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Modular head-neck adapter system and ceramic heads in revision hip arthroplasty: a registry study on 354 implants

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Modular head-neck adapter system and ceramic heads in revision hip arthroplasty: a registry study on 354 implants

Abstract

Background

Five to ten-year outcomes of modular head-neck adapter system with ceramic heads in revision hip arthroplasty on large populations are still lacking. A registry study about modular adapter system with Delta ceramic head in revisions was designed, aiming to assess: 1) the survival rates of the device; 2) the reasons for re-revisions of the device; 3) a comparison to factory assembled titanium sleeve and Delta head cohort in revision hips.

Methods

Using a regional arthroplasty registry, we investigated the modular adapter system with a ceramic head in revision hips. Demographics, implant features, and reasons for revision were recorded. Survival rates and reasons for re-revision were assessed. The modular adapter system with the ceramic ball was compared to a factory-assembled ceramic titanium-sleeved head in revisions, acting as a control group. There were 354 revisions included at a mean follow-up of 5 years (range, 0 to 13).

Results

The 5 and 7-year survival rates were 87.9% and 86.9%, respectively. Dislocations (2.8%) and cup aseptic loosening (4.2%) were the two most frequent reasons for re-revision. No breakage of the adapter system or the ceramic head occurred. A femoral neck failed (0.3%). No implant features, offset ($p=0.088$) or skirted ($p=0.870$) tapers, impacted on failures. No differences between the two cohorts were found regarding survival rates ($p=0.696$) and reasons for re-revision (dislocations, $p=0.983$; cup aseptic loosening, $p=0.296$).

Conclusion

Modular head neck adapter system with a ceramic head seems to be a valid option in revisions at 5 and 7 years, without additional risk of implant breakage in this registry.

Keywords: Bioball Merete, revision, head-neck modularity, ceramic head titanium adaptor, trunnion

29 **Introduction**

30 The incidence of revision hip arthroplasties is still increasing: in the United States, the revision rate
31 is expected to raise to 70% by 2030 [1,2]. To date, revisions achieve a survival rate of 80 to 90% at
32 5 and 7 years, with infection, instability, and cup loosening accounting for 15, 18, and 29% of
33 re-revisions, respectively [1,2].

34 In revision hips, a modular head neck adapter system that mates with the femoral stem is useful to
35 restore hip biomechanics, implement the soft tissue tension, and avoid the removal of well-
36 fixed components [3]. An expanded intraoperative flexibility allows fine-tuning of the proximal
37 femoral biomechanics and to improve implant stability, avoiding the unnecessary removal of well-
38 integrated components [4–7]. However, adjunctive modularity may come at some costs. Some
39 well-known drawbacks of modular implants are dissociation, breakage, and mechanically-
40 assisted crevice corrosion [5,8].

41 In the series with the longest follow-up, the survival rate of modular head-neck adapter system was
42 92.8% at mean 52.5 months of follow-up [9]. However, the available case series were
43 heterogeneous in terms of demographic and implant features, encompassed retrospective small-
44 sized populations, and reached an overall low level of evidence [7]. Thus, many concerns remain
45 about the safety profile of this system on large population samples [10,11].

46 Thus, a registry study was designed aiming to assess the 5 and 7-year outcomes of modular head-
47 neck adapter system with ceramic heads in revision hips. The aims of this study were: 1) to evaluate
48 the survival rate; 2) to investigate the reasons for re-revision, with a special focus on breakage, and
49 to assess the demographic and implant related factors leading to failure, and 3) to compare the
50 survival rates and the reasons for re-revision of modular head-neck adapter system with ceramic
51 heads and factory-assembled ceramic sleeved heads in revisions.

52 **Materials and Methods**

53 The institutional review board approval was waived due to the registry nature of the study, collecting
54 data as a standard practice and concealing the patients' identity.

55 The Registry of Prosthetic Orthopedic Implants of Emilia Romagna (RIPO) has been collecting all
56 prosthetic primary and revision implants in the Emilia Romagna region (68 orthopaedic
57 facilities) since January 2000. It is a member of the International Society of Arthroplasty
58 Registries (ISAR) [13–15]. The registry records the demographic features, the surgical procedure,
the type of implants

59 (batch and code), and the fixation, according to the standard form, every surgeon had to fill in every
60 time a primary or revision arthroplasty was performed [16]. Data retrievals and cross-over compari-
61 sons with multiple databases were adopted to improve the capture rate and check for accuracy. The
62 RIPO capture rate was 98%, with lack of adherence accounting for the remaining 2% [16].

63 RIPO was investigated about all Bioball Merete modular adapter systems (Medical GmbH, Berlin,
64 Germany) with Delta ceramic heads (Biolog Option, Ceramtec, Plochingen, Germany) in revision
65 hips implanted up to December 31, 2019. The registry was also investigated about assembled taper
66 sleeves coupled with Delta ceramic heads in revisions implanted up to December 31, 2019, which
67 acted as a control group. Only Emilia-Romagna residents were included to avoid the selection bias
68 due to loss at follow-ups: for economic reasons, all the surgical procedures involving residing
69 patients (even when performed elsewhere outside the region) were billed back to the region itself,
70 and can be captured by the registry [17]. All the other adapter sleeves, the modular systems not
71 coupled with a Delta ceramic head, and the primary implants were excluded.

72 Patient demographics and implant features were recorded and analyzed. Survival rates and reasons
73 for re-revision were assessed, underlining the possible association with demographics and implant
74 features. Survival rates and reasons for re-revision were evaluated and compared with all the other
75 factory assembled adapter sleeves coupled with a Delta ceramic head in revisions.

76 *Bioball Merete and Biolog Option Ceramtec: implants features and differences*

77 Merete brought the above-mentioned modular adapter system on the market at the end of 1990s:
78 since 2015, the system has had the Food and Drug Administration approval for the use in the United
79 States [18]. Built in titanium (TiAl6V4), the sleeves adapt to the different Morse tapers (12/14 and
80 14/16, and 8/10, 10/12, 11/12, 11/13, V40 upon request). The system provides multiple lengths
81 (-3mm to +21 mm; S to 5XL): from 2 XL, adapters are in skirted configuration (Figure 1). Eccentric
82 correction of 7.5°, which may be adjusted to achieve the best tridimensional orientation in terms of
83 offset and version. Moreover, there are modular heads available in different materials (cobalt-
84 chromium, ce-ramic) and sizes (from 28 to 58 mm) [7,9].

85 Biolog Option provides titanium sleeves which interlock with the tapers 8/10, 10/12, 12/14. The
86 available ceramic head sizes range from 28 mm to 48 mm. The maximum length of the system is 7
87 mm (XL), without skirted configuration. No eccentric correction is provided.

88 A total of 354 modular head-neck adapter systems coupled with ceramic heads in revision hips was
89 implanted between January 1, 2007 and December 31, 2019 and was included in the study.

Demographics of the cohort were described in the table (Table 1). The main reason for revision was the aseptic loosening of the cup (51.4%) (Table 2). In 270 cases (76.3%) a modular adapter system was implanted on a 12/14 trunnion, in 77 cases (21.8%) on a 14/16 trunnion, in 6 cases (1.7%) on a 10/12 trunnion, and in 1 case (0.3%) on a 11/12 trunnion. The standard configuration was adopted in 223 cases (63%) and the offset correction in 131 cases (37%). The adapter length was depicted in Figure 2. A 28 mm head was implanted in 49 patients (13.9%), a 32 mm in 111 patients (31.4%), a 36 mm in 145 patients (41.1%), and 40 mm balls in 49 patients (13.8%). Ceramic-on-ceramic bearings were implanted in 208 hips (59.8%), ceramic-on-polyethylene in 86 implants (24.7%), ceramic-on-cross-linked polyethylene in 50 cases (14.4%).

The modular adapter system cohort with ceramic head (354 implants), when compared to the factory assembled titanium sleeve cohort (395 cases) as a control group, was comparable in terms of mean age at surgery (*T*-test, $p=0.034$), sex (Fisher test, $p=0.351$), Body Mass Index (*Chi*-square test, $p=0.869$), weight (Fisher test, $p=0.793$), reasons for revision (Fisher test, $p=0.942$), head sizes (*Chi*-square test, $p=0.219$), and types of revision (*Chi*-square test, $p=0.529$). The mean follow-up was 5 years (range, 0 to 13) for the modular adapter systems and 4 years (range, 0 to 14) for the titanium sleeves.

Data analysis

Patient demographics, implant features and reasons for revision were analyzed using descriptive statistics, such as means, ranges, and percentages. Unpaired *T*-tests were adopted to compare independent groups. Categorical data were compared using *Chi*-square or Fisher tests. The survival analysis was performed using Kaplan-Meier method; 95% confidence intervals were established for all the required distributions. Implants were followed until the last date of observation (date of death or December 31, 2019). The proportionality hazards assumption (HR) was tested by the Schoenfeld residual method; age, sex, implant features and reasons for revision used for adjustment fulfilled the proportional hazard assumption for the whole period. Log-rank tests were used to compare the survival curves. Statistical analyses were performed using SPSS 14.0, version 14.0.1 (SPSS Inc, Chi-cago, Illinois), JMP, version 12.0.1 (SAS Institute Inc, Cary, North Carolina) and Stata, version 17.0.1 (StataCorp LLC, College Station, Texas). Threshold for significance: 0.05.

Results

119 The modular adapter system achieved a survival rate of 87.9% (95% CI 83.6-91.2) at 5 years,
120 86.9% (95% CI 82.3-90.4) at 7 years and 85.7% at 10 years (95% CI 80.6-89.7). There were 40 re-
121 revisions and 60 deaths.

122 At the last follow-up, the two most frequent reasons for re-revision were cup aseptic loosening (12,
123 4.2%) and dislocations (10, 2.8 %). No breakage of modular adapter system or ceramic head
124 occurred. A neck and a cup breakage occurred (0.3%). The neck breakage occurred in a 70-year-old
125 man (93 kilograms): the first THA with a titanium modular neck implant (long valgus neck) was
126 revised after two years for heterotopic ossifications. The liner and the head were revised and a
127 modular adapter system with a 32 mm head with offset correction was implanted with a ceramic
128 liner. The revision hip failed 10 years after the revision due to neck breakage. Reasons for re-
129 revision were listed in Table 3 (Table 3). When the modular head-neck adapter systems with
130 ceramic heads were divided into skirted (2XL length or longer; 148 devices, 41.8%) and non-
131 skirted devices (length: S, M, L, XL; 205 devices, 58.2%), no differences were observed in terms of
132 survival rates (Log rank test, $p=0.870$). The skirted head hazard ratio for failure, adjusted for age
133 and sex, was 1.12 (CI 95%: 0.60-2.17, $p=0.707$). When the modular adapter systems were
134 stratified into offset (131 implants) and standard devices (223 implants), no differences were
135 observed between the two cohorts (Log rank test, $p=0.088$). The offset implant hazard ratio for
136 failure, adjusted for age and sex, was 1.55 (CI 95%: 0.81-2.92, $p=0.182$). The multivariate
137 analyses using Cox proportional hazards model showed that age, sex, weight, Body Mass Index,
138 and implant-related factors did not affect the survival rates.

139 Both the cohorts achieved similar survival rates (Log-rank test, $p=0.696$) (Figure 3). The modular
140 system hazard ratio for failure, adjusted for age and sex, (1.01, CI 95%: 0.65-1.56) confirmed that
141 the two cohorts achieved similar outcomes ($p=0.960$). The reasons for re-revision of the two cohorts
142 were detailed in the table: one head breakage occurred in titanium sleeve cohort, but no cases were
143 traced among modular adapter systems (Table 3). When the survival rates of the two cohorts were
144 compared using the two most frequent reasons for re-revisions as end-points (dislocations and
145 cup aseptic loosening), there were no significant differences (Log rank test, $p=0.983$ and $p=0.296$,
146 respectively).

146 **Discussion**

147
148 Modular head neck adapter system coupled with the ceramic head used here showed good survival
149 rates at 5 to 7-year follow-up in revision hips. No mechanical failure of the modular adapter system
150 and no head fracture occurred, only a neck breakage was described (0.3%). The most frequent
reasons for re-revisions were dislocations and cup aseptic loosening (both accounting for about one
third of all the failures). No demographic- or implant-related features (even offset or skirted
devices) -

151 impacted the rate of failures. When a control group of revisions with factory assembled sleeved
152 heads (titanium adapter) was compared, no differences could be observed in terms of survival rates,
153 even when re-revisions for dislocations and cup aseptic loosening were used as end-points.

154 This study has some limitations, mostly due to the registry nature: among them, the lack of clinical
155 and radiographic data, revision system indications, titanium ion levels in the serum, as well as
156 retrieval and surgical data in re-revisions. Moreover, the follow-up was inferior to 10 years. At
157 7 years, only 102 modular adapter systems were exposed (28.8%): although the survival curve is
158 still fully reliable at this time, the number of implants exposed is modest. As registries capture only
159 re-revisions with at least one component exchange, conservatively treated complications such
160 as dislocations or infections could not be identified. Furthermore, clinical and radiological
161 outcomes were not investigated, especially restoration of biomechanical parameters.
162 Additionally, fretting corrosion could not be evaluated unless it led to re-revision. However, to our
163 knowledge, this is the largest sample of modular head neck adapter system ever analyzed at 5 to 7-
164 year follow-up. This also may be the largest study providing a control group of factory-assembled
165 ceramic sleeved heads.

166 The indications for modular adapter system in revisions were similar in the present cohort and in the
167 current literature: revisions for dislocations and cup aseptic loosening [9]. Even the use of adapter
168 length was roughly comparable to the current literature [19]. The survival rates of the present cohort
169 of modular adapter system with ceramic head were satisfying at 5 to 7years. These outcomes were
170 comparable to the largest and longest case series, with Hoberg et al. reporting a slightly better
171 survival rate at a similar follow-up (over 90%, mixed populations of metal and ceramic heads) [7].
172 The main reasons for re-revisions were dislocations and cup loosening, accounting for around one
173 third of all the failures: specifically, dislocations caused re-revision of the implant in 11 hips
174 (3.1% of cases), similarly to the current literature [9]. However, differently from the other papers
175 which reported third generation head failures, no ceramic head fractures were observed. This
176 difference could be easily attributed to the fourth-generation ceramic, with improved
177 toughness [2]. This report is also reassuring about neck failures: only one event occurred out of
178 354 devices (0.3%) at a mean follow-up of 5 years, despite the high correction and the long lever
179 arms provided by the modular adapter system [20]. No re-revisions due to metallosis or corrosion
180 were reported, probably due to the benefits of titanium adapter. However, registry provides generic
181 data about adverse reactions to metal debris and no conclusions should be drawn.

182 Implant and demographic factors did not impact on failures in the present report. Skirted and offset
183 devices did not influence the failure rate in the md-to-long terms. This is a notable finding: skirted
and offset devices may potentially predispose to instability and neck/stem mechanical failure due to

184 the lower head-neck ratio and the increased lever arms [21]. Moreover, no high-risk profile for
185 failure could be defined, despite the large case series. However, the present case series included a
186 modest rate of young and heavy men (mean age 70 years, only one fourth of the patients was
187 over 80 kilograms). Considering that dual-taper modular stems with titanium-on-titanium
188 modularity were reported to incur more failures in younger and heavier men, the modular adapter
189 system should be carefully evaluated in these patients and possibly discouraged: however, further
190 studies are required to draw any definitive conclusion in this subgroup [22].

191 In the comparison between modular adapter system with ceramic heads and factory-assembled
192 ceramic sleeved heads (titanium alloy taper sleeve), the two groups showed similar pre-operative
193 features, allowing a reliable comparison. The control group was chosen as the possible
194 “gold standard” in ceramic head revisions: last generation head material, compatible titanium
195 sleeve, and pre-assembled adaptor to reduce manual assembling errors. However, due to the
196 different features, modularity and cone adapter availability, the two solutions are not
197 alternatives, but rather complementary. However, the results of the two groups were similar and
198 should comfort modular adapter system users about the safety and the non-inferiority of the device
199 at 5 to 7 years. When the two main reasons for re-revisions in modular adapter cohort were used as
200 end-points, both the cohorts achieved comparable performances.

201 In conclusion, modular head-neck adapter system with a ceramic head achieved
202 excellent performances in revision hip arthroplasties and emerged as a dependable, safe device at 5
203 to 7-year follow-ups. The modular adapter system provided consistent results, not inferior to
204 more standard taper sleeve solutions, despite the higher taper compatibility, the larger head sizes,
205 the longer length correction, and the offset configuration (all these features possibly causing
206 more corrosion, more instability, more mechanical failures). Large, multi-center studies
207 evaluating the clinical and radiographic outcomes at longer-term and retrieval studies could
208 provide important data concerning instability, mechanical failures, wear and corrosion, and the
209 non-suitable candidates for modular adapter systems.

210

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278 **Table captions**

279 Table 1. Population under study. Descriptive statistics.

280 Table 2. Diagnosis leading to revision in the cohort with modular adapter system and Delta head.

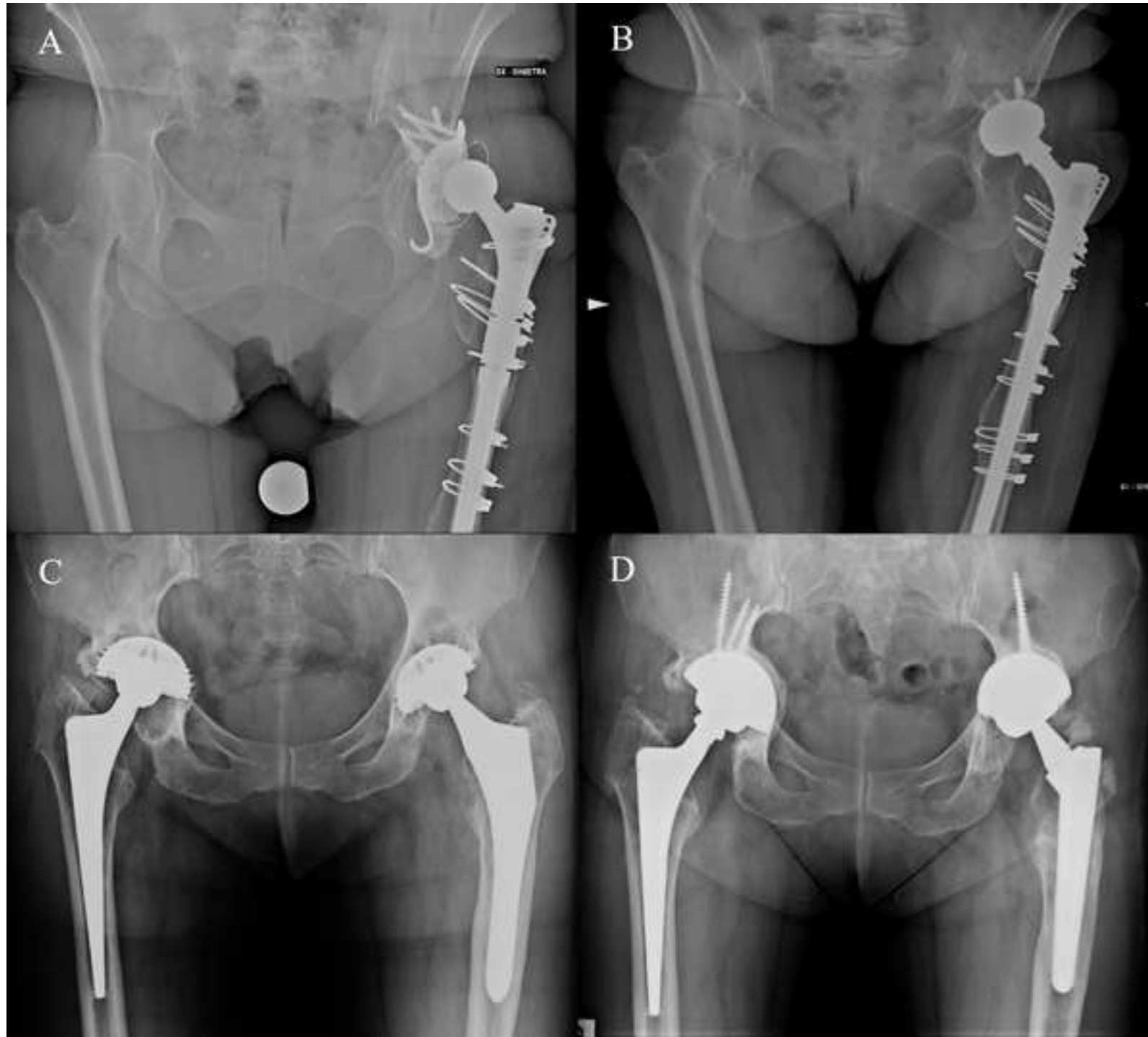
281 Table 3. Diagnosis of re-revision implants on the two populations.

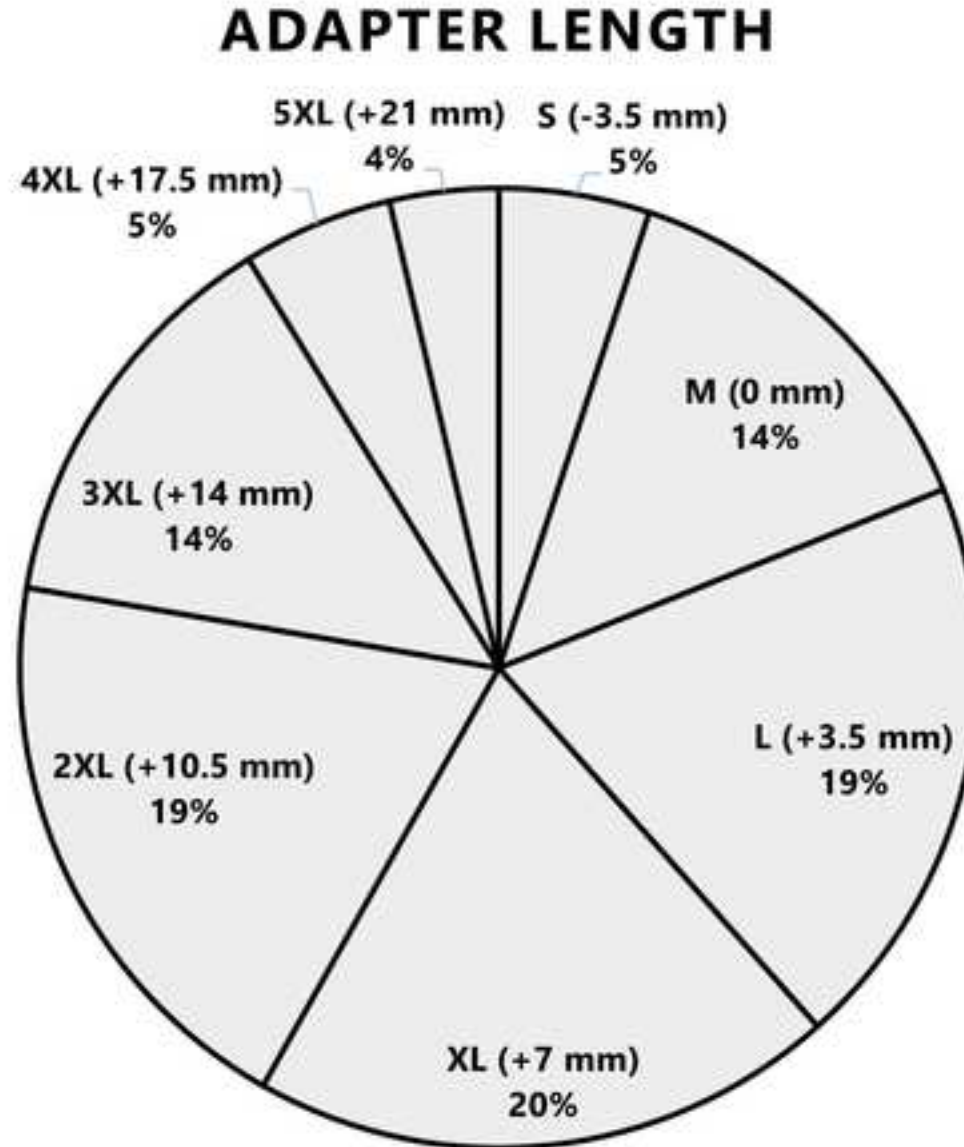
282 **Figure legends**

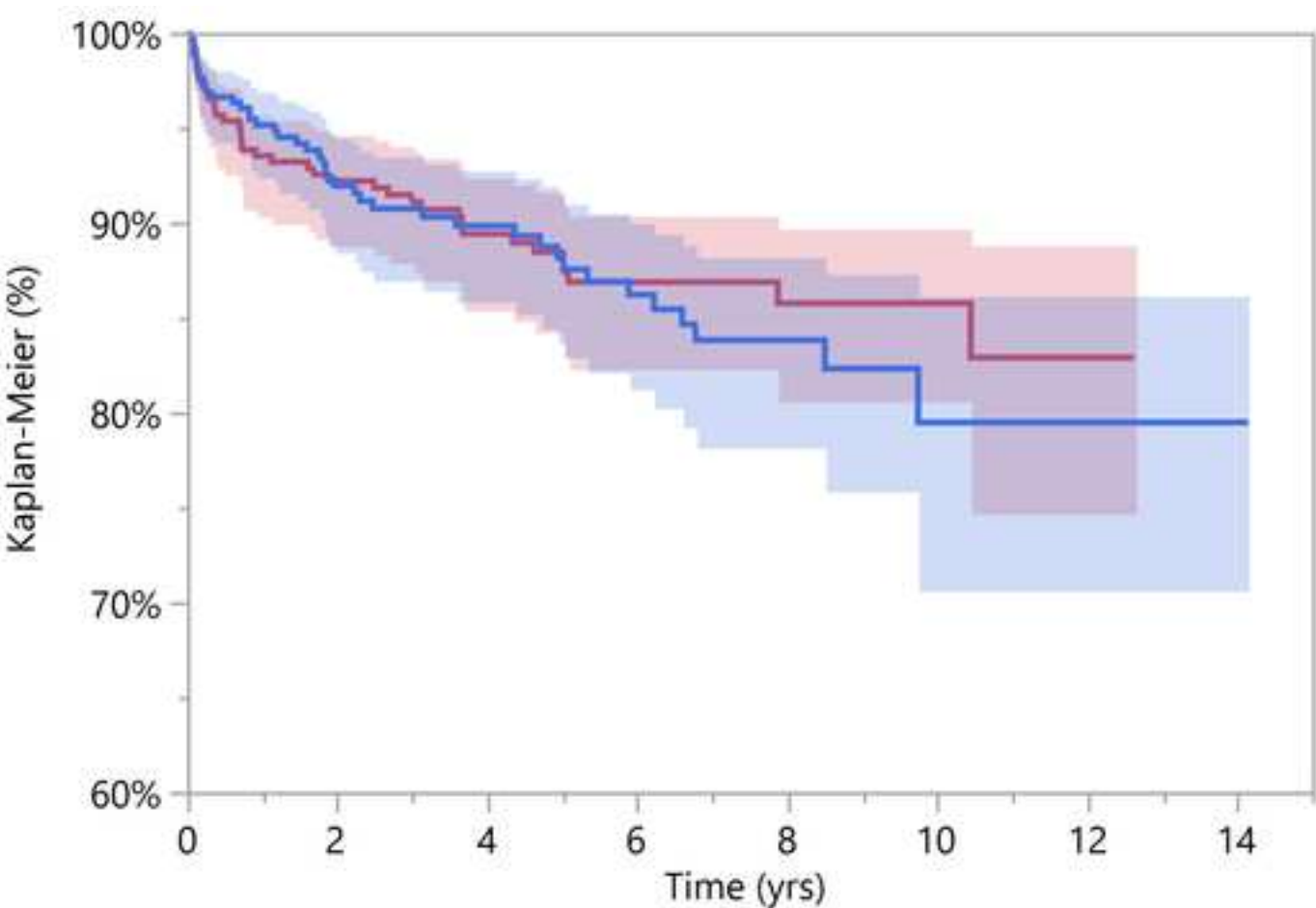
283 Figure 1. Two cases of cup aseptic loosening (A,C) were revised with a modular head-neck adapter
284 system and a skirted ceramic head: the stem (12/14 taper) was retained. Satisfying outcomes were
285 achieved at 3 (B) and 5 (D) years.

286 Figure 2. Adapters length distribution.

287 Figure 3. Implant survival rates of the two cohorts (both mated with ceramic heads) achieved
288 similar outcomes at 5 to 7-year follow-up.







Survival rates in percentages (confidence interval 95%)					
	1 yr	3 yrs	5 yrs	7 yrs	10 yrs
Modular adapter system	93.5 (90.3-95.7)	91.1 (87.4-93.7)	87.9 (83.6-91.2)	86.9 (82.3-90.4)	85.7 (80.6-89.7)
<i>Implants exposed</i>	293	236	168	102	39
Titanium sleeve	95.1 (92.4-96.9)	90.7 (87.0-93.5)	87.5 (82.9-91.0)	83.8 (78.2-88.2)	79.5 (70.6-86.2)
<i>Implants exposed</i>	308	208	146	95	26

1 **Figure legends**

2 Figure 1. Two cases of cup aseptic loosening (A,C) were revised with a modular head-neck adapter
3 system and a skirted ceramic head: the stem (12/14 taper) was retained. Satisfying outcomes were
4 achieved at 3 (B) and 5 (D) years.

5 Figure 2. Adapters length distribution.

6 Figure 3. Implant survival rates of the two cohorts (both mated with ceramic heads)
7 achieved similar outcomes at 5 to 7-year follow-up.

	Modular adapter system		Titanium sleeve	
	Implants			
Diagnosis	n.	%	n.	%
Cup aseptic loosening	15	35	7	16.3
Prosthesis dislocation	11	27.5	12	27.9
Total aseptic loosening	2	5	3	7
Stem aseptic loosening	2	5	3	7
Septic loosening	2	5	5	11.6
Superficial infection**	2	5	/	/
Periprosthetic fracture	1	2.5	1	2.3
Neck breakage	1	2.5	2	4.7
Cup breakage	1	2.5	1	2.3
Other	3	7.5	4	9.3
Total	40	100.0	43	100.0

*debridement, antibiotics and implant retention

Table 3. Diagnosis of re-revision implants on the two populations.

Table 1

	Modular adapter system
Implants n°	354
Patients n°	331
Sex Men (%)	31.4
Mean age (range)	69.8 (29-89)
Mean Body Mass Index (range)	26.1 (19.5-33.8)
Previous procedure Total hip arthroplasty (%) Hemiarthroplasty (%)	96.0 4.0
Type of revisions Cup and modular parts (%) Modular parts (%)	78.8 21.9

Table 1. Population under study. Descriptive statistics.

Table 2

Diagnosis	Implants revised n°	%
Cup aseptic loosening	182	51.4
Primary instability	66	18.6
Liner wear	28	7.9
Metallosis	15	4.2
Pain without loosening	14	4.0
Head breakage	10	2.8
Total aseptic loosening	7	2.0
Liner breakage	7	2.0
Periprosthetic fracture	5	1.4
Cup breakage	4	1.1
Ossification	4	1.1
Failure after partial revision surgery	3	0.8
Other	9	2.5
Total	354	100.0

Table 2. Diagnosis leading to revision in the cohort with modular adapter system and **ceramic** head.