients were offered an annual follow-up protocol for evaluation by an independent observer and were included after providing written consent. Fig. 1 shows the flow-chart of our series.

During this period, 170 anatomical THA with modular heads were implanted in 170 patients (excluding bilateral or previous contralateral THA). There were 49 men (29%) and 121 women (71%), mean age 75.4 ± 5.8 years old (52–85) and a mean body mass index (BMI) of 26.17 ± 4.5 kg/m² (16.6–42.1); 51 patients (19.2%) had a BMI above 30 (moderate to severe obesity).

2.2. Surgical technique

The procedure was performed in all patients through a Watson-Jones anterolateral approach, with patients in the supine position under general anesthesia in 119 cases (71%) or with spinal block in 51 cases (28%). Preoperative 2D planning of THA was performed using TraumaCad™ (Voyant Health, Petach-Tikva, Israel). All patients received a non-cemented cup with a polyethylene bearing (Trilogy TM™ (Zimmer, Warsaw, IN, USA)). Mean cup diameter was 52 mm (48–60). Primary cup stability was obtained by screw fixation in 158 cases (93%). An average of one screw was used (0–3). On the femoral side, a titanium alloy cemented anatomical stem Ti6Al4V was used in all cases (cemented Apta™, Adier-Ortho, Milan, Italy). A modular neck component, adjusted on the three planes (Adier-Ortho, Modula™ System, made of titanium Ti6Al4V; Fig. 2) was press-fit into the femoral stem and a 28-mm ceramic head was used.

Table 1 summarizes the frequency of use of the different modular neck components. The use of a non-standard neck was necessary in 28% cases (standard: defined as a neck with an NSA angle of 135°, 13° anteversion, average length: resulting in 38–44 mm femoral offset depending on the size of the stem). The different possibilities provided by the linear matrix for the modular design are presented in Fig. 2.

The postoperative protocol for analgesia and rehabilitation were the same for all patients with immediate weight bearing within 48 h after surgery. All patients received thrombosis prophylaxis therapy with low molecular weight heparin for 45 days.

2.3. Evaluation methods

Patients underwent clinical and radiological follow-up by their surgeon at 3 months and 1 year, then every year thereafter for systematic follow-up by an independent examiner. Function was evaluated using the Harris score [19].
A study of revision-free survival of implants was performed during follow-up with the end-point defined as implant revision for any reason (undesirable element).

X-rays (AP view of the pelvis and lateral view of the operated hip) at the final follow-up were compared with preoperative and mid-term follow-up images, all X-rays were performed in the same center, in the standing position with controlled rotation of the lower limb (15° internal rotation on postoperative images and internal rotation as close to 15° as possible on preoperative images), by a trained radiological technician. The anatomical parameters of the operated hip were compared to the contralateral native hip in all cases using Centricity\textsuperscript{TM} software (GE Healthcare, Barrington, IL, USA). The measured parameters were (Fig. 3): NSA angle, femoral offset [20], leg length discrepancy (measured by the distance between the U-landmark to the lesser trochanter) [21] and the position of the center of rotation in the horizontal C/D and vertical A/E directions according to the Pierchon index [22].

Radiological features suggesting complications due to modular necks were evaluated and defined by: periprosthetic proximal femoral osteolysis due to corrosion (Gruen zones 1 and 7) [23]. Heterotopic ossifications were described according to the Brooker et al. classification [24], Peri- and postoperative periprosthetic fractures were collected and classified according to Masri et al. (Vancouver classification) [25].

2.4. Statistical methods

Statistical analysis was performed using SPSS\textsuperscript{TM} 22 software (SPSS Inc., Chicago, IL, USA). Survival analysis was performed using the Kaplan-Meier method with the end-point defined as implant revision, death or lost to follow-up. Confidence intervals were determined at 95% and 5% (P < 0.05) was considered to be statistically significant. The preoperative Harris score was compared to the postoperative scores using the Student's t-test for paired samples. To study factors influencing the use of a modular neck, the quantitative variables were analyzed using a Student's t-test and the qualitative variables were compared by univariate analysis using the Chi\textsuperscript{2} test.

3. Results

At a mean follow-up of 71 ± 8 months (60–84), 5 patients had died (2.9%) and 7 (4.1%) were lost to follow-up. There were no implant revisions at the final follow-up. The cumulative revision-free survival was 100% after a maximum follow-up of 84 months. The mean Harris Score (Table 1) for the entire series at the final follow-up was 84.5 ± 15.2 (14–100). Mean Harris hip score significantly improved from 50.4 preoperatively to 84.5 points postoperatively (P < 0.001).

The results of the radiographic study are presented in Table 2. There was no significant difference between the operated and contralateral hip for femoral offset or the horizontal position of the center of rotation. There was no significant difference between the operated and the contralateral hip for the NSA angle (“mean valgus”: +2 ± 5° [−11 to +14°], P = 0.02), and for leg length (mean lengthening: 2 ± 3.6 mm [−7.4 to 12.7 mm], P = 0.01). Fifteen patients presented with a radiographic leg length discrepancy of more than 5 mm, 13 patients (7.6%) with a discrepancy of more than 10 mm.

### Table 1

<table>
<thead>
<tr>
<th>Type of neck</th>
<th>Implant design: NSA (‘) / version (’) / induced offset (mm)</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard average</td>
<td>135 / 13 / 38–44t</td>
<td>122</td>
<td>72</td>
</tr>
<tr>
<td>Standard short</td>
<td>135 / 13 / 33–39t</td>
<td>22</td>
<td>13</td>
</tr>
<tr>
<td>Standard long</td>
<td>135 / 13 / 48–54t</td>
<td>13</td>
<td>8</td>
</tr>
<tr>
<td>Varus long Av\textsuperscript{v} standard</td>
<td>128 / 13 / 48–54t</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>Valgus long Av\textsuperscript{v} standard</td>
<td>140 / 13 / 48–54t</td>
<td>3</td>
<td>2</td>
</tr>
</tbody>
</table>

Av\textsuperscript{v}: stem anteverision; NSA: implant neck-shaft angle.

* The amount of offset was dependent upon the size of the stem.
Our hypothesis was confirmed because we did not identify any complications associated with the use of a modular titanium neck implanted on a cemented stem. This confirms the in vitro data and emphasizes the advantage of titanium alloys over chrome-cobalt for the safety of modular necks [18].

There are several limits to our study: the lack of comparison with hip arthroplasty using a femoral stem without a modular neck design. During the study period, we only used modular or custom made neck components, so that to perform a comparative study we would have needed to work with another surgeon or center, creating a methodological bias. Moreover, our study analyzing safety and efficacy was purely descriptive. We did not perform pre- and postoperative CT, which limits the reliability of geometric measurements of the proximal femur. The number of patients included made it difficult to perform CT. We applied a standard radiographic protocol but probably underestimated femoral offset [20]. Comparison with the contralateral hip solves this problem but requires perfect control of rotation of the legs during X-rays. Our results confirm those of Pasquier et al. [26] in a comparison of X-ray and CT, which reported a preoperative, and postoperative radiological offset of 42.9 ± 5.4 mm and 44.7 ± 6.3 mm, respectively. On the other hand, we were able to include a large number of patients (170 for 170 hips), who were operated on in a single center using the same surgical technique with a low rate of lost to follow-up patients, seen for a limited period (which limits any change in practices from the beginning to the end of the study) and with a follow-up of at least 5 years.

The ideal value of femoral offset for each patient is still a subject of debate. Although the healthy contralateral hip can be a reflection of the optimal anatomy to be restored, results in literature do not provide a response to the question of the optimal biomechanics of the prosthetic joint [2,6,9]. Although modular necks can adapt femoral offset as well as control the neck-shaft angle and leg length discrepancies, in this study 8% (n = 15) of our patients presented with leg length discrepancy >5 mm. We did not evaluate whether this discrepancy was clinically relevant. This problem has rarely been reported following the use of modular necks. In our study, the relatively high number of leg length discrepancies (greater than 5 mm) was probably related to the use only of a 2D planning as no 3D planning is yet available for this implant.

Survival in our series was comparable to survival observed in recent series of modular or monoblock designs [5,7,8,27–29]. Moreover, in our study, there were no mechanical failures due to the use of the modular neck at the final follow-up. It should be noted that the use of the titanium implant may be associated with a high risk of mid-term and long-term femoral prosthesis osteolysis [29]. This did not occur in our series, however, the length of follow-up was probably too short. The creation of an additional interface between the stem and the neck is nevertheless a subject of debate [30], creating micromovements which increase the risk of stress related corrosion and fissures, which can result in mechanical failure [14–17]. Wear at the interface may also result in the circulation of metal microparticles [31] whose inflammatory effects have been described in metal on metal bearing cobalt-chromium devices [11]. There were no dislocations of the modular necks in our series or to our knowledge in the three published studies on anatomical modular titanium/titanium necks (no cases in 1094 hips after a mean follow-up of 66 months) [5,7,8]. Finally to prevent these risks,
Table 3
Published series reporting results of anatomical stems using modular neck.

<table>
<thead>
<tr>
<th>Type of stem</th>
<th>Number of patients</th>
<th>Etiology</th>
<th>Mean age (follow-up (months))</th>
<th>Postoperative clinical score</th>
<th>Number of revisions</th>
<th>Fracture/dislocation of the modular neck</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blakely et al. [5]</td>
<td>Anca-fit™</td>
<td>352</td>
<td>HO: 79% (HO sec: 21%)</td>
<td>HHS: 20</td>
<td>12 (3.4%)</td>
<td>0</td>
</tr>
<tr>
<td>Allouche et al. [27]</td>
<td>Anca-fit™</td>
<td>88</td>
<td>HO: 56% (HO sec: 30.7%)</td>
<td>PMA: 16.9</td>
<td>5 (5.6%)</td>
<td>0</td>
</tr>
<tr>
<td>Traina et al. [8]</td>
<td>Anca-fit™</td>
<td>61</td>
<td>HO: 100%</td>
<td>HHS: 74.7</td>
<td>1 (1.6%)</td>
<td>0</td>
</tr>
<tr>
<td>Loubignac and Rebourillat [28]</td>
<td>Heliate™</td>
<td>103</td>
<td>HO: 81.5% (HO sec: 13.5%)</td>
<td>PMA: 16.4</td>
<td>8 (7.7%)</td>
<td>0</td>
</tr>
<tr>
<td>Duweilus et al. [33]</td>
<td>ML Taper Kinectiv™</td>
<td>620</td>
<td>HO: 93% (HO sec: 7%)</td>
<td>HHS: 91.3</td>
<td>20 (3.2%)</td>
<td>0</td>
</tr>
<tr>
<td>Our series</td>
<td>Apta™ ecemented</td>
<td>170</td>
<td>HO: 90% (HO sec: 10%)</td>
<td>HHS: 91.3</td>
<td>3 (1.7%); 1 infection. 2 F</td>
<td>0</td>
</tr>
</tbody>
</table>

HO: primary hip osteoarthritis; HO sec: secondary hip osteoarthritis; F: proximal femoral fracture; HD: hip dysplasia; HHS: Harris hip score; PMA: Post-Stréle d’Aubigné Score.

cleaning of interfaces before impaction, impaction in the correct position with perfect adjustment between the neck and the stem, and the use of the same alloy for the neck and the stem are essential [11,12].

Our results in restoring the anatomy with a modular component confirm the series published by Bachour et al. [9], which described a significant decrease in planned femoral offset with the use of a monoblock design. Anatomical parameters were obtained with preoperative planning (position of the center of rotation, femoral offset) with no significant difference in postoperative results compared to the contralateral hip (which was used as a reference) except for leg length and NSA angle, which were significantly different between the two sides. These results confirm those of González Della Valle et al. [32] whose postoperative results in a series of 116 cemented THA corresponded to planned anatomical parameters except for increased limb length and the NSA angle determined by drawings. Table 3 shows a comparison of our results with the main studies on cemented THA.

In this study, we used an anatomical femoral stem which allowed the use of a modular neck and we used 2D planning (no 3D planning was available for these implants at that period) to restore the anteverision of the native femoral neck with the possibility (in case of instability or length in the final test) of modifying the length, femoral offset and neck (neck-shaft angle). The demographic characteristics of the patients in our series explains why we systematically used cement fixation of implants because of the high risk of fractures associated with the use of the anatomical stem on osteoporotic bone. Finally, we did not use the long varus neck in our daily practice because this design is associated with a higher potential risk of implant fracture. This approach could have resulted in an “underestimation” of the number of implant fractures in our study.

The results of our study suggest that a modular titanium implant based on a three-dimensional linear matrix optimally restores hip anatomy with good clinical and radiological results and no complications related to the modularity of the components. Long-term, comparative, randomized studies are needed to confirm the results obtained in this series, although the mid-term results suggest that the use of these implants should be continued.

Disclosure of interest
Jean-Noël Argenson is an educational and research consultant for Zimmer and receives royalties from Zimmer.
Sébastien Parratte is a consultant for Smith and Nephew, Graffys, Adler-Ortho and participates in the Zimmer educational program.

Xavier Flecher is a consultant for Zimmer.
Alexandre Lunebourg and Matthieu Ollivier declare that they have no conflicts of interest concerning this article.

References


