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Title Page (with full author details)

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 andceramic 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

Introduction

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

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

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

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

Materials and Methods

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

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

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

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

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

Bioball Merete and Biolox Option Ceramtec: implants features and differences

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

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

A total of 354 modular head-neck adapter systems coupled with ceramic heads in revision hips was 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 independ-ent 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 sur-vival 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

The modular adapter system achieved a survival rate of 87.9% (95% CI 83.6-91.2) at 5 years, 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-revisions and 60 deaths.

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

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

Discussion

Modular head neck adapter system coupled with the ceramic head used here showed good survival rates at 5 to 7-year follow-up in revision hips. No mechanical failure of the modular adapter system 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) -

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

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

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

Implant and demographic factors did not impact on failures in the present report. Skirted and offset 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

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

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

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

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Table captions

Table 1. Population under study. Descriptive statistics.

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

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

Figure legends

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

Figure 2. Adapters length distribution.

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

Figures 1

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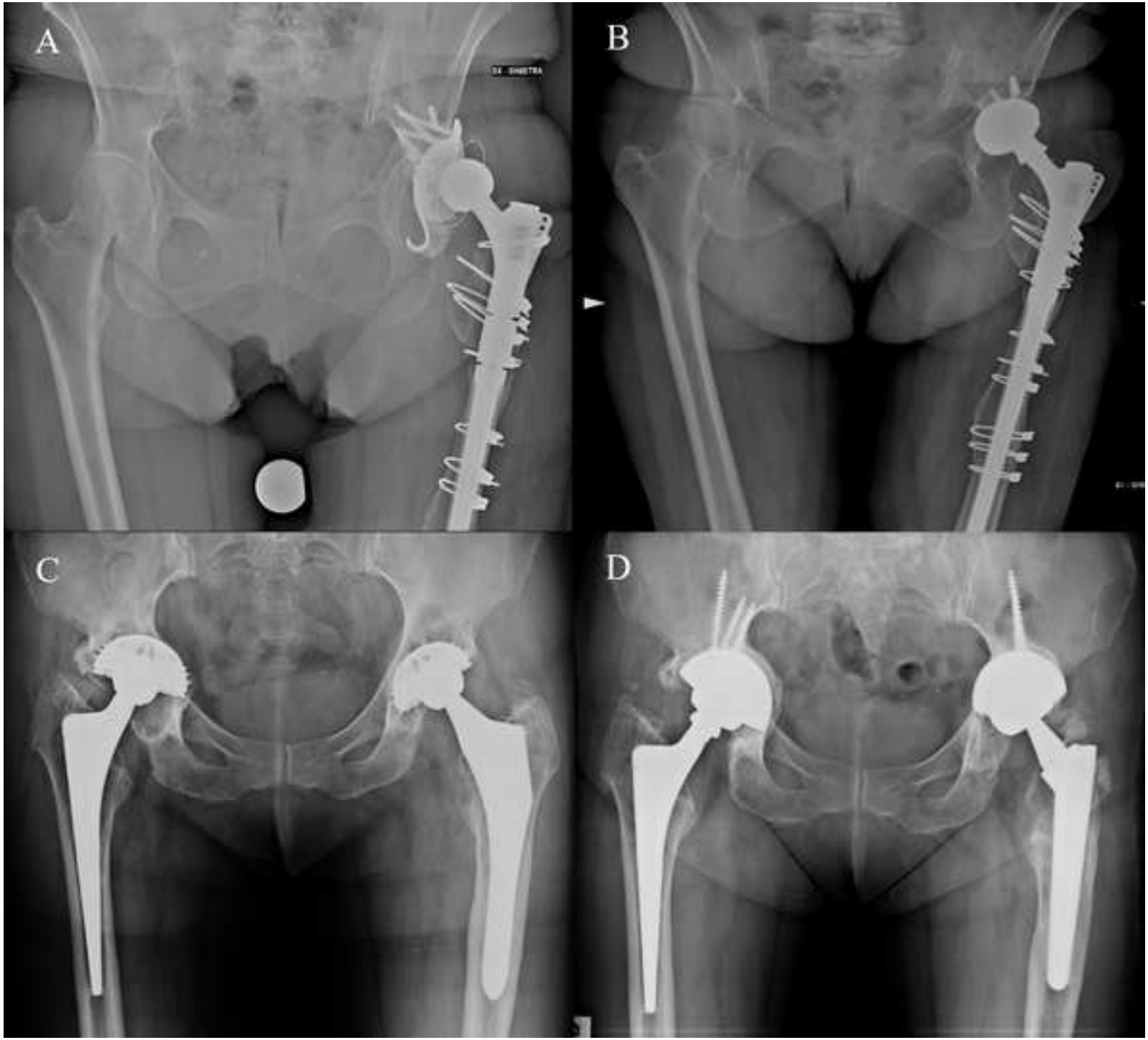

Figure 2

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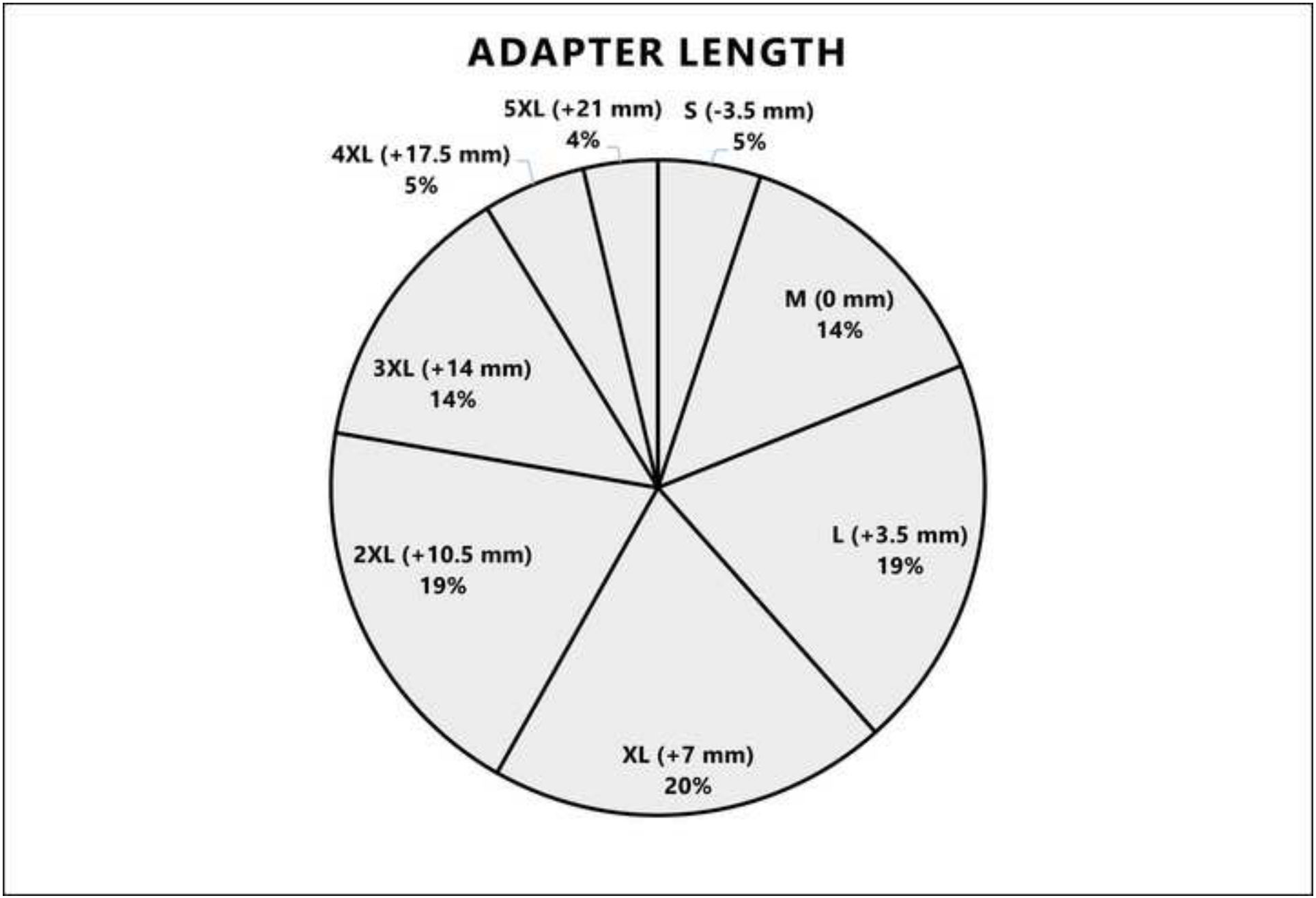

Figure 3

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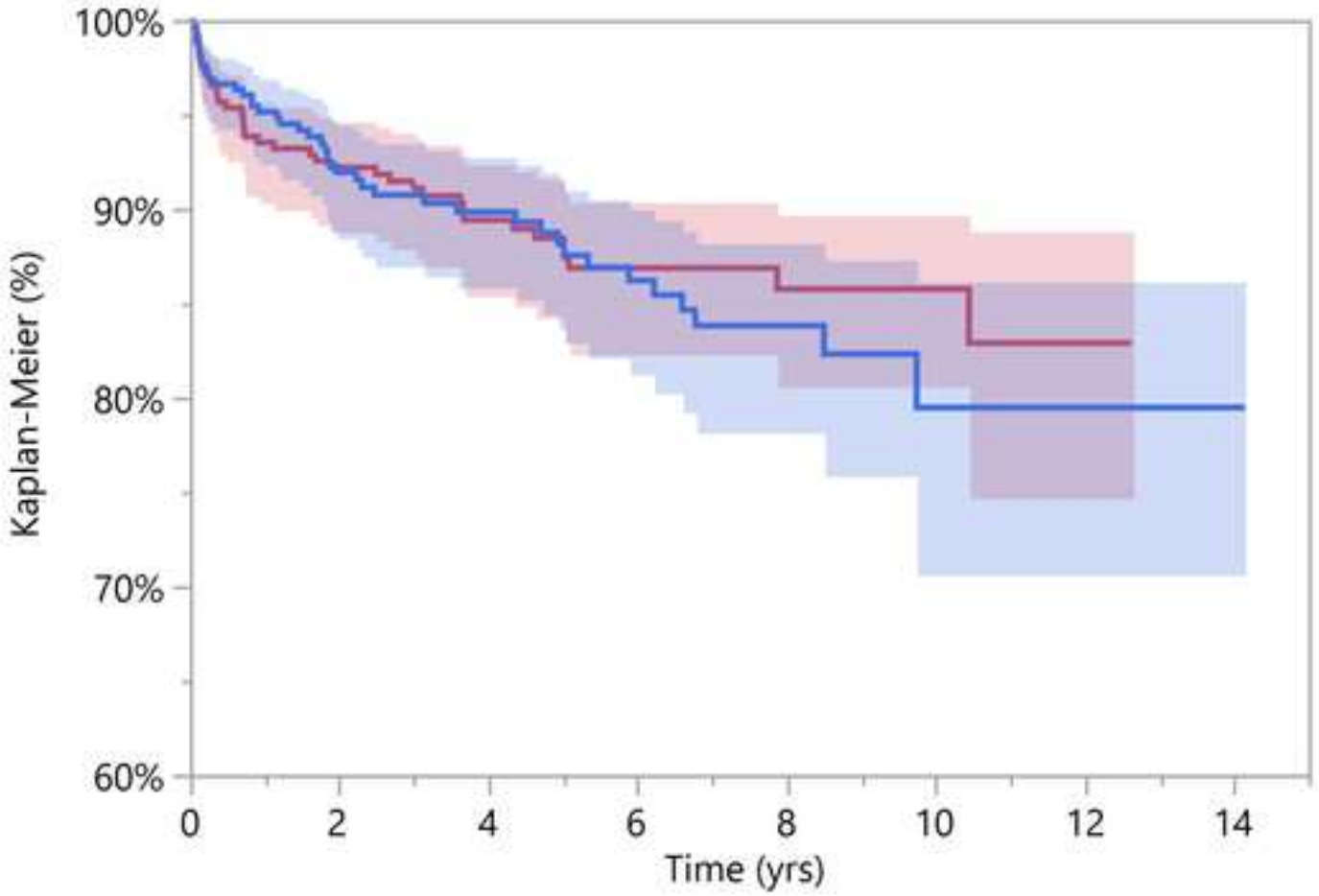

Survival rates in percentages (confidence interval 95%)					
	1 yr	3 yrs	5 yrs	7 yrs	10 yrs
Modular adapter system	93.5 (90.3-95.7)	91.1 (87.4-93.7)	87.9 (83.6-91.2)	86.9 (82.3-90.4)	85.7 (80.6-89.7)
Implants exposed	*293*	*236*	*168*	*102*	*39*
Titanium sleeve	95.1 (92.4-96.9)	90.7 (87.0-93.5)	87.5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

Figure legends

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

Figure 2. Adapters length distribution.

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

Table 3

	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 revisioned 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.