Safety and Efficacy of Hemispherical with Flattened Pole Dual-Mobility Acetabular Cup in Revision or Complex Hip Arthroplasty: The SYMCOR-2 study

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Research article

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Abstract

Background: This study estimated the short-term clinical safety and efficacy of hemispherical with flattened pole cobalt-chromium metal-back dual-mobility acetabular cup with porous outer hydroxyapatite coating and anchoring screw and pods (HFPC-DMR-HA) or cement fixation (HFPC-DM-CEM), in revision or complex total hip arthroplasty.

Methods: Single-center retrospective observational cohort study of consecutively operated patients who underwent THA with an HFPC-DMR-HA or HFPC-DM-CEM cup 2 years prior to study start. Prospective 2-year follow-up with letter and phone questionnaires.

Results: Sampling frame: 203 patients including 9.85% in the two cohorts with 15 HFPC-DMR-HA and 5 HFPC-DM-CEM. 3 (20%) and 2 (40%) patients were lost to follow-up, respectively. Median age was 85.6 years (range: 45.1; 93.3) and 78.8 (range: 68.8; 86.9). Median follow-up (years): HFPC-DMR-HA: 2.3, HFPC-DM-CEM: 3.3. Clinical indications: HFPC-DMR-HA 67% revision & 33% primary THAs, HFPC-DM-CEM 100% revision. Primary endpoint: 2-year implant survival rate: HFPC-DMR-HA 93% [59, 99], HFPC-DM-CEM 100%. Prosthetic dislocation: HFPC-DMR-HA 1 (6.7%), HFPC-DM-CEM 0%. Secondary endpoint: Modified HHS (pain & functional subscore) improved with HFPC-DMR-HA from baseline 26.8 [14.9, 38.7] to 82.2 [73.5, 90.9] at 2-year follow-up (p<0.0001); HFPC-DM-CEM from 41.6 [24.9, 58.3] to 80.7 [55.8, 100].

Conclusions: The authors deemed the short-term outcomes with these acetabular cups in revision or complex total hip arthroplasty to be satisfactory.

Study registration: clinicaltrials.gov NCT04209426.

Background

Hemispherical with flattened pole cobalt-chromium metal-back dual-mobility (HFPC-DM) acetabular cups for total hip arthroplasty (THA) have been developed by Dedienne Santé, France, and are available under different brands including Dedienne Santé SYMBOL CUP DM (“SYMBOL”), BBraun Gyracup E, Mathys Orthopédie DS Evolution.

Two versions of the HFPC-DM shell with reinforced fixation systems were used in this study: (1) HFPC-DMR-HA had an outer porous double layer coating consisting of a titanium layer covered with a hydroxyapatite (HA) layer, along with two pegs and one screw for anchoring, and (2) HFPC-DM-CEM had a bare metal outer surface designed for cement fixation.

A specific mobile polyethylene (PE) liner was fitted into the shell and a cobalt-chromium (CoCr) head or a ceramic femoral head was fitted in the insert. The two-bearing system was thus outer CoCr/PE with inner PE/CoCr or outer CoCr/PE with inner PE/ceramic.
The purpose of flattened pole hemispherical design in dual-mobility cups (DM) was to facilitate the surgical procedure and decrease impingement. Figure 1 shows the distinctive common geometric center of the shell, the liner and the head and compares it to a non-hemispherical DM design.

HFPC-DMR-HA and HFPC-DM-CEM were introduced in April 2014 and by the end 2018 about HFPC-DMR-HA about 1400 units and about 4700 HFPC-DM-CEM units had been implanted worldwide under different brands. This study, “SYMCOR-2”, clinicaltrials.gov NCT04209426, was sponsored by Dedienne Santé using the cups branded SYMBOL. The purpose of the study was to estimate short-term safety and efficacy of HFPC-DMR-HA and HFPC-DM-CEM in complex THA or revision THA in “real-life” practice, prior to considering a long-term prospective study.

Methods

Study design

This was a single-center retrospective observational cohort study of all consecutively operated patients who underwent THA with a HFPC-DMR-HA or a HFPC-DM-CEM prior to study start and who were eligible for a 2-year post-operative assessment at the time of the study.

This study was subject to MR3 regulation and was therefore notified to the CNIL commission without requiring medical ethics committee approval. The data source was the complete database of patient charts on March 1, 2018, including the sampling frame that included cohort patients.

Two-year follow-up status and missing information about cohort patients were obtained by mailed questionnaires and telephone interviews. The information letters were drafted according to regulations and informed patients that they may refuse participating in this study.

Patients

The investigator’s operative records were screened between his first HFPC-DMR-HA and HFPC-DM-CEM implantation from March 18, 2015 through December 13, 2016 and an exhaustive list of THAs was established. The sampling frame consisted of all patients who had undergone THA during that period while the cohorts were the subsets of patients in whom the THA had been performed using HFPC-DMR-HA or HFPC-DM-CEM respectively. Anonymous data from patient charts were recorded into a database for the entire sampling frame and included demographics, operative date, whether the THA was a primary or revision surgery as well as acetabular cup model. Detailed preoperative, operative and postoperative data were recorded for the HFPC-DMR-HA and HFPC-DM-CEM cohorts only.

Patient inclusion criteria in the cohorts were any THA performed by the investigator during the screening period using a HFPC-DMR-HA or HFPC-DM-CEM respectively. Exclusion criteria were patient refusal to participate in the study, minors less than 18 years of age and patients under guardianship. No patient was excluded from the cohorts because of the type of femoral stem, the need for additional surgery or missing data.
Standard patient charts at this site included physical, functional and radiographic assessments preoperatively and at 1-year follow-up. Intermediate assessments between the first and fifth year follow-up were not common practice at that site, unless patients reported an adverse event or required surgery on another joint, so the 2-year follow-up of most patients consisted of self-reported outcomes recorded in a questionnaire that had been mailed to the patient or a telephone interview in case of missing or inconsistent information.

**Intervention**

The index operation was past primary or revision THA on the target hip using a HFPC-DMR-HA or a HFPC-DM-CEM. Acetabular cup fixation was reinforced with one screw and two pegs, or with cement, respectively. Femoral heads used were cobalt-chromium or ceramic. The surgeon used the stem deemed the most suitable on an individual patient basis. Additional surgery was performed if required.

**Endpoints**

The primary endpoint was acetabular cup survival up to two years post-implantation. The endpoint was defined as joint patient survival and non-removal of the acetabular cup.

The secondary safety endpoints were: The rate of intraoperative adverse events and the rates of post-operative implant-related or procedure-related post-operative adverse events over 2-year follow-up. The rates of prosthetic dislocation and intra-prosthetic dislocation (IPD) were analyzed. IPD was defined as the femoral head dissociating from the mobile bearing PE liner.[1, 2]

The secondary effectiveness endpoints were the Harris Hip Score (HHS) and the modified HHS (mHHS) that consisted in the sum of pain & functional subscores without the range of motion and deformation. While the HHS could be computed preoperatively and at 1-year follow-up, the 2-year follow-up questionnaire only enabled computing the mHHS.

**Statistical analysis**

Descriptive statistical analysis of the sampling frame was performed on gender, age at the time of surgery, primary vs. revision THA and acetabular cup type. The HFPC-DMR-HA and HFPC-DM-CEM cohorts were respectively compared to the sampling frame with respect to those variables.

Demographic, preoperative, operative and postoperative descriptive statistical analysis was performed for each cohort. Adverse events were tabulated and counted. Implant survival was analyzed using the Kaplan-Meier survivor function.[3] The means of quantitative variables were compared between groups using the unpaired t-test when applicability criteria were met.[4, 5] The two-sample Wilcoxon-Mann-Whitney rank-sum non-parametric test was used otherwise. Mean changes in scores within individuals were tested using the paired t-test when applicable and the Wilcoxon signed-rank test was used otherwise.[6–8] Frequencies of categorical variables between independent groups were compared using the Chi-square when applicability criteria were met and the Fisher exact test was used otherwise.[9–10] Binomial categorical variables equality to 0.5 was tested using the exact binomial probability test. The
analysis was conducted on complete cases. Statistical analyses were conducted with a script programmed in STATA 15 software (StataCorp, College Station, TX, USA).

Results

Patient disposition

The sampling frame consisted of 203 patients, 88% of whom who had undergone primary THA and 24% revision THA. Fifteen cases used HFPC-DMR-HA and 5 HFPC-DM-CEM acetabular cups and all twenty cases were included in the cohorts. Three (20%) and 2 patients (40%) were lost to 2-year follow-up, respectively (Fig. 2).

Sampling frame characteristics

Acetabular cups used in the sampling frame were 31 (15.3%) standard acetabular cups (STD) and 172 (84.7%) DM. DM were 15 (7.5%) HFPC-DMR-HA, 5 (2.5%) HFPC-DM-CEM and 152 (74.92%) other models (Figure 2). The overall female/male ratio was 107/96 (53%/47%) (Table 1) and DM were used in non-significantly different frequencies in the two genders (54.1%/45.9% Fisher exact test p = 0.436).

Mean age at the time of surgery was 69.1 [67.3, 70.9]. Patients treated with STD were significantly younger than patients treated with overall DM (mean difference 22.2 years [18.3, 26.1], p<0.0001). Patients with HFPC-DMR-HA were significantly older than patients with other DM cups (mean difference 5 years) (rank sum test: p = 0.0196).

All STD were used for primary THA. All revision THAs were performed with DM and represented 14% of DM use. Revision surgery accounted for 100% of HFPC-DM-CEM, 67% HFPC-DMR-HA and 6% of other DM cups.

Patients undergoing primary THA were younger than those undergoing revision THA (mean difference: 9.6 years [5.4, 13.8], p<0.0001).

The cohort median post-operative time to study follow-up date was 2.3 years (range: 1.7 ; 3.3) in HFPC-DMR-HA and 3.3 years (range: 1.7 ; 3.4) in HFPC-DM-CEM.

HFPC-DMR-HA cohort preoperative characteristics

Median patient age at the time of surgery was 85.6 years (range: 45.1 ; 93.3), female/male ratio was 60% / 40% and a median body mass index (BMI) of 24.6 kg.m\(^{-2}\) (range: 14.5 ; 32.2) (Table 2). Revision THAs were due to loosening or fracture of the initial prosthesis (90%) and IPD (10%). Primary THAs were due to hip neck fracture or post-trauma necrosis (80%) and dysplasia (20%).

HFPC-DM-CEM cohort preoperative characteristics
Median patient age at the time of surgery was 78.8 years (range: 68.8 ; 86.9), female/male ratio was 60% / 40% and a median body mass index (BMI) of 25.8 kg.m$^{-2}$ (range: 22.8 ; 28.4) (Table 2). All cases (100%) were revision surgeries due to loosening or fracture of the initial prosthesis.

**HFPC-DMR-HA cohort operative characteristics**

All cases were performed with a posterior surgical approach. Acetabular shell diameters ranged from 44 mm to 64 mm. All shells were secured with two pegs and a screw and without cement and no bone grafting was reported. PE liners were fitted with mostly with ceramic femoral heads (87%) while the others were fitted with CoCr heads and a wide range of femoral stems were used (Table 2).

Median surgical time was 74 minutes (range: 40 ; 120). No patient required bone grafting. Associated surgery was stem replacement in 27% of cases. One case required femoral cerclage wiring. All presented excellent intraoperative stability.

**HFPC-DM-CEM cohort operative characteristics**

All cases were performed with a posterior surgical approach. Acetabular shell diameters ranged from 46 mm to 52 mm. All shells were cemented without pegs or screws and one case (20%) required autogenic bone grafting. PE liners were fitted with mostly with ceramic femoral heads (80%) while the others were fitted with CoCr heads and a wide range of femoral stems were used (Table 2).

Median surgical time was 87 minutes (range: 45 ; 120). Bone graft was required in one HFPC-DM-CEM. Associated surgery was stem replacement in 60% of cases. One case required femoral cerclage wiring. All but one presented excellent intraoperative stability.

**Primary endpoint: Implant survival**

One patient with HFPC-DMR-HA required revision surgery at 3 month follow-up related to a surgical site infection. No other revision or death occurred throughout follow-up. Implant survival was 94.7% [68.1; 99.2%] with a total time at risk of 31.3 years (Fig. 3).

No HFPC-DM-CEM required revision surgery and no patient death occurred at two year follow-up, implant survival was 100% with a total time at risk of 1.6 years.

**Secondary endpoints: Postoperative implant or procedure-related complications**

With HFPC-DMR-HA, 10 adverse events were reported in 9 (60%) patients, including 1 IPD (6.7%) at 1-year follow-up (Table 2). The most frequent adverse events were 3 deaths (20%) unrelated to the procedure and implant as well as 2 surgical site infections (13.3%) There was also 1 fracture of the operated area (Vancouver class A) after the patient fell at 2-year follow-up but no prosthetic revision was required.[11–12]

In patients with HFPC-DM-CEM, no post-operative adverse event was reported.
Secondary endpoints: Functional outcomes

In patients with HFPC-DMR-HA, mean within-patient HHS increased from preoperative baseline to 1-year follow-up by 44.9 [29.6, 60.3] (Wilcoxon signed-rank test p < 0.003) and mean within-patient mHHS increased from baseline to 1-year follow-up by 48.1 [33.9, 62.4] (p < 0.002) and from baseline to 2-year follow-up by 54.2 [36.2, 72.3] (p < 0.008).

In patients with HFPC-DM-CEM, mean within-patient HHS increased from preoperative baseline to 1-year follow-up by 27.7 [-11.1, 66.6] and mean within-patient mHHS increased from baseline to 1-year follow-up by 27.2 [-11.9, 66.3] and from baseline to 2-year follow-up by 45.3 [15.3, 75.4] but the small amount of data at follow-up prevented drawing statistical conclusions.

Pre- and postoperative HHS and mHHS summary in Table 3

Discussion

Need for this study

The safety and efficacy of medical devices are functions of several critical technical characteristics and the interplay between those characteristics. For that reason, the clinical risk-benefit of an implant with a given combination of critical characteristics cannot be predicted by examining the risk-benefit related to each characteristic separately reported in other models with different combinations of the critical characteristics. The European medical device clinical evaluation guideline requires device-specific clinical safety and performance data to be presented in order to establish the benefit-risk balance of medical device with a specific combination of critical characteristics.[13] That requirement was reinforced with the introduction of the European Medical Devices Regulation.[14]. Predicting the benefit-risk balance of a new medical device based on clinical evidence derived from a previously approved “predicate” device, is valid only if the two devices meet equivalence criteria and requires the same combination of critical characteristics and the same intended use. In the case of DM cups, equivalence requires shells to share the same combination of metal-back design and alloy, coating, fixation mechanism, clinical indications and any other feature that could modify clinical outcomes. This study was conducted because a systematic review of published clinical studies with DM cups revealed that HFPC-DMR-HA and HFPC-DM-CEM had no predicate devices. That systematic review was beyond the scope of this article, but shell differences were shown with a broad range of DM cups with clinical evidence reported in a compilation of articles (Table 4).[15]

Internal validity

The internal validity of this study is ensured by consecutive recruitment all eligible cases performed by a single surgeon and by their systematic follow-up. The limitations were the small sample size, especially with HFPC-DM-CEM, the relatively short follow-up duration, the inability to perform systematic physical and radiographic assessments at 2-year follow-up, and the large proportion of deaths and the lost to
follow-up. Patient contacts along with information retrieved in patient charts suggested that missingness was not procedure-related or implant related.

**External validity**

The external validity of this cohort study was based on the demonstrated completeness of recruitment and comparison with the sampling frame. The main limitations were the single-center recruitment and small sample size.

Pooling and comparing the results of SYMCOR-2 with those of other studies on DM would require a rigorous systematic review with risk of bias assessment and meta-analysis. Such a process would focus on common outcome variables and stratify over clinical indications, surgical/implant differences and risk factors.

**Conclusion**

This was the first cohort study to present two-year follow-up safety and efficacy data on the use of a dual-mobility acetabular cups in revision or complex total hip arthroplasty with a hemispherical with flattened pole cobalt-chromium metal-back shell with reinforced fixation based outer porous double layer titanium/hydroxyapatite along with a screw and two pods (HFPC-DMR-HA) or with cement HFPC-DM-CEM.

HFPC-DMR-HA was used for complex primary arthroplasty and for revision surgery. There was one early intra-prosthetic dislocation, one fracture due to patient fall and two surgical site infections were reported. Further revision surgery was required in one case due to infection so that 2-year implant survival was 94.7% [68.1; 99.2%]. With respect to efficacy, the HHS improved significantly from a baseline of 23.0 [21.1, 46.6] to 83.8 [67.7, 99.9] at 1-year follow-up. The mHHS also improved significantly from a baseline of 26.8 [14.9, 38.7] to 74.5 [60.9, 88.1] at 1-year and 82.2 [73.5, 90.9] at 2-year follow-up.

HFPC-DM-CEM was used for revision surgery only and no post-operative adverse event was reported. With respect to efficacy, the HHS improved from a baseline of 50.0 [32.9, 67.1] to 77.7 [35.2, 100] at 1-year follow-up. The mHHS also improved from a baseline of 41.6 [24.9, 58.3] to 68.8 [26.3, 100] at 1-year and 80.7 [55.8, 100] at 2-year follow-up. The small amount of data prevented statistical inference.

The authors deemed the short-term outcomes with these acetabular cups in revision or complex total hip arthroplasty to be satisfactory.

**Abbreviations**
| CoCr | Cobalt-Chromium |
|------|-----------------|
| DM   | Dual-mobility acetabular cups |
| HFPC-DM | Hemispherical with flattened pole cobalt-chromium metal-back dual-mobility acetabular cup |
| HFPC-DM-CEM | Hemispherical with Flattened Pole Cobalt-Chromium metal-back Dual-Mobility Cemented acetabular cup |
| HFPC-DMR-HA | Hemispherical with Flattened Pole Cobalt-Chromium metal-back with porous outer Hydroxyapatite coating Dual-Mobility Revision acetabular cup |
| HA   | Hydroxyapatite |
| HHS  | Harris Hip Score |
| IPD  | Intra-Prosthetic Dislocation |
| mHHS | modified Harris Hip Score |
| PE   | Polyethylene |
| STD  | Standard acetabular cups |
| THA  | Total Hip Arthroplasty |

**Declarations**

**Ethical approval**

CNIL notification N°2176595.

Ethical committee approval: Not applicable to retrospective studies according to current regulations in France.

**Informed consent**

An information letter sent to each patient in accordance with the CNIL notification. The letter explained the study and made clear to the patient he/she could decline participation. Consent was not required by current regulations in France for this type of study.

**Consent for publication**

This article does not contain individual data.

**Availability of data and materials**
The dataset generated during and/or analyzed during the current study are available at Medipole de Savoie, Challes-les-Eaux, France. The datasets generated during and/or analysed during the current study are not publicly available due to individual data protection law but specific anonymous subsets will available from the corresponding author on reasonable request.

**Competing interests**

- GE, NB, SL and OG are beneficiaries of royalties paid by the manufacturer of the study devices, who is the sponsor of this study.
- FD is a consultant in biostatistics and clinical research appointed by the sponsor.

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**Author’s contributions**

- GE was the principal investigator. He operated and followed-up all patients.
- FD wrote the protocol, performed the statistical analyses and wrote the study report.
- NB, LS, OG teamed with GE to interpret the results clinically. They teamed with GE and FD to write the manuscript.

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The sponsor played no role in patient observation, data analysis and manuscript writing.

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Tables

Table 1 - Sampling frame

| Cup             | Total n (%) | female / male n (%) | age mean (sd) | primary THA n (%) | revision THA n (%) |
|-----------------|-------------|---------------------|---------------|-------------------|-------------------|
| HFPC-DMR-HA     | 15 (7.4)    | 9 (60)/ 6 (40)      | 77.3 (13.4)   | 5 (33)            | 10 (67)           |
| HFPC-DM-CEM     | 5 (2.5)     | 3 (60)/ 2 (40)      | 77.6 (6.7)    | 0 (0)             | 5 (100)           |
| Other DM        | 152 (74.9)  | 81 (53)/ 71 (47)    | 71.8 (10.4)   | 143 (94)          | 9 (6)             |
| Standard        | 31 (15.3)   | 14 (45)/ 17 (55)    | 50.2 (6.4)    | 31 (100)          | 0 (0)             |
| Total           | 203 (100)   | 107 (53)/ 96 (47)   | 69.1 (12.9)   | 179 (88)          | 24 (12)           |

Table 2 - Cohort demographics & operative details
### HFPC-DMR-HA

#### Demographics

|                  | n  | mean | sd  | min | p25 | p50 | p75 | max |
|------------------|----|------|-----|-----|-----|-----|-----|-----|
| age (years)      | 15 | 77.3 | 33.4| 45.1| 69.5| 85.6| 92.9| 93.3|
| height (cm)      | 15 | 164.9| 9.9 | 150 | 157 | 165 | 173 | 180 |
| weight (kg)      | 15 | 67.6 | 18.4| 33.5| 52  | 70  | 82  | 93  |
| BMI (kg/m²)      | 15 | 24.4 | 4.8 | 14.5| 21.1| 24.6| 28.3| 32.2|

#### Gender

|                  | n (%)          |
|------------------|----------------|
| Male             | 6 (40)         |
| Female           | 9 (60)         |

#### Side

|                  | n (%)          |
|------------------|----------------|
| Right            | 10 (67)        |
| Left             | 5 (33)         |

#### Prior hip surgery

|                  | n (%)          |
|------------------|----------------|
|                  | 11 (73)        |

#### Etiology

|                  | Primary | Revision | Total |
|------------------|---------|----------|-------|
| - dysplasia      | 1 (6.7) | 0 (0)    | 1 (6.7) |
| - hip neck fracture or post-trauma necrosis | 4 (26.7) | 0 (0)    | 4 (26.7) |
| - intra-prosthetic dislocation of a DM      | 0 (0)   | 1 (6.7)  | 1 (6.7)  |
| - prosthetic loosening or fracture         | 0 (0)   | 9 (60)   | 9 (60)   |
| - TOTAL                                      | 5 (33)  | 10 (67)  | 15 (100) |

#### Operative details

|                  | n (%)          |
|------------------|----------------|

#### Bearing

|                  | n (%)          |
|------------------|----------------|
| PE/ceramic       | 13 (87)        |
| PE/CoCr          | 2 (13)         |

#### Shell diameter range (mm)

|                  | range          |
|------------------|----------------|
| PE/ceramic       | 48 ; 56        |
| PE/CoCr          | 44 ; 64        |

#### Bone graft

|                  | n (%)          |
|------------------|----------------|
| Cup              | 0 (0)          |
| Stem             | 0 (0)          |

#### Associated surgery

|                  | n (%)          |
|------------------|----------------|
| None             | 7 (47)         |
| Stem replacement  | 4 (27)         |
| Other            | 4 (27)         |

#### Operative time (minutes) median & range

- Total: 74 (40, 120)

#### Intraoperative events/outcomes

|                  | n (%)          |
|------------------|----------------|

#### Femoral cerclage wiring required

|                  | 1 (6.7)        |

#### Hip stability

|                  | n (%)          |
|------------------|----------------|
| Excellent / medium: | 14 (93.3) / 1 (6.7) |

### HFPC-DM-CEM

#### Demographics

|                  | n  | mean | sd  | min | p25 | p50 | p75 | max |
|------------------|----|------|-----|-----|-----|-----|-----|-----|
| age (years)      | 5  | 77.6 | 6.7 | 68.8| 74.4| 78.8| 78.9| 86.9|
| height (cm)      | 5  | 161.4| 9.5 | 148 | 158 | 160 | 170 | 171 |
| weight (kg)      | 5  | 67.6 | 10.7| 53  | 66  | 66  | 70  | 83  |
| BMI (kg/m²)      | 5  | 25.8 | 2.4 | 22.8| 24.2| 25.8| 28  | 28.4|

#### Gender

|                  | n (%)          |
|------------------|----------------|
| Male             | 2 (40)         |
| Female           | 3 (60)         |

#### Side

|                  | n (%)          |
|------------------|----------------|
| Right            | 2 (40)         |
| Left             | 3 (60)         |

#### Prior hip surgery

|                  | n (%)          |
|------------------|----------------|
|                  | 5 (100)        |

#### Etiology

|                  | n (%)          |
|------------------|----------------|
| - prosthetic loosening or fracture | 0 (0)          |

#### Operative details

|                  | n (%)          |
|------------------|----------------|

#### Bearing

|                  | n (%)          |
|------------------|----------------|
| PE/ceramic       | 13 (87)        |
| PE/CoCr          | 2 (13)         |

#### Shell diameter range (mm)

|                  | range          |
|------------------|----------------|
| PE/ceramic       | 44 ; 64        |
| PE/CoCr          | 44 ; 64        |

#### Bone graft

|                  | n (%)          |
|------------------|----------------|
| Cup              | 1 (20)         |
| Stem             | 0 (0)          |

#### Associated surgery

|                  | n (%)          |
|------------------|----------------|
| None             | 1 (20)         |
| Stem replacement  | 3 (60)         |
| Other            | 1 (20)         |

#### Operative time (minutes) median & range

- Total: 87 (45, 120)

#### Intraoperative events/outcomes

|                  | n (%)          |
|------------------|----------------|

#### Femoral cerclage wiring required

|                  | 1 (20)         |

#### Hip stability

|                  | n (%)          |
|------------------|----------------|
| Excellent / medium: | 4 (80) / 1 (20) |

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**Table 3 – HHS & safety**
| HFPC-DMR-HA       | n  | min | max | median | mean | sd  | 95% CI     |
|-------------------|----|-----|-----|--------|------|-----|------------|
| **HHS**           |    |     |     |        |      |     |            |
| Preoperative      | 15 | 4   | 70  | 34     | 23.0 | 37.7| [21.1, 46.6]|
| 1-year            | 11 | 20  | 100 | 89     | 83.8 | 24.0| [67.7, 99.9]|
| **range of motion** |    |     |     |        |      |     |            |
| Preoperative      | 15 | 0   | 5   | 4      | 3.0  | 2.1 | [1.9, 4.2]  |
| 1-year            | 11 | 0   | 5   | 5      | 4.5  | 1.5 | [3.5, 5.5]  |
| **mHHS**          |    |     |     |        |      |     |            |
| Preoperative      | 15 | 0   | 61  | 29     | 26.8 | 21.5| [14.9, 38.7]|
| 1-year            | 13 | 16  | 91  | 80     | 74.5 | 22.5| [60.9, 88.1]|
| 2-year            | 9  | 61  | 91  | 87     | 82.2 | 11.3| [73.5, 90.9]|

| Patients with post-operative severe adverse events | n (%) |
|--------------------------------------------------|-------|
| Description                                      | Year 1| Year 2| Total |
| Death                                            | 2     | 1     | 3     | 20%  |
| Surgical site infection                         | 2     | 0     | 2     | 13.3%|
| Intra-prosthetic dislocation                     | 1     | 0     | 1     | 6.7% |
| Fall and fracture of the operated area (Vancouver class: A) | 0     | 1     | 1     | 6.7% |
| Other                                            | 1     | 2     | 3     | 20%  |
| Total                                            | 6     | 4     | 10    | 67%  |

| HFPC-DM-CEM                                      | n  | min | max | median | mean | sd  | 95% CI     |
|--------------------------------------------------|----|-----|-----|--------|------|-----|------------|
| **HHS**                                          |    |     |     |        |      |     |            |
| Preoperative                                    | 5  | 29  | 61  | 58     | 50.0 | 13.8| [32.9, 67.1]|
| 1-year                                          | 5  | 18  | 100 | 86     | 77.7 | 34.2| [35.2, 100] |
| **range of motion**                             |    |     |     |        |      |     |            |
| Preoperative                                    | 5  | 4   | 5   | 4      | 4.4  | 0.5 | [3.8, 5]   |
| 1-year                                          | 5  | 5   | 5   | 5      | 4.9  | 0.1 | [4.8, 5]   |
| **mHHS**                                        |    |     |     |        |      |     |            |
| Preoperative                                    | 5  | 21  | 53  | 49     | 41.6 | 13.4| [24.9, 58.3]|
| 1-year                                          | 5  | 9   | 91  | 77     | 68.8 | 34.2| [26.3, 100]|
| 2-year                                          | 3  | 71  | 91  | 80     | 80.7 | 10.0| [55.8, 100]|

| Patients with post-operative severe adverse events | n (%) |
|--------------------------------------------------|-------|
| None                                             |       |

**Table 4 – Comparison of DM shell: design – biomaterials – fixation**
| Model                                      | metal-back alloy / outer coating                   | design            | fixation                        |
|-------------------------------------------|---------------------------------------------------|-------------------|---------------------------------|
| Dual Mobility Cup Tornier®                | stainless steel / porous double layer: Ti & HA     | cylindrospherical | cementless press-fit             |
| Tregor Medial Cup® (Aston Medical)        | stainless steel / none                             | cylindrospherical, peripheral rim with concentric grooves    | cemented                        |
| Ceraver Osteal DM Cup                     | stainless steel / none                             | cylindrospherical | cemented                        |
| Novae® Stick (Serf)                       | stainless steel / none                             | cylindrospherical | cemented                        |
| Novae® Sunfit TH (Serf)                   | stainless steel / porous double layer: Ti & HA     | cylindrospherical | cementless press-fit             |
| Novae-1 tripodal ® (Serf)                 | stainless steel / porous single layer: alumina     | cylindrospherical with 2 pegs & 1 screw                       | press-fit & anchoring            |
| Novae® E (Serf)                           | stainless steel / porous double layer: Ti & HA     | cylindrospherical with 2 pegs & 1 screw                       | press-fit & anchoring            |
| Avantage™ Cup (Biomet)                    | stainless steel / none                             | cylindrospherical with flattened pole & anatomic aperture    | cemented                        |
| Avantage™ Cup (Biomet)                    | stainless steel / porous double layer: Ti & HA     | cylindrospherical with flattened pole & anatomic aperture    | cementless press-fit             |
| Saturne® (Amplitude)                      | stainless steel / porous double layer: Ti & HA     | hemispherical with flattened pole & anatomical equatorial cut | cementless press-fit             |
| DePuy Gyros DMC of second generation      | stainless steel / porous single layer: HA          | cylindrospherical | cementless press-fit             |
| Anatomic ADM® (Stryker Orthopaedics)      | CoCr / porous double layer: Ti & HA                | cylindrospherical with 2 anatomical notches                   | cementless press-fit             |
| Modular MDM® X3® (Stryker Orthopaedics)   | CoCr / porous double layer: Ti & HA                | cylindrospherical with 2 anatomical notches & screws          | press-fit & anchoring            |
| Tregor® (Aston Medical)                   | CoCr / porous double layer: Ti & HA                | hemispherical with medialized center                          | cementless press-fit             |
| Ades® (Dedienne Santé)                    | CoCr / porous double layer: CoCr & HA              | cylindrical with posterior wall                                | cementless press-fit             |
| Quattro™ DM Cup (Groupe Lepine)            | CoCr Mo / none                                     | hemispherical with 6 equatorial fins & 4 tropical spikes      | cemented                        |
| Quattro™ DM Cup (Groupe Lepine)            | CoCr Mo / porous double layer: Ti & HA             | hemispherical with 6 equatorial fins & 4 tropical spikes      | cementless press-fit             |
| HFPC-DM-CEM (Dedienne Santé)              | CoCr / none                                        | hemispherical with flattened pole                             | cemented                        |
| HFPC-DM-HA (Dedienne Santé)               | CoCr / porous double layer: Ti & HA                | hemispherical with flattened pole                             | cementless press-fit             |
| HFPC-DMR-HA (Dedienne Santé)              | CoCr / porous double layer: Ti & HA                | hemispherical with flattened pole & 2 pegs & 1 screw          | press-fit & anchoring            |

CoCr: Cobalt-Chromium. Mo: molybdenum. Ti: sprayed titanium layer. HA: hydroxyapatite layer

**Figures**
Figure 1

Design: HFPC-DM vs. other DM
Figure 2

Patient disposition
Figure 3

HFPC-DMR-HA implant survival