Safety and Efficacy of Hemispherical with Flattened Pole Dual-Mobility Acetabular Cup in Primary Hip Arthroplasty: The SYMCOR-1 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 with porous outer hydroxyapatite coating dual-mobility acetabular cup (HFPC-DM-HA) in primary total hip arthroplasty.

Methods: Single-center retrospective observational cohort study of consecutive patients undergoing total hip arthroplasty with a HFPC-DM-HA 2 years prior to study start. Prospective 2-year follow-up with letter and phone questionnaires.

Results: Sampling frame: 361 patients including 59 patients (16.3%) in the cohort. 6 patients (10%) lost to follow-up. Median age 77.5 years (range: 67 ; 92), 32% female, median BMI 25.2 kg.m^{-2} (18.4 to 56.8). Clinical indications: Primary THA in all patients, resulting from primary osteoarthritis in 80% of them. Median follow-up 3.0 years (2.7 to 4.1). Primary endpoint: 2-year implant survival rate: 97% [87, 99]. Prosthetic dislocation: 0%. Secondary endpoint: Modified HHS (pain & functional subscore) improved from baseline 39.7 [34.6, 44.7] to 75.8 [72.1, 79.6] at 1-year and to 86.7 [83.7, 89.7] at 2-year follow-up (p<0.0001).

Conclusions: The authors deemed the short-term outcomes of this acetabular cup in primary total hip arthroplasty to be satisfactory.

Study registration: clinicaltrials.gov NCT04209374.

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.

The HFPC-DM-HA version was used in this study. It had a shell with an outer porous double layer coating consisting of a titanium layer covered with a hydroxyapatite (HA) layer. The shell was designed for press-fit fixation. A specific mobile polyethylene (PE) liner was fitted into the shell and a cobalt-chromium (CoCr) head or a ceramic femoral head is 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-DM-HA was introduced in July 2014 and by the end of 2018 about 10,000 units had been implanted worldwide under different brands. This study, “SYMCOR-1”, clinicaltrials.gov NCT04209374, 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-DM-HA in primary 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-DM-HA 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 SYMBOL DM HA implantation from July 3, 2014 through December 17, 2015 and an exhaustive list of THAs was established. The sampling frame consisted of all patients who had undergone THA during that period while the cohort was the subset of patients in whom the primary THA had been performed using HFPC-DM-HA. 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-DM-HA cohort only.

Patient inclusion criteria in the cohort were primary THA performed by the investigator during the screening period using a HFPC-DM-HA. 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 cohort because of the type of femoral stem, the need for additional surgery or missing data.

Standard patient charts at the investigation 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 THA on the target hip using a HFPC-DM-HA. Cup fixation was press-fit only. All femoral heads used were CoCr. 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 cup survival up to two years post-implantation. The endpoint was defined as joint patient survival and non-removal of the cup.

The secondary safety endpoints were: The rate of intraoperative adverse events and the rates of postoperative implant-related or procedure-related post-operative adverse events over 2-year follow-up. The rates of prosthetic dislocation and intraprosthetic 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-DM-HA cohort was compared to its sampling frame with respect to those variables.

The cohort’s demographic, preoperative, operative and postoperative descriptive statistical analysis was performed. 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. Ordinary least-squares linear regression of overall HHS vs. mHHS were plotted using preoperative and 1-year follow-up data in order to estimate how closely 2-year the mHHS could predict the 2-year HHS.[11] The analysis was conducted on complete cases providing missing data did not exceed 10%. 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 361 patients who had undergone primary THA. Fifty-nine cases used HFPC-DM-HA and all of them were included in the cohort. Six patients (10%) were lost to 2-year follow-up (Fig. 2).

**Sampling frame characteristics**

Acetabular cups used in the sampling frame were 242 (67.0%) standard acetabular cups (STD) and 111 (31.6%) DM. Fifty-nine (16.3%) of DMs were HFPC-DM-HA and 55 (15.2%) were other models (Fig. 2). The overall female/male ratio was 171/190 (47.4%/52.6%) (Table 1) and DM were used significantly more frequently in female than in male (58.8% vs. 41.2%, Fisher exact test p = 0.003). HFPC-DM-HA was used in female more frequently than other DM were, but the difference was not significant (67.8%/49.1%, Fisher exact test: p = 0.057).

| Cup             | Total n (%) | female / male n (%) | age mean (sd) | primary THA n (%) | revision THA n (%) |
|-----------------|-------------|--------------------|--------------|-------------------|-------------------|
| HFPC-DM-HA      | 59 (16.3)   | 40 (68)/19 (32)    | 78.8 (5.6)   | 58 (98)           | 0 (0.0)           |
| Other DM        | 55 (15.2)   | 27 (49)/28 (51)    | 78.0 (11)    | 36 (65)           | 18 (33)           |
| Standard        | 242 (67.0)  | 101 (41.7)/141 (58.3) | 58.6 (12.2) | 232 (95.9)        | 7 (2.9)           |
| Total           | 361 (100)   | 171 (47.4)/190 (52.6) | 65.2 (14.6) | 328 (90.9)        | 28 (7.8)          |

Mean age at the time of surgery was 65.2 [63.7, 66.7]. Patients treated with STD were significantly younger than patients treated with overall DM (mean difference 19.8 years [17.5, 22.1], p < 0.0001). There was no significant age difference between HFPC-DM-HA and other DM (rank sum test: p = 0.197).

Most cases, i.e. 90.9%, were primary THAs with 7.8% revision THAs. Revisions were performed mainly with other DM (72%) and less frequently with STD (28%) (p < 0.001). No HFPC-DM-HA was used for revision THA (although data was missing for one patient) while 33% of other DM were used for revision THA (p < 0.001).

There was no significant difference in gender (Fisher exact test: p = 0.057) or age distribution (t-test: p = 0.66) between the HFPC-DM-HA cohort and patients treated with other DM.

Patients undergoing primary THA were significantly younger than those undergoing revision THA (mean difference: 8.1 years [1.8, 14.5], p = 0.0134).

The cohort median post-operative time to study follow-up date was 3.0 years (range: 2.7 ; 4.1).

**HFPC-DM-HA cohort preoperative characteristics**
Median patient age at the time of surgery was 77.5 years (range: 67 ; 92), female/male ratio was 32% / 68% and a median body mass index (BMI) of 25.2 kg.m$^{-2}$ (range: 18.4 ; 56.8) (Table 2). The main etiologies were primary osteoarthritis of the hip was (80%) and acetabular protrusio (10%). One patient (2%) had prior surgery of the operated area with prior nail osteosynthesis of a pertrochanteric fracture.
## Table 2
### Cohort demographics & operative details

| Baseline | n  | mean | sd  | min | p25  | p50  | p75  | max  |
|----------|----|------|-----|-----|------|------|------|------|
| age (years) | 58 | 78.7 | 5.5 | 67.1 | 74.7 | 77.5 | 81.5 | 92.5 |
| height (cm) | 56 | 164.8 | 9.2 | 143 | 159 | 165 | 170.5 | 182 |
| weight (kg) | 56 | 74.3 | 24.1 | 48 | 60 | 71.5 | 81.5 | 180 |
| BMI (kg/m²) | 56 | 27.1 | 7.0 | 18.4 | 23.5 | 25.2 | 29.6 | 56.8 |
| Gender n (%) | | | | | | | | |
| male / female | | | | | | | | |
| Side n (%) | | | | | | | | |
| right / left | | | | | | | | |
| Prior hip surgery n (%) | | | | | | | | |
| Etiology n (%) | | | | | | | | |
| primary osteoarthritis of the hip | | | | | | | | |
| acetabular protrusion | | | | | | | | |
| rapidly destructive osteoarthritis (RDO) | | | | | | | | |
| hip dysplasia | | | | | | | | |
| other causes | | | | | | | | |
| TOTAL | | | | | | | | |

| Operative details | | | | | | | | |
| Shell diameter (mm): range | | | | | | | | |
| Bone graft n (%) | | | | | | | | |
| Cup | | | | | | | | |
| Stem | | | | | | | | |
| Associated surgery n (%) | | | | | | | | |
| none | | | | | | | | |
| hell repositioning | | | | | | | | |
| Operative time (minutes): median & range | | | | | | | | |

## Intraoperative events/outcomes
### Baseline

| Complications n (%)                          | 2 (3.4) |
|---------------------------------------------|---------|
| fracture of greater trochanter, Vancouver class A3 | 1 (1.7) |
| partial facture of greater trochanter & calcar fracture line, Vancouver class A2 | 1 (1.7) |
| calcar fracture line, Vancouver class A2     |         |

| Hip stability n (%)                          | excellent 59 (100) / medium 0 (0) |

### Operative characteristics

All THAs were performed using an anterior approach and most were on the right side (66%) (Table 2).

All HFPC-DM-HA were press-fit without the use of cement, screws or bone grafting. All had a PE liner fitted with a CoCr alloy femoral head. Acetabular shell diameters ranged from 48 to 56 mm and the most frequent used diameter range (54%) was 50 to 54 mm. Femoral stems were all cementless (100%).

One patient required intra-operative additional procedure for shell repositioning after testing.

Median operative time was 53 minutes (range: 42 ; 110). All prostheses presented excellent intraoperative stability. Four patients presented intraoperative periprosthetic fractures or fracture lines without need for additional treatment.

### Primary endpoint: Implant survival

Two patients required revision of their hip prosthesis including the HFPC-DM-HA. One was caused by a fall that caused a fracture of the operated area (Vancouver class A) on postoperative day-8. The other was caused by a surgical site infection on postoperative day-7.[12, 13]

The Kaplan-Meier cumulative survival rate of HFPC-DM-HA at 2-year follow-up was 96.6% [87.1, 99.1] with a total time at risk of 131.2 years (Fig. 3). That rate was calculated over the initial cohort of 59 patients taking into account the 2 known failures, 1 death and the 7 patients lost to follow-up.

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

Post-operative adverse events, whether related or not to the procedure or implant, were reported in 39 patients (66%) presented (Table 3). Nineteen patients (32%) presented postoperative complications that were adjudicated as procedure and/or implant related. These included the 2 events that caused prosthetic hip revision described previously, 13 with pain in the ipsilateral hip, pelvis or thigh and 4 with surgical scar-related problems. No prosthetic dislocation including IPD was reported during follow-up.
### Table 3

- **HHS - mHHS - Serious adverse events**

| Description                        | n  | min | max | median | mean  | sd   | 95% CI     |
|------------------------------------|----|-----|-----|--------|-------|------|------------|
| HHS preoperative                   | 55 | 21.3| 95.2| 44.7   | 49.5  | 19.1 | [44.3,54.6]|
| HHS 1-year                         | 57 | 40.0| 100.0| 88.6   | 84.6  | 14.3 | [80.8,88.4]|
| Range of motion preoperative       | 59 | 2.3 | 5.0 | 4.4    | 4.3   | 0.6  | [4.1,4.4]  |
| Range of motion 1-year             | 58 | 3.6 | 5.0 | 4.8    | 4.7   | 0.3  | [4.6,4.8]  |
| mHHS: preoperative                 | 59 | 7   | 87  | 36     | 39.7  | 19.5 | [34.6,44.7]|
| mHHS: 1-year                       | 57 | 31  | 91  | 81     | 75.8  | 14.3 | [72.1,79.6]|
| mHHS: 2-year                       | 51 | 31  | 91  | 91     | 86.7  | 10.6 | [83.7,89.7]|

### Patients with post-operative severe adverse events

| Description                                                                 | n (%) | 1-year | 2-year | Overall |
|-----------------------------------------------------------------------------|-------|--------|--------|---------|
| None                                                                       | 31 (25.4) | 31     | 24     | 15      |
| Dislocation                                                                 | 0 (0)   | 0      | 0      | 0       |
| Pain in the ipsilateral hip, pelvis or thigh                               | 7 (8.5)   | 7      | 8      | 5       |
| Scar-related problem                                                        | 4 (6.8)    | 4      | 1      | 4       |
| Surgical site infection                                                     | 1 (1.7)    | 1      | 0      | 1       |
| Fall and fracture of the operated area (Vancouver class A)                  | 1 (1.7)    | 1      | 0      | 1       |
| Cup insufficient fixation                                                   | 1 (1.7)    | 1      | 0      | 1       |
| Psoas syndrome or tendonitis                                                | 1 (1.7)    | 1      | 0      | 1       |
| Pain in the ipsilateral knee                                               | 3 (6.8)    | 3      | 1      | 4       |
| Spinal problem or sciatica                                                 | 3 (8.5)    | 3      | 2      | 5       |
| Disease, trauma or operation of contralateral hip                          | 2 (8.5)    | 2      | 3      | 5       |
| Unrelated death                                                            | 0 (1.7)    | 0      | 1      | 1       |
| Other                                                                       | 3 (18.6)   | 3      | 12     | 11      |
| Missing                                                                    | 2         | 2      | 7      | 7       |

### Secondary endpoints: Functional outcomes

HHS and mHHS were closely correlated preoperatively (R-squared: 0.9993, p < 0.0001,) and at 1-year follow-up (R-squared: 0.9995, p < 0.0001, Fig. 4). Detailed analysis of scores showed that the change in HHS was mostly driven by the change in mHHS items. This suggested that the mHHS at 2-year follow-up
could be reasonably compared to prior measurements, although the range of motion and deformation subscores were not available at 2-year follow-up. Pre- and postoperative HHS and mHHS summary in Table 3

Mean within-patient HHS increased from preoperative baseline to 1-year follow-up by 34.4 [28.5, 40.4] (Wilcoxon signed-rank test p < 0.0001). Mean within-patient mHHS increased from baseline to 1-year follow-up by 35.4 [29.6, 41.1] (p < 0.0001) and from baseline to 2-year follow-up by 46.5 [40.3, 52.8] (p < 0.0001).

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.[14] That requirement was reinforced with the introduction of the European Medical Devices Regulation.[15] 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, 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 revealed that HFPC-DM-HA had no predicate device. That systematic review was beyond the scope of this article, but shell differences were shown with a broad range of DM with clinical evidence reported in a compilation of articles (Table 4).[16].
### Table 4

**Comparison of DM shell: design – biomaterials – fixation**

| Model                                      | metal-back alloy / outer coating                      | design                             | fixation               |
|--------------------------------------------|------------------------------------------------------|------------------------------------|------------------------|
| Dual Mobility Cup                         | 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   |

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CoCr: Cobalt-Chromium. Mo: molybdenum. Ti: sprayed titanium layer. HA: hydroxyapatite layer
### 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 relatively small sample size, the relatively short follow-up duration, the inability to perform systematic physical and radiographic assessments at 2-year follow-up, 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. The strong associations between the HHS and the mHHS preoperatively, at 1-year follow-up and between their changes within patients over those two periods suggest that mHHS at 2-year follow-up is a reasonable estimator of the efficacy of THA with HFPC-DM-HA at that specific period, in the absence of 2-year physical and radiographic assessments to calculate the HHS. A secondary analysis of implant survival after multiple imputations of missing data was considered, but given the entire dataset at 2-year follow-up was missing in the concerned patients that method was not implemented.

### 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. It would be tempting to compare the results of SYMCOR-1 with those of a prospective "Regular Dual Mobility" cohort study of patients with similar demographics followed up 2 to 5 years. However, this would require adjusting for differences in clinical indications and fixation mechanism. Pooling the results of studies on DM and comparing them should be performed in the course of 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 cup in primary total hip arthroplasty with a hemispherical with flattened pole cobalt-chromium metal-back shell with outer porous double layer titanium/hydroxyapatite.
Two patients required revision surgery so that the implant survival rate at two-year follow-up was 97% [87, 99]. No prosthetic dislocation was reported. With respect to efficacy, the HHS improved significantly from a baseline of 49.5 [44.3, 54.6] to 84.6 [80.8, 88.4] at 1-year follow-up. The mHHS also improved significantly from a baseline of 39.7 [34.6, 44.8] to 75.8 [72.1, 79.6] at 1-year and 86.7 [83.7, 89.7] at 2-year follow-up.

The authors deemed the short-term outcomes of this acetabular cup in primary total hip arthroplasty to be satisfactory.

### Abbreviations

| CoCr   | Cobalt-Chromium                  |
|--------|----------------------------------|
| DM     | Dual-mobility acetabular cups    |
| HFPC-DM-HA | Hemispherical with Flattened Pole Cobalt-Chromium metal-back with porous outer Hydroxyapatite coating Dual-Mobility 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 Clinique de la Sauvegarde, Lyon, 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

- NB, GE, JG 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

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

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

References

1. Banka TR, Ast MP, Parks ML (2014) Early intraprosthetic dislocation in a revision dual-mobility hip prosthesis. Orthopedics 37:e395-e397.
2. Philippot R, Boyer B, Farizon F (2013) Intraprosthetic dislocation: a specific complication of the dual-mobility system. Clin Orthop Relat Res 471:965-970.
3. Kaplan EL, Meier P (1958) Nonparametric Estimation from Incomplete Observations. JASA 53:457.
4. Welch BL (1947) The generalisation of student's problems when several different population variances are involved. Biometrika 34:28-35.
5. Rubin DB (1973) Matching to Remove Bias in Observational Studies. Biometrics 29:159-183.
6. Wilcoxon F (1945). Individual Comparisons by Ranking Methods. Biometrics Bulletin 1:80-83.
7. Mann HB, Whitney D.R (1947) On a Test of Whether one of Two Random Variables is Stochastically Larger than the Other. The Annals of Mathematical Statistics 18:50-60.
8. Fay MP, Proschan A. FMP (2010) Wilcoxon-Mann-Whitney or t-test? On assumptions for hypothesis tests and multiple interpretations of decision rules. Stat Surv 4:1-39.
9. Greenwood Cindy, Nikulin, MS (1996) A guide to chi-squared testing, New York: Wiley.
10. Fisher RA (1934) Statistical Methods for Research Workers. 5th edn. Edinburgh: Oliver and Boyd.
11. Snedecor GW (1946) Statistical Methods. 4th edn. Ames, Iowa: The Iowa State College Press.
12. Duncan CP, Masri BA (1995) Fractures of the femur after hip replacement. Instr Course Lect 44:293-304.
13. Masri BA, Meek RM, Duncan CP (2004) Periprosthetic fractures evaluation and treatment. Clin Orthop Relat Res 420:80–95.
14. European Commission. Guidelines on medical devices (June 2016) Clinical evaluation: A guide for manufacturers and notified bodies on directives 93/42/EEC and 90/385/EEC. MEDDEV 2.7/1 revision 4.
15. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices amending Directive 001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
16. Dual Mobility Special Issue (2014). Int Orthop 41(3): 433-668.
17. Epinette JA, Béracassat R, Tracol P, et al. (2014) Are modern dual mobility cups a valuable option in reducing instability after primary hip arthroplasty, even in younger patients? J Arthroplasty 29(6):1323-1328.

Figures
Figure 1

Design: HFPC-DM-HA vs. other DM
Figure 2

Patient disposition

SAMPLING FRAME: Consecutive THA recruitment from Jul 3 2014 through Dec 17 2015
361 operations: 328 (90.9%) primary THA, 28 (7.8%) revisions THA

| Category          | Count (Percentage) |
|-------------------|--------------------|
| HFPC-DM-HA        | 59 (16.3%)         |
| other DM          | 55 (15.2%)         |
| STD               | 242 (67.0%)        |
| missing data      | 5 (1.4%)           |

non-selected cohort of consecutive HFPC-DM-HA: n = 59

Available for 2-year follow-up: n = 53 (90%)
Lost to 2-year follow-up: n = 6 (10%)

HFPC-DM-HA
Implant cumulative survival rate - Kaplan-Meier

Number at risk
59 49 49 11 0
0 25 5 75 1
0 1 2 3 4 years

95% CI
Survivor function
Figure 3

HFPC-DM-HA survival

Figure 4

HHS vs. mHHS at 1-year follow-up