Midterm outcomes of titanium modular femoral necks in total hip arthroplasty

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Background: Modular femoral necks present surgical and biomechanical advantages in total hip arthroplasty (THA), but their benefits remain controversial due to risks of corrosion and fracture at the additional junction. This study aimed to report 10-year survival and clinical outcomes of a titanium femoral stem with a titanium modular neck in consecutive series.

Methods: The authors reviewed the records of 97 patients (99 THAs) using uncemented modular stem and ceramic-on-ceramic acetabular components. Patients were evaluated at minimum follow-up of 5 years using the Harris Hip Score (HHS) and Postel Merle-D'Aubigné score (PMA). Survival was calculated using the Kaplan-Meier (KM) method with any reoperation or revision as endpoint.

Results: From the original cohort, 14 patients died, 6 were lost to follow-up, and 5 had revision operations with exchange of the femoral stem. The KM survival at 10 years was 94.2% (CI, 86.5–97.5). Clinical assessment was performed on 67 of the 72 patients (69 of the 74 hips) presently living with their original THA components. At mean follow-up of 9.4±1.0 years (median, 10; range, 5–11), the HHS was 93.6±8.2 and the PMA score 17.0±1.6. The X-rays revealed no signs of adverse reactions or bone loss.

Conclusions: The uncemented titanium hip stem with modular titanium neck provided a satisfactory 10-year survival and clinical outcomes. Neck modularity enabled restoration of patient-specific femoral offset and limb length thanks to five possible neck configurations, though greater follow up is required to confirm the long-term benefits and safety of this design concept.

Keywords: Total hip arthroplasty (THA); modular stem; modular neck; implant corrosion; implant fracture

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Introduction

Over the past three decades, total hip arthroplasty (THA) implants evolved with increasing options to restore or correct femoral offset, anteversion and limb length (1-6). This led to production of multiple models of monolithic femoral stems, with different neck lengths and angles, as well as modular femoral stems that allow flexible adjustments intra-operatively (3,7,8).

Modular implants, believed to facilitate restoration of physiological muscular tension and hip biomechanics (7,9), also permit good exposure when undertaking revision of the acetabular cup without removing the femoral component (10). On the other hand, the additional junction between a stem and a modular neck could increase risks of fretting corrosion and prosthetic fracture at the neck-stem interface,

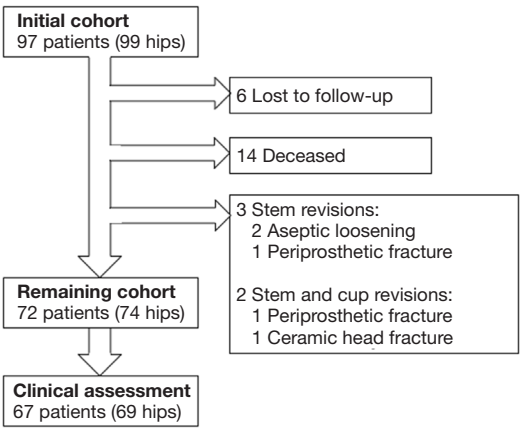

Figure 1 Flowchart detailing inclusion and exclusion of patients from the original cohort.

Table 1 Patient demographics and clinical scores at final follow-up

Variables	Cohort (n=74)
Male gender	27 (36.5%)
Age*	67.4±7.5 (47.1–87.0)
FU (years)*	9.4±1.0 (5.3–11.1)
Postoperative HHS*	93.6±8.2 (68.0–100.0)
Postoperative Postel Merle D'Aubigné score*	17.0±1.6 (12.0–18.0)

*, mean ± SD (range). HHS, Harris Hip Score.

reported in several series (11-16).

Whereas the surgical and biomechanical advantages of modularity are recognised, its clinical benefits to patients remain controversial (1,17,18). It has been demonstrated that Ti modular necks can fracture or dissociate at the Morse taper due to surface cracks (19,20). Conversely, CoCr modular necks withstand greater loads but are associated with corrosion and metal ion release, which could lead to adverse local tissue reactions (19,20). Though Ti-Ti modular junctions are more likely to fracture, their lower potential to generate metal ions makes them less harmful to surrounding soft tissues, compared to Ti-CoCr modular junctions (7,21).

To the authors' knowledge, few studies investigated long-term outcomes of a Ti femoral stem with a Ti modular neck. The purpose of the present study was to report 10-year outcomes of this stem design in consecutive series, and to evaluate their clinical outcomes and implant survival.

Methods

The authors reviewed the records of 99 consecutive THAs performed by two surgeons (FB and TC) between November 2005 and September 2007, using an uncemented modular stem (ACOR®, Amplitude, Valence, France) and uncemented ceramic-on-ceramic acetabular components. The series comprised 97 patients (2 bilateral) aged 67.7±7.7 years (median, 68.2; range, 47–87) at the index operation. Their gender distribution was balanced, with 40 men (41 hips), aged 67.4±8.5 years (median, 67.2; range, 47–87), and 57 women (58 hips) aged 67.9±7.2 (median, 68.6; range, 55–87). The indications for surgery were degenerative osteoarthritis in 90 hips, avascular necrosis in 4 hips, congenital dysplasia in 2 hips, and other reasons in 3 hips.

The anatomic modular ACOR® stem (Amplitude®, Valence, France) is made of Ti alloy (TA6V ELI) with an ovoid cross section. Its intra-medullary surface is entirely coated with 80 µm of hydroxyapatite (HA) and its extra-medullary surface (above the impaction line) is mirror-polished and anodized. The modular neck is made of the same Ti alloy (TA6V ELI), mirror-polished between the Morse tapers, and is available with different anteversion/retroversion options (± 8°) as well as lateralisation/medialisation options. In the present series, the modular necks were assembled to produce the following configurations: 61 lateralised, 30 extra-lateralised, 5 medialised, 2 anteverted and 1 retroverted.

Patients were contacted to update their records, and if deceased, their general practitioner or next of kin were contacted to confirm the date and cause of death, and whether they underwent any reoperations. From the initial 97 patients (99 THAs), 3 patients (3 hips) had isolated stem revisions, 2 patients (2 hips) had stem and cup revisions, 14 patients (14 hips) had died with their original stems in place, and 6 patients (6 hips) could not be reached, but their most recent follow-up records indicated that none had undergone revisions or reoperations (*Figure 1*). This left a cohort of 72 patients (74 hips) living with their original components for outcome assessment (*Table 1*).

Patients were invited for clinical evaluation at a minimum follow-up of 5 years using the Harris Hip Score (HHS) and Postel Merle-D'Aubigné score (PMA), as well as routine frontal X-rays to inspect for signs of loosening or adverse effects. The ethics committee (Comité de Protection de la Personne, CPP Est IV) waived the approval for this study and the competent authority for personal data certified that the study protocol is in accordance with national guidelines (Comission Nationale de l'Informatique et des Libertés, CNIL, 2001515v0).

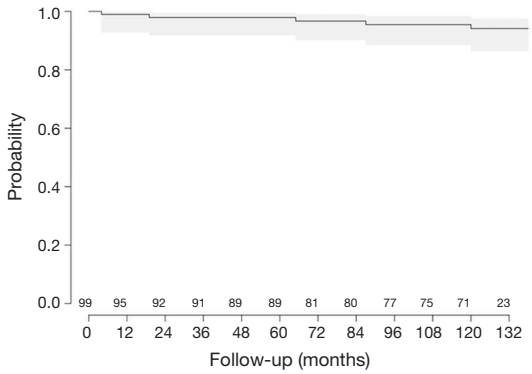

Figure 2 Kaplan-Meier survival curve considering revision of the femoral stem as endpoint.

Figure 3 Example of a hip with valgus femoral neck reconstructed to match native femoral offset and limb length (cf. contralateral hip).

Figure 4 Example of a hip with varus femoral neck reconstructed to match native femoral offset and limb length (cf. contralateral hip).

Statistical analysis

Survival analysis was performed using the Kaplan-Meier (KM) method with the endpoint defined as reoperation or revision of any component for any reason. Descriptive statistics were used to summarize the data. For non-Gaussian quantitative data, between group differences were evaluated using Wilcoxon rank-sum tests (Mann-Whitney U test). Categorical data were analyzed using chi-square tests. Statistical analyses were performed using R version 3.3.3 (R Foundation for Statistical Computing, Vienna, Austria). $P<0.05$ were considered statistically significant.

Source of funding

Financial support for statistical analysis (H Bothorel) and manuscript preparation (M Saffarini) was provided from Amplitude SAS, Valence, France.

Results

From the original 97 patients (99 hips), only 72 patients (74 hips) were confirmed to be presently living with their original THA components (*Figure 1*). It is worth noting that for this series, that the cumulative risk of mortality was greater than cumulative risk of revision. The remaining cohort comprised 26 men (27 hips) and 46 women (47 hips), assessed at mean follow-up of 9.4±1.0 years (median, 10; range, 5–11).

Five patients (5 hips) had revision operations with exchange of the femoral stem: 2 periprosthetic fractures due to trauma at 65 and 92 months, 1 ceramic head fracture also due to trauma at 19 months, 1 stem loosening with some subsidence revised at 120 months and 1 excessive stem subsidence at 4 months. Considering revision of the femoral stem as endpoint, the KM survival at 10 years was 94.2% (CI, 86.5–97.5) (*Figure 2*).

Clinical assessment was performed at 5 or more years on 67 patients (69 hips), while the remaining 5 other patients (5 hips) could not be evaluated because they were unable or unwilling to travel to the clinic, but they confirmed that their original stem was still in place, and that they had no other reoperations. The mean HHS was 93.6±8.2 (median, 96.5; range, 68–100) with excellent or good scores for 55 patients (57 hips, 82%). The mean PMA score was 17.0±1.6 (median, 18; range, 12–18). The X-rays did not reveal signs of adverse reactions, stem loosening or bone loss, even in hips with substantial valgus (*Figure 3*) or varus (*Figure 4*) femoral necks.

Table 2 Kaplan-Meier survival rates and clinical scores for modular stems series reported in the literature

Authors	Year	Stem model	Manufacturer	Hips (N)	Age at surgery, mean [range], years	KM survival [%], years	Postoperative HHS	
							Years	Mean [range]
This study	2017	ACOR	Amplitude	99	67.7 [47–87]	10 [94.2]	9.4	94 [68–100]
Toni *et al*.	2017	ANCA-Fit	Wright Medical	300	55.5[a] [28–80]	15 [93.2]	16.5	–
Vanbiervliet *et al*.	2017	Profemur Xm	Wright Medical	95	68.5 [44–89]	–	6.5	90 [44–100]
Yi *et al*.	2016	Kinectiv	Zimmer	34	62.4	–	4.0	89
Benazzo *et al*.	2015	MODULUS	Lima Corporate	173	55[b] [21–81]	8 [97.6]	7	92 [76–100]
Silverton *et al*.	2014	Profemur Z	Wright Medical	195	59.5[c] [20–87]	8 [89.4]	4.5	86 [30–100]
Duwelius *et al*.	2013	Kinectiv	Zimmer	594	62	–	2.0	92
Cossetto *et al*.	2012	BMA	Groupe Lepine	185	70	10 [96]	7.8	–
Blakey *et al*.	2009	ANCA-Fit	Wright Medical	352	64.4 [28–97]	5 [97.5]	7.2	–

[a], lost to follow up excluded; [b], series on patients with developmental hip dysplasia; [c], died and lost to follow up excluded. KM, Kaplan-Meier; HHS, Harris Hip Score.

Discussion

The aim of the present study was to report 10-year outcomes and survival of an uncemented Ti stem with a modular Ti neck. The cumulative incidence of revision at 10 years in the present series was 5%, which is better than the 6-year revision incidence reported in a recent nationwide study (7,680 uncemented modular neck stems) from France (7%) (22). It is worth noting that our 10-year revision incidence is closer to that reported by the Australian Orthopaedic Association (AOA) for fixed neck stems (4.9%) than that reported for modular neck stems (9.3%) (23).

The KM survival at 10 years in the present series was 94.2%, with any revision or reoperation as endpoint, which is comparable to survival rates reported for other uncemented femoral stems with modular necks. Cossetto *et al.* (24) reported 10-year KM survival of 96% for the BMA stem; Blakey *et al.* (10) reported 5-year KM survival of 97.5% for the ANCA-Fit stem; Toni *et al.* (25) reported 15-year KM survival of 93.2% for the 3rd generation (alumina-on-alumina) ANCA-Fit stem; and Silverton *et al.* (21) reported 8-year KM survival of 89.4% for the uncemented modular Profemur® Z stem (21) (*Table 2*).

In our series, the mean postoperative HHS was 93.6±8.2 at a mean follow-up of 9.4 years, which is greater than other results reported by several authors (between 85 and 91 at 2–8 years of follow-up) (1,6,9,21,26). The mean postoperative PMA score at final follow-up was 17.0±1.6, which is as good as the results reported in the literature by Cossetto *et al.* (24) (16.36 at a mean follow-up of 7.8 years) and slightly lower than the score reported by Toni *et al.* (25) (17.4 at a mean follow-up of 16.36 years) (*Table 2*).

Modular implants were originally intended to facilitate restoration of physiological muscle tensions and hip biomechanics (7,9), also to improve visibility during revision of the acetabular cup without removing the femoral component (10). In the present series, creating the configurations possible using the different modular necks would have required five different models of monolithic stems to be available in the operating room, which would have incurred greater cost and complexity for the hospital inventory. However, the additional junction between a stem and a modular neck could increase risks of fretting corrosion and prosthetic fracture at the neck-stem interface, reported in several series (11-16). The surgical and biomechanical advantages of modularity are recognised, but its clinical benefits remain controversial (1,17,18). Ti modular necks can fracture or dissociate at the Morse taper due to surface cracks, while CoCr modular necks withstand greater loads but are associated with metal ions release and corrosion (19,20). Though Ti-Ti modular junctions are previously thought to be at greater risks of fracture, their lower potential of generating metal ions are less harmful to surrounding soft tissues than Ti-CoCr modular junctions (7,21,27).

Contrary to the high revision rates and complications of modular stems reported in the literature during the past ten years, mostly on modular stems with Ti-CoCr junctions, our

series of modular stems with Ti-Ti junctions confirms satisfactory 10-year survival and excellent clinical outcomes after a minimum follow-up of 5 years.

The present study has several limitations, notably the small cohort size, the retrospective collection of data, the absence of a control group with fixed neck designs and the absence of blood analyses for metal ion levels. Nevertheless, the study has a number of strengths, notably the relative long follow-up for this particular stem design and the consistency of this consecutive series by virtue of the concise inclusion period of 2 years.

Conclusions

The ACOR® uncemented modular stem provided a satisfactory 10-year survival and excellent clinical outcomes, with no noticeable adverse effects resulting from the additional modular junction. In this series, neck modularity enabled restoration of patient-specific femoral offset and limb length thanks to five possible neck configurations, though greater follow up is required to confirm the long-term benefits and safety of this design concept.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: The ethics committee (Comité de Protection de la Personne, CPP Est IV) waived the approval for this study and the competent authority for personal data certified that the study protocol is in accordance with national guidelines (Comission Nationale de l'Informatique et des Libertés, CNIL, 2001515v0).

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