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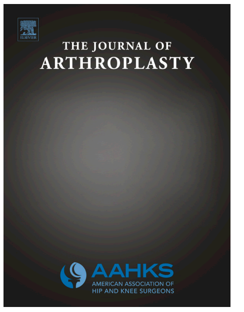

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Sebastian Simon[1,2], Jan Pawlik[1], Jennyfer A Mitterer[1,3], Stephanie Huber[1,3], Martin Dominkus[3], Jochen G. Hofstaetter[1,3]

1. Michael Ogon Laboratory for Orthopedic Research, Orthopedic Hospital Vienna Speising, Vienna, Austria
2. AUVA Trauma Center Meidling, Kundratstr. 37, 1120, Vienna, Austria
3. 2nd Department, Orthopedic Hospital Vienna Speising, Vienna, Austria

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***Corresponding author:**

Jochen G. Hofstaetter
Michael Ogon Laboratory for Orthopaedic Research
Orthopaedic Hospital Vienna-Speising,
Speisinger Straße 109, Vienna 1130, AUSTRIA
Phone: +43 1 80182 1952
Email: researchlab@oss.at

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Abstract

Background: Ceramic femoral heads with titanium sleeves are commonly used in revision total hip arthroplasty (rTHA). Companies advise against combination with a retained femoral component from another manufacturer. However, no data are available. The aim of this study was to evaluate and compare the implant failure and revision rates of ceramic heads with a 12/14 titanium sleeve used on manufacturer-compatible versus non-compatible retained femoral components.

Methods: A retrospective single-center cohort analysis was performed using a prospectively maintained institutional arthroplasty registry. We identified 439 patients who received a titanium 12/14 ceramic head during rTHA between January 1st, 2007 and December 31st, 2022. There were 229 manufacturer-compatible and 210 manufacturer-non-compatible retained femoral stems, according to the company's official product compatibility list. Implant failure and re-revision rates were evaluated.

Results: After a median follow-up of 6.6 years (IQR (Interquartile-range): 4.5 to 9.3), there was no significant difference (P = 0.770) in the re-revision rate between the manufacturer-compatible group (17.0%) and the non-compatible group (18.1%). Revision-free survival after rTHA was 81.2% in the manufacturer-compatible group and 78.9% in the manufacturer-non-compatible group after 15 years (P = 0.653). Most re-revisions occurred in the first year after rTHA, with 29 of 229 (12.7%) in the manufacturer-compatible group and 24 of 210 (11.4%) in the manufacturer-non-compatible group (P = 0.705). We observed only one implant failure in the manufacturer-non-compatible group, but this was not related to a mismatch problem.

Conclusion: Although legal uncertainties remain, this study showed no increased risk of implant failure or revision rates when a ceramic femoral head with a 12/14 titanium sleeve was used on a non-compatible femoral stem from a manufacturer.

Key Words: Ceramic heads with 12/14 titanium sleeves, Mis and match, manufacturer-non-compatible, manufacturer-compatible, implant failure rate

Introduction

In revision total hip arthroplasty (rTHA), the femoral head must often be removed from the stem taper. Removal of the femoral head can easily damage the trunnion, resulting in increased wear between the head and the stem taper. Inadequate morse taper junctions carry the risk of increased relative motion at the taper contact surface, resulting in taper corrosion, fretting, and metallic debris, leading to premature implant failure. [1–3] To reduce the risk of taper corrosion in rTHA, ceramic femoral heads with titanium sleeves should be used because the taper is likely to be damaged by the removal of the femoral head. [4–6]

Most products manufactured by one company were not originally designed to be compatible with products from other manufacturers, and companies advise against combining with a component from another manufacturer due to a lack of safety. The companies place the responsibility on the surgeon to check the taper of the remaining stem for compatibility. [7,8] In hip revisions where the femoral component is to be retained, it is not always possible to use a manufacturing-matched revision head due to a lack of operative reports or logistical issues. However, to date, the International Organization for Standardization (ISO) and the American Society for Testing and Materials have not defined a uniform taper in terms of dimensions, metallurgy, manufacturing tolerances, or surface finish.[9]

Even small variations in geometry can increase fretting, and thus its contribution to corrosion, in modular connections. [10] The most commonly used taper is 12/14 in diameter, but studies show that 12/14 stem and head tapers are not uniform and vary between manufacturers. [9] Biomechanical analyses find a wide geometrical variation in taper interface designs between the head and stem of total hip arthroplasty prostheses.[11,12] Although off-label use and the use of non-proprietary manufacturer stem 12/14 taper stems are common, there is no literature on whether these small differences in geometry and topography between manufacturers have a clinical impact on implant survival in rTHA. [13]

The aim of this study was to compare the implant failure rates and the survival rates of revision hip arthroplasties of ceramic femoral heads with a 12/14 titanium sleeve from one manufacturer that were used on retained femoral stems that were compatible according to the company's official product compatibility list with stems that were not officially compatible.

Patients and Methods

This retrospective single-center cohort study with prospective follow-up was approved by the institutional review board (EK11/2020). We analyzed our prospectively maintained arthroplasty registry. In this study, we included patients who received a titanium sleeve 12/14 Biolox Option head system (Zimmer Biomet©, Warsaw, USA) during revision hip arthroplasty in our institution where the femoral stem was retained. We are a tertiary care orthopaedic institution, and several experienced orthopaedic consultants performed the included rTHA.

This study compared revision hip arthroplasties with retained femoral stems that were compatible with the 12/14 head system according to the company's official product compatibility list with stems that were not officially compatible and were proprietary to another company. [7] Not all manufacturers have ceramic heads with Ti-sleeves. In the majority of cases, they were not available in our hospital, and therefore, the Biolox Option head system was used.

<u>Study-Cohort's stem identification</u>

All operative reports were analyzed for patients who had their primary THA at our institution. The primary THAs were performed in our institution or at other institutions between 1982 and 2021. All pre- and postoperative radiographs after rTHA were analyzed by an orthopaedic surgeon for stem identification if the primary THA was performed elsewhere and no operative report was available. The minimum follow-up was 2 years. Patients were then divided into two groups according to the manufacturer: Group 1) manufacturer-compatible; and Group 2) manufacturer-non-compatible. Patient demographics (sex, age at primary, and revision THA) and the reasons for revision are listed in Table 1.

Patient outcomes were analyzed by assessing the implant failure rates and the re-revision rates. All septic and aseptic re-revisions were included a detailed list of reasons for revisions is given in Table 2.

Follow-up was conducted by telephone interview, review of our clinical databases for clinical visits, and review of the Austrian electronic health record (ELGA), including all medical records if revisions were performed elsewhere. The median follow-up was 6.6 years (IQR (Interquartile-range): 4.5 to 9.3).

Patient cohort

After a median follow-up of 6.6 years (IQR: 4.5 to 9.3), we analyzed 439 rTHAs. There were 229 patients in the manufacturer-compatible group and 210 patients in the manufacturer-non-compatible group. The mean age of patients in the manufacturer-compatible group was 59 (IQR 50 to 72) years, significantly higher compared to 57 (IQR 45 to 68) years in the manufacturer-non-compatible group (P = 0.035). In addition, the time between primary and revision was significantly longer in the manufacturer-compatible group compared to the manufacturer-non-compatible group (P = 0.001). There was no significant difference in the distribution of reasons for rTHA between the two groups (Table 1). The different stem types and manufacturers are listed in Table 3.

Data analyses

Descriptive statistics were used with means (M), standard deviations (SD), and medians (Md) for continuous study parameters and frequencies and percentages for categorical variables. When the data were skewed, the interquartile ranges (IQR) were used. Continuous data were compared using *Mann-Whitney U* tests or 2-sample t-tests for non-parametric and parametric data, respectively. Categorical data were compared using Pearson's *Chi*-square tests or *Fisher's* exact tests, as appropriate. Patients who died were censored. The *Kaplan-Meier* method with 95% confidence intervals (CI) was used to determine revision-free implant survival at 1, 3, 5, 10, and 15 years for both groups, with subsequent septic or aseptic revision as the end point. The 95% CIs were calculated using *Greenwood's* asymmetric exponential formula. Statistical significance was 2-tailed and set at a P-value ≤ 0.05. All analyses were performed using IBM

Statistical Package for the Social Sciences (SPSS®) Version 25 (Armonk, New York) and GraphPad Prism 8 (GraphPad Software, Boston, Massachusetts).

Results

Revision rate and survival

Overall, there was no significant difference in the re-revision rate between the two groups (Table 2). Based on a survival analysis, there was also no significant difference berween septic revisions and aseptic revisions at 1, 3, 5, 10, and 15 years of follow-up (Figure 1). Revision-free survival after rTHA was 81.2% in the manufacturer-compatible group and 78.9% in the manufacturer-non-compatible group at 15 years (log-rank test P = 0.653). The proportional hazards assumption was checked, and no violations were found. Most re-revisions occurred in the first year after rTHA, with 29 of 229 (12.7%) in the manufacturer-compatible group and in 24 of 210 (11.4%) in the manufacturer-non-compatible group (P = 0.705).

The reason for revision did not differ between the two groups. There were 14 (6.1%) dislocations in the manufacturer-compatible group (11 of 229 (4.8%) revisions and 3 of 229 (1.3%) closed reductions) and 10 (5.8%) dislocations in the manufacturer-non-compatible group (8 of 210 (3.8%) revisions and 2 of 210 (1.0%) closed reductions), but there was no significant distribution of dislocations (P = 0.534). Due to the earlier primary THA in the manufacturer-compatible group, significantly smaller head sizes were used, and follow-up was longer than in the manufacturer-non-compatible group (Table 2).

Additionally, a sub-analysis was performed between the three most used manufacturers in the non-compatible group (Smith and Nephew©, Medacta©, and Intraplant©) and the compatible group. There was no significant distribution in either septic or aseptic re-revision within the three most used groups in the non-compatible group (septic P = 0.232; aseptic P = 0.505) and between these three used groups and the compatible group (septic P = 0.284; aseptic P = 0.523).

We observed only one implant failure in the manufacturer-non-compatible group. This patient was a young man who received his primary THA with a stem that was not compatible with the 12/14 head according to the official product compatibility list, at the age of 19 years after a traumatic hip fracture elsewhere. The rTHA was performed 16 years later, at the age of 35 years and when he had a weight of 110 kilograms (BMI: 32.2) due to aseptic loosening of the cup. At the time, there were logistical problems with the supply of a suitable revision head. A mechanical fatigue related trunnion failure occurred 2.9 years after the rTHA and 19 years after the primary THA at the age of 38 years.

Discussion

This study compared the rates of implant failure and revision of ceramic femoral heads with a 12/14 titanium sleeve used on manufacturer-compatible and non-compatible retained femoral stems in rTHA. Although manufacturers recommend against using the revision head on officially non-compatible femoral components, we did not find a higher re-revision rate due to component incompatibility.

There was only one case of implant failure in the non-compatible group with a stem trunnion mechanical fatigue failure. The stem did not undergo an engineering analysis, but the patient fulfills many factors that are associated with implant failure, such as being a man, having a high BMI and being highly active. The stem was implanted 19 years ago, had a very thin neck, and the failure occurred after multiple revision surgeries. There was no intra-operative macroscopic taper fretting or crevice corrosion visible. Therefore, the failure may not be related to the non-compatibility of the taper and femoral head.

There were significantly more 28-mm heads used in the compatible group than in the non-compatible group for primary THA. This could be partly explained by the fact that the implantation of 28-mm heads changed over time to larger head sizes. Patients in the compatible group underwent primary THA between July 1st 1982 and May 9th 2019, and those in the non-compatible group between June 15th 1990 and December 20th 2021.

The titanium sleeve should compensate for any small differences as the tapers adapt to the impact. The Bioball Head Adapter (Bioball Merete, Medical GmbH, Berlin, Germany) is a revision head that is officially compatible with all tapers that meet the CeramTec BIOLOX® specification, taper 12/14, and sizes up to 5XL. [14] However, these heads were not available in our institution below size XL before 2022.

Alternatively, the high revision-free survival of the heads with titanium sleeves on officially non-compatible components in this study is consistent with other studies with titanium sleeves. [5,6] However, previous studies have not evaluated results with officially non-compatible components. On the other hand, a systematic review by Doesburg et al. demonstrated that combining components from different manufacturers is a risk factor for stem trunnion mechanical fatigue failure. [15] Furthermore, the National Joint Registry of England and Wales has shown higher failure rates when a head and a femoral stem from different manufacturers are used. [16] The use of heads on incompatible stems may be an option if needed, but the risk of complications should be discussed with the patient.

The single implant failure observed in this study was not related to an incompatibility problem, but rather to other circumstances such as male gender, previous revision surgery, and high body weight.

The use of components from different manufacturers that have not been explicitly approved by both is considered an unnecessary risk. [17] However, off-label use is frequently practiced in primary and revision arthroplasty, as there may be indications for the application of implants for purposes outside the ones the manufacturers intended. In some cases, the manufacturer of the stem on retained femoral components might not offer the option of a revision system, or it is not available everywhere.

The European Federation of National Associations of Orthopaedics and Traumatology (EFORT) has issued recommendations regarding the off-label use and mix-and-match approach in rTHA. These recommendations pertain to the use of medical devices in off-label settings for hip arthroplasty. Prior to the off-label use of a medical device for hip arthroplasty, surgeons are advised to consider the risks and benefits to the patient. [13] In the context of THA, if only one component requires revision, then a mix-and-match approach should be permitted. In light of the patient’s risk-benefit balance, the available evidence, and the current state of the art, surgeons should be permitted to avoid replacing a component solely for the purpose of avoiding mix-and-match. [13]

Several potential limitations of this study should be noted. It is important to acknowledge the inherent limitations of a retrospective study design, such as selection bias and information bias. To minimize selection and information bias, we included all revisions of patients who underwent rTHA with a specific head; there was no significant distribution in the reasons for different head revision options between the groups. All patients and all reported re-revisions and closed reductions were analyzed. In addition, due to the retrospective design, it was not possible to analyze blood metal ion levels, fretting and corrosion at the metal interface, or unreported, possibly metal-related soft tissue reactions. This study focused on the long-term re-revision rate. However, it is worth noting that this study has a long follow-up. Furthermore, a notable distinction in the duration between the revision and primary implantation was observed between the two groups. Another limitation of the study was the heterogeneity of stem manufacturers; each manufacturer is likely to have "different" 12/14 tapers, and some combinations of officially incompatible combinations may therefore have a higher or lower risk of potential trunnion damage. However, in our sub-analyses, we did not find any significant distribution between different manufacturers.

Conclusion

In conclusion, although legal uncertainties remain, this study demonstrated that the use of non-compatible femoral stems and heads does not result in an increased risk of implant failure or revision rates. It may be safe to use technically matching components, even if they have not been explicitly approved by the manufacturer.

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Figure legends

Figure 1 Revision free implant survival after 1a, 3a, 5a, 10a, and 15a (95%-Confidence-interval); a (years),

Parameter	Manufacturer-compatible (n=229)	Manufacturer-non-compatible (n=210)	*P*-value
Sex men (%)	82 (35.8)	61 (29.0)	0.131
women (%)	147 (64.2)	149 (71.0)	
Age at primary (years; IQR)	59 (50, 72)	57 (45; 68)	0.035*
Primary arthroplasty (year)	1982-2019	1990-2021	
Age at revision (years; IQR)	70 (59; 76)	68 (58; 76)	0.549
Revision arthroplasty (year)	2008-2022	2007-2022	
Time between primary/revision (years; IQR)	9.5 (2.8; 16.0)	5.6 (1.0; 14.0)	0.001*
Reason for revision			
Aseptic loosening cup (%)	119 (52.0)	122 (58.1)	0.197
Dislocation (%)	40 (17.5)	31 (14.8)	0.442
Wear (%)	33 (14.4)	23 (11.0)	0.278
Infection (%)	12 (5.2)	15 (7.1)	0.407
Heterotopic ossification (%)	8 (3.5)	4 (1.9)	0.308
Inlay/head breakage (%)	7 (3.1)	5 (2.4)	0.664
Acetabular fracture (%)	6 (2.6)	7 (3.3)	0.660
Pain/impingement (%)	4 (1.7)	3 (1.4)	1.00

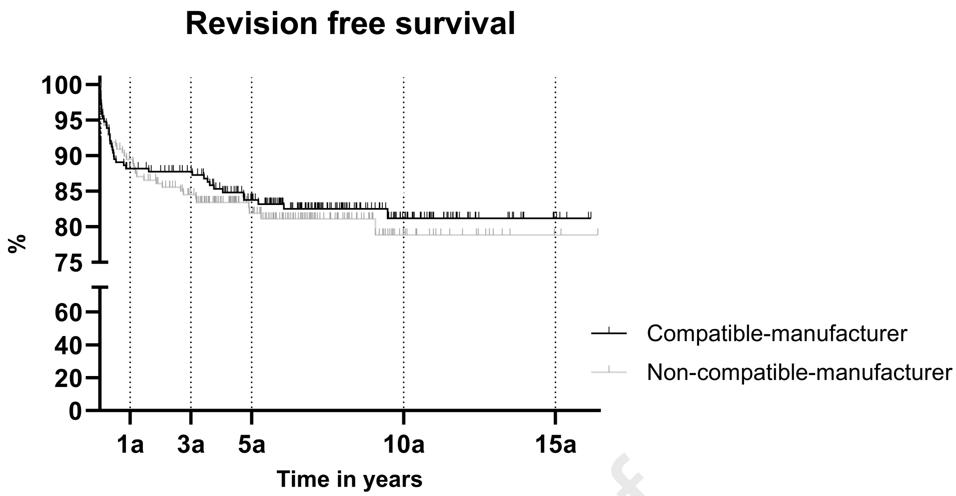
Table 1: Patient demographics and reason for revision mean with SD (standard deviation) and Median with IQR (Inter-quartile-range); $^{**}P < 0.001$, $^{*}P < 0.05$.

Parameter	Manufacturer-compatible (n=229)	Manufacturer-non-compatible (n=210)	*P*-value
Biolox Option Size S (%)	14 (6.1)	19 (9.0)	0.244
M (%)	29 (12.7)	41 (19.5)	0.050
L (%)	86 (37.6)	78 (37.1)	0.929
XL (%)	100 (43.7)	72 (34.3)	0.044
External diameters 28mm (%)	46 (20.1)	15 (7.1)	<0.001**
32mm (%)	84 (36.7)	67 (31.9)	0.293
36mm (%)	99 (43.2)	128 (61.0)	<0.001**
Re-Revision	39 (17.0)	38 (18.1)	0.770
Time to previous revision (days, IQR)	141 (34; 980)	239 (44; 533)	0.729
Aseptic	27 (11.8)	28 (13.3)	0.626
Dislocation (%)	11 (4.8)	8 (3.8)	
Aseptic cup loosening (%)	11 (4.8)	11 (5.2)	
Periprosthetic fracture (%)	2 (0.9)	6 (2.9)	
Other (%)	3 (1.3)	3 (1.4)	
Implant failure (%)	-	1 (0.5)	
Septic (%)	12 (5.2)	10 (4.8)	0.819
Acute (<90 days after revision, %)	6 (50.0)	5 (50.0)	
Time to previous revision (days, IQR)	15 (11; 29)	18 (14; 22)	
Chronic >90days after revision, %)	6 (50.0)	5 (50.0)	
Time to previous revision (days, IQR)	164 (124; 279)	192 (126; 406)	
Follow up (years, IQR)	7.2 (5,1; 10.0)	6.0 (4.1; 8.3)	<0.001
Deceased/lost to follow-up within 2 years (%)	7 (3.1)	7 (3.3)	0.869

Table 2: Biolox option information and re-revision rate and follow up, mean with SD (standard deviation) and Median with IQR (Inter-quartile-range); $^{**}P < 0.001$, $^{*}P < 0.05$

Manufacturer-compatible		n=229
Zimmer & Biomet©	Alloclassic Variall SLV	89
	Alloclassic SL	88
	PPF Primary	30
	Alloclassic SLL rev.	9
	CLS Spotorno	6
	Weber	2
	Avenir	2
	CPT	1
	Revitan	1
	Taperloc	1
Manufacturer-non-compatible		**n=210**
Smith & Nephew©	SL-Plus MIA	58
	Endoplus	22
	SL-Plus	6
	Polarstem	2
Medacta©	AMIS	43
	Quadra	10
Intraplant©	Knahr-Salzer hip	21
DePuy©	Corail	7
	AML	2
Artiquo©/Implantec©	Ananova	5
Mathys©	Optimys	5
Falcon©	Medico Monocon	4
Stryker©/Wright Medical©	Zwettler hip	4
Microport©	Profemur	2
Braun©	TRJ	2
	Meta stem	1
Aesculap©	Weller	1
ARISTOTECH©	Series 150	1
C2F©	Vienna	1
Hyperion©	Revision	1
Stemcup medical products©	SCS/SCL lat.	1
Symbios©	Custom made	1
LIMA©	corparate C2	1
Link©	MP Reconstruction System	1
Peter Brehm©	MRP Titan	1
Implantcast©	Mutars proximal femur	1
Unknown		6

Table 3 Manufacturer and stem type



Survival (CI-95%)	1a	3a	5a	10a	15a	p-value
Compatible manufacturer (%)	88.2 (83.3-91.7)	87.7 (82.7-91.4)	83.8 (78.2-88.0)	81.2 (74.8-86.1)	81.2 (74.8-86.1)	0.653
Non-compatible-manufacture (%)	89.5 (84.4-92.9)	84.5 (78.8-88.8)	81.9 (75.7-86.7)	78.9 (70.8-85.0)	78.9 (70.8-85.0)	