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The Corail stem as a reverse hybrid – survivorship and x-ray analysis at 10 years

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ABSTRACT

Background: The use of a cemented cup together with an uncemented stem in total hip arthroplasty (THA) has become popular in Norway and Sweden during the last decade. The results of this prosthetic concept, reverse hybrid THA have been sparsely described.

We report our experience of reverse hybrid THA, using the Elite plus polyethylene cemented cup together with the Corail fully hydroxyapatite-coated uncemented stem and a 28-mm alumina ceramic head.

Patients and methods: 132 consecutive reverse hybrid hip arthroplasties were performed from January 2000 to December 2003 in 126 patients with a mean age of 54.3 years (28-65). All patients were routinely reviewed at 3 months, 1, 5, 7 and 10 years postoperatively. At each follow-up patients were seen either by a consultant orthopaedic surgeon or a senior trainee. Anteroposterior pelvic and lateral x-rays of the hip were taken at each visit. To estimate the survival of the THAs we used the Kaplan-Meier method with 95% confidence interval (CI). Logistic regression analysis was performed to determine which factors affected the presence of radiolucency around the femoral stem.

Results: The mean follow-up was 11.1 years (9.0-14.2). 1 patient was lost to follow-up, and 7 patients were deceased at the time of 10-year follow up. At 10 years 7 patients have had further surgery. 5 for infection, 1 periprosthetic femoral fracture and 1 heterotopic bone formation. All stems were classified as well fixed. 2 cups were defined as loose at 10 years. 1 patient is scheduled for revision the other refused revision. The clinical outcome and radiological findings were assessed in 123 hips. The mean Harris Hip Score was 94 (35-100) at 10 years and the mean WOMAC score was 89 (30.2-100).

Conclusions: We report good results with respect to clinical outcome and survival of the reverse hybrid concept in patients younger than 65. A successful outcome depends on meticulous preoperative planning, use of modern cementing techniques in the acetabulum and experience in implanting an uncemented stem.

Keywords: Corail, Radiologic findings, Reverse hybrid, Survival

Introduction

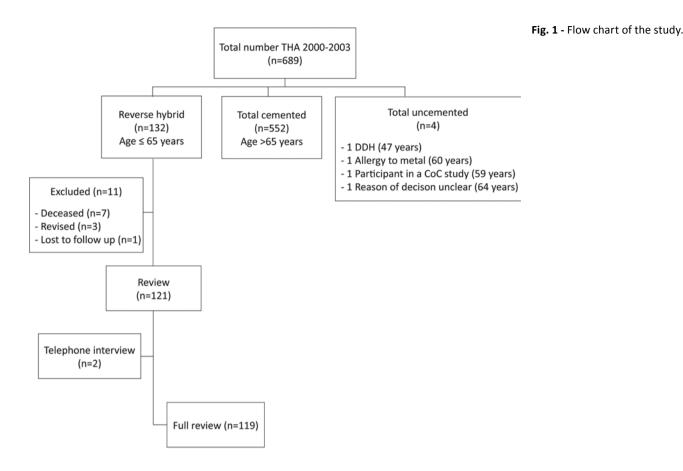
Total hip arthroplasty (THA) was introduced in Norway in 1970. An all cemented metal-on-polyethylene THA had been the first choice until the beginning of 2000. Since then there has been a growing use of reverse hybrid THAs in primary

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Corresponding author: Helge Wangen Orthopaedic Department Elverum Innlandet Hospital Trust PB 407 2407 Elverum, Norway helge.wangen@sykehuset-innlandet.no hip replacements in Norway, and to some extent in Sweden. A reverse hybrid is a cemented all polyethylene (ultra-highmolecular-weight polyethylene [UHMWPE]) socket together with an uncemented stem. The concept was based on the findings in the Norwegian Arthroplasty Register (NAR) with good long-term results for uncemented stems in young patients combined with the fact that cemented cups performed better than uncemented. Havelin et al (1) proposed that randomised studies with hybrids of cemented cups, inserted with modern cementing technique, combined with uncemented HA- or porous-coated stems should be done in young patients. The same year McNally et al (2) published a paper that demonstrated greater than 90% survival with a cemented cup/uncemented stem combination after 12 years.

In our centre, we elected to use the Corail stem and the Charnley elite cemented socket due to their heritage and results. This was combined with an alumina ceramic head to





reduce wear rate. Age 65 was set as the maximum for using the reverse hybrid. In patients >65 years we used a fully-cemented prosthesis.

The primary aim of this study was to report the clinical and radiographic outcome of 132 consecutive reverse hybrids in terms of implant survival, pain, outcome scores, and radiographic outcome in patients ≤65 years.

Patients and methods

Between the January 04, 2000 and December 31, 2003 a total of 689 THAs were performed in our hospital. Except for 4 patients, those ≤65 years received a reverse hybrid THA (Fig. 1) with 132 being performed in 126 patients in a consecutive series at the Orthopaedic Department Elverum Innlandet Hospital Trust. 9 different surgeons performed the operations. There were 79 women, 5 with bilateral hip replacement, and 47 males, one with bilateral prostheses. Mean age was 54.3 years (28-65 years). 59 had a left THA and 61 had a right THA (Tab. I).

Surgical technique

A collarless cementless and fully hydroxyapatite-coated stem was used in 118 cases (Corail®KS, Depuy) in 14 cases a high offset stem with a collar (Corail® KLA, Depuy) was used. The indication for stem type was made prior to surgery based on radiographic templating. Each stem was used in combination with an all cemented polyethylene acetabular cup (Elite Plus Cemented Cup, Depuy) and a 28-mm alumina ceramic head (CeramTec GmbH). Palacos[®] bone cement with gentamycin was used for the cup in all cases.

All procedures were carried out using a direct lateral Hardinge approach in lateral decubitus position.

Preoperative planning with templating was performed in all cases. All patients received cefalotin 2g immediately preoperatively and 3 further doses at 6 hourly intervals. Lowmolecular-weight heparin was given the evening before surgery and once daily until discharge from hospital.

The acetabulum was reamed to remove all cartilage and expose bleeding bone throughout the cavity. In order to promote penetration of cement into the bone, multiple drill holes were made in the peripheral part of acetabulum. The aim was to ream a cavity 4 mm wider than the size of the templated cup in order to have a layer of 2-mm cement all around the cup. Modern cementing techniques with pulse lavage, vacuum mixing of the cement together with a pressurising device to facilitate penetration of cement into the bone before inserting the cup, were used.

Bone compacting broaches were used to prepare the femur. When broaching we increased the size of the broach size by size until we reached axial stability, then we checked for rotational stability of the broach. Axial and rotational stability was defined as primary stability but the final size of the broach was also guided by preoperative planning.

In males, stem sizes ranged from 10 to 20 mm and in females from 9 to 14. The acetabular cup sizes ranged from 43



TABLE I - Demographic data and size of	prostheses of the cohort
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Total n = 132	Men	Women	
Gender/no. prostheses	47/48	79/84	
Age, years (mean, range)	54.1, SD 7.6 (28-64)	54.8, SD 6.9 (38-65)	54.3, SD 7.3 (28-65)
Primary diagnosis OA, FNF, Dyspl, CLP, AVN	37/0/5/3/3	64/0/11/1/4	101/4/16/4/7
Cup size, mm (mean, range)	50 (47-53)	47 (43-53)	50 (43-53)
Stem size, mm (mean, range)	13 (10-20)	11 (9-14)	12 (9-20)

AVN = avascular necrosis; CLP = Calvé Legg Perthes disease; Dyspl = dysplastic hip with osteoarthritis; FNF = femoral neck fracture; OA = osteoarthritis; SD = standard deviation.

to 53. The head size was always 28 mm and 3 lengths of head were used (-3.5 mm, 0 and 3.5 mm).

Follow-up

All patients were routinely reviewed at 3 months, 1, 5, 7 and 10 years postoperatively. At each follow-up patients were seen either by a consultant orthopaedic surgeon or a senior trainee. Anteroposterior (AP) pelvic and lateral x-rays of the hip were taken at each visit. The 1st author reviewed all radiographs. In addition, all immediate postoperative and latest follow-up radiographs were reviewed by an independent coauthor from a different institution with considerable experience of interpreting THA radiographs (JGB).

Radiographic analysis

Radiographic evaluation of the stem included assessment of bone remodelling, osteolysis and fixation of the stem. Diaphyseal fill was calculated by dividing the AP diaphyseal stem area on diaphyseal canal area according to Martell et al (3), and the femur was classified according to Dorr (4). We also evaluated in each case whether the stem used was the correct size as would be determined from the preoperative plan or undersized by 1 or undersized by 2 or more sizes. There is inevitably a degree of subjectivity to sizing and therefore only undersizing by 2 or more sizes was considered significant. Subsidence of the femoral component was measured by the vertical distance from the tip of the trochanter to the lateral shoulder of the prosthesis, using a change of more than 5 mm as significant. This limit of migration was arbitrarily set, but it was based on analysis of manual measurements of migration of hip prostheses (5). Alignment of the femoral component was classified as valgus, neutral or varus with ±5° being considered as neutral. Femoral zone analysis was performed as described by Gruen et al (6). The status of the biological fixation of the stem was assessed by a modification of the criteria described by Engh et al (7). Radiographic bony incorporation was defined as extensive intimate bone implant contact, periprosthetic bone formation and remodelling, and the absence of migration. Femoral remodelling was assessed as a change in bone density, either as cortical or endosteal bone formation. A decrease in bone density was recorded as atrophy and an increase as hypertrophy. X-rays were assessed for

the presence of radiolucent lines (RLLs). THAs were classified into 5 different groups based on lines in different zones (no lines, lines in Gruen zone 1 or 8, lines in Gruen zone 1 and 8 together, lines in Gruen zone 7 with or without other zones) and lines in all 4 proximal zones. In the case of Gruen zone 7 involvement the interpretation was that there was a fibrous layer between the stem and the underlying bone.

Any focal area of cortical or trabecular bone loss was considered evidence of osteolysis (8). Heterotopic ossification was classified according to Brooker (9).

Linear wear of the polyethylene was measured on AP pelvic views by a method described by Charnley et al (10).

Acetabular cup inclination angles were measured from the day one postoperative AP radiograph using the teardrop method (11). Changes around the cups were described according to DeLee and Charnley (12).

Harris Hip Score (HHS) and Western Ontario and Mc-Master Universities Arthritis Index (WOMAC) Score were recorded at 5, 7 and 10 years. The WOMAC score for osteoarthritis was used to assess the functional results (13). This well validated 24 item instrument has a total score of 0 (worst) – 96 (best) which we converted into a 1-100 scale with 100 as best.

Since the study was a service review no ethical approval was required.

Statistical analysis

The endpoint in the analyses was implant revision meaning the exchange or removal of either the whole THA or any part of it. To estimate the survival of the THAs we used the Kaplan-Meier method with 95% confidence interval (CI). Logistic regression analysis was performed to determine which factors affected the presence of radiolucency around the femoral stem. For statistical analyses, we used the statistical software package SPSS, version 22.0.

Results

The survival for the whole prostheses at 10 years followup was 96.9 (Cl, 94.0-100).

7 of the total cohort had further surgery. Case 1 was revised as a 2-stage procedure because of early postoperative infection. Cases 2 and 3 had a successful debridement

Parameter Total	Men	Women		
HHS at 5 years	97.0, SD 6.9 (71-100)	95.1, SD 9.8 (50-100)	95.3, SD 9.3 (50-100)	
HHS at 7 years	98.1, SD 4.9 (77-100)	94.6, SD 9.5 (63-100)	95.4, SD 8.8 (63-100)	
HHS at 10 years	95.4, SD 10.1 (55-100)	93.6, SD 11.0 (35-100)	94.1, SD 10.7 (35-100)	
WOMAC 5 years	91.1, SD 11.1 (57.2-100)	85.9, SD 14.4 (35.4-100)	87.2, SD 13.8 (35.3-100)	
WOMAC 7 years	90.9, SD 13.9 (38.5-100)	86.9, SD 16.7 (36.4-100)	88.3, SD 15.8 (36.4-100)	
WOMAC 10 years	90.5, SD 14.1 (36.4-100)	88.4, SD 15.4 (32.2-100)	89.0, SD 15.0 (30.2-100)	

TABLE II - Harris Hip Scores (HHS) and WOMAC scores at 5, 7 and 10 years

Data are presented as mean values with standard deviation (SD) and range. WOMAC = Western Ontario and McMaster Universities Arthritis Index.

procedure for early postoperative infection. Both remain part of the 10-year follow-up. Cases 4 and 5 also had an early debridement procedure because of infection. In both the infections resolved but both had a cup revision within 2 years after index surgery. 1 of these are a part of the 10 years stem review, the other 1 died 7 years postoperatively with a well fixed stem. Case 6 had excision of heterotopic bone at 1 year with retention of components and remains in the cohort. Case 7 had a stem revision at 8 years because of a periprosthetic fracture. 1 patient had emigrated and was lost to follow up. 6 patients were deceased at follow-up. All except the 4th case above, who had a revision of the cup after 2 years, had a well-functioning THA at the time of death. 2 patients were unable to attend for clinical and radiological review at our hospital. Both had a telephone review and a radiograph at their nearest hospital (Fig. 1). This left 110 Corail® KS stems (noncollared) and 12 Corail® KLA (high offset with collar) stems for follow-up in this study. The mean follow-up was 10.1 years (standard deviation [SD] 0.6 years, range 7.0-12.7 years).

The mean postoperative HHS was 94 (SD 10.7). The mean postoperative WOMAC score was 89.0 (SD 15.0). There were no significant changes of the clinical scores from 5 to 10 years (Tab. II). Preoperative scores were not available.

The cemented acetabular cups were well fixed according to DeLee and Charnley's classification (12) except for 2 that were loose at 10 years. 1 aseptically loose cup is scheduled for revision. The other was loose due to late infection. The patient was admitted 2 years postoperatively with an acute infection in the hip. Because of comorbidities and the patient's own decision the infection has been suppressed with antibiotics only. Despite a loose cup 10 years postoperatively the patient still refuses revision.

In 68 of the cups (56 %) there was a 1-mm RLL in Charnley zone 1 at 3 months follow-up. These lines did not progress at later follow-ups. The mean angle of inclination of the acetabular component was 46.1° (35°-60°). There was no measurable wear at 10 years.

At the latest follow-up of the 122 stems assessed 93 stems (76%) had no lines, 5 stems had lines in zone 1. 12 stems had lines in zone 1 and 8. In 5 stems (4%) lines were noted in zone 7. These all had additional lines in 1 or more further proximal zones (Fig. 2). 2 cases (2%) had lines in all 4 proximal zones

STEMS N=122

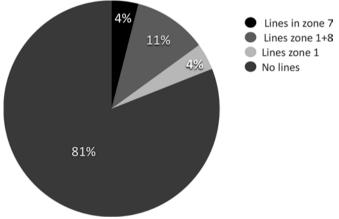


Fig. 2 - Number of prostheses with lines in different proximal zones.

(1, 7, 8 and 14). In 2 of the stems with RLLs in zone 7 we found a progression to zone 6 comparing 5 years post op x-rays to 10 years post x-rays. For those with lines in other zones we did not see any progression.

For those cases with proximal RLLs there was no correlation with respect to age, side, implant size, femoral size, alignment, resection level and presence of heterotopic ossification. Looking at the implant fill of the diaphyseal part of the femur the data suggest a trend towards the presence of proximal silent radiolucent lines in cases with a narrow femur Dorr type A. In 2 out of 110 Corail[®] KS (2%) cases there were RLLs in all 4 proximal Gruen zones indicating partial proximal fibrous nonosseous integration. 2 stems had lines in zone 1 and 7 only. Of the 12 Corail® KLA stems 1 had RLLs in all 4 proximal Gruen zones indicating partial proximal fibrous nonosseous integration, this particular case was a male with a narrow femoral diaphysis and a slightly undersized Corail stem placed in some varus (Fig. 3). None of the stems had subsided when comparing immediate post-op x-rays to those at 3 months. We did not find any relationship between the postoperative function scores and the presence of lines.







Fig. 3 - KLA stem with radiolucent lines in all 4 proximal Gruen zones (1, 2, 6, 7) in anteroposterior view and in zone 8 in lateral view.

Looking at the size of the implanted stems the independent assessor identified 3 cases (2.5%) were he thought the stem was undersized by 2 sizes.

Discussion

In this series, the concept of the reverse hybrid THA performed well with respect to clinical and radiological outcome at 10 years follow-up in patients 65 years or younger with a survivorship of 96.9% (Cl, 94-100). We are aware of only 1 other publication describing results for a single series of reverse hybrid in THA. McNally et al (2) presented the outcome of 100 THAs in 86 patients with an uncemented HA-coated Furlong stem together with an ultra-high-density-polyethylene cemented cup and a 32-mm ceramic head. They found 97% survival for the whole prostheses and 99% for the stem at 10 years. The NAR published results of 3,963 reverse hybrid THAs in 2011 (14). They found no difference in implant survival of reverse hybrids and cemented THAs at 5 and 7 years in patients regardless of age. The Nordic Arthroplasty Register Association (NARA) study by Mäkelä et al (15) demonstrated better results for cemented THAs compared to reverse hybrids in patients 65 years or older. In another study from the same collaboration they found a tendency towards lower rates of revision for reverse hybrids compared to both uncemented and cemented THAs in patients younger than 55 years of age (16).

The Corail KS cementless, collarless and fully hydroxyapatite coated femoral stem has been available for almost 30 years and worldwide registry results show favourable survivorship data (17). Hallan et al (17) published data on medium- and long-term performance on uncemented primary femoral stems from the Norwegian arthroplasty register. The Corail stem had a 15-year survival of 97%.

In this series 93 stems (76%) had no radiolucent lines. In 22 cases (18%) lines were identified in 1 or 2 proximal zones. 17 of these had lines in zone 1 or in both zone 1 and 8. We believe lines in 1 zone and lines in both zone 1 and 8 together are benign since we found no progression of RLLs in these zones. On the other hand, we believe a line in zone 7 either alone or in combination with lines in other proximal zones represents a warning sign suggesting a partial fibrous non-osseous integration and might be a predictor of longer-term problems such as stem loosening or breakage.

In this study lines were found in zone 7 in 5 cases (4%) and except for 1 case there were lines in 2 or 3 additional proximal zones. In 2 of the 5 cases the zone 7 line had progressed to zone 6 at 10 years post-op. However, neither patient had pain. Both were KS standard stems and again in both we feel that there was a metaphyseal/diaphyseal mismatch where stem size was dictated by a relatively small diaphysis without ideal metaphyseal cancellous bone compaction. It may be possible to minimise these lines by reaming the canal in situations where its diameter is less than 9 mm. 1 of the 5 was a KLA stem, which was undersized and implanted in a varus position. The other 2 cases with zone 7 changes were KS stems and we were unable to find a particular reason for the radiographic findings. Although the lines did not correlate with pain, hip score, function or loosening of the Corail stem it would seem preferable to have no lines. Also, there was no evidence of subsidence or distal migration or rotation of the stem despite the lack of a collar. We believe this is related to the surgical technique and in particular the avoidance of undersizing the stem. In this study the broaching technique was influenced by the fact that the surgeons had used sharp broaches up until 1998, which may have resulted in a more aggressive broaching than generally advocated. These findings also correspond to published long



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term results for the Corail stem which is mainly based on implants without a collar (17). In contrast to what Mäkelä et al (15) reported in their study, we experienced no early periprosthetic fractures. 1 reason may be related to the age of the patients studied. Older patients with a lower femoral bone stock seems to have a higher risk for periprosthetic fracture. In our study, all the patients were ≤ 65 years at the time of surgery while Mäkelä et al (15) studied patients 55 years or older. These results may not be generally applicable as they relate to a single centre where all the surgeons were experienced with the stem and the surgical technique prior to the start of the study. Also, the number of patients in the study is relatively small. The cemented all polyethylene acetabular Charnley Ogee cup has good results (18). The Elite cup has the same outer geometry as the Charnley Ogee cup but is made for 28 mm heads. We do not know if this will affect the results for the cup in the longer term.

Except for 2 cups classified as loose, all the other cups were functioning well and classified as well fixed at 10 years follow-up. In 68 of the cups there was a RLL in zone 1 on the x-rays at 3 months postoperatively. These findings are similar to those reported for the Charnley Ogee cup (12). Lines at the cement-bone interface may represent a risk for loosening in the future (19). The lines we found did not progress from 3 months to 10 years. Despite this it would be preferable to have no lines. We believe improved surgical technique can reduce the frequency of these lines. Studies have shown better results when removing the subchondral bone plate regarding development of lines and early micro-motion, implying better long-term cup survival (20).

When we started to use reverse hybrid as a concept in 2000 inferior results for the uncemented cups reported by NAR was the main argument. Since then results for the contemporary uncemented cups have improved and are at least equal to cemented cups especially in younger patients (21). This means that today use of reverse hybrids can no longer be based on outcome only. A cemented cup is cheaper than an uncemented contemporary cup, and the justification for continuing to do reverse hybrids in certain groups of patients could be based on cost-effectiveness rather than better long-term survivorship.

There are some limitations of this study. Firstly, the number of patients is relatively small and secondly the surgery was performed in a single centre. A single centre may achieve very good results with 1 concept, which is difficult to reproduce elsewhere. This could be related to certain local experience with the implants and the surgical technique preformed. Therefore, the results do not necessarily only reflect the results of the implant or the concept reverse hybrid THA.

Thirdly, the follow-up is only 10 years, which is a relatively short period of time, particularly for a cohort of young THA patients.

Conclusions

This study demonstrates that the concept of a reverse hybrid THA with a cementless Corail stem and an all polyethylene cemented cup combined with a 28-mm alumina femoral head works well in patients ≤65 years at an average follow-up of 10 years.

Disclosures

Financial support: None.

Conflict of interest: HW, JGB and DEB are paid as consultants from Synthes Depuy. DEB has research support from Synthes Depuy and Zimmer.

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