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Research Article

Results of the Novation Crowncup™ porous-coated uncemented acetabular component in total hip arthroplasty: a 10-year clinical and radiological assessment

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ABSTRACT

Objective: The aim of this study was to evaluate theclinical, radiological, and survivorship results of a porous-coated uncemented acetabularcup (Novation Crowncup TM Exactech, Gainesville, Florida, USA) in patientsundergoing total hip arthroplasty at the mid to long term follow-up.

Methods: We prospectively analyzed 185 consecutivetotal hip replacements in 176 patients during 2009. All the patients received aNovation Crowncup™ uncemented cup. All surgeries were performed by one ofthe 4 joint replacement specialists. Several clinical and radiographic outcomemeasures were evaluated.

Results: There was no cupmigration recorded. Six cups (5.2%) had a thin (less than 1 mm) radiolucentline without signs of loosening or clinical manifestation, but under close followup. The wear was not significative at the end of the follow up. The mean HarrisHip Score increased from 45.7 (range = 28 to 65) preoperatively to 89.8 (range= 87 to 96) at the final follow-up. Subjectiveevaluation showed excellent results in 82.6%, good in 8.6%, fair in 5.9%, andpoor in 2.9% of the cases. Eight patients, 3 stems, and 5 cups (5% of the series)were revised, the survival of the series was 95% when the failure was the needfor additional acetabular or femoral revision surgery for any reason. If wedefine failure as the need for an acetabular revision for some reason, thesurvival was (97.5%). When we evaluated survival only for aseptic loosening ofthe cup at 10 years of follow-up, 98.4% of the implants survived.

Conclusion: In our series,when we evaluated survival only for aseptic loosening of the cup at 10 years offollow-up, 98.4% of the implants survived. The Crowncup acetabular cup survivalrate was 97.5% including all causes of loosening and 95% including all causesfor revision at 10 years of follow-up.

Level of Evidence: Level IV, Therapeutic Study

Introduction

Since 1959, when Sir John Charnley introduced total hip arthroplasty (THA), it has been called the orthopedic procedure of the century. Currently, more than a million procedures are performed annually.

Cemented cups have been shown to have very good long-term results with good surgical techniques; however, they have been replaced as the gold standard by uncemented cups in recent decades.[1] The concept of noncemented cups emerged to achieve direct implant-bone union via biological fixation, resulting in long-lasting fixation and performance.

Uncemented fixation is currently the most widely used method for fixation of the acetabular component worldwide.[2] Although there is abundant evidence supporting the use of this type of fixation,[3] the wide availability and the ease with which an implant can be introduced to the market means that multiple models can be used without sustainable evidence to support their outcomes. The survival of an implant is critical, and guidelines from different countries recommend a maximum revision rate of 10% at 10 years as a limit for the commercialization of a prosthesis.

This study aimed to evaluate the survival and clinical-radiological outcomes of a porous-coated uncemented cup (Novation Crowncup, Exactech, Gainesville, FL) during intermediate- to long-term follow-up.

Materials and Methods

After obtaining approval from the Internal Review Board and written informed consent from all the patients or their authorized guardians, we prospectively analyzed 185 consecutive total hip replacementsin 176 patients in 2009.

We included all patients between 21 and 85 years of age with a diagnosis of osteoarthrosis, avascular necrosis, fracture, Crowe's dysplasia type 1 or 2, or rheumatoid arthritis without a history of previous surgery on the acetabulum who underwent implantation with the uncemented cup under study. This number of surgeries represents almost a third of the surgeries performed by the authors annually (Table 1).

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Table 1. Preoperative diagnosis after applying exclusion criteria

Diagnosis	No. of Hips (%)
Osteoarthritis	56.7
Fracture	13.9
Avascular necrosis	9.4
Dysplasia	9.4
Posttraumatic OA	6.3
Rheumatoid arthritis	4.4
TOTAL	159 (100%)

The exclusion criteria were pathologic fracture, metastatic disease, Crowe's dysplasia type 3 or 4, age over 85 years, irradiated bone, conversions, revisions, or previous surgery on the acetabulum.

All patients received a Novation Crowncup uncemented cup and GXL polyethylene liner, with posterior elevated rim with 10 degrees (Exactech, Gainesville, FL) in combination with an uncemented Novation Element (Exactech, Gainesville, FL) or a twynSys cemented stem (Mathys, Bettlach, Switzerland); 32-mm metal heads were used in all the patients.

The Novation Crowncup uncemented cup has a titanium hemispherical design, plasma spray to increase scratch fit, cluster hole type, with ultra-congruent surface with polyethylene insert, anti-rotational tabs and apical tab as fundament of locking mechanism.

All the surgeries were performed by one of the 4 joint replacement specialists. After hypotensive epidural anaesthesia was established, a posterolateral approach was applied in all the patients with posterior complex reattachment, as described by Pellici and coworker.[4] All the patients received antibiotic prophylaxis with 3 doses of intravenous cefazolin (1 g/8 h) and routine thromboprophylaxis with 40 mg of subcutaneous enoxaparin sodium during the first postoperative month.

The rehabilitation protocol included early mobilization from the first postoperative day and ambulation with a walker and full load. Control radiographs were obtained before the consultation with the specialist. Clinical and functional data were also recorded immediately, 15 days, 6 weeks, 3 months, and 6 months after surgery and then annually thereafter. All the patients were scheduled for clinical-radiological control examinations. Radiographs were simultaneously reviewed by 2 of the authors.

Radiological evaluation

The following radiographic parameters were examined using a supine anteroposterior X-ray of the pelvis and lateral X-rays from the preoperative and sequential evaluations until the last follow-up.

Femoral radiolucency

Femoral radiolucencies and periprosthetic osteolysis were evaluated using the Gruen zones.[5] Stem subsidence was determined using the method described by Loudon and Charnley.[6] Loosening was considered a sag greater than 5 mm or a progressive demarcation around the stem.

Acetabular radiolucency

Acetabular radiolucency was evaluated according to the 3 zones described by DeLee and Charnley.[7]

Acetabular inclination

Acetabular inclination was evaluated using the Lewinnek safe zones.[8]

Acetabular anteversion

Acetabular anteversion was evaluated according to the Auckland method.

Cup migration

Cup migration was defined as migration >5 degrees on sequential X-rays and/or broken screws.

Femoral cementing

The femoral cementing technique was evaluated according to the Barrack classification on immediate postoperative radiography.[9]

Heterotopic ossification

The Brooker classification was used to determine the presence of heterotopic ossification during the last control examination.[10]

Polyethylene wear was measured using the dual-circle technique based on vector analysis, as described by Martell and Berdia[11]

The clinical evaluation included determination of the HHS preoperatively and during the subsequent scheduled visits[12] and subjective evaluation according to Roles y Maudsley score (excellent no pain no limitations after the procedure, good significative improvement after the procedure, fair limited improvement after the procedure, or similar symptoms as before surgery).

Surgery time, incision length, blood loss, American Society of Anaesthesia (ASA) Score and type of anesthesia were recorded. (Table 2)

Survival analysis

Defining failure to calculate implant survival as (a) the need for additional acetabular or femoral revision surgery for any reason, (b) the need for acetabular revision for any reason, and (c) the need of acetabular revision due to mechanical failure.

Statistical analysis

Continuous variables are expressed as medians and interquartile ranges. Categorical variables were reported as frequencies and percentages. Continuous variables were compared using the independent sample Student's *t*-test when the data were normally distributed and the Mann–Whitney *U*-test when they were not. Categorical

Table 2. Surgery Data

Surgery Data	
Variables	Series (n = 159)
Median surgery time	71 min (IQR 49–95)
Blood loss during surgery	400 mL (IQR 240–630)
ASA Classification	
ASA I	50 hips (31%)
ASA II	92 hips (58%)
ASA III	17 hips (11%)
Anaesthesia	
Spinal	139 (87%)
General	20 (13%)

HIGHLIGHTS

- This acetabular implant was found to be effective at 10 years of follow-up in our hands.
- The outcomes at medium follow-up of this study suggest that in the long term, these results probably will be high.
- We believe in the importance of reporting the results of each new design because of the wide range of offers by the industry in orthopedic implants. Not only with medium- and long-term follow-up but also in the short term to detect early any type of implant-related failure.

variables were compared using Chi-square and Fisher's exact tests. Kaplan–Meier methodology was utilized to estimate the 10-year survivorships free from additional acetabular or femoral revision surgery for any reason, acetabular revision for any reason, and acetabular revision due to mechanical failure. Odds ratios were reported with their 95% confidence intervals (CI). Statistical significance was defined by a value of $P < 0.05$. All the analyzes were performed using Stata 13 ™ statistical software (Stata Corp., College Station, TX).

Results

Of the 185 initial eligible hips, 26 were lost to follow-up. In all, 14 patients did not consent to participate in the study, and of the 12 who had incomplete data on clinical and radiological follow-up, 5 had lost their insurance coverage and had to change specialists; they were contacted by phone, and implant survival was confirmed in all of them. However, it was decided not to include them in the analysis. The remaining 159 patients had complete clinical and radiographic data and were eligible to be included in the study at a minimum follow-up of 10 years (Table 3).

Radiographic evaluation

There were no recorded cases of cup migration. Six cups (5.2%) had a thin (less than 1 mm) radiolucent line without signs or clinical manifestations of loosening but were under close follow-up observation. Wear was not significant at the end of the follow-up period. The mean wear detected was 0.9 ± 0.5 mm (Figures 1 and 2).

Table 3. Hips Flow Chart

Received 231
Excluded 46
35 older than 85 years
9 (MTS or pathologic fractures 5 cases, 4 cases dysplasia Crowe 3 or 4)
2 previous acetabular surgery (PAO)
Included 185
Lost of follow up 26 hips
14 not accepted study inclusion
Incomplete charts 12 (failure to assist in clinical radiological evaluations)
159 hips followed with a minimum of 10 years
Female/male 97/62 (61%/39%)
Age range 21–85 years, average years 65.5 years

Uncemented stems: We found subsidence in 6 cases, all of which were identified in the first month and then stabilized without any symptoms, except for in one case. In 4 cases, the patient suffered an intraoperative proximal calcar fracture resolved with cerclage. All fractures but one were fixed according to Engh's criteria (revised at the 8.5-year follow-up). One patient presented with thigh pain and underwent revision surgery with a cemented stem, and the radiographic evaluation suggested undersizing.

Cemented stems: No migration was detected in any patient, except for 1 patient positive for septic loosening (PCR +, ERS 100, and gammagraphy +).

The preoperative HHS was 45.7 points, ranging from 28 to 65 points, and at the final follow-up, the score was 89.8 points, ranging from 87 to 96 points.

Subjective evaluation showed excellent results in 82.6%, good in 8.6%, fair in 5.9%, and poor in 2.9% of the cases.

Overall revision rate

One cup required revision due to repetitive dislocation in a patient with dementia, where stability was evaluated intraoperatively and was satisfactory. It was decided to exchange the cup for a dual mobility cup without replacing the stem. Four patients underwent revision for loosening (2 cases due to infection and 2 cases due to aseptic loosening). Regarding the septic loosening, one failed at 6.7 and the other at 9.3 years of follow-up. In both cases, a 2-stage replacement of both acetabular and femoral components was performed. There was one case of screw breakage in the patient with aseptic loosening.

Eight patients, 3 stems and 5 cups (5% of the series), underwent revision surgery, and the survival rate of the series was 95% (95% CI, 93%-97%) when failure was defined as the need for additional acetabular or femoral revision surgery for any reason (Figure 3). If we defined failure as the need for acetabular revision for any reason, the survival rate was 97.5% (95% CI, 95%-99%). Finally, when we evaluated survival only according to aseptic loosening of the cup after 10 years of follow-up, 98.4% (95% CI, 96%-99%) of the implants survived.

Discussion

In our series, the Crowncup survival rate was 97.5%, including all causes of loosening, after 10 years of follow-up. Similar results have

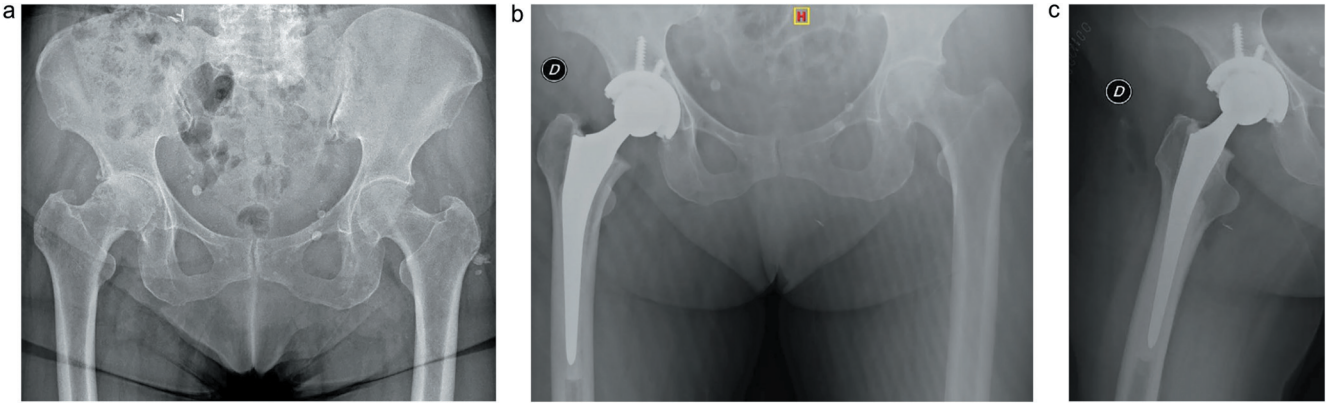

Figure 1. a-c. (a) Preoperative A-P X-ray shows right hip osteoarthritis in a female of 65 years old. (b) Same patient's immediate postoperative A-P X-ray with a hybrid total hip replacement with a well-fixed Crowncup implanted in a safe zone. (c) Lateral view of the same patient shows a good femoral version.

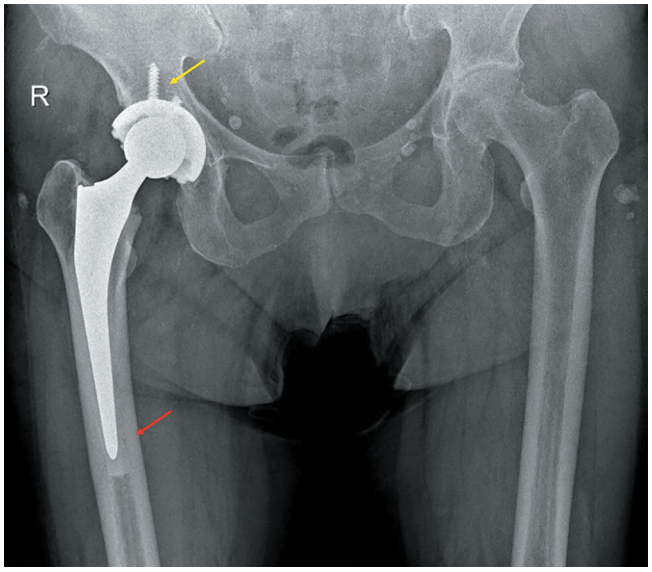

Figure 2. Postoperative A-P X-ray shows a well-fixed acetabular component, a radiolucent line can see around the screw (yellow arrow), and minimal radiolucent line in zone 5 of Gruen (red arrow) without any symptoms at 10 years of follow-up.

Figure 3. Kaplan-Meier survivorship free from any cause of revision.

been published for the most commonly used acetabular components worldwide.[1,3,13,14]

Loosening of the acetabular component is recognized as a major long-term problem associated with cemented cups; for this reason and the occurrence of cement-related disease, this fixation technique is now in disuse.[15] However, cementless fixation is not free of complications, and radiolucencies, lack of press-fit, and early aseptic loosening are major concerns for joint reconstruction surgeons.[16–18]

We found 5 acetabular complications. One cup required revision due to repetitive dislocation in a patient with dementia, where immediate postoperative X-rays showed the component into the Lewinnek safe zones. In 4 cases, revision was required due to loosening; In 2 of those cases, a deep infection led to both femoral and acetabular revision surgery, and in the other 2 cases, failure occurred due to mechanical issues. Screw breakage occurred in the patient with aseptic loosening, which could be attributed to poor primary press-fit fixation. If we define failure as the need for revision surgery due to aseptic loosening, 98.4% of the series survived at the end of the follow-up period.

When the wear rate is compared with that of other uncemented cups and even with cemented cups, the average rate of 0.9 mm is similar to that obtained with similar cemented and uncemented designs.[19] Uncemented cup fixation has been reported to be reliable and can be maintained successfully over the medium and long term, but problems related to polyethylene wear and osteolysis may compromise long-term survival. A report on conventional noncrosslinked liners showed a consistent decline in survival after 10 years of follow-up.[20,21] In our series, all 176 patients underwent implantation with an HXLPE liner with a 32-mm internal diameter, and there were no wear problems or osteolysis.

A high rate of pelvic osteolysis with uncemented cups with or without screws has been reported in several studies, most of them with large femoral heads and thin liners.[22–24] In our series, the use of a 32-mm head allowed even smaller cup sizes with an adequate polyethylene thickness (minimum, 6 mm). Similar results have been reported for modular cups, as Udomkiat et al. reported a rate of radiolucent lines around their cups of 7% and a rate of focal osteolysis of 4%.

Ritter et al. reported that functional scores after hip replacement tended to decrease in relation to impaired functional capacity in the elderly population. In contrast, satisfaction scores have been found to improve with ageing.[25] Similarly, Celebi et al. reported in their series of uncemented implants in patients with a mean age of 39 years that the mean HHS increased from 41.5 (range, 33–52) to 87.1 (range, 74–96) after the treatment ($P < 0.001$).[26] Similar to Ritter's study, we found that there was a decrease in the HHS with age, but the satisfaction score increased with increasing age.

This study has several limitations. First, although the sample size was relatively small, the data were well recorded, there were few losses to follow-up, and all surgeries were performed by surgeons specializing in hip reconstruction who work at centres with volumes of more than 500 surgeries per year. Second, there was no control group for direct comparison with another cementless cup already established globally. Furthermore, we are aware of the heterogenicity of implants on the femoral side; however, this difference did not affect the implant survival results. The strengths of the study include a minimum long-term follow-up period of 10 years, at which point a detailed analysis of acetabular implant survival was performed detailing when the implant failure was septic or mechanical.

In our series, when we evaluated survival according to only aseptic loosening of the cup after 10 years of follow-up, the implant survival rate was 98.4%. The Crowncup acetabular cup survival rate was 97.5% including all causes of loosening and 95% including all causes of revision after 10 years of follow-up.

Our experience with this implant supports the literature about this fixation technique, with a low rate of both septic and aseptic loosening and polyethylene wear of the implanted primary acetabular cup and without cup migration in our patients.

Ethics Committee Approval: Ethics committee approval was received for this study from the Comité de en Investigación Clínica (CEIC) Traum-3/2008).

Informed Consent: Written informed consent from all the patients or their authorized guardians.

Author Contributions: Concept - D.G-M., A.C.C., S.S.; Design - D.G-M., A.C.C., S.S.; Supervision - D.G-M., A.C.C., S.S.; Fundings - S.S.; Materials - D.G-M., A.C.C., S.S.; Data Collection and/or Processing - D.G-M., A.C.C., S.S.; Analysis and/or Interpretation - D.G-M., A.G-M.; Literature Review - D.G-M., A.G-M.; Writing - D.G-M., A.G-M.; Critical Review - D.G-M., A.G-M., A.C.C., S.S.

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