ISSN: 2690 - 9189

Research Article

International Journal of Orthopaedics Research

Hemispherical with Flattened Pole Dual-Mobility Acetabular Cup in Revision or Complex Hip Arthroplasty: Safety and Efficacy. The SYMCOR-2 study [NCT04209426]

Gilles Estour[1], Nicolas Bonin[2], Schneider Loïc[3], Olivier Guyen[4] and Frederic Daoud[5*]

[1]*Medipole de Savoie, Challes-les-Eaux, France*

[2]*Clinique de la Sauvegarde, Lyon, France*

[3]*Clinique Mutualiste Chirurgicale, Saint-Etienne, France*

[4]*Clinique de Genolier, Genolier, Switzerland*

[5]*M.D., M.Sc., Epidemiologist-Biostatistician, Paris, France*

[*]Corresponding author

Frederic C Daoud, M.D., M.Sc., Epidemiologist-Biostatistician, Medextens SARL 75 rue de Lourmel, 75015 Paris, France, ORCID: 0000-0002-0469-9723.

Submitted: 30 Aug 2021; **Accepted:** 09 Sep 2021; **Published:** 24 Sep 2021

Citation: *Gilles Estour, Nicolas Bonin, Schneider Loïc, Olivier Guyen and Frederic Daoud (2021) Hemispherical with Flattened Pole Dual-Mobility Acetabular Cup in Revision or Complex Hip Arthroplasty: Safety and Efficacy. The SYMCOR-2 study [NCT04209426]. Int J Ortho Res, 4(3): 116-124.*

Abstract

Purpose: *To Estimate the short-term clinical safety and efficacy of hemispherical with flattened pole chromium-cobalt metal back dual-mobility acetabular cups with porous outer coating and anchoring (HFPC-DMR-HA) or cement fixation (HFPC-DM-CEM), in revision or complex THA.*

Methods: *Single-centre retrospective observational cohort study (title: SYMCOR-2, clinicaltrials.gov: NCT04209426) 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. 30% lost to follow-up. Median follow-up (years): HFPC-DMR-HA: 2.3, HFPC-DM-CEM: 3.3.*

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 sub score) 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 short-term benefit-risk balance was deemed satisfactory.*

Keywords: Primary hip arthroplasty, Revision 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.

Two versions of the HFPC-DM shell with reinforced fixation systems were used in this study:

1. HFPC-DMR-HA with a porous double layer outer coating, a titanium (Ti) layer covered with a hydroxyapatite (HA) layer, along with two pegs and one screw for anchoring, and
2. HFPC-DM-CEM with bare metal outer surface designed for cement 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.

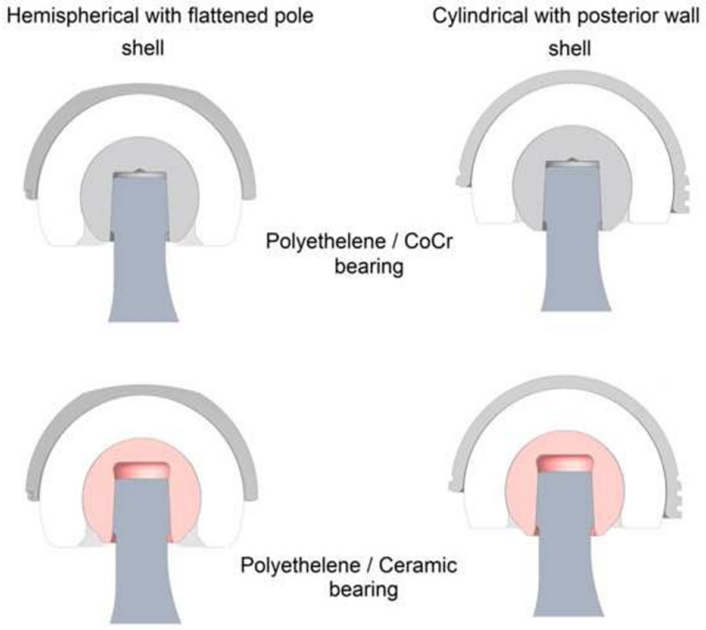

Figure 1: Progressive press-fit hemispherical versus non-hemispherical dual-mobility cups

HFPC-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", was sponsored by Dedienne Sante 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 complex or revision THAs 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-DMR-HA cup or a HFPC-DM-CEM cup prior to study start and who were eligible for a 2-year post-operative assessment. This study was subject to MR3 regulation and was therefore notified to the CNIL without requiring IRB approval. 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 underwent THA during that period while the cohort was the subset of patients in whom the primary THA had been performed using HFPC-DMR-HA or HFPC-DM-CEM 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-DMR-HA and HFPC-DM-CEM cohort only. Patient inclusion criteria in the cohort were any THA performed by the investigator using a HFPC-DMR-HA or HFPC-DM-CEM 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 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 procedure was past primary or revision THA on the target hip using a HFPC-DMR-HA or a HFPC-DMCEM. Acetabular cup fixation was reinforced with one screw and two pegs, or with cement, respectively. All 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 is defined as *the femoral head dissociating from the mobile bearing PE liner) were analysed* [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-DMR-HA and HFPC-DM-CEM cohort groups were respectively compared to the sampling frame with respect to those variables.

Demographic, preoperative, operative and postoperative descriptive statistical analysis was performed for each group. 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. 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 with primary THA and 24% with 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 (25%) and 2 (40%), respectively, were lost to 2-year follow-up (Figure 2).

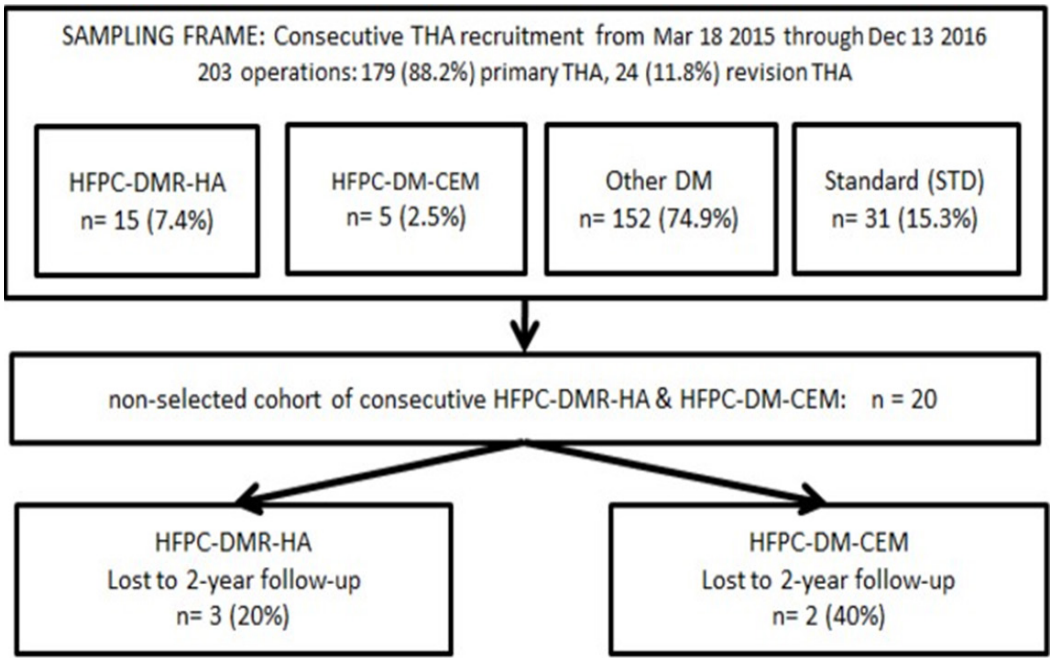

Figure 2: Patient disposition

Sampling Frame Characteristics

Acetabular cups used in the sampling frame were 31 (15.3%) standard cups (STD) and 172 (84.7%) dual-mobility cups (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 although more female than male was treated with DM, the difference in proportions was not significant (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 standard cups were significantly younger than patients treated with overall DM cups (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: $p = 0.0196$).

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)*

All STD were used for primary THA. All revision THAs were performed with DM cups and represented 14% of DM cup 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 significantly younger than those undergoing revision THA (mean difference: 9.6 years [5.4, 13.8], p<0.0001).

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

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%).

Table 2: Cohort demographics & operative details

HFPC-DMR-HA								
Demo-graphics	**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 n (%)	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

Bearing n (%)	Shell diameter (mm) range	Bone graft n (%)	Associated surgery n (%)	Operative time (minutes) median & range
PE/ceramic 13 (87) PE/CoCr 2 (13)	48 ; 56	Cup 0 *(0)* Stem 0 *(0)*	none 7 *(47)* stem replacement 4 (27) other 4 *(27)*	74 (40, 120)

Intraoperative events/outcomes

femoral cerclage wiring required n (%)	Hip stability excellent / medium: n (%)
1 *(6.7)*	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					Primary 0 (*0*)	Revision 5 (*100*)	Total 5 (*100*)	
Operative details								
Bearing n (%) PE/ceramic 13 (*87*) PE/CoCr 2 (*13*)	Shell diameter range (mm) 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 median & range (minutes) 87 (45, 120)		
Intraoperative events/outcomes								
Femoral cerclage wiring required n (*%*) 1 (*20*)				Hip stability n (*%*) excellent / medium: 4 *(80)* / 1 (*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 44mm to 64mm. 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 74mn (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 46mm to 52mm. 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 87mn (range: 45, 120). Bone graft was required in one HFPC-DM-CEM cup. 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 (Figure 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. Therefore, no figure required for HFPC-DM-CEM survival function.

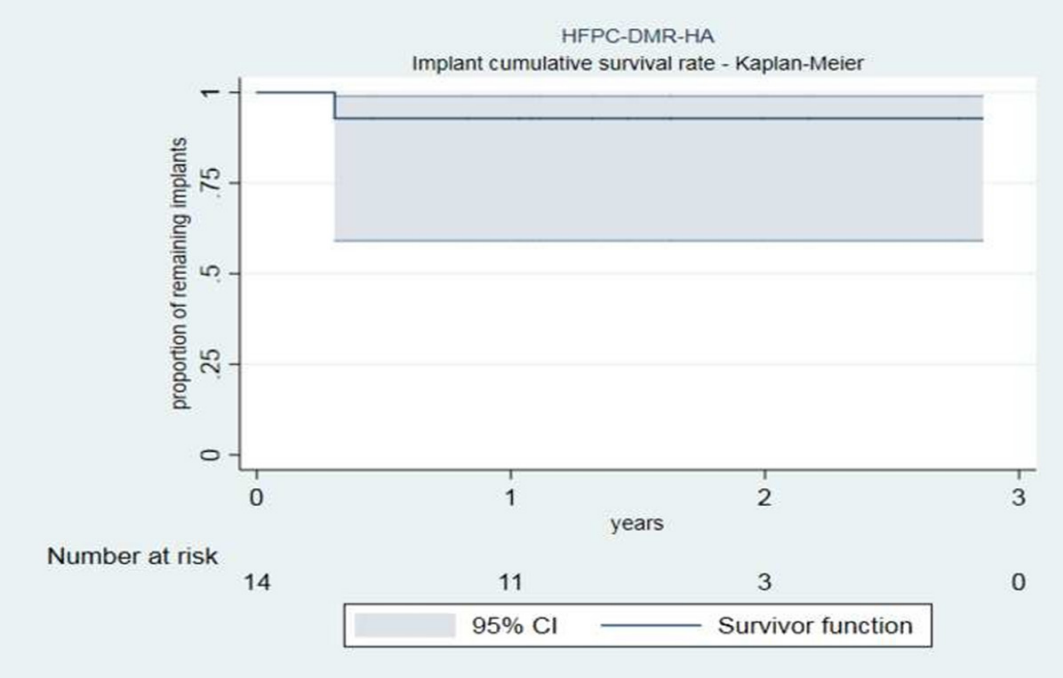

Figure 3: HFPC-DMR-HA implant survival

Secondary Endpoints: Postoperative implant or procedure-related complications

In the HFPC-DMR-HA group, 10 adverse events were reported in 9 (60%) patients, among which, 1 case (6.7%) of IPD 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 of the 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] (Wilcoxon signed-rank test $p<0.002$) and from baseline to 2-year follow-up by 54.2 [36.2, 72.3] (Wilcoxon signed-rank test $p<0.008$).

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 are summarized in Table 3.

Table 3: HHS & safety

HFPC-DMR-HA							
HHS	**n**	**min**	**max**	**median**	**mean**	**sd**	**95% CI**
HHS preoperative	15	4	70	34	23.0	37.7	[21.1, 46.6]
HHS 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]
range of motion 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]
mHHS: 1-year	13	16	91	80	74.5	22.5	[60.9, 88.1]
mHHS: 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							
HHS	n	min	max	median	mean	sd	95% CI
HHS preoperative	5	29	61	58	50.0	13.8	[32.9, 67.1]
HHS 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]
range of motion 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]
mHHS: 1-year	5	9	91	77	68.8	34.2	[26.3, 100]
mHHS: 2-year	3	71	91	80	80.7	10.0	[55.8, 100]
Patients with post-operative severe adverse events n (%)							
None							

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].

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

Internal validity of this study

The internal validity of this study was ensured by a consecutive recruitment 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 initial 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 in observational settings, and the large proportion of deaths and patients 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 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 small sample size by type of cup and intention recruited in a single-center.

A valid comparison of outcomes from this study on progressive press-fit hemispherical dual-mobility cups with those obtained using cylindrical cemented or screwed dual-mobility cups in revision surgery or complex primary THA could not be carried out given the scarcity of published evidence along with the lack of details to enable case matching on baseline characteristics.

Conclusion

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

In patients with HFPC-DMR-HA, one early intra-prosthetic dislocation, one fracture due to patient fall and two surgical site infections were reported. Revision surgery was required in one of the infections 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.

All patients with HFPC-DM-CEM were revision surgeries and no post-operative adverse event was reported so that implant survival was 100% with no intra-prosthetic dislocation.

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 benefit-risk balance to be satisfactory.

Competing Interests

- G.E., 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.

Funding

This work was sponsored and funded by Dedienne Sante S.A.S.

Acknowledgements

The study was sponsored by Dedienne Sante SAS who manufactures the studied implants.

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: 395-397.
2. Philippot R, Boyer B, Farizon F (2013) Intraprosthetic dislocation: a specific complication of the dualmobility 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 DR (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. Duncan CP, Masri BA (1995) Fractures of the femur after hip replacement. Instr Course Lect 44: 293-304.
12. Masri BA, Meek RM, Duncan CP (2004) Periprosthetic fractures evaluation and treatment. Clin Orthop Relat Res 420: 80-95.
13. 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.
14. 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
15. Dual Mobility Special Issue (2014). Int Orthop 41: 433-668.