



THE CORAIL[®] HIP SYSTEM:

Clinical and radiographic outcomes
at 25 to 30 years of the CORAIL
Uncemented Hip Stem

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Clinical and Radiographic Outcomes at 25 to 30 Years of the CORAIL Uncemented Hip Stem

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Introduction

Total Hip Arthroplasty (THA) was introduced over 50 years ago, and its long-term survival is well documented in numerous clinical studies^{10,27,28,30,40} and registry investigations.^{12,16,18,31,38} There are few published studies, however, that report implant survival beyond 20 years.^{1-3,23,26,27,43} Even fewer articles report survival up to 30 years, and they all concern the Charnley cemented stem design,^{5,6,8,29,44,46} with limitations due to long inclusion periods (> 40 years)⁴⁶ or high proportions of deceased patients (~90%).⁶

The CORAIL Uncemented Tapered Stem was introduced 30 years ago, incorporating a thick coat of hydroxylapatite (HA).⁴² The clinical and radiographic outcomes of this hip stem are well documented in the literature,^{7,9,11,13,17,19,32-34,39} which continues to demonstrate its excellent long-term performance in comparison to other cemented and uncemented stem designs.

The authors have already reported the clinical and radiographic outcomes of the first consecutive series of THAs using the CORAIL Stem,¹⁵ including survival at follow-up of 20 to 25 years.⁴³ The authors therefore aimed to update and report the clinical and radiographic outcomes of this series at a follow-up of 25 to 30 years, and to calculate the survival for different endpoints of interest. The authors also sought to analyse cases in which the stem was revised to better understand its mechanisms of failure in the long term.

Patients and Methods

The authors reviewed the records of all 347 consecutive THAs performed between 1986 and 1990 by the same surgeon (AM) using the CORAIL Stem (DePuy Synthes, Leeds, UK). The series comprised 320 patients (24 bilateral) aged 63.3 ± 11.3 years (median, 65; range, 20 – 89) at the index operation. The authors updated the records by contacting all patients, unless they had been noted as deceased with specified date and cause of death, with a confirmation whether any of their THA components had been revised. Patients were contacted by telephone and/or mail to enquire about their general health, and to record any adverse events or revisions that they had on the operated hip. For patients that did not respond, the authors contacted their next of kin or their general practitioner, to update the information.

All patients that responded were invited for clinical and radiographic evaluation. Those unable to travel due to limited mobility or poor health were surveyed by telephone or paper questionnaires, and if possible, were asked to send standard x-rays from their nearest radiology centre. The clinical questionnaire included the Harris Hip Score (HHS) as well as general satisfaction with

the operated hip. The radiographic examination included standard coronal and lateral x-rays of the hip. All x-rays were evaluated independently by two surgeons (AM, LJ) who completed identical forms documenting the type, location, and extent of all radiographic signs (subsidence, osteolysis, radiolucencies, granulomas, etc...). Particular attention was given to x-rays and clinical notes of patients in which the femoral stem had been revised.

Survival analysis was performed for three different endpoints: (i) Revision of the femoral stem for any reason; (ii) Revision of the acetabular cup for any reason; (iii) Reoperation or revision of any component for any reason. The authors estimated survival using the Kaplan-Meier (KM) method and using the Cumulative Incidence Function (CIF), both of which were deemed important for this study. The KM survival is the most commonly reported for joint arthroplasty and enables direct comparison to survival data, while the CIF is recommended for reporting survival at 10 or more years^{4,14,20,21,35,45}, where risks of revision are overestimated due to greater proportions of patients deceased and/or lost to follow-up.

Results

Of the initial 347 THAs (320 patients), 12 stems (12 patients) had been revised, 225 hips (205 patients) had deceased and 28 hips (27 patients) were lost to follow-up. This left 82 hips (76 patients) on file with the original stem in place at a mean follow-up of 26.8 ± 1.2 years (median, 27; range, 25 – 30). There were 42 hips in 39 men and 40 hips in 37 women. Their mean age at last follow-up was 82.7 ± 9.0 years (median, 84; range, 57 – 101). It is worth noting that of the 82 hips (76 patients) on file, 27 hips (27 patients) had a revised acetabular cup and 8 hips (8 patients) had a revised polyethylene insert and/or femoral head.

Clinical outcomes

Full clinical assessment was performed by one surgeon (LJ) on 17 hips (16 patients), while telephone or paper questionnaires were obtained for the 61 hips (57 patients) who were unable to travel to the clinic. The remaining 4 hips (3 patients) could not be evaluated because the patients were either bed-ridden or confined to nursing homes with impaired mobility, but their general practitioner or next of kin confirmed survival of their original stem and specified whether any reoperations or revisions had been performed.

From a total of 73 patients (78 hips) assessed, 70 patients (96%) responded that they were still satisfied with their operation, while 53 patients (72%) affirmed that their hip was totally pain-free. It was possible to calculate the HHS for 71 patients (75 hips) who had a mean score of 81.1 ± 15.4 (median, 84; range, 37 – 100). The majority of patients scored excellent or good on the HHS (Table 1).

Harris Hip Score n = 71			
Categories	Score	n	(%)
Excellent	> 90	12	(16.9%)
Good	≥ 80	27	(38.0%)
Fair	≥ 60	25	(35.2%)
Poor	< 60	7	(9.9%)

Table 1: Clinical scores regrouped per outcome

Radiographic outcomes

Standard coronal and lateral x-rays were available for 38 hips (37 patients). Those included 17 hips (16 patients) that were x-rayed at our centre, and 21 hips (21 patients) that were x-rayed elsewhere. There were no signs of subsidence, migration, pedestal formation, and neither cortical atrophy nor hypertrophy (Figure 1).

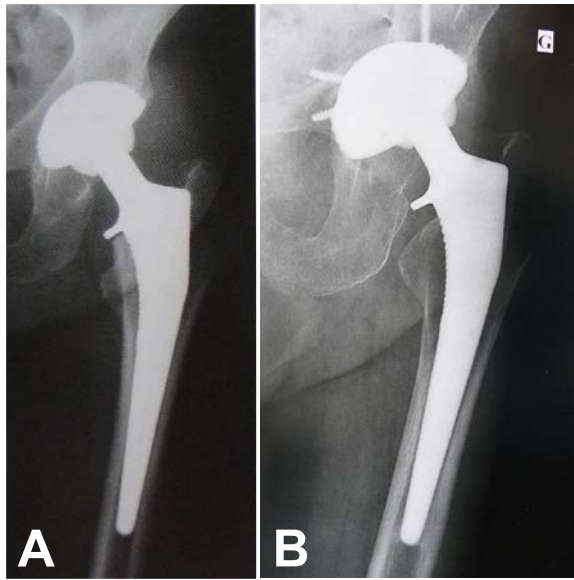


Figure 1: (A) Immediate postoperative (patient aged 53 years) and (B) last follow-up (30 years) coronal x-rays showing good osteointegration and no radiographic signs. The patient had undergone revision of the acetabular component 13 years after the index operation, but the original stem is still well-fixed in place.

Radiolucencies were observed around 10 stems (26.3%), all in Gruen zone 1, none exceeding 2 mm in length. Reactive lines were observed around 5 stems (13.1%), 4 in Gruen zone 1, and 1 in Gruen zone 2. Only 1 granuloma was observed in Gruen zone 2 of 1 stem. There were signs of calcar remodelling in 9 hips (23.7%) (Figure 2), as well as calcar lysis (< 5 mm) in 3 hips (7.9%) (Figure 3), and evidence of stress-shielding in only 1 hip (2.6%). Radiographic signs were not correlated with patient age or activity, nor with stem size or positioning (Figure 4). The Sedel score³⁷ was therefore of grade A in 26 patients, indicating that 68% of patients had 'silent' hips, with both excellent functional outcomes and no radiographic signs (Table 2).

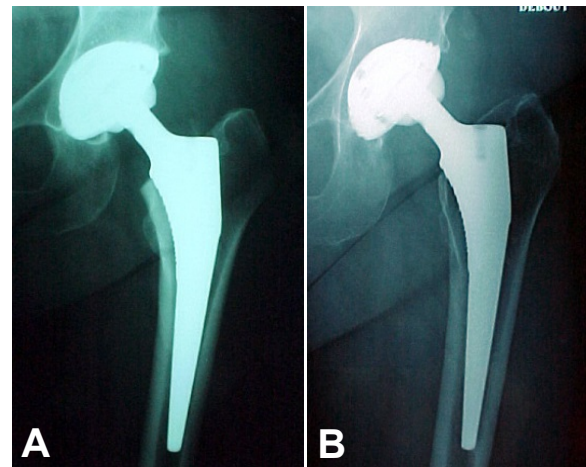


Figure 2: (A) Immediate postoperative (patient aged 54 years) and (B) last follow-up (25 years) coronal x-rays showing signs of calcar remodelling without osteolysis.

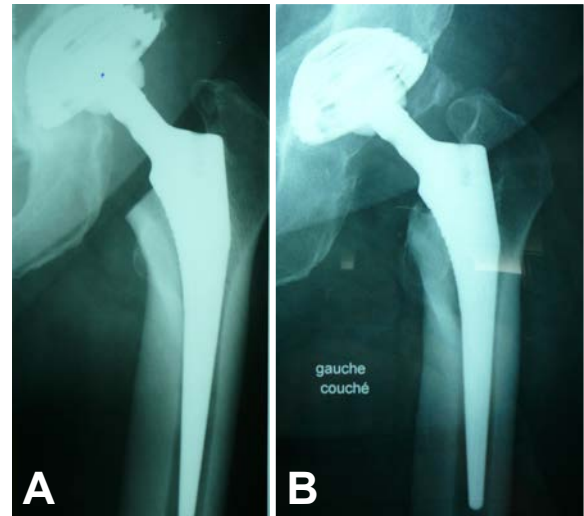


Figure 3: (A) Immediate postoperative (patient aged 60 years) and (B) last follow-up (26 years) coronal x-rays showing limited signs of osteolysis.

Categories	Collared n = 14	Collarless n = 24	Total n = 38
	n (%)	n (%)	n (%)
A Excellent function and no x-ray symptoms	12 (86%)	14 (61%)	26 (68%)
B Excellent function with x-ray symptoms	1 (7%)	7 (30%)	8 (21%)
C Poor function & no x-ray symptoms	1 (7%)	1 (4%)	2 (5%)
D Poor function with x-ray symptoms	0 (0%)	2 (9%)	2 (5%)

Table 2: Sedel scores for stems with complete clinical and radiographic outcomes

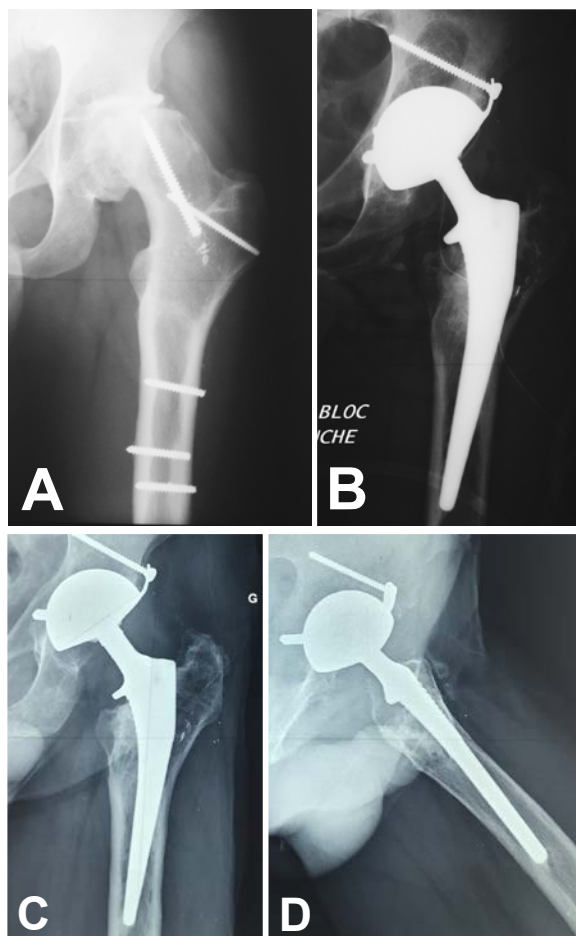


Figure 4: (A) preoperative and (B) immediate postoperative (patient aged 41 years) coronal x-rays of a hip corrected by valgus osteotomy; (C) coronal and (D) lateral x-rays at last follow-up (28 years) proving no change in alignment nor any radiographic signs despite initial valgus of stem.

Survival analysis

Of the initial 347 THAs (320 patients), 86 (24.8%) had a reoperation or revision procedure, of which 37 hips were in deceased patients. The revisions included 12 (3.5%) exchanges of femoral stem (in which the acetabular component was also revised), 55 (15.9%) exchanges of acetabular component, and 17 (4.9%) exchanges of polyethylene insert.

There were only 2 (0.6%) reoperations for simple lavage and/or debridement without any implant removal.

Considering revision of the femoral stem as endpoint, the revision risk (reciprocal of survival) calculated following the KM method was 6.4% (CI, 3.6 – 11.2), while using the CIF it was 3.7% at 30 years (CI, 1.6 – 5.8) (Figure 5). Of the 12 revised stems, the causes of revision were: aseptic loosening (n=1), sepsis (n=1), and size-matching with a revised head-cup combination (n=1), peri-prosthetic fracture (n=4), and granulomas limited to the metaphyseal region without loosening (n=5).

Considering revision of the acetabular cup as endpoint, the revision risk (reciprocal of survival) calculated following the KM method was 32.6% (CI, 26.2 – 40.1), while using the CIF it was 21.0% at 30 years (CI, 16.2 – 24.5%) (Figure 6). The majority of acetabular cups were revised for wear of the polyethylene insert which led to loosening of the acetabular component, but rarely affected fixation of the femoral stem.

Considering any reoperation or revision of any component as endpoint, the revision risk (reciprocal of survival) calculated following the KM method was 41.5% (CI, 34.5 – 49.4), while using the CIF it was 26.0% at 30 years (CI, 21.2 – 30.8) (Figure 7).

Discussion

The aim of the present study was to update and report the long-term outcomes and survival of the CORAIL Hip Stem. By virtue of their advanced age at index operation (63.3 ± 11.3 years; 20 – 89), and because of the long follow-up period (26.8 ± 1.2 years; 25 – 30), large proportions of the patients had died (64.1%) or were lost to follow-up (8.4%). The remaining patients represent just under a quarter of the initial cohort (23.8%), some of whom have

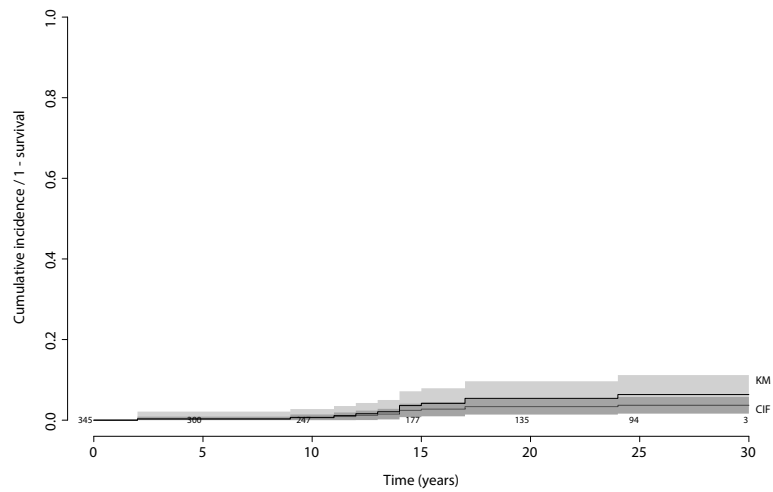


Figure 5: Risk of revision (reciprocal of survival) calculated following the KM and CIF considering revision of the femoral stem as endpoint.

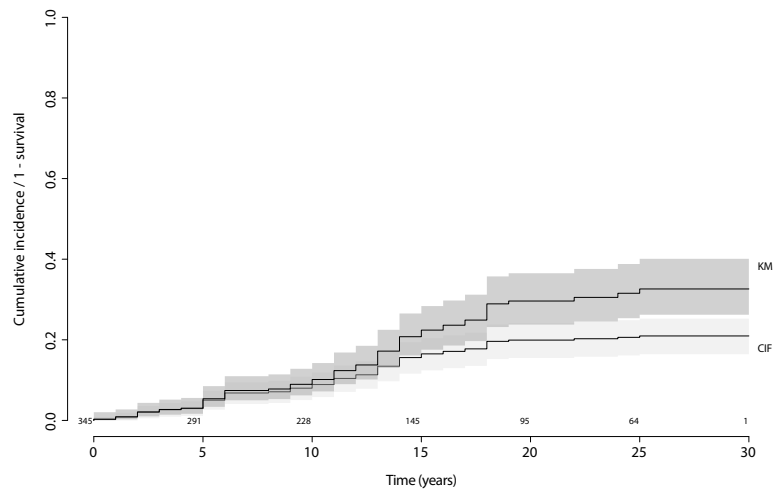


Figure 6: Risk of revision (reciprocal of survival) calculated following the KM and CIF considering revision of the acetabular component as endpoint.

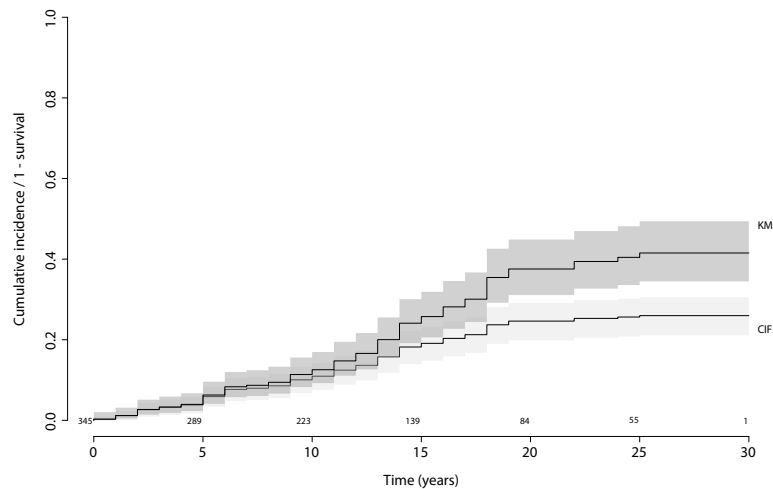


Figure 7: Risk of revision (reciprocal of survival) calculated following the KM and CIF considering any revision or reoperation as endpoint.

impaired function and mobility due to pathologies unrelated to the hip. Nearly half of the patients on file had undergone revision of the acetabular cup or liner (46.0%), though most patients remain satisfied (96%) and pain-free (72%).

The only published studies reporting survival of THA at 25 years or longer are on the CHARNLEY Cemented Stem,^{5,6,8,29,44,46} with common limitations due to long inclusion periods (> 40 years)⁴⁶ or high proportions of deceased patients (~90%).⁶ The original series of CHARNLEY THAs had 51 of the original 262 patients (19.5%) living and available for follow-up at a minimum of 25 years.⁵ The high incidence of deaths and loss to follow-up in survival studies that extend beyond 10 years renders traditional Kaplan-Meier (KM) estimates somewhat invalid, because the competing risks falsely exaggerate the revision rates.^{4,14,20,21,35,45} For this reason, the Cumulative Incidence Function (CIF) is recommended as an alternative or complement, though this method was only recently introduced in orthopaedic research.^{21,23,45}

Using the KM method, the 30-year survival of our present series is 93.6% considering stem revision as end point, 67.4% considering acetabular revision as end point, and 58.5% considering any reoperation or revision as end point. Our estimates compare favourably with the 30-year survival of the CHARNLEY THA⁵ which were 91% considering stem revision for aseptic loosening as end point, 87% considering acetabular revision for aseptic loosening as end point, and 76% considering revision for any reason as end point. It is important to note the differences in endpoints used in the present study that considers all component revisions, compared to the endpoints used in the CHARNLEY Implant that consider only revisions for aseptic loosening, and could therefore underestimate real revision rates considerably.

Comparing revision rates for the present series using the KM and CIF estimates reveals that the former exaggerates revision rates by 55% to 73%. Nevertheless, the KM estimate is the most frequently reported in the literature so far, and remains the only option for comparison with other THA survivals reported in the literature. To our knowledge, there are few studies reporting outcomes and survival of uncemented stems

beyond 20 years of follow-up.^{2,10,22,25,27,36,40,41} Streit et al.⁴¹ reported 22-year survival of 86% in 354 CLS stems (Zimmer) without reporting clinical scores. Lombardi et al.²² reported 20-year survival of 99% in 196 Mallory-Head stems (Biomet) with mean HHS of 83 (range, 18–100) at last follow-up. Corten et al.¹⁰ also reported 20-year survival on 126 Mallory-Head stems (Biomet) of 99% without clinical scores. McLaughlin and Lee²⁴ published 2-year survival rate of 99% in 145 Taperloc stems (Biomet) with a mean HHS of 83 (range, 18–100) at last follow-up. Belmont et al.² reported 20-year survival of 98% in 223 AML uncemented stems without clinical scores. Finally, Meding et al.²⁷ reported 20-year survival of 89% on 157 Bi-Metric (Biomet) stems with mean HHS of 87 (range 57–100). Nationwide arthroplasty data is rarely available at follow-up longer than 15 years, but it is worth mentioning the recent study of Hailer et al.¹⁶ who analysed 116,069 THAs performed using 11 different brands of uncemented stems, from the Nordic Arthroplasty Registry Association (four countries). The reported unadjusted 10-year survival was 92% considering revision of any component for any reason as end point, and 97.8% considering stem revision as endpoint.

In the present series using the CORAIL Stem, despite the incidence of acetabular osteolysis due to wear of polyethylene inserts, the femoral fixation was seldom affected beyond the proximal calcar region. Peri-prosthetic bone remodelling was limited, and in most cases proved natural, by comparison to the intact contra-lateral hip. Comparison of serial radiographs revealed great stability of stem fixation beyond 20 postoperative years with no signs of radiolucency, migration nor pedestal formation. Considering both clinical and radiographic outcomes in combination, the Sedel score³⁷ for our series was of grade A, i.e. clinically and radiographically 'silent' hips, in 68% of patients, which is remarkable considering the very long follow-up of the study.

Conclusion

The present study is the first to report outcomes and survival of an HA-coated uncemented hip stem beyond 25 years of follow-up. Our results demonstrate excellent survival of the stem and of

the total arthroplasty, in comparison to the world reference CHARNLEY Cemented Stem, and by comparison to shorter-term arthroplasty registry studies. Using the KM method, the 30-year survival of our present series is 93.6% considering stem revision as end point, 67.4% considering acetabular

revision as end point, and 58.5% considering any reoperation or revision as end point. It is worth noting that the KM method revision overestimates the revision rates by 55% to 73% due to large proportions of patients deceased and lost to follow-up.

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