Minimum Seven-year Follow-up of Cementless Total Hip Arthroplasty with the COREN Hip System

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Purpose: We previously reported results of a mean 3.2-year follow-up of the COREN hip system, which is the first total hip prosthesis developed in Korea. The aim of this prospective study was to update the previous report with regard to the hip function and radiographic implant performance.

Materials and Methods: Between 2003 and 2004, a consecutive series of 68 primary, cementless, total hip prostheses (COREN) were implanted in 57 patients (68 hips) and followed up for a minimum of 7 years. Sixty-three of the 68 hips were available for clinical scoring and radiographic analysis.

Results: The mean Harris hip and WOMAC scores were improved from 48.1 and 54.7, preoperatively, to 96.4 and 22.1 at the final follow-up. The mean patient activity increased from 3.1, preoperatively, to 8.2 at the final follow-up. All hips showed stable bony ingrowth on the radiographs. No hips showed evidence of osteolysis or prosthesis loosening, and no revision was required during the follow-up. A Periprosthetic fracture (Vancouver type B1) was encountered in one hip 4.7 years after surgery, which was treated by reoperation.

Conclusion: This study shows that the COREN hip system produces excellent mid-term results in cementless hip arthroplasty.

Key Words: Hip, Cementless total hip arthroplasty, COREN hip system

Introduction

Total hip arthroplasty (THA) is currently one of the most widely performed procedures in orthopedic practice. Over recent years, THA gained much improvement in terms of prosthesis design, availability of suitable component materials and manufacturing techniques, and a better understanding of hip mechanics.

In a previous study, we reported results at a mean 3.2 years following implantation of the COREN hip system (Corentec, Seoul, Korea) in a consecutive series of 68
primary cementless total hip arthroplasties performed in 57 patients\(^1\). All bearings were made of third generation BIOLOX forte alumina (CeramTec, Plochingen, Germany). After a mean follow-up of 3.2 years, no hip showed evidence of osteolysis or prosthesis loosening. No complication such as deep infection, dislocation, or ceramic fracture occurred in any hip, and no revision surgery was required. The purpose of this study was to reevaluate this cohort of patients after a minimum follow-up of 7 years to assess clinical and radiological outcomes of the COREN hip system.

**Materials and Methods**

Between July, 2003 and March, 2004, a consecutive series of 68 primary uncemented total hip prostheses were implanted in 57 patients. Two centers located at academic institutions participated in the study, with 1 contributing surgeon at each center. The protocol for investigating the clinical outcomes and radiologic findings was approved by Korea Food and Drug Administration and ethics committees at the two institutions. All subjects who were provided with an explanation of the objectives and requirements of the study and the characteristics of the implant and consented to this study were entered into this prospective cohort study.

Preoperative diagnosis include avascular necrosis of the femoral head in 50 hips(73.5%), sequelae of Legg-Calve-Perthes disease in 5 hips(7.4%), hip dysplasia in 4 hips(5.9%), traumatic osteoarthritis in 3 hips(4.4%), sequelae of septic hip in 3 hips(4.4%), ankylosing spondylitis in 2 hips(3%), and primary osteoarthritis in 1 hip(1.4%). Patients with primary or secondary carcinoma during the five years prior to study commencement, with neurovascular compromise of lower extremity, and patients that failed to provide informed consent were excluded. The initial cohort was composed of 36 males (43 hips) and 21 females(25 hips) with a mean age of 48 years (range, 20-68 years) at the time of surgery. Thirty-eight procedures were performed on left hips and 30 procedures on right hips. However, of the 57 patients(68 hips), 5 patients(5 hips) were lost to follow-up. Four patients were lost due to an unexpected change in residency and 1 patient succumbed to pneumonia at 4.2 years after surgery. Accordingly, the final cohort was composed of 52 patients(63 hips), who were followed for a minimum of 7 years (mean 7.6 years, range 7-7.9 years).

The COREN hip system used in this study is the first prostheses to be developed and produced in Korea (Fig. 1). The femoral prosthesis (BENCOX\(^\circ\)) is made of titanium alloy (Ti6Al4V Titanium alloy) with a wide range of selection(15 different sizes). It was designed as a straight, double wedged, tapered stem with a rectangular cross-section. Surface treatment was performed using grit blasting with a roughness of 5.5 \(\mu\)m. The stem has anterior, posterior, and lateral vertical ribs on its proximal portion to reduce rotational forces. Neck-shaft angle is 135° and the neck has a 12-14 taper with circular cross-section. The acetabular cup (COREN\(^\circ\)) is made of titanium alloy (Ti6Al6V Titanium alloy) and has 2 holes for dome screws. The external diameter of the cup is designed to be 1.7 mm larger than that of the same-sized reamer to augment both peripheral contact and polar contact. The cup surface is treated with a 200-400 \(\mu\)m coating of porous titanium using plasma-spray technique. A 28 mm diameter alumina ceramic head and liner (BIOLOX forte, CeramTec, Plochingen, Germany) were used in all hips.

All operations were carried out in a lateral position via anterolateral(49%) or posterolateral approach(51%) without the aid of C-arm or portable radiographs.
Thromboprophylaxis was not routinely given during the preoperative or postoperative period. Antibiotic prophylaxis was administered to all patients from 1 hour before surgery to 3 days after surgery. Suction drains were routinely removed 2 days after surgery and patients were then allowed partial weight-bearing, which was followed by consecutive full weight-bearing at 4 to 6 weeks after surgery.

1. Clinical and radiographic evaluations

Patients were monitored using laboratory blood test to check hepatotoxicity, renal toxicity, and other adverse effects preoperatively, at 1, 2, 3, and 6 months postoperatively and then annually. Clinical and radiographic outcomes were determined preoperatively, at 1, 3, 6, and 12 months postoperatively and then annually.

An independent investigator prospectively collected all clinical information. Surgical data including operative times, intraoperative estimated blood losses, total blood losses, and perioperative complications were obtained by reviewing patients’ records. Clinical performances were evaluated using Harris hip scores (HHS) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores. In addition, patient activity levels were assessed using University of California Los Angeles (UCLA) scores. Postoperative subjective satisfaction was graded 4 steps as excellent, good, fair, or poor. All patients were asked about the incidence and severity of any thigh pain. Postoperative complications and reoperation procedures including revision were also recorded.

Plain weight-bearing radiographs in anteroposterior and lateral view were evaluated using the zone classification by an independent orthopedic surgeon experienced in reviewing hip radiographs. Cup abduction angles were determined using the method described by Woo and Morrey, and outliers were defined as hips with a cup abduction angle of $\leq 30^\circ$ or $\geq 50^\circ$. Stem alignments were assessed by the method reported by Martell et al. Varus or valgus positioning was used to describe a stem with $>5^\circ$ of alignment with respect to the neutral axis of the femoral canal. Stem stability was classified into 3 types - bony ingrown, fibrous ingrown or unstable as described by Engh et al. The appearance of ectopic ossification was graded according to the criteria of Brooker et al. Engh criteria were used to grade stress shielding.

Much attention was paid to any signs of osteolysis or loosening, or implants subsidence. Osteolysis was defined as focal bone resorption evidenced by a cystic lesion. Implant loosening was evaluated in immediately postoperative radiographs and final radiographs. Cup loosening was defined as the presence of a radiolucent line around the entire circumference, a change in inclination angle of at least 5°, or migration of at least 2 mm. Stem loosening was defined as a complete radiolucent line, the presence of varus or valgus migration, or subsidence of at least 5 mm. Stem subsidence was determined by evaluating preoperative to postoperative changes in distance between the top of the greater trochanter and the lower edge of the stem.

2. Statistical analysis

The Shapiro-Wilk test was used to confirm that clinical outcome scale scores were normally distributed. The paired t test and Wilcoxon’s signed rank test, the nonparametric equivalent of the paired t-test, were used to detect differences between preoperative and final follow-up clinical scores. A Kaplan-Meier survival analysis was used to calculate survival rates using any reoperation and revision for any reason as the end point. In addition to these analyses, a worst-case survival curve was plotted for revision for any reason. Worst-case survival analysis was based on the assumption that revision has been performed in all patients lost to follow-up. P values of less than 0.05 were considered significant. The SPSS statistical software package (SPSS 16.0; SPSS, Chicago, Illinois) was used for all statistical calculations.

Results

The mean operative time for THA was 73.2 minutes (range, 40-104 minutes), and mean intraoperative and total blood losses were 380.2 ml (range, 140-810 ml) and 1,034.3 ml (range, 402-1,800 ml), respectively. Laboratory findings and physical examinations during follow-up failed to reveal any evidence of organic or systemic toxicity or adverse effects.

The mean Harris hip and WOMAC scores were improved significantly from 48.1 points (range, 20-67 points) and 54.7 points (range, 45-69 points) preoperatively to 96.4 points (range, 83-100 points) and
22.1 points (range, 12-42 points) at final follow-up, respectively ($P<0.001$, paired t test; $P<0.001$, Wilcoxon’s signed rank test, respectively). UCLA activity level significantly improved from an average of 3.1(range, 1-5) preoperatively to an average of 8.2 (range, 6-10) at final follow-up ($P<0.001$, Wilcoxon’s signed rank test). Clinical scores were presented with more detail in Fig. 2. Patient self-assessed subjective satisfaction at final follow-up was excellent in 38 hips (60.3%), good in 22 hips(34.9%), fair in 3 hips(4.8%) and poor in no hip. Thigh pain at final follow-up was reported in 2 hips, but neither of these hips showed signs of implant loosening or limited daily activities.

At final follow-up, mean cup abduction angle was 41.2° (range, 28-52°). Two outliers less than 30° or more than 50° were observed, but neither showed signs of loosening. The stem alignment was neutral in 59 hips (93.6%), varus in 2 hips(3.2%), and valgus in 2 hips (3.2%). Stress shielding of first degree was observed in 11 hips(17.5%), and of second degree in 2 hips(3.2%), but no progressive stress shielding was seen. Grade 1 heterotrophic ossification was observed in 2 hips(3.2%) and grade 2 heterotrophic ossification was observed in 1 hip(1.6%). No osteolysis or loosening which needed revision in the acetabular cup or femoral stem was observed. Stable fixation of implanted prostheses with bony ingrowth was demonstrated in all 63 hips. A typical radiographic series is shown in Fig. 3.

During the follow-up period, no sciatic nerve palsy, wound infection, or deep infection occurred and no revision was required. There is no dislocation after surgery. Intraoperative femoral fracture occurred in 2 hips. One of these calcar cracks were identified during stem insertion, but healed in situ without the need for any additional procedure. The other fracture which occurred in the greater trochanter during femoral canal preparation was treated with cerclage cable fixation with grip and subsequently healed without affecting functional outcome. A periprosthetic femoral fracture (Vancouver type B1) occurred in one patient, who underwent open reduction and internal fixation at 4.7 years after surgery.

The survival rate of the COREN hip system was 98.4%(95% confidence interval, 95.3 to 100.0), 100%, respectively based on any reoperation and revision for any reason after 7 years (Fig. 4). The worst-case-scenario survival rate (i.e., with consideration of patients lost to follow-up as having had a revision for any reason [n=4]) was 94%(95% confidence interval, 89.3 to 98.7).

**Discussion**

This study was prospectively designed to evaluate the COREN hip system which is the first total hip prosthesis system...
to have been developed specifically for the Korean population. This hip system was developed based on the anatomical characteristics of Korean hip and has tried to restore the range of motion to comply with traditional demand to sedentary lifestyle\(^1\).

The COREN hip system produced satisfactory results of the stem alignment with neutral position in 93.6\%. Our findings seemed to be superior than previous studies in which neutral stem alignment is achieved from 50\% to 72\%\(^{21-23}\). Three vertical ribs may contribute the femoral component to be seated on neutral position, but further study is required to prove this hypothesis. It is still unclear whether malposition of the cementless femoral stem is associated with poor outcome of THA although varus placement of the femoral component in cemented THA is known to increase a risk of aseptic

![Fig. 3](image1)

**Fig. 3.** (A) Preoperative radiograph of a 44-year-old man with osteoarthritis following septic sequelae of the left hip. (B) Postoperative radiograph 4 weeks after index arthroplasty showing a well-positioned prosthesis. (C) A Radiograph at 7 years after surgery showing stable bony fixation of both the acetabular cup and femoral stem.

![Fig. 4](image2)

**Fig. 4.** Seven-year Kaplan-Meier survival curves using (A) any reoperation and (B) any revision for any reason as the end point.
loosening of the prosthesis. Vresilovic et al. described that varus malalignment of the stem was associated with unstable fixation and Ries et al. reported that varus migration of PCA stem led to a lower percent canal fill and poor distal stem stability. On the other hands, Min et al. found that malalignment of a tapered-wedge cementless femoral stem dose not compromise the outcomes after THA. In the present study, we could not find significance of the stem alignment in terms of clinical and radiographic outcomes. The type of surgical approach was also not associated with the stem position.

In the present study, only 5 patients were lost during follow-up period, which represents a reasonable follow-up rate as compared with similarly studies. The COREN hip system was found to have a reoperation rate of 1.6% and a survival rate of 100% at minimum 7 years after surgery. Furthermore, survival of the COREN stem was found to be comparable to those found in other studies on cementless stems with good clinical results. The Zweymuller stem was reported to have a 99% survival rate after 10 years and is likely to show similar results in a reevaluation. Ten-year follow-up of CLS survival showed overall survival rates of 92% in patients of all ages. The COREN prosthesis also produced a good result according to National Institute for Clinical Excellence criteria of the UK National Health Service, which defines a revision rate of 10% or less at 10 years as ‘good’. Even in worst-case scenario, the revision rate was acceptable. It was reassuring to find no evidences of osteolysis or loosening which have been reported in some early-term studies of the CLS prosthesis (Genterpulse, Bern, Switzerland), which has a design similar to that of the COREN prosthesis. The COREN acetabular cup also showed good results. The survivorship of this cup was 100% at 7-year follow-up. Rozkydal et al. reported that in their study of 112 hips undergoing THA, the CLS acetabular cup showed 92% survival rates with revision for any reason at a minimum 15 years follow-up. Hrubina et al. described that at 8.5-year follow-up of 40 cases using the Ultima acetabular components, 88.9% were without radiographic signs of loosening.

Thigh pain is known to be associated with distal canal reaming, the use of cobalt-chromium implants, and tight fit. Interestingly, in the present series, thigh pain

![Fig. 5. Photographs showing the upgraded COREN hip system. (A) Increased neck offset to prevent soft tissue laxity. (B) A surface treatment with micro-arc oxidation (MAO). (C) A metallic cup with increased hole number and surface porosity and roughness.](image)
has been found in only 2 hips (3.2%). We believe that this may be due to the more flexible titanium alloy, the lack of tight distal canal fill, and the more proximal metadiaphyseal loading of the COREN stem. In the present study, no osteolysis was observed around stem during follow-up, which was comparable to the findings of other uncemented implants with ceramic-on-ceramic bearing. In addition, distal cortical hypertrophy was observed in no cases. The wedge-shaped tapered design of the COREN stem might reduce severe stress shielding and radiographic distal cortical hypertrophy although in previous studies, it has been found that uncemented implants had tight stem fits, which were regarded as a prerequisite for long-term survival. However, trochanteric fractures related to stress shielding and osteolysis have been reported in up to 22% of cases treated using anatomic medullary locking uncemented components.

The limitations of this study include the relatively small number of patients enrolled and the lack of a control group. Further, power analysis was not performed before initiating the study, and thus, the volume of subjects analyzed may be insufficient to provide sufficient power. In addition, the follow-up period was relatively short and our findings might not reflect longer term problems. However, this study was conducted prospectively, and provides helpful information about the performance of the COREN hip system.

The COREN hip system currently available has been remodeled several times from the first generation model. Three major improvements have been made to the femoral stem. First, the surface treatment is now conducted using the Micro Arc Oxidation (MAO) technique, a plasma assisted electro-chemical process, which forms thicker and much more porous surface oxide layer (Fig. 5). This technique induces the vigorous attachment of osteoblastic cells, and thus, promotes bony ongrowth. Second, the neck offset has been increased and the ball head center lowered to reduce soft-tissue laxity (Fig. 5). Femoral offset is an important design feature that should be optimized since it profoundly affects mechanical function of the replaced hip. Reduced femoral offset reduces the range of motion and detrimentally affect polyethylene wear and acetabular loosening rates. Third, to improve range of motion and minimize prosthetic impingement, the head-to-neck ratio was increased by using a 36 mm femoral head and a decreased neck diameter. Regarding acetabular cup, improvements were shown in two aspects. Surface porosity increased from 15-30% to more than 30% and surface roughness from >100 μm to >250 μm (Fig. 5). In addition, the number of holes increased from two to three to facilitate transacetabular screw fixation. There may be some concerns including third body war in term of the increased hole numbers of the acetabular cup. However, COREN hip system use only ceramic-on-ceramic bearing and thus, this concern would be reduced.

The clinical and radiographic evaluations of cementless THA using the COREN hip system revealed excellent outcomes after a minimum follow-up of 7 years. Furthermore, the survival rate of this prosthesis was also found to be excellent, and in particularly, no aseptic loosening or progressive osteolysis was encountered. It will be important to see if these results continue with a longer period of follow-up.

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국문초록

COREN Hip System을 이용한 무시멘트 고관절 전치환술의 최소 7년 추시 결과

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목적: 예전에 보고하였던 국내 최초로 개발된 인공 고관절인 COREN hip system (COREN, Corentec, Seoul, Korea)을 이용한 무시멘트 고관절 전치환술의 추시 결과를 연장하여 보고하고자 한다.

대상 및 방법: 2003년 7월부터 2004년 3월까지 COREN hip system을 이용한 무시멘트 고관절 전치환술을 시행받았고 7년 이상의 추시가 가능하였던 52명(63예)을 대상으로 임상적, 방사선학적 분석을 시행하였다.

결과: Harris 고관절 점수는 수술 전 평균 48.1점에서 수술 후 마지막 추시 96.4점으로 향상되었고, WOMAC 점수는 수술 전 평균 54.7점에서 수술 후 마지막 추시 22.1점으로 향상되었다. 모든 고관절에서 술 후 안정된 골성 고정 소견을 보였으며, 골용해나 삽입물의 해리를 보인 예는 없었다. 추시 기간 중 재치환술이 필요한 예는 없었으며, 한 예에서 술 후 4.7년에 치환률 주위 골절로 재수술을 시행하였다.

결론: COREN hip System을 이용한 무시멘트 고관절 전치환술의 7년 이상 추시에서 만족할만한 임상적, 방사선학적 결과를 얻을 수 있었다.

색인단어: 고관절, 무시멘트 고관절 전치환술, COREN hip system