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Basic Science

Fretting and Corrosion Damage in Taper Adapter Sleeves for Ceramic Heads: A Retrieval Study

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ABSTRACT

Background: During revision surgery with a well-fixed stem, a titanium sleeve can be used in conjunction with a ceramic head to achieve better stress distribution across the taper surface. In vitro testing suggests that corrosion is not a concern in sleeved ceramic heads; however, little is known about the in vivo fretting corrosion of the sleeves. The purpose of this study was to investigate fretting corrosion in sleeved ceramic heads in retrieved total hip arthroplasties.
Methods: Thirty-seven sleeved ceramic heads were collected during revision. The femoral heads and sleeves were implanted 0.0-3.3 years. The implants were revised predominantly for instability, infection, and loosening. Fifty percent of the retrievals were implanted during a primary surgery. Fretting corrosion was assessed using the Goldberg-Higgs semiquantitative scoring system.
Results: Mild-to-moderate fretting corrosion scores (score = 2-3) were observed in 92% of internal tapers, 19% of external tapers, and 78% of the stems. Severe fretting corrosion was observed in 1 stem trunnion that was previously retained during revision surgery and none of the retrieved sleeves. There was no difference in corrosion damage of sleeves used in primary or revision surgery.
Conclusion: The fretting corrosion scores in this study were predominantly mild and lower than reported fretting scores of cobalt-chrome heads in metal-on-polyethylene bearings. Although intended for use in revisions, we found that the short-term in vivo corrosion behavior of the sleeves was similar in both primary and revision surgery applications. From an in vivo corrosion perspective, sleeves are a reasonable solution for restoring the stem taper during revision surgery.

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Fretting corrosion at the head-stem taper junction has recently re-emerged as a clinical concern [1]. The material released from this junction, especially from cobalt chrome (CoCr) alloys, may cause adverse local tissue reactions and in some patients require revision [1–3]. The mechanism responsible for the corrosion behavior of these interfaces is considered to be mechanically assisted crevice corrosion [4]. One way to mitigate the corrosion damage and associated metal release from the head-taper modular junction is through the use of ceramic femoral heads. Stem tapers that use a ceramic head have previously demonstrated reduced levels of fretting corrosion damage and metal release when compared with a matched CoCr cohort [5–7]. However, in vitro testing has identified damage to the stem taper (even microscopic damage that is not seen with the naked eye) as a factor for early failure of the ceramic femoral head [8]. As such, device manufacturers do not recommend the use of a ceramic head on a well-fixed stem in revision surgery. One option during revision surgery with a well-fixed stem that the surgeon wishes to retain is to utilize a titanium sleeve used in conjunction with a ceramic head. By using a metallic sleeve in conjunction with a ceramic head, surgeons are able to recreate a pristine taper surface to interact with a new ceramic head. However, this reintroduces a metal-metal taper interface and, thus, reintroduces the possibility of corrosion.

Recent studies have investigated the use of a ceramic head with a sleeve in revision surgery have focused on clinical results [9,10]. Jack et al [9] investigated the outcomes of revision surgery with ceramic heads with titanium sleeves in routine revision surgery. The index revisions were due to osteolysis or loosening and the state of the well-fixed stem was not documented. The resulting bearing couple was ceramic-on-ceramic in all cases. The survivorship for any cause of failure at a mean follow-up of 4.8 years was 96.6% for acetabular components and 94.0% for the femoral components. Thorey et al [10] looked at the early results of ceramic heads with titanium sleeves used in revision surgery in 91 patients with a mean follow-up of 2.1 years. The authors reported complications in 6 patients (dislocation [n = 1], infection [n = 1], and heterotopic ossification [n = 4]) unrelated to the sleeve-taper interface. There were no cases of ceramic head fracture. In both studies, the authors recommended the use of a titanium sleeve with a ceramic head in the case of a revision surgery with a well-fixed stem.

Although the early and midterm clinical studies have reported good results, the in vivo fretting corrosion of the sleeve is not known. In vitro testing has suggested that corrosion may not be a concern in sleeved ceramic heads [11]. Preuss et al [11] conducted fretting corrosion testing under in vivo–like loading conditions in a corrosive environment. They used 3 different test methods to assess the corrosion behavior of sleeved ceramic heads: Fretting corrosion testing according to the American Society for Testing and Materials standard ASTM F1875-98, corrosion behavior of cyclic fatigue vs static compression loads, and frictional rotational torque and frictional bending torque fatigue tests. The liquid environment was solution composed of sodium hydrogen carbonate, potassium chloride, potassium thiocyanate, and sodium phosphite + water. They tested Ti-6Al-4V sleeves that articulated on CoCr Molybdenum alloy, Ti-6Al-4V, and Stainless Steel femoral stems. They reported “no signs of excessive surface deterioration or progressive degradation.” However, all the tests were performed under idealized conditions with dry, properly impacted head-sleeve-taper junctions and, thus, do not necessarily simulate the complete range of real-world situations in which these systems may operate.

The purpose of this study was to investigate fretting corrosion in sleeved ceramic heads. We asked the following questions: (1) What is the prevalence of fretting corrosion in sleeved ceramic heads? (2) Is there a difference in fretting corrosion scores between heads used on primary stems and heads used on revision stems? (3) What implant and patient factors influence fretting corrosion of the sleeves?

Methods

Between 2001 and 2016, 37 sleeved ceramic heads (CeramTec, Plochingen, Germany) were collected during routine revision surgery as part of a multicenter, institutional review board–approved, orthopedic implant–retrieval program. The sleeves were implanted for 0.7 ± 0.9 years (range, 0.0-3.3 years). Seventeen of 37 (46%) sleeves were implanted during a revision surgery, whereas 19 of 37 (53%) were implanted in a primary surgery. For 1 sleeve, the previous revision history could not be ascertained. The predominant reasons for revision were instability (17 of 37 [46%]), infection (11 of 37 [30%]), and loosening (5 of 37 [14%]). In addition, malalignment, periprosthetic fracture, hematoma, and a subsided femoral stem were identified as the reasons for revision in 1 case each. None of the sleeved ceramic heads were revised for a reaction to metal debris. Eighteen of 37 (49%) patients were female. Patient age at insertion was 58 ± 9 years. Activity levels were assessed using a self-administered questionnaire ranging from a score of 1 to 10 (University of California, Los Angeles [UCLA] activity score). The UCLA score was 5 ± 2 (range, 2-10) corresponding to patients sometimes participating in moderate activities (eg, unlimited housework or shopping).

The sleeves were all fabricated from titanium alloy (Ti-6Al-4V) and were manufactured by CeramTec (Plochingen, Germany), and the femoral heads were made from Zirconia-toughened Alumina (CeramTec, Plochingen, Germany). The sizes of the femoral heads ranged from 28 to 44 mm (28 mm [n = 2], 32 mm [n = 3], 36 mm [n = 16], 40 mm [n = 14], and 44 mm [n = 2]). Eighteen of the 37 femoral heads were also revised with femoral stems. The remaining 19 stems were deemed by the revising surgeon to be well-fixed and were retained in the patients. All the stems in this study were fabricated from Ti-6Al-4V.

Sleeves that were received were still attached to the stem and/or head and were disassembled with a head-stem disassembly sleeve and a sleeve adapter extraction tool, respectively. Sleeve dimensions (length and thickness) were measured using calibrated calipers. Alloy composition of all retrieved sleeves and stems was confirmed using an X-ray fluorescence detector (Niton XL3t GOLDD+; Thermo Scientific, Waltham, MA).

Fretting corrosion of the sleeves and available stems was scored using the previously described 4-point, Goldberg-Higgs semi-quantitative scoring system [12,13]. In this system, a score of 1 corresponds to fretting damage occurring on <10% of the surface with no evident corrosion. A score of 2 is >10% surface with fretting damage and/or corrosion attack confined to ≥1 small areas. A score of 3 is >30% surface with fretting damage and/or local corrosion attack. Finally, a score of 4 corresponds to severe damage to the taper (>50%) with an aggressive local corrosion attack with abundant corrosion debris (Fig. 1).

Nonparametric statistical testing was used due to the non-normal distribution and ordinal nature of the data. For comparisons between scores at the stem, internal taper, and external taper, we used a paired Wilcoxon test. For correlations, we relied on the Spearman rank correlation test. A *P* value <.05 was used for significance in all tests performed. All statistical testing was performed using commercially available software (JMP 12; SAS Institute, Cary, NC).

Results

Mild-to-moderate fretting corrosion scores (score = 2-3) were observed in 92% (34 of 37) of internal sleeve tapers (sleeve-femoral stem contact), 19% (7 of 37) of external sleeve tapers (sleeve-femoral

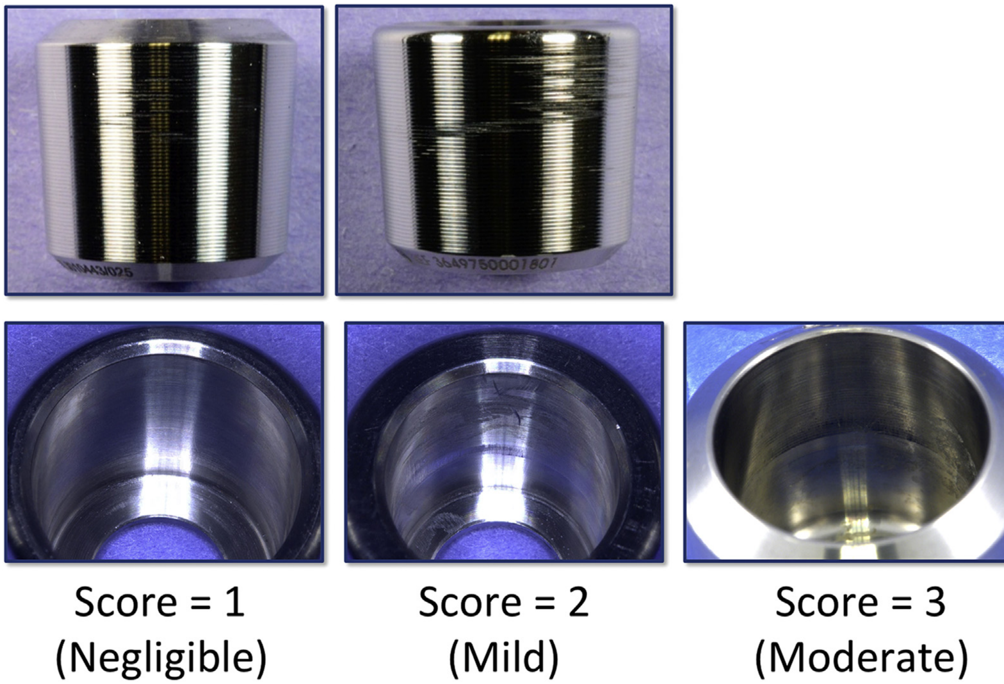

Fig. 1. Examples illustrating the range of fretting corrosion scores observed on taper surfaces of the titanium alloy sleeves.

head contact), and 78% (14 of 18) of the stems (Figs. 1 and 2). Negligible fretting corrosion (score = 1) was observed on 8% (3 of 37) of internal tapers, 81% (30 of 37) of external tapers, and 17% (3 of 18) of the stems. The internal taper and femoral stem had higher fretting corrosion scores than the external sleeve taper (mean score difference = 0.9; $P = .0002$ and mean score difference = 0.7; $P = .001$, respectively; Fig. 2).

We were not able to detect a difference between sleeves used in primary surgery and sleeves used on a well-fixed stem in revision surgery at the internal sleeve taper ($P = .46$), external sleeve taper ($P = .28$), or the stem tapers ($P = .57$), with the numbers available. Severe fretting corrosion (score = 4) was observed in 1 stem trunnion that was previously retained during revision surgery. The corresponding titanium alloy sleeve had a fretting corrosion score

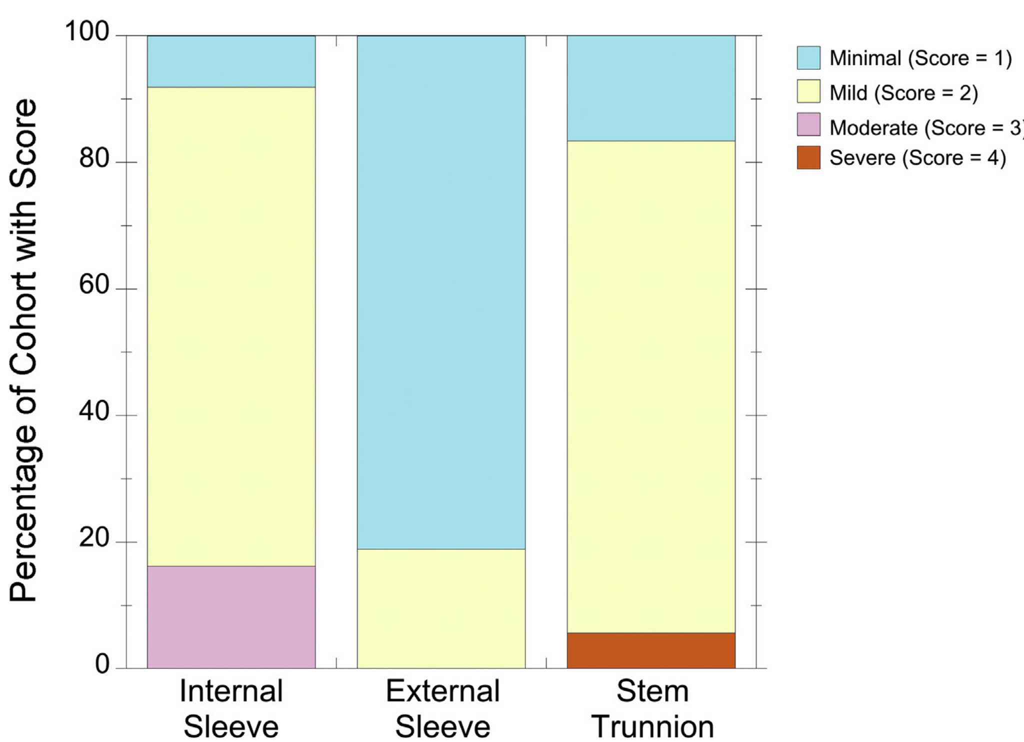

Fig. 2. Distribution of fretting corrosion scores for the retrieved sleeves and stems.

of 3. There were no other components in this study that exhibited severe corrosion.

Fretting corrosion scores were correlated with implantation time at the external sleeve surface (Rho = 0.37; $P = .03$). The fretting corrosion scores at all other surfaces were not correlated with any other patient factors (height, weight, age at insertion, UCLA activity score, or implantation time). The length of the sleeve was positively correlated with the fretting corrosion scores and the internal sleeve taper (Rho = 0.34; $P = .04$) and inversely correlated with the fretting corrosion scores of the stem trunnion (Rho = −0.49; $P = .03$). No other implant factors (sleeve thickness, sleeve length, and femoral head size) were correlated with the fretting corrosion scores of the taper surfaces.

Discussion

Fretting corrosion of the taper junction in metal-on-polyethylene total hip arthroplasty (THA) has reemerged as clinical concern as the debris released can cause adverse local tissue reactions. A previous study observed that ceramic heads reduce, but do not eliminate fretting corrosion of the stem trunnion [5]. However, that study excluded ceramic heads that had adapter sleeves. Therefore, the in vivo fretting corrosion behavior of these systems is still unclear. In vitro testing has suggested that fretting corrosion would be low in sleeved ceramic heads; however, there are limited data on the in vivo fretting corrosion behavior of sleeved ceramic heads. The retrieval data in the present study demonstrate that fretting corrosion can occur in these components; however, it was generally mild in this cohort of sleeves. Moreover, we did not observe any differences in corrosion between sleeves implanted in a primary surgery vs sleeves implanted on a well-fixed stem in revision surgery.

This study has several limitations. First, the implantation time of the sleeves in this study is short term. Second, we used a semi-quantitative method to assess the presence of fretting corrosion on the sleeves and stems, and thus, we did not measure material loss. However, a recent study showed that fretting corrosion scores do correlate with material loss, but that the amount of material loss is particularly variable in implants with a score of 3 or 4 [7]. Moreover, they found that >90% of material loss occurred at the CoCr femoral head as opposed the femoral stem taper. We only had 1 component (femoral stem) with score of 4 in our implants. Therefore, the volume of material loss may not be particularly relevant with this cohort of retrievals. In addition, this study is limited due to the fact that it is a retrieval study and thus represents “failed” implants. However, none of the retrievals in this cohort were revised for reactions to metal release. Fourth, we only investigated the fretting corrosion behavior of sleeved ceramic heads of one manufacturer. Therefore, the findings from this study may not be applicable to sleeves and heads produced by other device manufacturers.

The data in this study show that the fretting corrosion scores in retrieved sleeved ceramic heads are generally low and not likely to produce large volumes of metal release. We observed corrosion scores that were lower than levels observed in prior studies of tapers of CoCr femoral heads in metal-on-polyethylene bearings [5,13–15]. In a matched cohort study, Kurtz et al [5] observed a median score of a 3 in the CoCr femoral head cohort. In a subsequent study [14] investigating fretting corrosion in THAs with a highly cross-linked polyethylene liner, the same group investigated 508 retrieved THA systems implanted for 3 years. The median score in that study was 2. However, 20% of the retrieved femoral heads in that study had a fretting corrosion score of 4. Similarly, in a study of 252 CoCr femoral heads by Higgs et al [15], the median fretting corrosion score was 2, but 12%-23% of the heads had severe corrosion depending on the taper geometry. Goldberg et al [13] (using a similar, but not identical scoring system) found severe corrosion occurred in 8%-12% (depending on material combination) of the CoCr Molybdenum alloy heads in a study of 231 retrieved devices. This is in contrast to the results of this study where none of the sleeves had severe corrosion (score = 4) on either the internal or external sleeve surface. Although we did observe some moderate fretting corrosion of the internal sleeves, the clinical consequences of these findings are not clear. The metal sleeves are fabricated from Ti-6Al-4V compared with CoCr, which is the material typically used in metallic femoral heads. Titanium particles are believed to be better tolerated by biological systems than either cobalt or chromium particles [16].

Titanium sleeves were designed to allow a surgeon the option of using a ceramic femoral head on a well-fixed stem during revision surgery. Before the introduction of sleeves, surgeons were cautioned against using a new ceramic head if they were not also revising the stem due to the potential for damage to the stem taper. Although not looking at corrosion, several studies have reported good outcomes of the use of sleeved ceramic heads in revision surgery [9,10]. Jack et al [9] investigated the outcomes of revision surgeries using ceramic heads with sleeves in ceramic-on-ceramic bearings. They reported “excellent rates of survival and function.” In the present study, approximately half of the sleeves were implanted in a primary surgery on an undamaged stem allowing us to compare if retaining a potentially damaged stem influences the fretting corrosion behavior. The results of this study do not suggest that there is a difference in fretting corrosion scores for sleeved ceramic heads used in primary and revision surgery.

The most important factors contributing to increased fretting corrosion were implantation time (at the external sleeve surface) and length of the adapter sleeve. This is similar to other studies that have demonstrated implantation time is a predictor of fretting corrosion [5,12,13,15]. For the stem trunnion, we found that the length of the sleeve was inversely correlated with fretting corrosion scores. The increased length may reduce the amount micromotion and disruption to the passive layer, thus, lessening the amount of fretting corrosion. Previous studies have found stem material to have an impact on fretting corrosion in THA [5,13]. In this study, all the sleeves and stems were fabricated from a titanium alloy. Therefore, we were not able to ascertain in this study the impact of different stem materials on the fretting corrosion behavior of sleeved ceramic heads.

Fretting corrosion of titanium sleeves was generally milder than fretting corrosion scores of CoCr femoral heads reported in the literature. Moreover, sleeves implanted in revision surgery had similar levels of fretting corrosion as sleeves implanted in primary surgery. Owing to the short implantation times and relatively small sample size, future studies may be warranted to corroborate these findings. In this controlled cohort study, implant and patient factors were generally not predictors of the fretting corrosion behavior of the sleeved ceramic heads. The results of this study, taken together with the available literature, support the use of sleeved ceramic heads in revision surgery with a well-fixed femoral stem.

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