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Can severity of trunnion damage be estimated by visual inspection alone?

INTRODUCTION OF AN ENHANCED VISUAL GRADING SYSTEM AND VALIDATION USING METROLOGY

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Aims
Taper corrosion has been widely reported to be problematic for modular total hip arthroplasty implants. A simple and systematic method to evaluate taper damage with sufficient resolution is needed. We introduce a semiquantitative grading system for modular femoral tapers to characterize taper corrosion damage.

Methods
After examining a unique collection of retrieved cobalt-chromium (CoCr) taper sleeves (n = 465) using the widely-used Goldberg system, we developed an expanded six-point visual grading system intended to characterize the severity, visible material loss, and absence of direct component contact due to corrosion. Female taper sleeve damage was evaluated by three blinded observers using the Goldberg scoring system and the expanded system. A subset (n = 85) was then re-evaluated following destructive cleaning, using both scoring systems. Material loss for this subset was quantified using metrology and correlated with both scoring systems.

Results
There was substantial agreement in grading among all three observers with uncleaned (n = 465) and with the subset of cleaned (n = 85) implants. The expanded scoring criteria provided a wider distribution of scores which ultimately correlated well with corrosion material loss. Cleaning changed the average scores marginally using the Goldberg criteria (p = 0.290); however, using the VGS, approximately 40% of the scores for all observers changed, increasing the average score from 4.24 to 4.35 (p = 0.002). There was a strong correlation between measured material loss and new grading scores.

Conclusion
The expanded scoring criteria provided a wider distribution of scores which ultimately correlated well with corrosion material loss. This system provides potential advantages for assessing taper damage without requiring specialized imaging devices.

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Keywords: Modular implant, Taper, Corrosion, Fretting, Grading

Article focus
- Developing an enhanced taper damage grading system that increases the resolution of the currently used.

Key messages
- The proposed grading system provides advantages for assessing taper damage without needing specialized imaging devices.
- The grading system can be used by clinicians with minimal training.

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- The proposed system provides more information in describing the extent and type of corrosion and fretting damage.

Strengths and limitations

- Grading criteria were developed based on the examination of 465 retrieved implants and correlated with actual corrosion material loss quantified using metrology.
- Three observers conducted blinded evaluations to assess interobserver reliability.
- Evaluated implants were the same taper design from a single manufacturer, and only female tapers were evaluated.

Introduction

Modularity in total hip arthroplasty allows a surgeon to adjust the head size and offset to recreate and/or improve the biomechanics of the diseased hip joint. Corrosion and fretting wear of modular taper junctions have been noted in a variety of revised and retrieved explants, generating debate over their contribution to the overall failure of the joint arthroplasty.[1-4] Assessment of taper damage during revision may provide information related to the precise failure mechanism and host tissue response at the time of removal.

The recent ASM Handbook on fatigue and fracture defines fretting as "a special wear process that occurs at the contact area between two materials under load that is subject to minute relative motion by vibration or some other force,"[5] while classically Fontana and Greene[6] have described "fretting corrosion" to occur at the contact areas between materials under load, which are susceptible to vibration and slip. Crevice corrosion occurs within metal crevices where small volumes of stagnant fluid are present.[6] The modular total hip arthroplasty ball-taper junction is subject to bending and rotational loads that can result in fretting motion, and is immersed in an aqueous synovial joint, which provides lubrication for the bearing surfaces, which may also increase taper corrosion. Therefore, in vivo damage of the femoral neck and head taper surfaces can be chemical, mechanical, or a combination of the two. This damage has also been described as crevice corrosion, mechanically assisted crevice corrosion, or fretting wear.[7]

Currently, there are two general categories of stem trunnion topography used for the modular femoral head-stem junction, or trunnion: a smooth surface, or the more recently introduced microgrooved surface. Although the microgrooved trunnion surface was developed to enhance taper fixation for ceramic femoral heads, it is widely used with metal alloy heads as well. These microgrooved male surfaces often cause fretting wear, which can lead to imprinting on the female taper surface,[8,9] which has not been commonly observed with smooth tapers.[8]

Material loss in the taper junction can be caused by the electrochemical process of crevice corrosion, mechanical fretting damage, or both, and can result in the discharge of loose particles and ions. In both of these processes, particles often accumulate within the non-contact areas of the taper junction, where there is space available, or are released into the body, which may provoke a tissue response.[1,2]

The scoring system most commonly used for the evaluation of both male and female modular component taper damage is Goldberg et al's[3] four-point grading system. The key criteria for this system involve the consideration of corrosion and fretting damage together, as both processes may occur simultaneously. Appearance of corrosion damage is considered when there is discolouration, deposits, and surface damage from metal ion and particle discharge. The criteria for damage produced by fretting is considered when there are micro scars.

While the Goldberg scoring system has been reported to be reproducible for experienced investigators with substantial interobserver reliability for assessment of corrosion damage, difficulties have been reported for the characterization of fretting damage.[10] For example, without high magnification or electron microscopy, fretting damage is often difficult to discern. Further, retrieval and extraction damage on the taper surface can be mistaken for fretting damage.[9,11] Additionally, evidence of fretting wear can be worn away by severe corrosion or obscured by corrosion product deposits. Moreover, in cases where fretting wear and subsequent imprinting is observed, severity is not well defined. Accordingly, investigators often report modifications to the criteria, rendering comparisons between different research centres difficult.[12]

Purpose. The purpose of the present study was to introduce and evaluate an expanded visual grading system (VGS) based on the Goldberg system, for the evaluation of modular tapers. The VGS was intended to provide a wider distribution of damage scores to improve the correlation between visual assessments and quantified taper material loss. In this study, evidence is presented to: 1) establish the VGS inter-reliability; and 2) validate its accuracy by correlating the scores against material loss quantified using metrology.

Methods

We previously reported findings from the inspection of 555 metal-on-metal ASR total hip arthroplasty retrievals (ASR-XL; Depuy Synthes, USA) revised between early 2007 and 2016.[13] From this collection, 465 heads with cobalt-chromium (CoCr) taper sleeves which had male titanium alloy taper counterparts with microgrooved trunnions (12/14 tapers) which were evaluated. Duration of implantation and femoral head diameters were available for most components. Head diameters ranged from 39 mm to 57 mm, with 45 mm being the most common size. Time in vivo ranged from two weeks to 9.5 years, with a median of 4.0 years (IQR 32.3 to 65.2 months). A total of 201 cases were from males, with ages ranging from 21 to 88 years (median 57), and 264 cases were

Table I. Goldberg et al[3] taper corrosion and fretting score criteria.

Severity of corrosion and fretting	Score	Criteria
None	1	No visible corrosion observed No signs of fretting
Mild	2	< 30% of taper surface is discoloured or dull Single band or bands of fretting scars involving three or fewer machine lines
Moderate	3	> 30% of taper surface is discoloured or dull < 10% of taper surface contains black debris or etch marks Several bands of fretting scars or single band involving more than three machine lines
Severe	4	> 10% of taper surface contains black debris or etched marks Several bands of fretting scars involving several adjacent machine lines

from females, with ages ranging from 43 to 88 years (median 58). Overall, this cohort of patients was revised for numerous reasons, including metal sensitivity, wear, malpositioning, unknown reasons, and a desire to avoid future complications. Collectively, this cohort of retrievals represented a wide range of volumetric articular surface wear. Only the female CoCr alloy taper sleeves were included in the present analysis, as very few male counterparts (femoral stems) were removed during revision.

Non-destructive analysis. Non-destructive analysis was conducted on all specimens. All implants underwent non-destructive decontamination prior to handling. Specifically, specimens were soaked in a 10% neutral buffered formalin solution for no less than 20 hours (Azer Scientific, USA). The taper sleeves' surfaces, typically attached to the femoral head taper, were rinsed with running deionized water without rubbing, to remove loose dried fluid and simultaneously preserve densely adhered corrosion products. Specimens were then placed in an air dryer for 24 hours. All specimens were inspected by naked eye by three blinded observers: one expert in retrieval analysis (SHP), and two trained volunteer engineering students with no prior experience. Following inspection and grading, all specimens were photographed for documentation purposes, using a macro-lens (Nikon 60 mm, F 2.8, Japan).

Corrosion features of the inner taper surface were graded using the four-point scale introduced by Goldberg et al[3] (Table I), and the expanded six-point system VGS, developed in-house (Table II). The alternative scoring system is notable for the inclusion of four additional features: 1) contact and non-contact regions are identified, with scoring focused on the contact region; 2) intensity of microgrooved taper imprinting is graded by severity; 3) presence of apparent localized visible material loss is evaluated as a separate category (Figure 1); and 4) thick deposits that obscure > 50% of the contact region are evaluated as a separate category (Figure 2).

Visual inspection following destructive cleaning. As the developed cleaning protocol was considered to be destructive, patient consent was required and was obtained for 85 implants. This additional cleaning process facilitated the removal of corrosion deposits from the taper. The purpose of the cleaning process was to identify the origin and cause of the damage. While cleaning is considered 'destructive inspection' and cannot always be performed, it may be useful to reveal the underlying surface features that provide evidence as to the nature of the corrosion or fretting process. Furthermore, cleaning was a necessary step prior to quantitative measurement of material loss using metrology.

All 85 tapers were soaked in biodegradable laboratory detergent solution for 30 minutes (Liquinox, USA). The inside taper surface was then cleaned with a soft nylon bristle brush using a rotary tool, followed by ultrasonic cleaning. Taper surfaces were photographed and regraded by three blinded observers (SHP; see Acknowledgements) using both corrosion grading systems.

Quantification of taper material loss using metrology. Following taper cleaning and visual inspection, taper corrosion material loss volume and maximum damage depth were measured using a coordinate-measuring machine (Mitutoyo Legex 322; Mitutoyo America, USA) and a surface profilometer (Mitutoyo SVC3100, Mitutoyo America). A total of 360 longitudinal line traces circumferentially spaced at 1° intervals were measured using contact profilometry and combined with the reconstructed 3D geometry obtained by the coordinate-measuring machine.[14]

Statistical analysis. SPSS Statistics (SPSS Statistics 17.0; USA) was used for analyses. Among all specimens evaluated with non-destructive analysis (n = 465), Fleiss' kappa coefficient was calculated to determine the degree of agreement among the three observers. Specifically, the Fleiss' kappa coefficient was calculated for interobserver agreement using the Goldberg scoring criteria and separately using the VGS scoring criteria.

For the cohort of specimens that underwent destructive cleaning followed by repeated metrology (n = 85), the same Fleiss' kappa coefficient and bivariate Spearman correlation analyses were conducted. Specifically, both Fleiss' kappa and Spearman correlation were calculated comparing observer grades using the Goldberg scale, then observer grades using the alternative VGS. Spearman correlation analyses were conducted to evaluate any correlations between observer scores within the same scoring system. In addition, the significance of changes in average observer scores before and after destructive cleaning was assessed using paired *t*-tests.

Table II. Visual grading system criteria.

Severity	Score	Criteria (engaged portion of the head and taper only)	Examples
None	1	New, no visible corrosion observed on the taper surface	
Mild	2	< 30% of contact surface is discoloured or dull Or several bands of imprinting scars are visible (no depth perceived)	
Moderate	3	> 30% of contact surface is discoloured, < 10% taper contact surface has dark deposits or a corroded, rough surface Or taper contact surface has moderately imprinted grooves (slight perceived depth) Non-contact surface has no corrosion deposits	
Severe	4	>30% of contact surface is discoloured, > 10% taper contact surface has dark deposits or a corroded, rough surface. Or taper contact surface has severely imprinted grooves, with deposits in the grooves (groove depths are perceived). Dark deposits may partially fill in the grooves. Deposits may be present on the non-contact surface	
Severe with visible loss	5	Grade 4 features with one or more localized, deeply regressed, corroded surface(s) Or several imprinted grooves corroded further, merged showing a shiny, flattened wide bottom or showing deeper than imprinted groove	
Thick deposit	6	> 50% of contact surface is covered with thick black deposit that obscures surface texture Deposits extend toward non-contact area Contact boundary is not clear	

Once the interobserver analysis was conducted and agreement among observers was established for the complete cohort (n = 465), the three observers' grades (both Goldberg and VGS) for each specimen were then averaged for subsequent analyses. Spearman's correlation coefficient was used to evaluate the correlation between the Goldberg scoring criteria and physical measurements taken from each specimen (n = 85). Spearman's correlation coefficient was also used to evaluate the correlation between the VGS scoring criteria and physical measurements taken from each specimen. Separate analyses were conducted using the scores before and after cleaning for all available specimens (n = 85). Physical measurements included volumetric material loss due to corrosion and maximum linear depth of material loss.

Results

Non-destructive analysis. The 12/14 male taper micro-grooved surface engaged with approximately 60% to 70% of the female taper surface, primarily in the central region of the taper junction rather than uniformly from the proximal and distal ends. The resulting damage was primarily composed of imprinting of the male taper geometry on the engaged area and corrosion products deposited in the imprinted grooves and/or the outside of the contact area, which was more exposed to the synovial fluid. This was more pronounced in the distal region, where the tapers diverge. This type of damage corresponded to grades of 3 to 4 using the VGS. In severe cases, several imprinted grooves on the distal contact boundary appeared to merge into one flattened surface, often with black deposits or a deep, rough, yet shiny region of localized material loss, corresponding to a grade

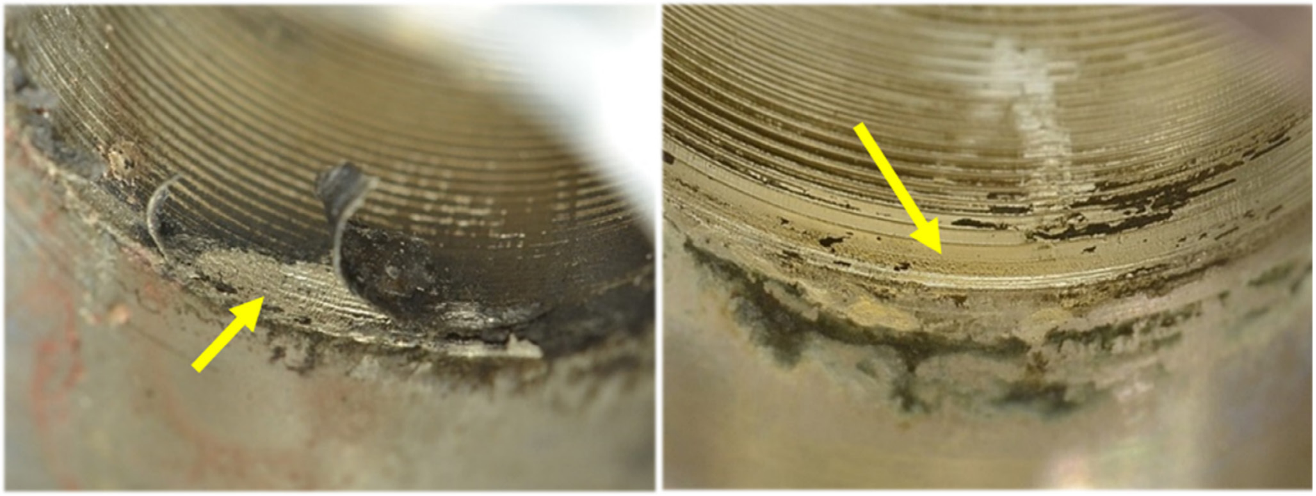

Fig. 1

Two examples of corrosive damage that would receive a grade of 4 using the Goldberg score due to the presence of deposits, but are further distinguished as a 5 using the visual grading system score, due to the presence of significant localized material loss as indicated by the arrows (maximum opening at the distal taper sleeve is 14 mm.)

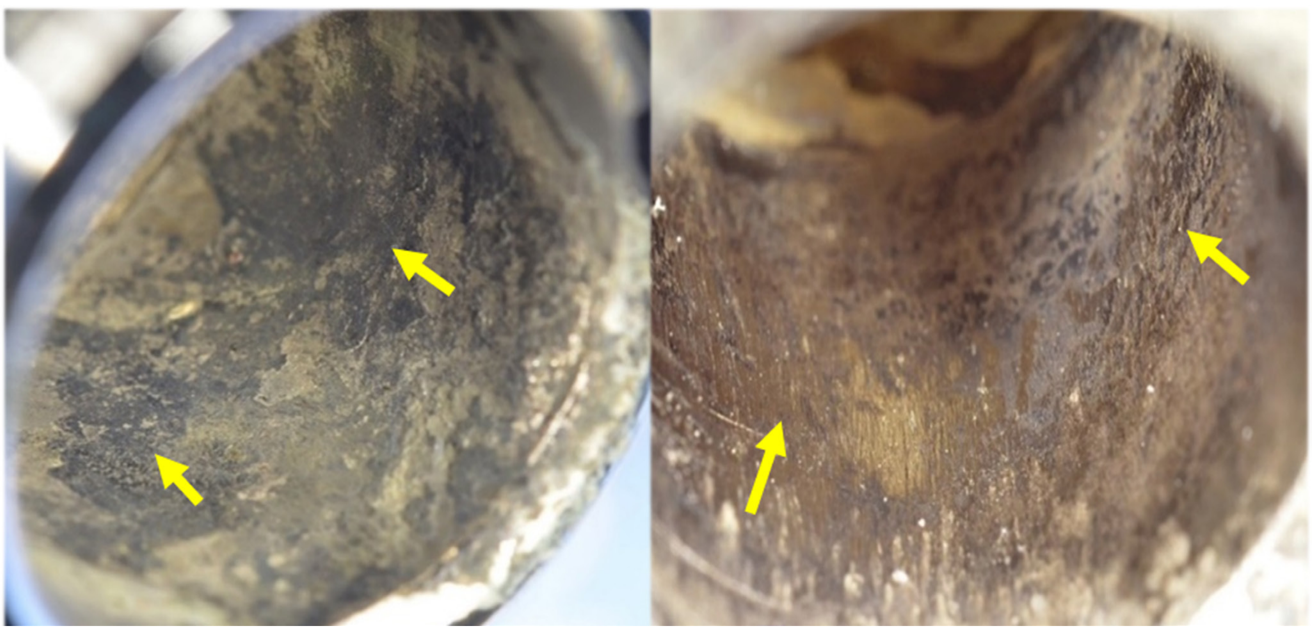

Fig. 2

Two examples of corrosive damage that would receive a grade of 4 using the Goldberg score due to the presence of deposits, but are further distinguished as a 6 using the visual grading system score, due to the extent or severity of the deposit, which is both thick, black, and obscures more than 50% of the contact surface, as indicated by the arrows (note: photographs were taken prior to destructive cleaning).

of 5 using the VGS (Figure 1). In a few cases, portions of the taper surface were covered with thick deposits which, prior to cleaning, obscured the taper surface features and engagement area, corresponding to a grade of 6 using the VGS (Figure 2).

Overall, Goldberg scores ranged from 2 (mild, < 5% of specimens) to 4 (severe, ≥ 73% of specimens), with observer-specific means of 3.7, 3.9, and 4.0, and with a mode of 4 for all three observers. The VGS scores ranged from 2 to 6, with observer-specific means of 4.1, 4.3, and 4.3, and modes of 5 for all three. The majority of the specimens, 74% to 99% depending on the observer, were scored as grade 4 (severe) using the Goldberg scoring system (Figure 3a). Evaluation of the same specimens using the alternative VGS, however, redistributed the large number of grade 4 Goldberg scores into a wider range of scores, with no more than 62% of specimens falling into a single grade (Figure 3b).

Generally, there was weak agreement among the observers using the Goldberg system (Fleiss' kappa: κ =

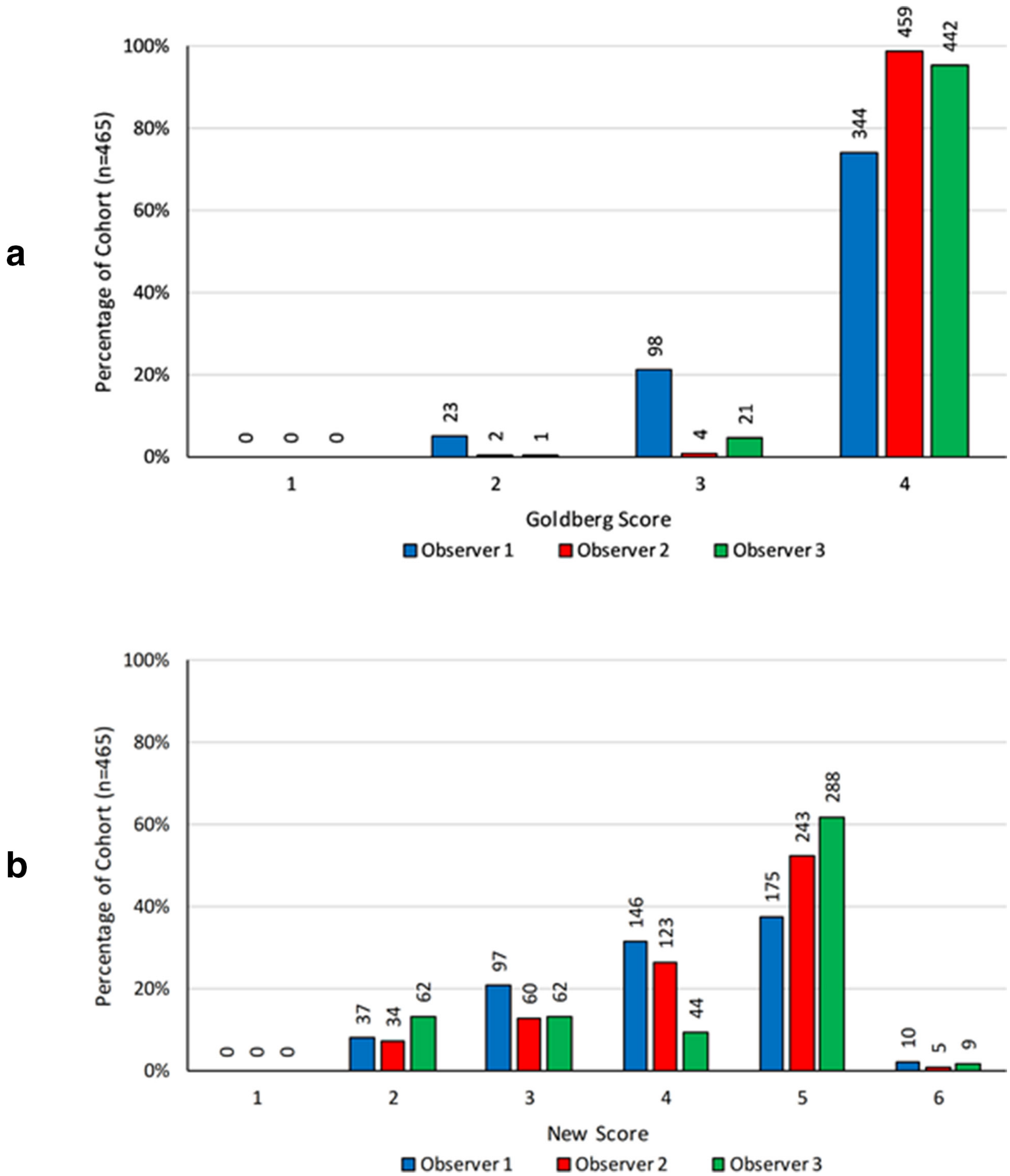

Fig. 3

The percentage distribution for all 465 tapers prior to cleaning evaluated by all three observers using the a) Goldberg score and b) visual grading system score.

0.058, $p = 0.014$). In contrast, using the VGS, the distribution of severity scores expanded (Figure 3b) and the agreement of observers was moderate (Fleiss' kappa: $\kappa = 0.440$, $p < 0.001$).

Visual inspection and quantification of taper material loss following destructive cleaning. The majority of the loose deposits were removed from the taper surface during destructive cleaning, but tenacious deposits, especially within the imprinted grooves, were not removed by contact-cleaning with the brush. The average scores of three observers following cleaning remained similar to the initial scores using the Goldberg criteria (from 3.84 to 3.86, $p = 0.290$, paired *t*-test); however, using the VGS, approximately 40% of the scores for all observers changed following cleaning and the overall average score increased from 4.24 to 4.35 ($p = 0.002$, paired *t*-test). As expected, following the removal of dark deposits at the contact boundary of the microgrooved tapers,

Fig. 4

Two examples of corrosive damage and their relative scores assigned before and after cleaning are presented. On the top row, prior to cleaning (left) the taper was assessed as a 4, using both grading scores. However, after cleaning (right), most of the dark deposits were removed, and the new Goldberg score remained the same, yet the visual grading system (VGS) score increased to a 5, due to the presence of significant, localized material loss. In contrast, on the bottom row, prior to cleaning (left) the taper was assessed as a 4 using the Goldberg score, but a 6 using the VGS, due to the extent of the thick, black deposit obscuring more than 50% of the surface. However, after cleaning (right) most of the dark deposits were removed, which changed the scores using both methods of scoring to a 3. The number in the figures indicates VGS grading score only (maximum opening at the distal taper sleeve is 14 mm).

specimens that initially received a grade of 4 were now revealed to fall into the category of grade 5 as a result of the newly revealed deep and wide corroded areas (Figure 4). Similarly, specimens that were initially graded as a 6 were downgraded to 3 or 4, as the surfaces were revealed to be less damaged than previously assessed following the removal of obstructive deposits (Figure 4). Observer agreement improved for both the Goldberg system (Fleiss' kappa: $\kappa = 0.431$, $p < 0.001$) and VGS (Fleiss' kappa: $\kappa = 0.524$, $p < 0.001$) following cleaning.

Volumetric material loss following cleaning quantified using metrology ranged from 0.04 to 25.57 mm^3 (mean 6.23 mm^3 (SD 7.12)) (Figure 5). The maximum linear depth of material loss ranged from 2.3 μm to 136.2 μm (mean 46.2 μm (SD 34.4)) (Figure 6).

Overall, there was a strong correlation between quantitative volumetric material loss and average visual corrosion scores using both grading systems (Figures 5 and 6). There was a strong correlation between maximum linear depth of material loss and mean corrosion scores using both grading systems (Figures 5 and 6). Maximum linear depth of material loss was more highly correlated with the VGS (Rho = 0.760, $p < 0.001$) than volumetric material loss with the VGS scoring (Rho = 0.660, $p < 0.001$).

Discussion

The proposed corrosion damage grading system introduced several key features to expand the widely used method of visual assessment introduced by Goldberg et al.[3] These expanded criteria characterize more features, such as the degree of imprinting and localized material loss, commonly seen with contemporary taper designs, without requiring high-magnification imaging or special

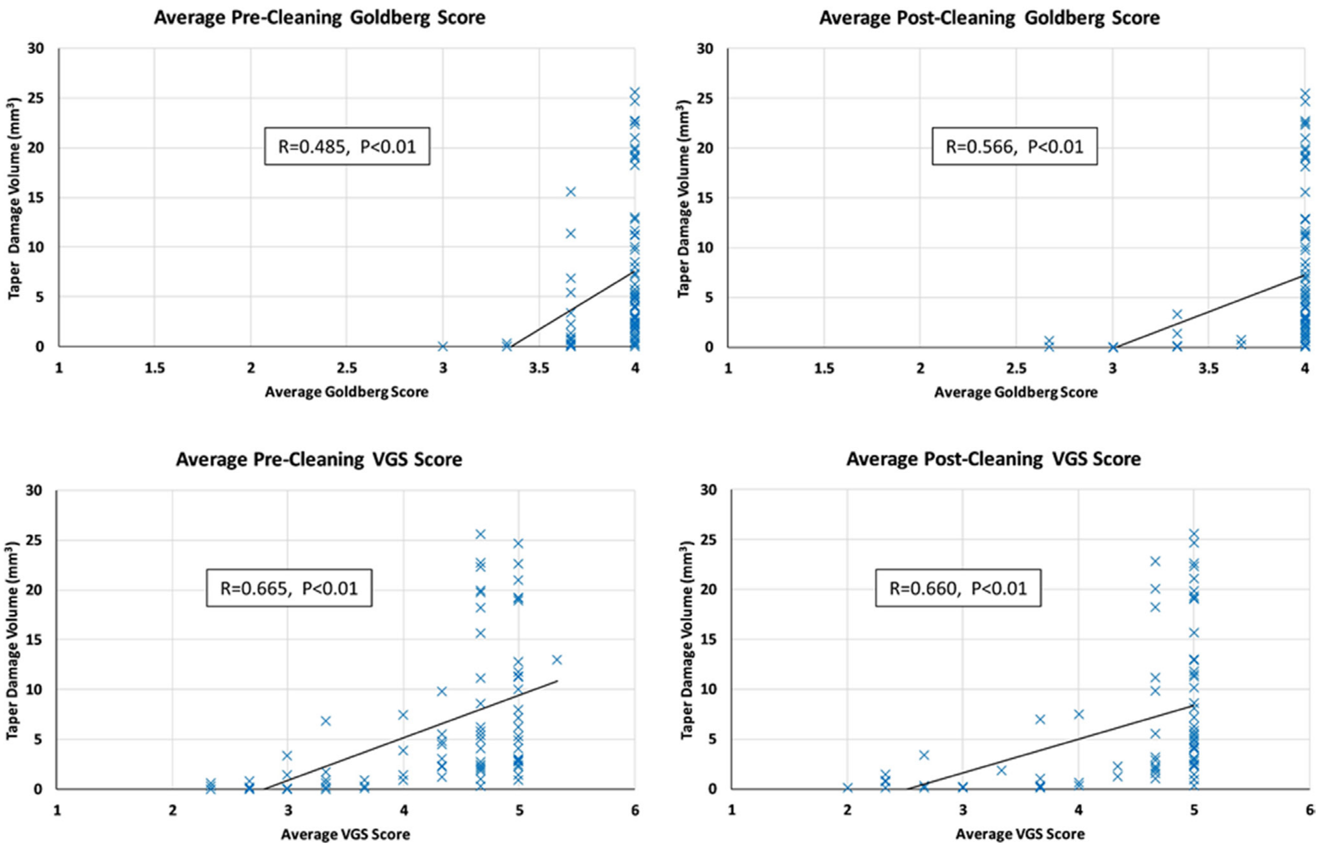

Fig. 5

The distribution of the average grades assigned by all observers is plotted against quantified corrosion material loss volume from taper surface. Top: mean Goldberg scores of before (left) and after (right) cleaning. Bottom: mean visual grading system (VGS) scores of before (left) and after (right) cleaning.

expertise.[8] In the present study, taper evaluation using the VGS was consistent with and without destructive cleaning techniques. Further, visual scoring with the expanded scale was easily performed by novices. Finally, blinded interobserver average scoring was highly correlated with actual material loss quantified using metrology.

The proposed system added two additional categories to differentiate severe damage described by the Goldberg system as a grade 4 into three unique categories: grades 4 through 6. Specifically, severe corrosion that also included a wide region of visible localized material loss (additional to imprinting damage) of the implant was identified by a grade of 5 (Figure 1). Severe corrosion that also included a thick layer of deposits over the surface of the contact region, potentially indicating compromised fixation, was identified by a 6 (Figure 2). Severe corrosion that did not include a loss of material or a thick layer of deposits remained a 4, as in the Goldberg system. The VGS redistributed the Goldberg severe grades of 4 to VGS grades between 3 and 6 (Figure 4). This observation was further validated by the quantitative volumetric material loss and maximum depth measurements.

Microgrooved male tapers appeared to induce fretting and were frequently observed to imprint a microgrooved pattern on the female taper surface.[8] The Goldberg system defines the severity of fretting by the number of imprinted bands and the respective widths over the original machine lines. Counting the number of machine lines can be difficult and often requires assistance of high-magnification imaging. In addition, in the present study fretting bands appeared in most of the contact areas with different degrees of depth. Therefore, many of the specimens that were graded as a score of 4 under the Goldberg system were differentiated by severity and apparent depth of imprinting using the new criteria, and were regraded with scores of 3 to 5. This challenge has been previously reported by other investigators, who have introduced their own modifications to address this issue.[10,15-17]

In the present study, accelerated crevice corrosion and localized deep damage were noted near the distal taper contact boundary in all of the grade 4 and 5 cases. In these severe cases, several imprinted grooves had merged into one large flat groove and was covered by deposits at the distal contact boundary. It is possible that portions of the deposits could be sheared off by micromotion under bending and torsion, such that the exposed metallic surface exhibits a shiny, rough surface. Further, in cases where the interface was likely loosely engaged, fretting and corrosion could have been exacerbated by micromotion, resulting in the production of wear debris. Subsequently, this debris combines with serum proteins and

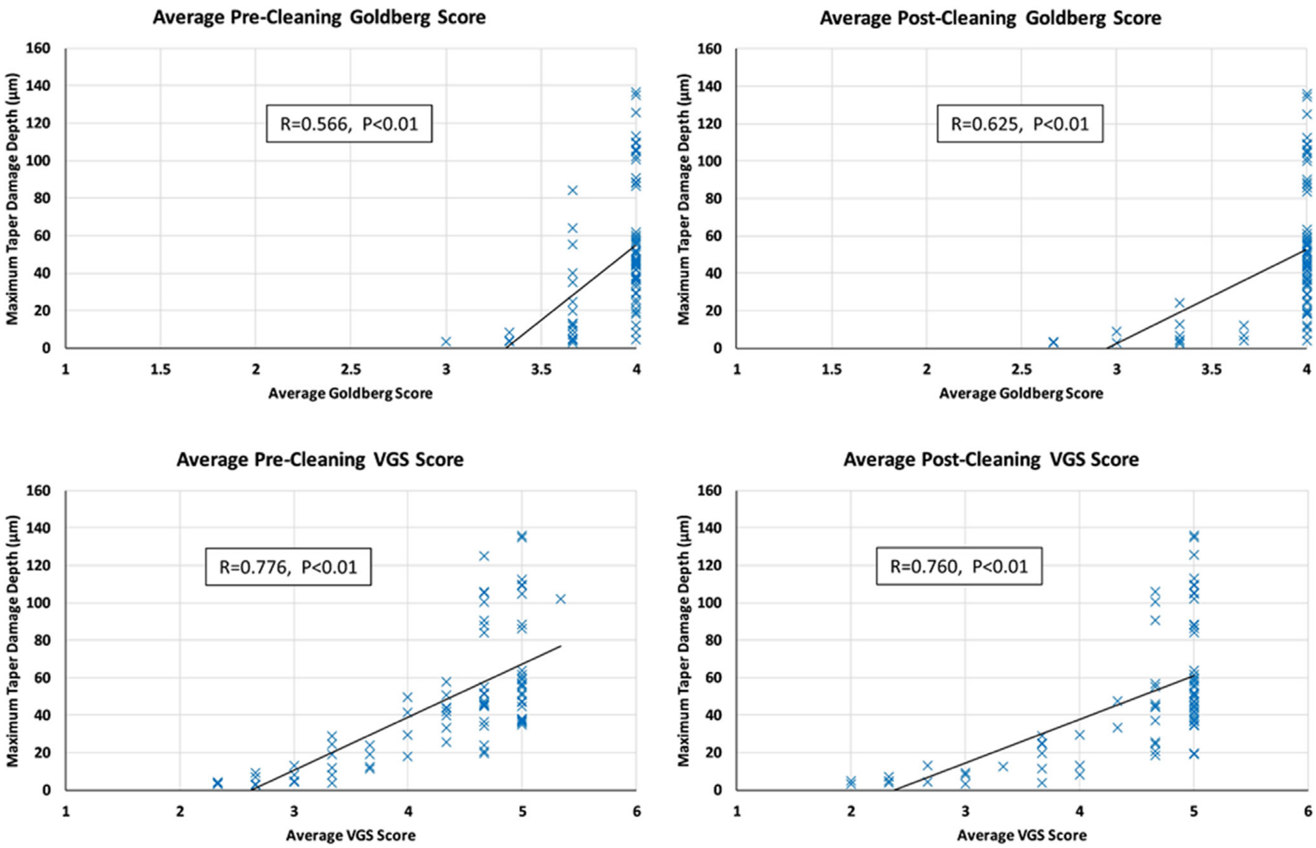

Fig. 6

The distribution of the average grades assigned by all observers is plotted against quantified corrosion maximum linear depth of material loss from taper surface. Top: mean Goldberg scores of before (left) and after (right) cleaning. Bottom: mean visual grading system (VGS) scores of before (left) and after (right) cleaning.

accumulates as corrosion products in the space between the two interfaces. Observations consistent with this potential in vivo mechanism were scored as a grade 6 in our proposed system. Although the two interface surfaces were engaged by thick corrosion product layers, it is possible that the taper could maintain secure seating, similar to a rusted bolt and nut. For this reason, highly corroded taper heads may require higher pullout forces than non-damaged tapers in certain cases.[18] Conversely, clinical observations of loosened taper assemblies during revision have also been reported, suggesting that severe corrosion may lead to weakening of the integrity of the assembly by corrosion products separating the two components.[19,20]

In the present study, cleaning was not found to significantly alter the Goldberg scores, with only a small percentage shifting by one grade up or down, for a change in average score of 0.02. In contrast, cleaning altered nearly half of the scores up or down using the VGS criteria, which increased the average grade from 4.24 to 4.35 ($p = 0.002$, paired *t*-test). Removal of dark deposits at the contact boundary revealed deep and wide areas which resulted in a refined VGS grade of 5, but did not affect grades by the Goldberg criteria. In contrast, in some cases removal of a thick layer of surface deposits previously scored as a grade 6 revealed only mild corrosion and were assigned a grade of 3 (Figure 4).

Overall, there was moderate interobserver reliability in the present study using the VGS system, but weak reliability using the Goldberg method. This is in contrast to a previous study that has reported good interobserver reliability using the Goldberg method.[3] One explanation may be that the observers in the present study had limited prior experience with retrieval analysis and did not use any high-magnification imaging devices to conduct their visual assessments. This was supported by the observation that the two novices appeared to have more difficulty discerning original machining lines than the expert (Figure 3). In contrast, the interobserver agreement was substantial in the present study using the VGS approach. One explanation for this may be that the criteria for the grading are expanded, which improves clarity for scoring the severity of corrosion and localized damage for novice observers.

This study had a number of limitations. In the present study, only the female CoCr taper sleeves paired with microgrooved male tapers from a single manufacturer were included. While this eliminated confounding variables from material mixing and implant design changes, it is unknown if additional features may have been observed with more implant designs. Another limitation was that destructive analysis (including cleaning, the second visual inspection, and metrology) could only be performed on the specimens for which individual patient consent could be obtained (n = 85), representing a smaller cohort of specimens that was included in the non-destructive inspection (n = 465). Finally, it is unknown if the intraobserver reliability may have been higher for both systems, had the observers had more prior experience and/or time to train.

In conclusion, the expanded corrosion grading system provides potential advantages for assessing taper damage without the need for specialized imaging devices, and is easily performed by novices with substantial interobserver reliability. This grading system enhances the sensitivity of corrosion severity scoring when applied to microgrooved taper surfaces.

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