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Research Article

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Dual-Mobility Progressive Press-Fit Hemispherical Acetabular Cup in Primary Hip Arthroplasty: Safety and Efficacy. The SYMCOR-1 study [NCT04209374]

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Abstract

Purpose: *To Estimate the short-term clinical safety and efficacy of hemispherical with flattened pole chromium-cobalt metal back dual-mobility acetabular cup with porous outer coating (HFPC-DM-HA), in primary THA.*

Methods: *Single-center retrospective observational cohort study of consecutive patients undergoing THA with a HFPC-DMHA cup 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 (67, 92), 32% female, median BMI 25.2 kg.m-2 (18.4 to 56.8). Primary osteoarthritis in 80%. 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 sub score) 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 ($p<0.0001$).

Conclusions: *The short-term benefit-risk balance was deemed satisfactory*

Keywords: Primary Hip Arthroplasty, Hemispherical, Flattened Pole, Dual-Mobility, Acetabular Cup, Implant Survival, Dislocation

Introduction

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

HFPC-DM-HA has a shell with a porous double layer outer coating, a titanium (Ti) layer covered with a hydroxyapatite (HA) layer designed for press-fit fixation. A specific dual mobility polyethylene (PE) liner is fitted into the shell and a cobalt-chromium (CoCr) or ceramic femoral head can be fitted in the insert. The two-bearing system is thus outer CoCr/PE with inner PE/CoCr or outer CoCr/PE with inner PE/ceramic.

The purpose of the progressive press-fit hemispherical dual-mobility design is 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 dual-mobility design.

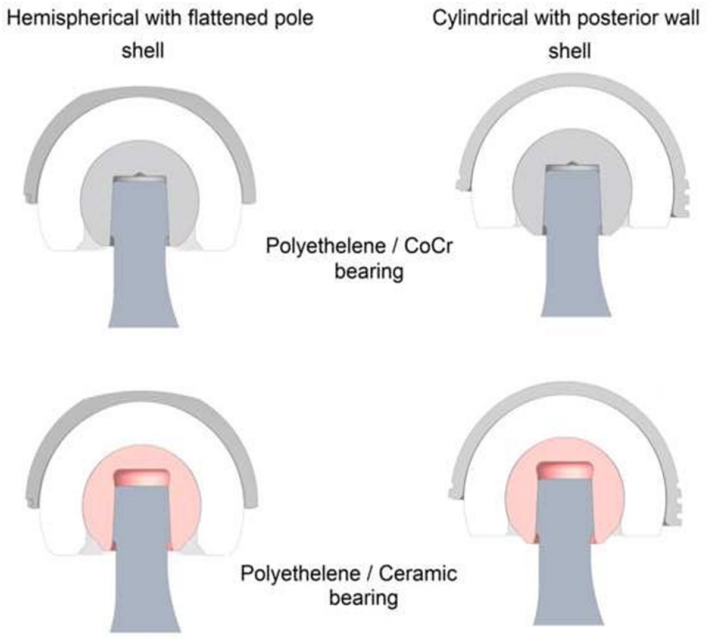

Figure 1: Progressive press-fit hemispherical versus non-hemispherical dual-mobility cups

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", was sponsored by Dedienne Sante using the cup 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.

Patients and 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 cup 2 years prior to study start and who were eligible for a 2-year postoperative assessment. This study was subject to MR3 regulation and was therefore notified to the CNIL without requiring IRB 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 underwent THA during that period while the cohort was the subset of patients in whom the primary THA had been performed using HFPC-DM-HA cups. Anonymous data recorded in a database from patient charts for the entire sampling frame included demographics, operative date, whether the THA was a primary or revision surgery and 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 using a HFPC-DM-HA cup during the screening period. 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 in relation to 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 procedure was past primary THA on the target hip using a HFPC-DM-HA. Acetabular cup fixation was press-fit. All femoral heads used were cobalt-chromium. 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 intraprosthetic dislocation (defined as the femoral head dissociating from the mobile bearing PE liner) were analyzed [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 sub scores 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 to compute 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 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 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 with THA, all being primary THA. Fifty-nine cases used HFPC-DMHA acetabular cup and all of them were included in the cohort. Six (10%) were lost to 2-year follow-up (Figure 2).

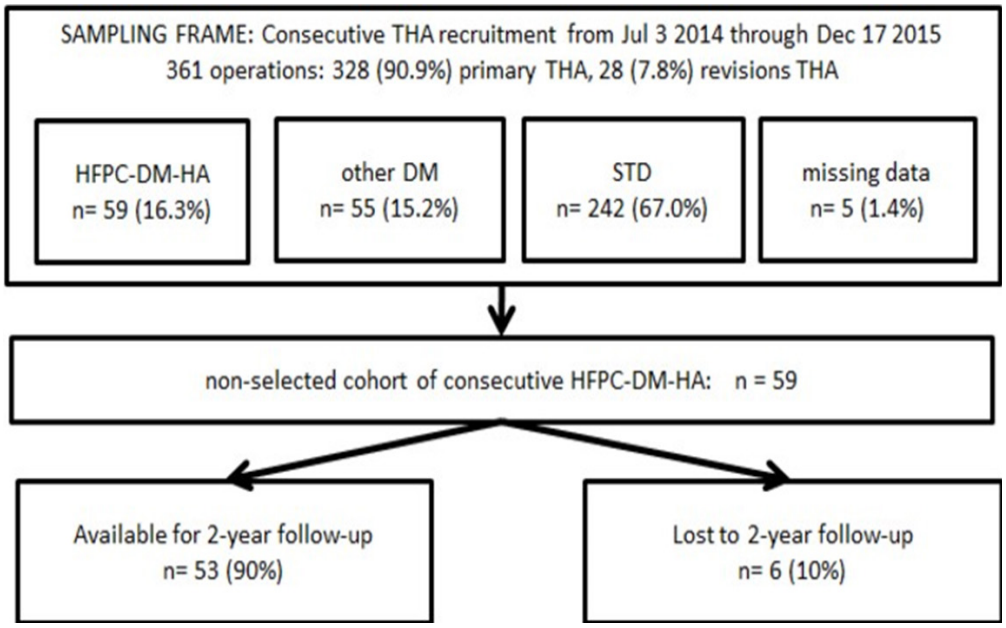

Figure 2: Patient disposition

Sampling Frame Characteristics

Acetabular cups used in the sampling frame were 242 (67.0%) standard cups (STD) and 111 (31.6%) dual-mobility cups (DM). DM were 59 (16.3%) HFPC-DM-HA and 55 (15.2%) other models (Figure 2). The overall female/male ratio was 171/190 (47.4%/52.6%) (Table 1) and there were significantly more female than male treated with DM (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).

Table 1: Sampling frame

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 standard cups were significantly younger than patients treated with overall DM cups (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 cups (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 cups (72%) and less frequently with standard cups (28%) (p<0.001). No HFPC-DM-HA was used in revision surgery (although data was missing for one patient).

When comparing the HFPC-DM-HA cohort to patients treated with the other DM cups, no significant difference was found in terms of gender (Fisher exact test: p = 0.057) or age distribution (t-test: p=0.66). The only significant difference found was that

33% of other DM cups were used for revision THA (p<0.001). Patients undergoing primary THA were significantly younger than those undergoing revision THA (mean difference: 8.1 years [1.8, 14.5], p=0.0134). Median post-operative time to study date was 3.0 years (range: 2.7, 4.1).

HFPC-DM-HA cohort subgroup 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 where 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 per trochanteric 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								40 (*68*) / 19 (*32*)
Side n (%) right / left								39 (*66*) / 20 (*34*)
Prior hip surgery n (%)								1 (*2*)
Etiology n (%) primary osteoarthritis of the hip acetabular protrusion rapidly destructive osteoarthritis (RDO) hip dysplasia other causes TOTAL								 47 (*80*) 6 (*10*) 3 (*5*) 1 (*2*) 2 (*3*) 59 (*100*)
Operative details								
Shell diameter (mm): range								48 ; 56
Bone graft n (%) Cup Stem								 0 (*0*) 0 (*0*)
Associated surgery n (%) none hell repositioning								 58 (*98.3*) 1 (*1.7*)
Operative time (minutes): median & range								53 (*42, 110*)
Intraoperative events/outcomes								
Complications n (%) fracture of greater trochanter, Vancouver class A3 partial facture of greater trochanter & calcar fracture line, Vancouver class A2 calcar fracture line, Vancouver class A2								 2 (*3.4*) 1 (*1.7*) 1 (*1.7*)
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 cups 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 cup. 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 acetabular cup at 2-year follow-up was 96.6% [87.1, 99.1] with a total time at risk of 131.2 years (Figure 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.

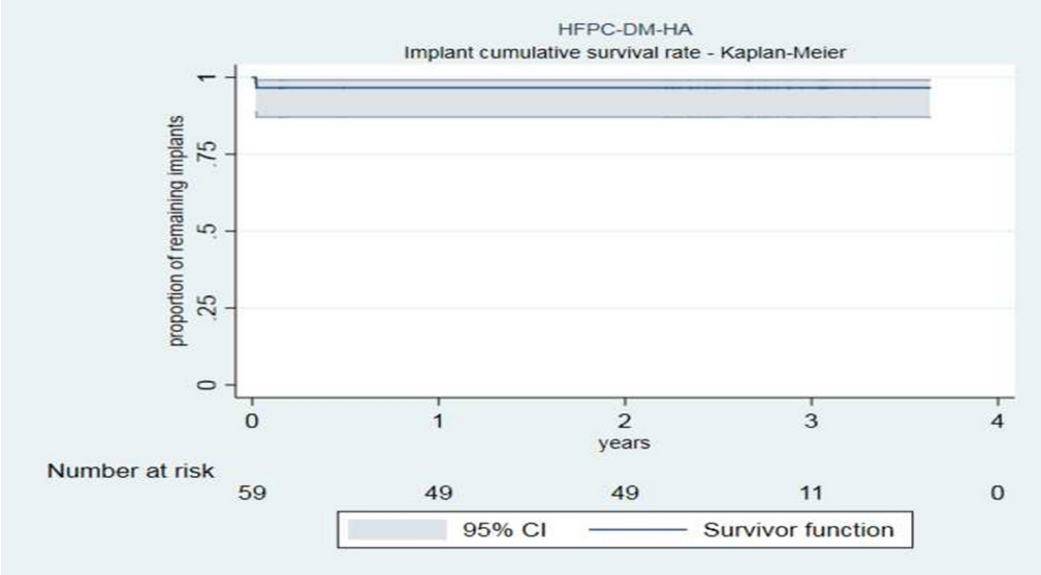

Figure 3: HFPC-DM-HA implant survival

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

HHS	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 n (%)							
description	1-year		2-year		Overall		
none	31		24		15 (*25.4*)		
dislocation	0		0		0 (*0*)		
pain in the ipsilateral hip, pelvis or thigh	7		8		5 (*8.5*)		
scar-related problem	4		1		4 (*6.8*)		
surgical site infection	1		0		1 (*1.7*)		
fall and fracture of the operated area (Vancouver class A)	1		0		1 (*1.7*)		

cup insufficient fixation	1	0	1 (*1.7*)
psoas syndrome or tendonitis	1	0	1 (*1.7*)
pain in the ipsilateral knee	3	1	4 (*6.8*)
spinal problem or sciatica	3	2	5 (*8.5*)
disease, trauma or operation of contralateral hip	2	3	5 (*8.5*)
unrelated death	0	1	1 (*1.7*)
other	3	12	11 (*18.6*)
missing	2	7	

Secondary Endpoints: Functional Outcomes

The HHS and mHHS are closely correlated preoperatively (R-squared: 0.9993, p<0.0001,) and at 1-year follow-up (R-squared: 0.9995, p<0.0001, Figure 4). Detailed analysis of scores shows 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 sub scores were not available at 2- year follow-up. Pre- and postoperative HHS and mHHS are summarized in Table 3.

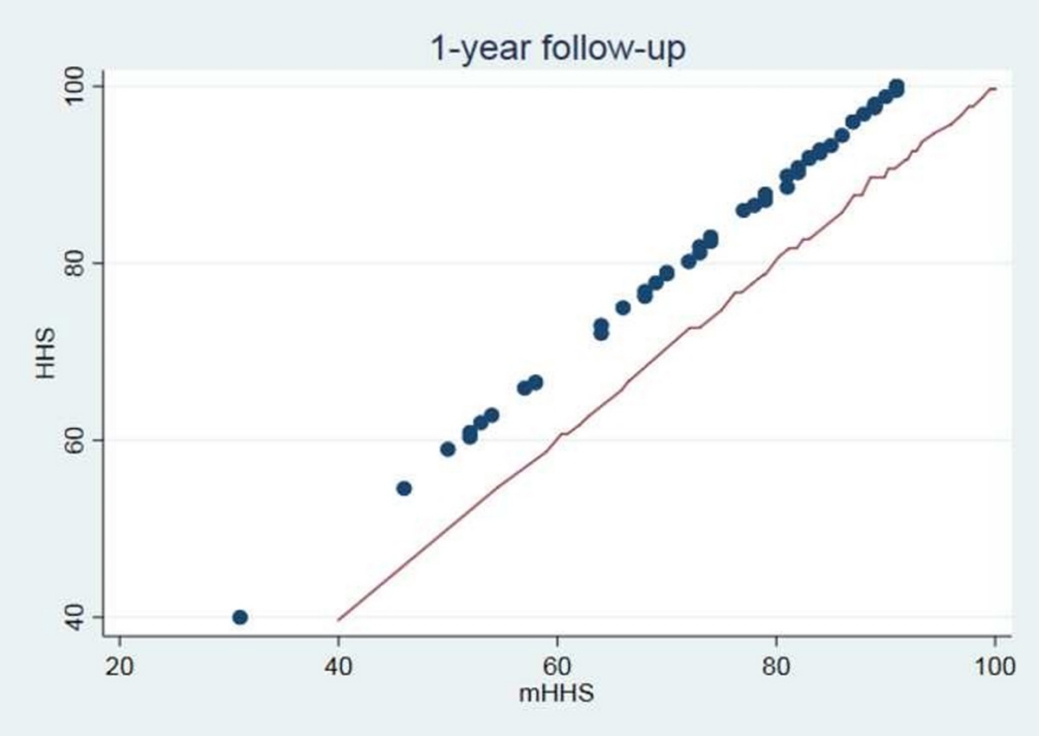

Figure 4: HHS vs. mHHS at 1-year follow-up

The 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). The mean within-patient mHHS increased from baseline to 1-year follow-up by 35.4 [29.6, 41.1] (Wilcoxon signed-rank test p<0.0001) and from baseline to 2-year follow-up by 46.5 [40.3, 52.8] (Wilcoxon signed-rank test 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 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-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 cups 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 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	stainless steel / porous single	cylindrospherical	cementless press-fit
second generation	layer: HA	cylindrospherical with 2 anatomical notches	cementless press-fit
Anatomic ADM® (Stryker Orthopaedics)	CoCr / porous double layer: Ti & HA	cylindrospherical with 2 anatomical notches & screws	press-fit & anchoring
Modular MDM® X3® (Stryker Orthopaedics)	CoCr / porous double layer: Ti & HA	hemispherical with medialized center	cementless press-fit
Tregor® (Aston Medical)	CoCr / porous double layer: Ti & HA	cylindrical with posterior wall	cementless press-fit
Ades® (Dedienne Santé)	CoCr / porous double layer: CoCr & HA	hemispherical with 6 equatorial fins & 4 tropical spikes	cemented
Quattro™ DM Cup (Groupe Lepine)	CoCr Mo / none	hemispherical with 6 equatorial fins & 4 tropical spikes	cementless press-fit
Quattro™ DM Cup (Groupe Lepine)	CoCr Mo / porous double layer: Ti & HA	hemispherical with flattened pole	cemented
HFPC-DM-CEM (Dedienne Santé)	CoCr / none	hemispherical with flattened pole	cementless press-fit
HFPC-DM-HA (Dedienne Santé)	CoCr / porous double layer: Ti & HA	hemispherical with flattened pole & 2 pegs & 1 screw	press-fit & anchoring
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

Internal Validity of This Study

The internal validity of this study is ensured by consecutive recruitment of primary THA only, performed by a single surgeon, and by a systematic follow-up process at equal time intervals.

The limitations in terms of internal validity 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 in observational settings, and the fact that 6 patients were missing to 2-year follow-up (10.2%) of the cohort. 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 its combined pain & functional sub scores preoperatively, at 1-year follow-up and between their changes within patients over those two periods suggest that the combined pain & functional sub score at 2-year follow-up is a reasonable estimator of the efficacy of THA with HFPC-DM-HA cup at that specific period, in the absence of 2-year physical and radiographic assessments to calculate the overall HHS. A secondary analysis of implant survival after multiple imputations of missing data was considered, but given for primary outcome (implant survival) but given all variables at 2-year follow-up was missing in concerned patients, the authors considered that post hoc imputations presented little advantage over complete case analysis.

External Validity of This Study

The external validity of this cohort study was based on the demonstration of the completeness of recruitment and comparison with the sampling frame. The main limitation was the limited sample-size recruited in a single-center. The comparability of this study with other dual-mobility cup cohort studies is difficult to establish due to few report data strictly primary THA. One prospective multicenter cohort study, however, reports results in a "Regular Dual Mobility Group" in 311 patients followed up between 2 and 5 years. Although the cohorts differed in the distribution of clinical indications as well as in the use of cemented cups, the groups were very similar in terms of age and gender distribution [17].

Conclusion

This was the first cohort study to present two-year follow-up safety and efficacy results on HFPC-DM-HA in primary THA.

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 benefit-risk balance to be satisfactory.

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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