

Survivorships of Small Cementless Femoral Stems are Similar to Mid-Size Stems. A Case-Control Study on Four Hundred and Twenty Total Hip Arthroplasties

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ABSTRACT

The aim of this study was to assess the clinical outcomes and survivorships of cementless Corail small stems to mid-size stems at a mid-term follow-up. A retrospective case-control study included 420 primary hip arthroplasties performed between 2006 and 2010. A case group of small size stems (8 to 10, n=173) were compared to a control group (mid-size stem 11 to 13, n=247). Complications and revisions were recorded. Kaplan-Meier survivorships were measured. Mean follow-up was 6 ± 1.1 years (range, 4-9). The mean PMA score and complication rate at last follow-up were not significantly different between cases and controls. No significant difference was noted between the groups for survivorship free of stem aseptic loosening ($p=0.2$), free of stem removal for any reason ($p=0.09$), and free of stem or cup revision for any reason ($p=0.3$). Small Corail stems were not associated with higher complication or revision rates compared to mid-size stems.

Introduction

Initially developed to be implanted in young patients [1], cementless THA (Total Hip Arthroplasty) are now commonly used, with a proportion that recently surpassed cemented THA in England (39.1% in 2016 [2]) and Australia (63.3% in 2015 [3]). Several series reported excellent long-term survival [4-8], up to 96% at a 23 years follow up with the Corail™ stem (DePuy Synthes, Saint Priest, France) [8]. However, few studies reported the influence of the stem size on the clinical outcomes after THA [9-12]. The British National Joint Register suggested that the revision rate of the Corail stem was higher with small femoral stems (8 to 10) compared to mid-size stems (11 to 13) [12]. The purposes of our study were to assess the clinical outcomes and survivorships of standard small stems (exposed group) to standard mid-size stems (control group)

at a mid-term follow-up. We hypothesized that the use of small stems was not associated with a higher risk of revision compared to mid-size stems.

Patients and Methods

We retrospectively recorded 807 patients who underwent primary THA in our institution between September 2006 and December 2010. During this period, 460 Corail standard stems were implanted in 417 patients. Flow chart of the study is presented in (Figure 1). Exclusions criteria were: revision THAs, lateralised stems and THA for tumor or fracture. Patients were classified based on whether a small (size 8 to 10) or a medium (size 11 to 13) Corail stem was implanted. A total of 420 primary THAs in 380 patients

(40 bilateral) were available at a mean follow-up of 6 ± 1.1 years (range, 4-9), including 173 small stems (cases) vs. 247 mid-size stems (controls). Demographics data are summarized in (Table 1) (Figure 1). The stem used was a straight implant made of forged titanium alloy (TiAl6V4), entirely coated with hydroxyapatite

($155 \pm 35 \mu\text{m}$). The standard Corail stem was declined from size 8 to 20. From size 8 to 13, stem length varied from 115 to 155mm, width from 7 to 10mm, and offset from 38 to 41.5mm. Neck length, height and shaft angle were similar for all stems (respectively 38.5mm, 36mm and 135°). The stem was used in a collared version.

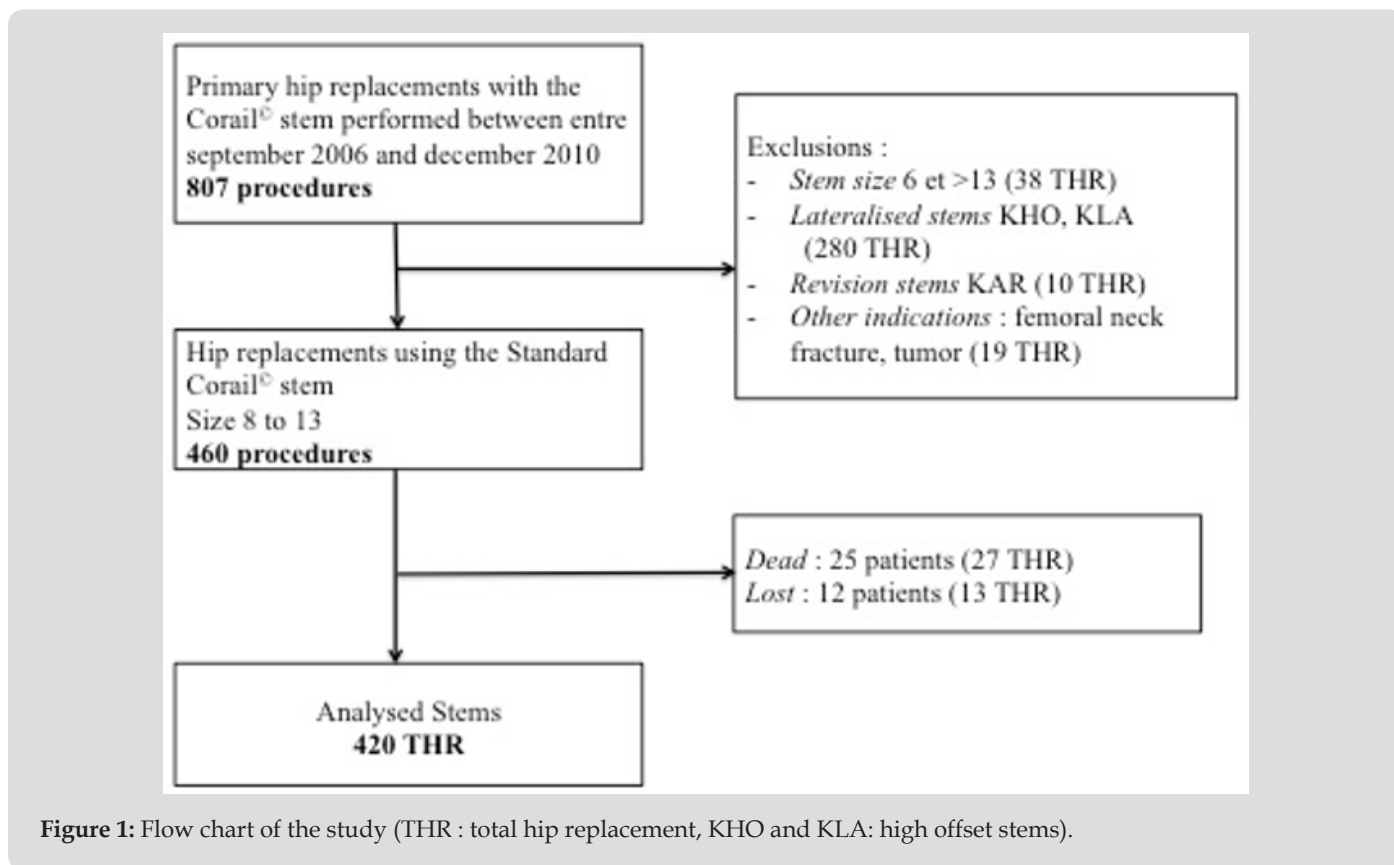


Figure 1: Flow chart of the study (THR : total hip replacement, KHO and KLA: high offset stems).

Table 1: Patient demographics and pre-operative data.

	Stems size 8 to 10 N=173	Stems size 11 to 13 N=247	P
Age, mean \pm SD (range)	63 \pm 14 (20 -87)	67 \pm 12 (17 - 90)	0.06
Gender, n (%)			<0.001
Male	43 (25%)	115 (47%)	
Female	130 (75%)	133 (53%)	
BMI (kg/m ²) , mean \pm SD (range)	26 \pm 5 (17 -46)	27 \pm 4 (18 - 39)	0.2
Follow-up (months) , mean \pm SD (range)	70 \pm 15 (52 - 102)	69 \pm 11 (51-100)	0.6
Etiology, n (%)			0.114
Primary OA	131 (75%)	194 (79%)	
Post-traumatic OA	9 (5%)	10 (4%)	
Avascular osteonecrosis	7 (5%)	28 (11%)	
Hip Dysplasia	17 (10%)	9 (4%)	
Other	9 (5%)	6 (2%)	
Bearings, n (%)			0.4
Dual Mobility	97 (56%)	144 (58%)	
CoC	74 (43%)	93 (38%)	
MoM	2 (1%)	10 (4%)	
Pre-operative PMA Score, mean \pm SD (range)	13 \pm 2 (5 -17)	13 \pm 2 (5 -17)	0.8
BMI body mass index, OA osteoarthritis, PMA Postel Merle D Aubigné Score, CoC Ceramic on ceramic, MoM Metal on metal			

Different cementless cups were used: 241 dual-mobility cups (57%) (Sunfit™, Serf, Decines, France), 167 ceramic-on-ceramic bearings (39%) (Pinnacle™, DePuy Synthes, Saint Priest, France), and 12 metal-on-metal cups (ASR™, DePuy Synthes, Saint Priest, France). Complications and revisions were recorded each year since surgery. Patients were evaluated clinically using PMA score [13].

Surgical Technique

Procedures were all performed through a posterolateral approach by the same senior surgeon. Femoral preparation technique aimed for optimal filling of the trial broaches with good vertical and rotational stability keeping a bed of cancellous bone. A standard rehabilitation protocol was initiated after surgery with full-weight bearing allowed immediately.

Statistical Analysis

SPSS v.19 (IBM) was used for statistical analysis. Qualitative variables were compared with a Mann Whitney or Student t-test. Comparisons between categorical variables were performed using Chi-2 or Fisher’s exact test. Survival curves were calculated according to Kaplan-Meier (KM) method and compared using the log rank test. Statistical significance was set at $p \leq 0.05$.

Ethical Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the

institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The CPP Sud Est ethical comitee of Hospice Civils de Lyon (HCL) approved this study that complies to the MR004 methodology, registered in CNIL under number 18-130. For this type of study formal consent is not required (retrospective and anonymous study). All data were fully anonymized before their access. The ethics committee did not require an informed consent.

Results

Complications and Revisions

Seven dislocations were identified (six in the patients with a single mobility cup, and one in a dual mobility cup), among which 4 cases needed cup revision. One patient had a fracture of a ceramic liner and one early revision was performed two days after surgery for leg length discrepancy. Seven femoral stems were revised: one case for periprosthetic fracture, 4 cases for infection and 2 cases for aseptic loosening (both in small stems). A 69-year old patient had a stem revision 1.5 year after surgery in a context of femoral Paget’s disease (stem size 8). A malposition and an under sizing of the stem could explain this early failure. After revision with a bigger stem (size 11), the PMA score was 15 points at 6 years. A 56-year old man had a stem revision 5 years after surgery (size 9) (Figure 2A & 2B). During revision, the surgeon reported a mobility of the stem, but no evidence of infection was recorded. The revision rates depending on stem size are detailed in (Table 2).

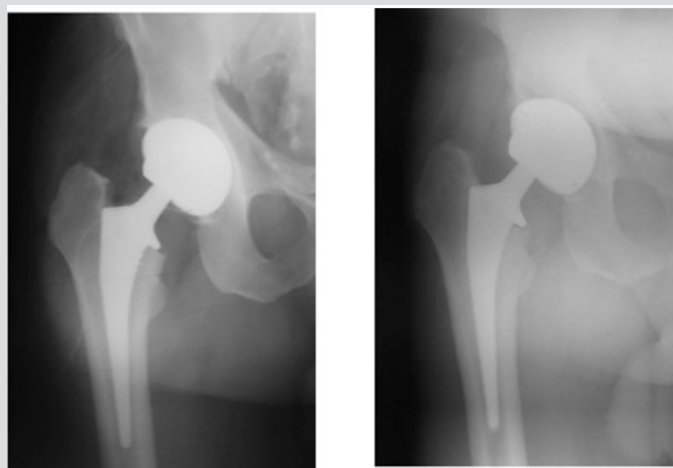


Figure 2: Radiographs of a 56 years old man who had a stem revision for aseptic loosening. Immediate (Fig 2A) and three years post-operative (Fig 2B) X-rays with development of femoral lines in Gruen’s zones 1, 2, 3 and 6.

Table 2: Revision THA performed depending on stem size.

Stem size	No. of THA	No. of revision	No. of stem revision	No. of aseptic loose stems
8	49 (12%)	3 (6%)	2 (4%)	1 (2%)
9	38 (9%)	1 (2.6%)	1 (2.6%)	1 (2.6%)
10	86 (20%)	4 (4.6%)	2 (2%)	0
11	127 (30%)	3 (2.3%)	0	0
12	82 (20%)	0	0	0
13	38 (9%)	4 (10.5%)	2 (5.2%)	0
Total	420 (100%)	15 (3.6%)	7 (1.7%)	2 (0.4%)

Survivorships

The KM survivorship free of stem aseptic loosening was respectively 99% (95% CI [96.8-100%]) in the small stem group, and 100% in the medium size stem group (p=0.2) (Figure 3). The KM survivorship free of stem revision or stem removal for any reason was 98% (95% CI [96.9-99.5%]) at five years (97% (95% CI [94.9-99.6%]) in the small size group, and 99% (95% CI [98-100%]) in the mid-size group, p=0.09) (Figure 4). The KM survivorship free of cup or stem revision for any reason was 96% (95% CI [94.2-97.8%]) in the overall cohort at five years (95% (95% CI [91.7-98.4%]) in cases vs. 98% (95% CI [95.1-99.2%]) in controls, p=0.3) (Figure 5). In a univariate analysis, none of the following factors were risk factors for revision: age, gender, stem size, BMI and bearing (Table 3).

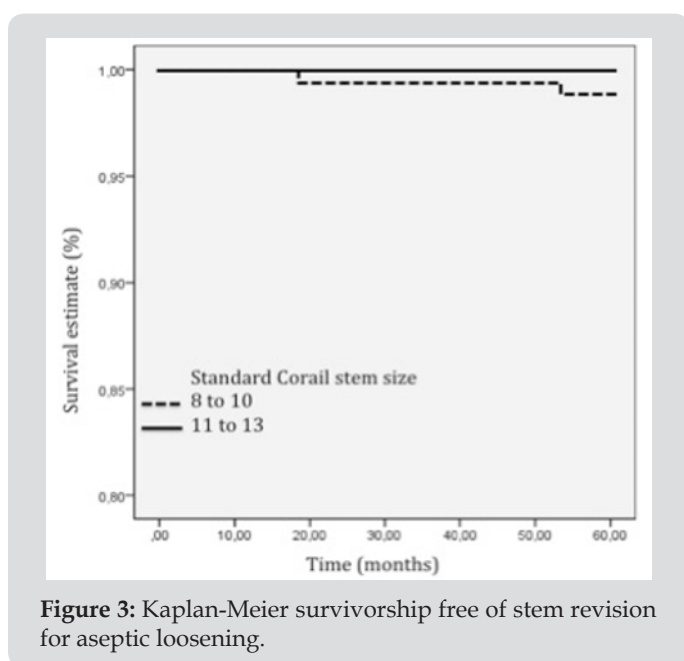


Figure 3: Kaplan-Meier survivorship free of stem revision for aseptic loosening.

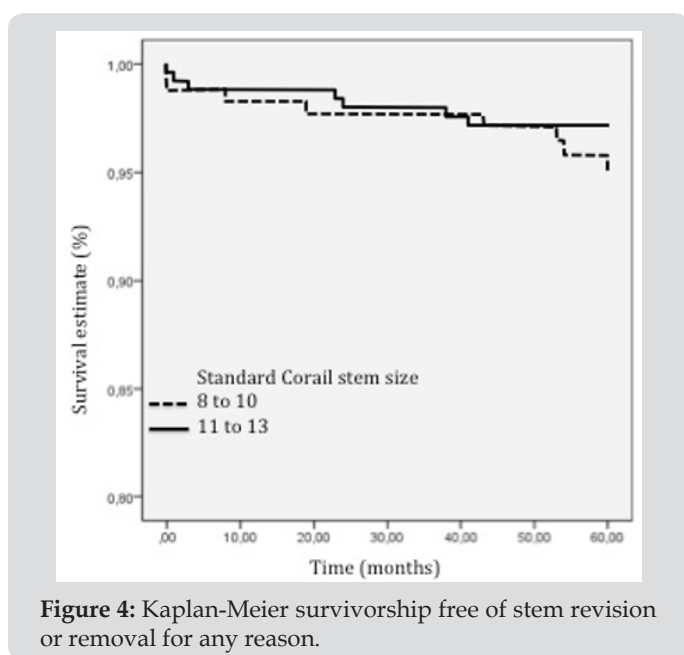


Figure 4: Kaplan-Meier survivorship free of stem revision or removal for any reason.

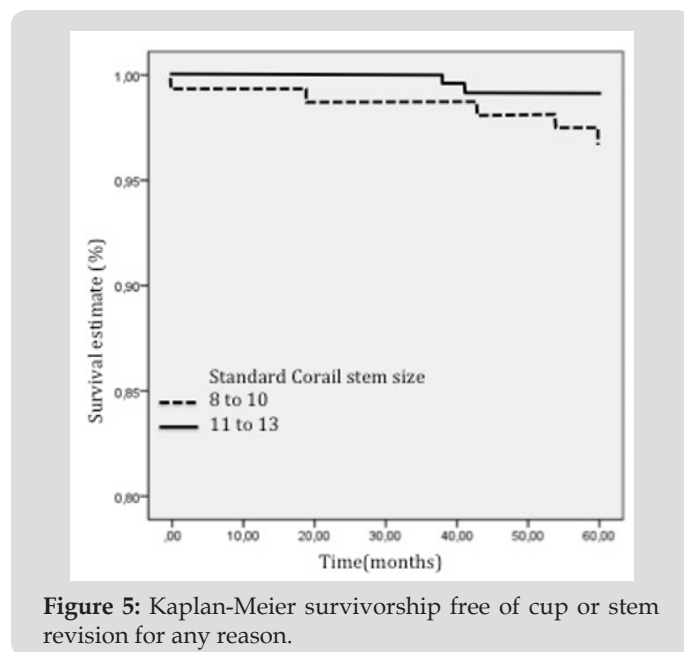


Figure 5: Kaplan-Meier survivorship free of cup or stem revision for any reason.

Table 3: Univariate analysis of risk factors for stem revision.

Variables	Hazard Ratio (95% Confidence Interval)	P
Age		
<60 years	Reference	-
60-80 years	0,8 (0,3 - 2,2)	0,6
>80 years	1,1 (0,2 - 5,3)	0,9
Gender		
Female	Reference	-
Male	2,6 (0,9 - 7,2)	0,08
Stem sizes		
8 to 10	1,7 (0,6 - 4,6)	0,3
11 to 13	Reference	-
BMI		
<25 kg/m ²	Reference	-
25-30 kg/m ²	0,9 (0,3 - 2,9)	0,9
>30 kg/m ²	1,3 (0,4 - 4,7)	0,7
Bearings		
Dual mobility cups	Reference	-
Single mobility cups	2,0 (0,7 - 5,7)	0,2

(HR : hazard ratio ; CI : confidence interval)

Clinical Outcomes

The mean PMA score at last follow-up was not significantly different between small stems (17±1.6) (range, 7 to 18) and mid-size stems (17±1.6)(range, 5 to 18), (p=0.38).

Discussion

Since 1986, Corail stem has been implanted and evaluated many times with excellent results [4-6,8,12,14-17]. This original stem design may be considered as the gold-standard of cementless stems. At 5 and 10 years, survivorships were about 98% in most

of the series [4-6,12], and at 23 years up to 96% for Vidalain [8]. Our results are consistent with these previous series, with an overall stem survival of 98% (95% CI [96.9-99.5]) at a five-year follow-up, considering stem removal for any reason. Jameson et al. [12] demonstrated that complication rates were higher for small femoral stems than for mid-size stems (HR=1.8 [99% CI [1.4-2.37]; $p < 0.001$). In this current study, the size of femoral stems did not influence complication rates (HR=1.7 (95% CI [0.6-4.6]; $p = 0.33$) and clinical outcomes and survivorships were similar between both groups. Clinical evaluation using PMA score, mostly based on pain and walking, did not show significant differences between small and mid-size stems ($p = 0.4$). PMA scores were good or excellent in >90% of the patients in both groups. These results are consistent with the study by Engh et al. [11] who did not find any relation between stem size and satisfaction ($p = 0.24$), pain (0.17), or function ($p = 0.4$). Only standard Corail stems were included as lateralised stems previously demonstrated a higher risk of loosening [18,19].

Demey et al. [20] showed that the use of a collared Corail stem increased the horizontal and vertical stability. In our series, we only implanted collared stems, while most of stems were collarless for Jameson et al [12]. Two cases of stem aseptic loosening were recorded in our study (13% of the causes for revision). This was consistent with the results of Jameson et al [12] with a revision rate of 16.5% for stem aseptic loosening. At 15-year, Engh et al. [11] calculated the overall survivorship of the stem was 98%. Survivorship was not significantly different among the different stem sizes ($p = 0.4$). Vresilovic et al. [9] reported the survivorship of 296 femoral stems at 2-year follow-up and did not find any significant difference according to stem size. Our study had several limitations. First, we did not perform radiological analysis, as it was not the purpose of this study but to focus on survivorship. Second, the study was retrospectively performed. The strengths were its homogeneity, as the same senior surgeon performed all procedures and the mid-term follow-up.

The influence of stem size on revision rate is controversial. In the current study, small size stems (8 to 10) were not associated with higher revision rates compared to mid-size stems (11 to 13). Further studies including a larger sample size, at a longer follow-up, with radiological analysis must be performed in the future.

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