Ceramic Bearings with Titanium Adapter Sleeves Implanted During Revision Hip Arthroplasty Show Minimal Fretting or Corrosion: a Retrieval Analysis

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Abstract *Background:* The BIOLOX® *option* system, consisting of a BIOLOX® *delta* ceramic femoral head with a titanium alloy adapter sleeve, is being increasingly utilized in revision hip arthroplasty. The sleeve protects the ceramic head from fracture and improper motion about the stem trunnion when a damaged trunnion is encountered at revision surgery. Corrosion and fretting due to metal-metal contact at the taper region of hip prosthesis create the potential of causing periprosthetic osteolysis and adverse local tissue reactions. *Questions/Purposes:* The objective of this study was to identify the type and extent of damage to retrieved sleeves and ceramic heads to determine their in vivo performance. *Methods:* Twenty-four ceramic heads with titanium alloy sleeves were examined. The articular and taper surfaces for each ceramic head were assessed for metal transfer using a subjective grading system. All surfaces of the 24 titanium sleeves and stem trunnions (only available for 7 of 24 cases) were assessed for corrosion and fretting using an established grading system. Scanning electron microscopy and energy dispersive X-ray analysis were conducted on representative sample of sleeves. *Results:* Fretting and corrosion were higher at the inner surface of the taper

sleeve than the outer sleeve. Mean fretting scores at the inner taper and outer taper sleeve surfaces were 1.8 and 1.2, respectively. The mean corrosion score at the inner taper surface was 1.8; no corrosion was observed on the outer surface of any taper sleeve. SEM and EDS analyses provided further indications of low levels of damage. *Conclusion:* Fretting and corrosion were less severe than previously reported for conventional THA metal-metal taper connections, indicating that a ceramic head and titanium sleeve is a safe alternative in revision THA.

Keywords total hip arthroplasty · retrieval analysis · fretting · corrosion · adapter sleeve

Introduction

Concerns regarding fretting and corrosion between modular connections of modern total hip arthroplasties (THAs) have existed for years, and recent reports have implicated trunnion damage as a significant failure mechanism [11, 13]. Trunnion-associated problems are thought to arise from motion between metal-metal modular connections, resulting in material loss (fretting) and electrochemical material damage (corrosion) [4–6]. Both fretting and corrosion release soluble and particulate debris that can lead to local periprosthetic osteolysis and adverse local tissue reaction (ALTR) [4–6].

Due to these concerns, the use of ceramic femoral heads has gained popularity in THA over the last decade [10]. While several studies have demonstrated that trunnion fretting can still occur with the use of ceramics, the magnitude of both fretting and corrosion is less than that observed in stem trunnions paired with metal femoral heads [8, 10], and combined with the low wear rates associated with ceramic femoral bearings [2, 3, 12, 15], explain their increased usage in THA.

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Table 1 Patient demographic data for 24 BIOLOX® *option* taper sleeves collected in this study

	BMI	Age at index	LOI (years)	Implant side	Reason for revision	Stem material
1	27.4	62.0	1.96	L	ALTR	CoCrMo
2	27.9	56.9	1.84	L	Leg length discrepancy	Ti-6Al-4V
3	26.6	40.1	1.35	L	Infection	Ti-6Al-4V
4	25.2	55.3	2.58	L	Loosening	Ti-6Al-4V
5	20.2	81.4	1.58	R	Heterotopic ossification	Ti-6Al-4V
6	29.3	58.3	2.27	R	Infection	Ti-6Al-4V
7	26.3	59.5	0.56	R	Infection	CoCrMo
8	25.7	66.2	0.30	R	Periprosthetic fracture	Ti-6Al-4V
9	30.1	58.6	0.12	L	Periprosthetic fracture	Ti-6Al-4V
10	30.3	73.5	1.02	R	Dislocation	Ti-6Al-4V
11	21.8	61.1	4.76	L	Loosening	Ti-6Al-4V
12	27.5	60.5	1.54	L	Dislocation	Ti-6Al-4V
13	63.5	66.1	5.46	L	Periprosthetic fracture	Ti-6Al-4V
14	29.3	65.0	1.19	R	ALTR	TMZF
15	27.7	56.0	0.58	R	Instability	CoCrMo
16	33.5	66.0	0.35	R	Dislocation	Ti-6Al-4V
17	26.3	60.0	0.26	L	Pain	CoCrMo
18	29.4	79.0	0.35	R	Dislocation	CoCrMo
19	26.4	54.0	0.81	L	Pain	Ti-6Al-4V
20	21.1	44.0	0.56	R	Dislocation	Ti-6Al-4V
21	24.0	73.0	0.20	R	Dislocation	TMZF
22	25.8	67.0	0.22	R	Infection	CoCrMo
23	26.0	69.0	0.75	L	Loosening and infection	Ti-6Al-4V
24	27.4	33.0	0.44	L	Dislocation	TMZF

The use of ceramic heads at revision THA surgery in the situation of a well-fixed femoral stem is limited by the state of the stem trunnion. Excessive damage to the trunnion caused by wear and corrosion against the primary metallic or ceramic femoral head can leave the trunnion too misshapen to safely accept a ceramic femoral head. A recently proposed solution is the BIOLOX® *option* system (CeramTec GmbH, Plochingen, Germany), which employs a modular tapered titanium alloy adapter sleeve over the existing stem trunnion. The sleeve is intended to protect a new ceramic head from the risk of fracture and to limit micromotion at the trunnion interface due to a mismatch in taper geometry caused by preexisting mechanical and corrosive trunnion damage from the primary THA.

However, the addition of a sleeve has a potential disadvantage; in that, it creates new ceramic-metal and metal-metal modular junctions. Little clinical data exist on the clinical performance of this system. The purpose of this study was to evaluate the performance of the ceramic head and titanium alloy adapter sleeve system by examining a series of retrieved sleeves paired with ceramic femoral heads obtained from revision THAs. The aims of our study were to determine the extent and severity of fretting, corrosion, and metal-transfer at the modular junctions of titanium adapter sleeves and ceramic femoral heads.

Materials and Methods

Between December 2011 and December 2015, 198 BIOLOX® *delta* femoral heads were revised at our institution and collected through our ongoing Institutional Review Board-approved implant retrieval program. Of these, 24

heads were paired with titanium alloy adapter sleeves in 14 primary and 10 revision THAs. For seven of the cases, the femoral stems were retrieved with the heads and sleeves. Clinical and demographic data were collected from patient medical records including length of implantation (LOI), age at index procedure, body mass index (BMI), sex, and reason for revision (Table 1). Average length of implantation (LOI) was 15.5 months (range 1–65 months), average patient age at index THA was 61.1 years (range 33–81 years), and average BMI was 28.3 (range 20–63 kg/m²). Thirteen patients were male; 11 were female. Reason for revision was dislocation in eight (33.3%) cases, infection in four (16.7%), periprosthetic fracture in three (12.5%), loosening in three (12.5%), ALTR in two (8.3%), pain in two (8.3%), and leg length discrepancy and heterotopic ossification in one (4.1%) case each. Operative notes confirmed the composition of 15 of the femoral stems as Ti-6Al-4V, 6 as CoCr alloy, and 3 as TMZF.

The articular and taper surface regions of the ceramic heads were subjectively graded using a previously developed scoring system for metal transfer [1] on a scale of 1 to 5 based on the extent and severity of the metal transfer

Table 2 Grading criteria for the severity of metal transfer

Grade	Description
1	No markings present
2	Some metal transfer present, light markings, or ≤3 dark markings ≤0.5" long
3	>3 dark markings ≤0.5" long or ≥1 dark markings ≤1" long
4	Metal smear <20% of surface area or >3 lines 1" long
5	Metal smear >20% of surface area

Fig. 1. Zones of the **a** articular surface of the femoral head, the **b** female taper of the femoral head, and **c** inner and outer adaptor sleeve surfaces used for evaluation of metal transfer, fretting, and corrosion.

(Table 2). The articular surface of the ceramic head was divided into three regions (apex, equator, and below the equator), while the taper surface of the ceramic head was divided into deep and superficial regions (Fig. 1). Total possible scores were 15 (3 regions $\times$ maximum score of 5) for the articular surface and 10 (2 zones $\times$ maximum score of 5) for the taper surface. Each implant was graded under optical microscopy between $\times 10$ and $\times 30$ magnification by two independent graders.

The metal transfer scores from this series were then compared against our previous published series of BIOLOX® *forte* femoral heads from conventional THAs that had not incorporated titanium adapter sleeves [1]. In that study, 68 ceramic heads, 24 alumina and 44 zirconia, were used for characterization of wear damage to the articular surface. The heads have been retrieved from 40 females and 28 males. Patient age at the time of revision was 58.7 (± 11.1) years; BMI was 27 (± 6.14). The length of implantation was 5.7 (± 5.438) years (range from 7 days to 18 years). The most common reasons for revision were osteolysis or loosening (35%), followed by dislocation or instability (25%).

The titanium alloy adapter sleeve and the stem trunnion were subjectively graded for fretting and corrosion according to the previously established scoring methods developed by Goldberg et al. [5]. The inner and outer surfaces of the sleeves were divided into deep and superficial regions congruent with those of the ceramic head taper region. The stem trunnion was divided into anterior, posterior, medial, and lateral regions. Each zone was inspected under optical microscopy and given a Goldberg score between 1 and 4 based

on the extent and severity of fretting and corrosion damage (Table 3) [5].

For all visual scoring, two graders evaluated components independently. When the total score (e.g., the total fretting score for the outer surface of the sleeve) for a surface differed between graders by more than three points, a third investigator (EB) provided a grade to level the discrepancy. Scanning electron microscopy (SEM) was used on selected titanium alloy sleeves to provide a more detailed assessment of surface damage than was available from light microscopy. Two undamaged sleeves and three sleeves with corrosion scores of 3 were selected for comparison. Energy dispersive X-ray analysis (EDS) was used to qualitatively identify the material composition of the sleeves and any debris observed on the sleeves.

Statistics were performed with SigmaPlot 12.3 (Systat Software Inc., San Jose, CA). Metal transfer scores at the apex, equator, and below equator regions of the ceramic heads were compared using a Kruskal-Wallis one-way analysis of variances on rank test. Metal transfer in the deep and superficial regions of the ceramic head taper, fretting scores, corrosion scores, and total damage scores between the inner and outer sleeve surfaces were compared with Mann-Whitney rank sum tests. Damage scores were compared between sleeve groups based on stem material using Kruskal-Wallis one-way analysis of variance on rank tests. Significance was set to $p < 0.05$ for all analysis. Patient demographics, metal transfer scores, fretting scores, corrosion scores, and total damage scores are described using mean $\pm$ standard deviation (range).

Table 3 Grading criteria for fretting and corrosion

Grade	Corrosion description	Fretting description
1	No visible corrosion	No visible fretting
2	<30% surface discolored/dull	Band(s) of fretting scars across $\leq$ machine lines
3	>30% surface discolored/dull or <10% containing black debris, pits, or etch marks	Band(s) involving >3 machine lines
4	>10% surface containing black debris, pits, or etch marks	Several bands of fretting scars involving several machine lines or flattened areas with nearby fretting scars

Fig. 2. Metal transfer on the female taper of the ceramic head exhibiting scores of 2 through 5.

Results

The average metal transfer score for all the articular surface zones (apex, equator, below equator) of the ceramic heads was 2.3 ± 0.9 (1–5). In our original retrieval study of ceramic femoral heads, the mean metal transfer at the articular surface was slightly higher at 2.6 ± 1.3 . Like in our original study, metal transfer scores in our current study were higher in the equator ($p = 0.02$) and below equator ($p = 0.04$) regions than at the apex. The deep and superficial regions of the femoral head taper surface had an average metal transfer score of 3.1 ± 0.6 (1–5), indicating mild metal transfer (Fig. 2). Metal transfer scores were higher in the deep taper regions of the femoral heads than the superficial regions (3.3 ± 0.7 vs. 2.8 ± 0.7 ; $p < 0.01$). No correlation was found between the metal transfer scores on the articular surface and taper surface of the ceramic heads ($p = 0.42$).

The total Goldberg score of the overall inner surface of the titanium alloy sleeves was significantly higher than that

of the outer surface ($p < 0.01$). This difference was dominated by higher scores in the deep region of the inner surface of the sleeve compared to those of the deep outer surface ($p < 0.01$). Neither the deep nor the superficial region of the outer surface of the titanium alloy sleeve showed evidence of corrosion, while the deep and superficial regions of the inner surface of the sleeve had an average corrosion score of 1.8 ± 0.6 ($p < 0.01$). The outer surface of the sleeve had lower fretting scores than the inner surface, with an average fretting score of 1.2 ± 0.3 , compared to an average fretting score of 1.8 ± 0.6 ($p < 0.01$) for the inner surface's deep and superficial regions (Fig. 3). The outer surface of the titanium alloy sleeves that contacted the ceramic femoral head taper were nearly pristine (Fig. 4a) regardless of the damage seen at the inner surface of the sleeve or the metal transfer score of the ceramic taper surface.

No differences emerged for fretting or corrosion scores at the outer or inner sleeve surfaces when sleeves matched to CoCr, Ti6Al4V, and TMZF stems were compared. Fretting was higher for outer sleeve surfaces matched to Ti6Al4V stems (3.0 ± 0.6) than those matched to CoCr stems (1.3 ± 0.3) and TMZF stems (1.5 ± 0.5); however, the differences were not significant ($p = 0.27$). At the inner sleeve surface, fretting and corrosion were higher for sleeves matched to TMZF stems (2.4 ± 0.6 for fretting and 2.0 ± 0.9 for corrosion) when compared to sleeves matched to CoCr stems (1.5 ± 0.4 for fretting and 1.4 ± 0.5 for corrosion) and Ti6Al4V stems (1.8 ± 0.7 for fretting and 1.9 ± 0.6 for corrosion); however, again, these differences were not significant ($p = 0.12$ for fretting and $p = 0.25$ for corrosion).

Mean trunnion fretting was 1.8 ± 0.9 and mean trunnion corrosion was 1.5 ± 0.9 for the seven stems available for analysis. Of these seven stems, two were composed of CoCr and five were Ti6Al4V. Mean trunnion fretting was 2.0 ± 1.4 for CoCr trunnions and 1.8 ± 0.9 for Ti6Al4V trunnions. No corrosion was observed on the two CoCr trunnions. Ti6Al4V trunnions had a mean corrosion score of 1.7 ± 1.0 . Statistical comparisons between material groups were underpowered for analysis.

SEM images revealed fretting on the three damaged taper sleeves (Fig. 4b). However, SEM images demonstrated little evidence of the typical granular deposits associated with corrosion. Black debris and discoloration seen visually on the metal sleeves was initially suspected to be corrosion product. Debris on the inner surfaces of three damaged sleeves were analyzed using EDS; however, the debris on two sleeves was identified as a biological carbon compound, likely proteinaceous material that remained after the cleaning procedure. Composition peaks were similar on EDS profiles of undamaged and damaged regions of these two titanium alloy sleeves. Black debris on the third sample (Fig. 5a) was identified as corrosion product, suggested by oxygen-rich peaks in the EDS spectra (Fig. 5b).

Discussion

In this series of retrieved BIOLOX® option system titanium alloy adaptor sleeves, the femoral stem-inner sleeve

Fig. 3. Fretting and corrosion on the inner surface of the titanium alloy sleeve exhibiting scores of 1 through 4.

Fig. 4. The outer surfaces of the titanium alloy sleeves (**a**) were nearly pristine; SEM images demonstrate undisturbed machine marks. Fretting damage was more often visible on the inner sleeve surfaces (**b**).

interface exhibited low levels of fretting and corrosion and the ceramic taper-outer sleeve interface showed minimal damage. The low levels of fretting and corrosion may be due to the fact that 18 of the 24 sleeves had been paired with stems composed of a titanium alloy, so that the stem trunnion-inner sleeve connection was between similar metals. Previous studies showed that fretting and corrosion are markedly less in connections between similar metals, when compared to mixed alloy couples [5, 17]. When compared to fretting and corrosion scores at other similar alloy couple modular junctions from previous studies, our titanium sleeves showed lower Goldberg scores, which may reflect the short length of implantation [4, 5].

Our study has limitations. Retrieval studies innately draw conclusions based from clinical failures. These results do not necessarily represent a group of well-functioning THAs; however, they do provide valuable information about the performance of the implants. The sample size is small, and our retrievals had short LOIs, which impeded our power to draw conclusions about important factors that might affect sleeve performance. For example, longer LOIs are correlated with higher corrosion scores in modular connections in conventional THAs [4, 17], though our results did not show

this for our short LOIs. For this reason, retrievals with longer times in vivo should be evaluated as soon as they become available. Additionally, only 7 of 24 femoral stems were available for analysis, so damage to the stem trunnion could not be evaluated. The best way to evaluate the performance of modular junctions in THA is to analyze all of the components that comprise the junction. In this series, we were limited to the components that were removed at revision surgery, and therefore, we could not comment on the performance of all the components in the junction. However, the fact that femoral stems were retained in 17 of the 24 THAs (70.8%) suggests that the stem trunnion was not of concern to the revising surgeon, so that the addition of a new sleeve and head was determined to adequately restore the integrity of the THA. In fact, a review of the operative notes for the cases in which the seven stems were revised showed non-trunnion-related complications as the reasons for removal (two for infection, two for periprosthetic fracture, two for dislocation, and one for loosening). Another limitation is that we did not know why the surgeon chose to use a titanium sleeve. Criteria for the use of a sleeve remain unclear, but we were unable to add information about the surgeons' decisions in our cases.

Fig. 5. Corrosion debris **a** on the inner surface of one titanium alloy sleeve was identified as corrosion product with EDS, indicated by **b** oxygen peaks in the EDS spectra.

As expected, metal transfer to the articular surface of the ceramic head was similar to what we reported in previous retrieval studies [1], providing validation that the components in the present study were behaving much as those in our larger previous series without sleeves. The higher LOI in the original series likely explains the slight increase in articular metal transfer score compared to the current series (mean metal transfer of 2.3 ± 0.9 after 1.3 ± 1.4 years). The introduction of the taper sleeve should not impact the articulation of the femoral head and acetabular component at the bearing surface. Based on previously reported ceramic femoral head taper damage, the addition of the titanium alloy sleeve apparently does not create any additional damage to the inside taper of the head [9, 10]. The relatively low fretting and corrosion scores of the available femoral stems are consistent with the findings of previous studies where identical corrosion scores were found in 71% of necks and identical fretting scores in 68% of necks [4].

Corrosion products described in the literature are characterized by chromium orthophosphate particles, which were not identified using EDS analysis in two of the three sleeves analyzed from our series of retrievals [5]. This was not an unexpected finding considering that the two sleeves that did not show evidence of corrosion on EDS had been paired with Ti6Al4V alloy stems, making the sleeve-trunnion interface a homogenous metal couple. The carbon peaks identified by EDS on these two sleeves is most likely a proteinaceous substance, which was heavily resistant to removal when the titanium sleeves were cleaned. Oxygen-rich peaks were identified by EDS in the region of black debris on the inner surface of the third sleeve, indicating that corrosive debris was in fact present in this retrieval (Fig. 5). This sleeve had been paired with an Accolade TMZF (Stryker, Mahwah, NJ) femoral stem (in vivo for 1.2 year; revised for ALTR), which has a lower modulus of elasticity than standard Ti6Al4V, predisposing the trunnion to micromotion, and subsequently fretting and corrosion [7, 16]. But our study also included two other sleeves that had been paired to TMZF femoral stems, neither of which showed visual evidence of corrosion. Both were in service for less than 5 months, which may explain the lack of visual discoloration and debris. Following the Goldberg scoring system, any black debris was assumed to be a corrosion product and subsequently scored from 1 to 3 based on severity [5]. Black debris on femoral stem trunnions and femoral head tapers has historically been suggestive of corrosion; however, our results point out that the source of this discoloration is not exclusive to corrosion.

In summary, our series of retrieved titanium alloy taper sleeves and the accompanying ceramic heads with which they were implanted showed little mechanical or corrosive damage. In a recent clinical review of 27 patients revised for ALTR secondary to corrosion at the head-neck junction of metal on polyethylene THAs, Plummer et al. reported that all patients converted to ceramic heads with titanium alloy adaptor sleeves exhibited decreased cobalt and chromium ions levels, and no recurrence of ALTR had occurred at a mean follow-up of 2.7 years [14]. In our series of retrievals, two patients with ceramic heads and titanium adaptor

sleeves were revised for ALTR after 1.2 and 1.9 years. As noted above, one sleeve was paired with a TMZF femoral stem and exhibited visible signs of corrosion that was confirmed by EDS. The second sleeve revised for ALTR had been paired with a CoCr alloy femoral stem, but exhibited minimal damage.

Careful long-term follow-up of patients with ceramic heads and titanium adaptor sleeves will be needed to determine the clinical performance of these designs. At the short term, our findings support the use of the BIOLOX® option system in revision hip arthroplasty. To be sure, our findings do not constitute evidence that this particular combination is safe in the long term. But we believe that our findings support its use when arthroplasty surgeons are faced with a well-fixed stem with a badly damaged trunnion and the need for a ceramic head to reduce the recurrence of ALTR without compromising the strength of the ceramic head or the corrosion resistance of the modular connection.

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Compliance with Ethical Standards

Conflict of Interest: Chelsea N. Koch, BS; Mark Figgie Jr., BS; and Marcella E. Elpers, BS have declared that they have no conflict of interest. Timothy M. Wright, PhD, reports other from Exactech, Inc., Orthobond, Stryker, and Wolters Kluwer Health-Lippincott Williams & Wilkins, outside the work. In addition, Dr. Wright reports patents and royalty payments from Exactech, Inc., Lima, and Mathys Ltd. Douglas E. Padgett, MD, reports personal fees from DJO, PixarBio, and Stryker, outside the work. Mark P. Figgie, MD, reports other from Mekanika, outside the work. In addition, Dr. Figgie reports a patent with Lima and receives royalties.

Human/Animal Rights: All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5).

Informed Consent: Informed consent was waived from all patients for being included in the study.

Required Author Forms Disclosure forms provided by the authors are available with the online version of this article.

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