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Clinical article

10 TO 16 YEARS RESULTS OF A MODERN CEMENTLESS DUAL-MOBILITY ACETABULAR IMPLANT IN PRIMARY TOTAL HIP ARTHROPLASTY

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1 **10 to 16 years results of a modern cementless dual-mobility acetabular**
2 **implant in primary total hip arthroplasty.**

3
4 **ABSTRACT**

5
6 **BACKGROUND**

7 The purpose of this study was to assess the radiographic results, clinical outcomes and
8 survivorship of a modern cementless DMC implant as a primary THA with a minimum of 10
9 years follow-up.

10
11 **METHODS**

12 This study retrospectively assessed a series of 310 primary THAs using a modern generation
13 cementless DMC (Saturne® acetabular cup; Amplitude, Valence, France) between April 2001
14 and December 2005 at a single center. Patients were followed prospectively clinically and
15 radiographically after surgery. Hips with follow-up less than 120 months were excluded from
16 the study (5 lost to follow-up and 167 deceased). In total, a cohort of 138 hips were included
17 for pre- and post-operative analysis with an average follow-up of 152.4 months. All
18 complications were collected, and a Kaplan-Meier survival analysis was performed.

19
20 **RESULTS**

21 There was a significant increase of the mean Harris and PMA scores between pre- and post-
22 operative cohorts ($p<0.001$). No loosening of the cup and no acetabular osteolysis were found
23 at final follow-up. No prosthetic dislocation, no intraprosthetic dislocation and no infections
24 were reported. The survival curve of THA in the total cohort (N=310) was about 98% at 10
25 years with three stems revision for femoral fracture. One psoas impingement was also
26 described.

27
28 **CONCLUSION**

29 This study showed no acetabular component failure and no reported cases of acetabular
30 osteolysis with this DMC acetabular component retention at 10 years. No prosthetic or
31 intraprosthetic dislocation were reported.

32 **KEYWORDS:** THA, dual mobility cup, cementless, dislocation

33

34 **CLINICAL RELEVANCE:** Excellent survival rate of a modern cementless dual-mobility
35 acetabular implant in primary total hip arthroplasty

36

37

38

39

40 **ABBREVIATIONS:**

41 DMC: dual mobility cup

42 THA: total hip arthroplasty

43 PMA: Postel-Merle d'Aubigne

44 UHMWP: ultrahigh-molecular-weight polyethylene

45 **INTRODUCTION**

46 Dual-mobility cup (DMC) prosthesis for total hip arthroplasty (THA) was developed
47 by French surgeon Professor Gilles Bousquet in 1974 in order to decrease risk of post-
48 operative instability and dislocation. Published studies report that dislocations represent a
49 major postoperative complication with an incidence of 0.2-7% in primary THA and 10-25%
50 in revision THA [1]. Additionally, the risk of THA dislocation reportedly increases 1-1.39%
51 for every five years of implant survival [2–10].

52
53 The first-generation DMC prosthesis for THA has been widely studied with over 20
54 year follow up. The reported incidence of dislocation in these studies ranges from 0-2.2% for
55 both primary and revision surgery combined. Epinette et al. reported good clinical and
56 radiological results at 2–5 years of an hydroxyapatite anatomical cup on 437 patients [5].
57 Long-term outcomes studies of the first-generation DMC, however, showed significant rates
58 of high polyethylene wear as a result of liner material and design issues. Polyethylene wear
59 was then responsible for acetabular component loosening and osteolysis as well as
60 intraprosthetic dislocation, both of which require revision surgery [11–15].

61 More recent short and midterm studies, however, show promising results of new
62 generation DMC, with significantly decreased incidence of polyethylene wear and,
63 consequently, low related complications with a maintained low incidence of prosthetic
64 dislocation [16,17]. Likewise, the few published mid and long-term follow-up studies
65 regarding modern cementless DMC implants show excellent outcomes and survivorship with
66 a low complication rate [18,19].

67
68 The purpose of this study is to assess the results of a modern cementless DMC implant
69 as a primary THA with a minimum of 10 years follow-up (survivorship, clinical evaluation,
70 radiological evaluation).

71
72
73 **METHODS**

74 *Study population*

75 We assessed retrospectively all primary DMC THAs performed between April 2001
76 and December 2005 at a single center by a senior surgeon using the same surgical technique.
77 Patients were prospectively followed clinically and radiographically after surgery. This series
78 consists of 310 primary consecutive THAs using a modern generation cementless DMC. Hips

79 having clinical and radiographic follow-up less than 120 months were excluded from the
80 study, which consisted of hips lost to follow-up (N=5) and hips deceased (N=167). Patients
81 deceased and lost to follow-up had a mean follow-up of 25 months (range of 0-117 months).

82 In total, a cohort of 138 hips were included for pre- and post-operative analysis with
83 an average follow-up of 152.4 months (range of 121-188 months) (Figure 1).

84
85 All operative technical data including the operative reports as well as pre- and post-
86 operative clinical and radiographic data were prospectively collected and stored in a computer
87 database. Clinical follow-up was performed using the Postel-Merle d'Aubigne (PMA) Score,
88 the Harris Hip Score and the Charnley modification of the PMA Score. Radiographic
89 evaluation consisted of anteroposterior and lateral x-ray views of the operative hip with
90 measurement of cup inclination, positioning of the femoral stem, assessment of polyethylene
91 wear, and examination for radiolucent lines and osteolysis. Polyethylene wear was assessed
92 on radiographs, and was defined as a migration of the femoral head in the polyethylene liner.
93 Coronal alignment of the stem was determined by measuring the angle formed between the
94 long axis of the prosthesis and the long axis of the femur. Coronal alignment greater than 3°
95 was considered a varus or a valgus placed stem. All local and systemic complications
96 resulting from the surgery were noted and recorded in the database.

97
98 *Operative technique*

99 All DMC THAs were implanted using a posterolateral surgical approach (Moore
100 approach) with intraoperative positioning in lateral decubitus. At the conclusion of the
101 procedure, closure of the hip capsule was performed with transtrochanteric non-absorbable
102 sutures and the piriformis tendon repaired at its native insertion site. A layered fascial and soft
103 tissue closure was performed. No drain was used, and the same accelerated post-op recovery
104 protocol was performed for all patients (full weight bearing, mobilization on the day of
105 surgery, early discharge at 3 or 4 days postoperatively after therapeutic education, optimized
106 pain treatment, therapeutic education about the dislocating movements...). Hyperflexion was
107 contraindicated for six weeks post-operative.

108 All of the DMC implants were designed and fabricated by the same manufacturer
109 (Amplitude, Valence, France). The Saturne® acetabular cup was cementless, with a stainless-
110 steel metal back and double coating of plasma sprayed titanium and hydroxyapatite using a
111 vacuum plasma spray process. The equatorial press-fit is ensured by a regular peripheral band

112 of slightly raised ridges which contribute to primary stability, without holes. The cup design is
113 anatomical with a superior augment and an inferior notch (Figure 2).

114 The polyethylene liner is a mobile ultrahigh-molecular-weight polyethylene
115 (UHMWP) component. To hold the femoral head, the mobile UHMWP component envelops
116 greater than 50% of the femoral head and its opening diameter is smaller than the femoral
117 head. When reduced, the head is captured within the polyethylene liner.

118 The Intégrale® femoral stem was the design associated implant for the Saturne®
119 acetabular implant. It consisted of a straight titanium forged stem with a double coating of
120 plasma spray titanium and hydroxyapatite in the same vacuum plasma spray process. The
121 neck had a cylindrical section of 10/12 mm. Heads were available in metal with a diameter of
122 22.2mm or alumina with a diameter of 28mm.

123

124 *Statistical analysis*

125 Statistical data was analyzed using the Student's t-test for comparison of quantitative
126 values between the pre- and post-operative results (large and normal-law variables), using R©
127 software (R Foundation for Statistical Computing, <http://www.R-project.org>). The Kaplan-
128 Meier survival curves were made and compared using a Log-Rank test with the help of the
129 Technical University of Denmark's online site (<https://www.statcom.dk>). The results were
130 considered significant if $p < 0.05$.

131

132

133 **RESULTS**

134 *Population characteristics (Table 1)*

135 The mean age at surgery was 68 years, with a mean body mass index at 24.5 kg/m² (14
136 patients (10.1%) had a BMI ≥ 30 kg/m²). 90 patients (65.2%) were Charnley A and 48
137 (34.8%) Charnley B or C.

138 Primary osteoarthritis was the most prevalent etiology (131 patients; 94.9%). Other
139 etiologies were hip dysplasia (5 patients; 3.6%) and post-traumatic osteoarthritis (2 patients;
140 1.5%). The main sizes of the acetabular component implanted were 50 to 58 mm.

141

142 *Post-operative results (Table 2 and 3)*

143 There was an increase of the mean Harris and PMA scores between pre- and post-
144 operative cohorts, which was statistically significant ($p < 0.001$). Hip flexion also showed a
145 statistically significant increase between pre- and post-operative cohorts ($p < 0.001$).

146 107 patients out of 138 (77.5%) had a complete radiographic follow-up at 10 years.
147 Cup positioning was good (between 40 and 50° of inclination) for 96 patients (89.7%),
148 horizontalized (<40° inclination) for 6 patients (5.6%) and verticalized (>50° inclination) for
149 5 patients (4.7%). Stem positioning was neutral for 100 patients (93.5%), valgus for 2 patients
150 (1.8%) and varus for 5 patients (4.7%). No loosening of the cup or the stem were found at
151 final follow-up (Figure 3). No out-of-round of the femoral head in the polyethylene was found
152 on radiograph. One patient showed an isolated radiolucent line in the Gruen zone 1 (Figure 4).

153

154 *Complications*

155 In the population with a follow-up greater than 10 years, there were 2 complications
156 (1.4%) found in 2 different patients: 1 femoral fracture (0.8%) with stem revision for
157 mechanical loosening (Figure 5), and 1 partial sciatic nerve palsy (0.8%). No prosthetic
158 dislocation, no intra-prosthetic dislocation and no infections were reported.

159

160 *Survival*

161 The survival curve of THA in the total cohort (N=310) with an event defined as the
162 revision of at least one prosthetic component (cup or stem) was 98% +/-1% with a 95%CI
163 between 97 and 99% at 10 years (Figure 6).

164

165 *Patients deceased and lost to follow-up*

166 The mean age at surgery was 78.2 years [48.3-96.2], with a mean body mass index at
167 25.3 kg/m² (11 patients (6.4%) had a BMI ≥30 kg/m²). 72 patients (41.9%) were Charnley A
168 and 100 (58.1%) Charnley B or C.

169 Primary osteoarthritis was the most prevalent etiology (132 patients; 76.7%). Other
170 etiologies were femoral neck fracture (31 patients; 18%), hip dysplasia (3 patients; 1.7%) and
171 post-traumatic osteoarthritis (6 patients; 3.5%).

172 There was an increase of the mean Harris and PMA score between pre- and post-
173 operative cohorts, which was statistically significant (46.9 vs 92.4 p<0.001 and 11.8 vs 17.1
174 p<0.001). Hip flexion showed a statistically significant increase between pre- and post-
175 operative cohorts (90.5 vs 106.5 p<0.001).

176 6 complications (3.5%) were found for 6 different patients: 3 femoral fractures (1.7%)
177 with 2 stem revisions for mechanical loosening (1.2%) and 1 isolated osteosynthesis (0.6%), 1
178 psoas impingement (0.6%) and 2 post-operative hematomas (1.2%). No prosthetic dislocation,

179 no intraprosthetic dislocation and no infections were reported. No loosening of the cup or the
180 stem were found for these patients on radiographs at final follow-up.

181

182

183 **DISCUSSION**

184 This study shows 10 years results of the modern dual mobility implants with
185 survivorship of 98% without any type of revision or component failure. No prosthetic or
186 intraprosthetic dislocation were reported.

187

188 Other series of modern DMC implants, like our series, have shown similar outcomes
189 and have vastly improved the outcomes when compared to early generation DMC implants
190 [7,17,19–28] (Table 4).

191 The first-generation acetabular cups were coated with plasma sprayed alumina, which
192 did not promote osteointegration and were associated with an increased risk of aseptic
193 loosening [29]. The fixation of modern DMC was enhanced with the development of a
194 hydroxyapatite-coated, pure titanium, macrostructured, bone-metal interface [30–32]. This is
195 due to the great osteointegration properties of titanium [33].

196

197 The dislocation rate in our study was zero, which corroborates data in published
198 literature on this kind of component [7,17,19–28] (Table 4).

199 Contrary to standard acetabular cups with metal-polyethylene bearing, the dislocation
200 rate does not increase as a function of time with wear of the bearing couple [2]. Dual mobility
201 was also demonstrated to be efficient for obese patients [34]. When compared with a standard
202 acetabular component, Berry et al. [35] reported a dislocation rate of 1.8 % at one post-
203 operative year, 7% at five years then a constant rate of approximately 1% every five years in a
204 series of 19,680 hips.

205

206 Prior studies had shown intraprosthetic and acetabular component failure of implants
207 caused by high levels of polyethylene wear resulting in intraprosthetic dislocation [14,15,36–
208 38] and acetabular loosening [2,10,29,39]. Both of these complications led to revision surgery
209 and higher implant failure rates of DMC implants when compared to a traditional implant
210 design. One significant difference between first generation DMC and modern DMC
211 componentry is the incorporation of UHMWP for polyethylene liners. The UHMWP used in
212 contemporary DMC devices, like the Saturne, leads to a lower rate of polyethylene wear,

213 helping to decrease the risk of intraprosthetic dislocation and cup loosening [40,41]. The
214 absence of cup loosening or acetabular osteolysis can also be explained in our study by the
215 relative low weight of the patients in our population with a mean BMI at 24.5 kg/m² and only
216 14 obese patients (10.1%).

217

218 Published literature has established cost savings (\$39,008 versus \$40,031 U.S. dollars)
219 and higher QALYs (13.18 versus 13.13) of DMC compared to conventional THA [20]. DMC,
220 however, was not cost-effective when the probability of revision from any unforeseen failure
221 mechanism exceeded 0.29%, leading to the probability of intraprosthetic dislocation exerting
222 the most influence on results. In a French study, DMC was associated with a relative risk of
223 dislocation of 0.4 versus conventional THA, which translated into 3283 fewer dislocations per
224 100,000 patients [21]. The corresponding cost-savings for the 140,000 primary THA
225 procedures done in France annually was 39.62 million Euros, with the potential annual cost-
226 savings increasing to 56.28 million Euros if a relative risk of 0.2 could be achieved [21].

227

228 This study showed no acetabular component failure and no reported cases of
229 acetabular osteolysis with this DMC acetabular component retention at 10 years. The
230 strengths of our study were the number of patients included with 10 years follow-up and the
231 homogeneity of the series with same surgeon, same technic and same clinical and radiologic
232 follow-up.

233 Unfortunately, one major limitation of this study was the important number of patients
234 lost to follow-up, essentially due to the deceased patients. Indeed, the mean age at the time of
235 the surgery was 78.2 years in the population deceased before ten years of follow-up versus 68
236 years in the population with more than ten years of follow-up. Additionally, this population
237 was mostly rural and less healthy with an increased rate of femoral neck fracture (18%),
238 which is a well-known risk factor of early death. Prudhon et al. described the same problem at
239 10 years follow-up with 692 THAs initially implanted and 105 finally followed-up [7]. An
240 important rate of deceased and lost of follow-up patients was described as well by Leclercq et
241 al. with 194 patients initially included and 107 patients finally followed-up [24].

242 Another weakness of this study was the incomplete radiological follow-up of the
243 patients at more than 10 years with only 107 complete analysis (77.5%), and lack of
244 knowledge of the radiological status for all patients with less than 10 years follow-up. It may
245 moderate our conclusions about the poor rate of cup loosening and acetabular osteolysis with
246 DMC component.

247 The final limitation was the lack of accurate assessment of polyethylene wear. Indeed,
248 the polyethylene wear was roughly estimated on radiographs with the migration of the
249 femoral head within the polyethylene liner, however, no radiostereometric analysis was
250 performed.

251

252 Given our results, the modern DMC implant shows to be an excellent option for
253 primary THA with nearly total implant survival at 10 years, resulting in annualized cost
254 savings over conventional THA based on prior studies. Additionally, patients with a high risk
255 for dislocation would benefit from the modern DMC implant due to its inherent stability, as
256 well as, the outcomes reported in this paper in regard to implant survival at 10 years.

257

258

259 **CONCLUSION**

260 This study showed excellent results of the modern cementless dual-mobility acetabular
261 implant, using properties of titanium-hydroxyapatite coating for osteointegration. No
262 loosening and no dislocation were reported at a minimum of 10 years follow-up in a
263 homogeneous series.

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391

392 TABLES

393 Table 1 Population characteristics

N	138		
Sex			
<i>Male</i>	65 (47.1%)		
<i>Female</i>	73 (52.9%)		
Mean age at surgery (years)	68 [40.4-83.5]		
Mean follow-up (months)	152.4 [121-188]		
Mean BMI (kg/m ²)	24.5 [18-43]		
<i>Patients with ≥ 30 kg/m²</i>	14 (10.1%)		
<i>Patients with ≥ 35 kg/m²</i>	4 (2.9%)		
Charnley classification			
<i>Charnley A</i>	90 (65.2%)		
<i>Charnley B</i>	32 (23.2%)		
<i>Charnley C</i>	16 (11.6%)		
Medical history			
<i>Ipsilateral UKA</i>	0		
<i>Contralateral UKA</i>	0		
<i>Ipsilateral TKA</i>	1 (0.7%)		
<i>Contralateral TKA</i>	0		
<i>Contralateral THA</i>	27 (19.6%)		
Etiologies			
Primary osteoarthritis	131 (94.9%)		
Post-traumatic osteoarthritis	2 (1.5%)		
Dysplasia	5 (3.6%)		
Neck femoral fracture	0		
Head osteonecrosis	0		
Size of the cup	<i>Head 22.2</i>	<i>Head 28</i>	<i>Total</i>
46	1	0	1 (0.7%)
48	7	4	11 (8%)
50	13	9	22 (16%)
52	15	14	29 (21%)
54	6	28	34 (24.6%)
56	5	9	14 (10.2%)
58	3	15	18 (13%)
60	0	6	6 (4.3%)
62	0	1	1 (0.7%)
64	0	2	2 (1.5%)

394

395 **Table 2** Post-operative functional results

	Pre-op (N=138)	Post-op (N=138)	<i>p</i>
Mean Harris Score	45.7 [16-73]	94.9 [76-100]	<0.001
Mean PMA Score	11.7 [5-16]	17.6 [15-18]	<0.001
<i>Pain</i>	2 [0-4]	5.9 [3-6]	<0.001
<i>Function</i>	4.2 [1-6]	5.7 [4-6]	<0.001
<i>Mobility</i>	5.5 [1-6]	6 [5-6]	<0.001
Hip flexion	92.4 [30-130]	108.7 [60-120]	<0.001

396

397

398 **Table 3** Post-operative radiographic results

Radiographic analysis	N=107
Cup position	
<40°	6 (5.6%)
40-50°	96 (89.7%)
>50°	5 (4.7%)
Stem position	
<i>Valgus</i>	2 (1.8%)
<i>Neutral (-2°/+2°)</i>	100 (93.5%)
<i>Varus</i>	5 (4.7%)
Complications	
<i>Radiolucent line Gruen zone 1</i>	1
<i>Radiolucent line others Gruen zones</i>	0
<i>Cup loosening</i>	0
<i>Stem loosening</i>	0
<i>Polyethylene wear</i>	0

399

400 **Table 4** Studies on primary THA using a dual mobility cup

	Fixation interface	Aseptic loosening rate	Dislocation rate	Intraprosthetic dislocation rate	Mechanical revision	Cup survival
Leclercq et al. (2008) [20]	Cementless HA coating	0	0	0	1.5%	100% at 5y
Bauchu et al. (2008) [21]	Cementless HA coating	1.6%	0	0	1.6%	97.4% at 7y
Prudhon et al. (2011) [22]	Cementless HA coating	0	1.9%	0	0	98.4% at 6y
Hamadouche et al. (2012) [23]	Cementless HA/Ti coating	0	0	2.4%	2.4%	94.2%
Leclercq et al. (2013) [24]	Cementless HA coating	0.5%	0	0	2%	99% at 10y
Prudhon et al. (2013) [7]	Cementless HA coating	0.9%	0.9%	0	1.9%	95% at 10y
Mohammed et al. (2015) [25]	Cementless HA coating	0	0	0	0	100%
Epinette (2015) [17]	Cementless HA coating	0	0	0	0	100% at 4y
Vigdorchik et al. (2015) [26]	Cementless HA coating	0	0	0	0	100%
Vermersch et al. (2015) [19]	Cementless HA coating	0	0	0	0	100%
Chugtai et al. (2016) [27]	Cementless HA coating	0	0	0	0.2%	99.8%
Our series (2019)	Cementless HA coating	0	0	0	0	100%

401

402 **FIGURES**

403

404

405 **Figure 1** Flowchart

406

407 **Figure 2** Cementless Saturne® cup

408

409 **Figure 3** No loosening of the cup or the stem and no polyethylene wear on x-rays at 11
410 (a) and 15 years (b)

411

412 **Figure 4** Radiolucent line in the Gruen zone 1

413

414 **Figure 5** Stem revision for femoral fracture

415

416 **Figure 6** Bipolar implant 10 years survival on total cohort (N=310): 98% +/-1%

Initial cohort
(n=310)

Lost of follow-up (n=5)

Deceded before 10 years
of follow-up (n=167)

Studied cohort (pre- and
post-operative analysis)
(n=138)



D DEBOUT



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