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Comparison of in vivo and simulator-retrieved metal-on-metal cervical disc replacements

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Abstract

Background: Cervical disc arthroplasty is regarded as a promising treatment for myelopathy and radiculopathy as an alternative to cervical spine fusion. On the basis of 2-year clinical data for the PRESTIGE[®] Cervical Disc (Medtronic, Memphis, Tennessee), the Food and Drug Administration recommended conditional approval in September 2006 and final approval in July 2007; however, relatively little is known about its wear and damage modes in vivo. The main objective was to analyze the tribological findings of the PRESTIGE[®] Cervical Disc. This study characterized the in vivo wear patterns of retrieved cervical discs and tested the hypothesis that the total disc replacements exhibited similar surface morphology and wear patterns in vitro as in vivo.

Methods: Ten explanted total disc replacements (PRESTIGE[®], PRESTIGE[®] I, and PRESTIGE[®] II) from 10 patients retrieved after a mean of 1.8 years (range, 0.3–4.1 years) were analyzed. Wear testing included coupled lateral bending ($\pm 4.7^\circ$) and axial rotation ($\pm 3.8^\circ$) with a 49 N axial load for 5 million cycles followed by 10 million cycles of flexion-extension ($\pm 9.7^\circ$) with 148 N. Implant surfaces were characterized by the use of white-light interferometry, scanning electron microscopy, and energy dispersive spectroscopy.

Results: The explants generally exhibited a slightly discolored, elliptic wear region of varying dimension centered in the bearing center, with the long axis oriented in the medial-lateral direction. Abrasive wear was the dominant in vivo wear mechanism, with microscopic scratches generally oriented in the medial-lateral direction. Wear testing resulted in severe abrasive wear in a curvilinear fashion oriented primarily in the medial-lateral direction. All retrievals showed evidence of an abrasive wear mechanism.

Conclusions: This study documented important similarity between the wear mechanisms of components tested in vitro and explanted PRESTIGE[®] Cervical Discs; however, the severity of wear was much greater during the in vitro test compared with the retrievals.

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Cervical disc arthroplasty is regarded as a promising treatment for myelopathy and radiculopathy as an alternative to cervical spine fusion.^{1,2} The concept of disc arthroplasty was introduced in the 1960s by Fernström,³ who first implanted stainless-steel ball-bearings in the cervical spine to preserve motion of the degenerated levels.⁴ Three decades later, Cummins et al.⁵ began implantations of a novel cervical metal-on-metal cervical prosthesis, fabricated with spherical bearing surfaces of stainless steel at the Frenchay

Hospital in Bristol, England. The prosthesis achieved fixation using a pair of bone screws through a flange in the anterior aspect of each component.

After 5-year clinical follow-up, the Bristol/Cummins design was modified to a superior ball articulating against an inferior trough by Medtronic (Memphis, Tennessee), and a prospective observational trial of the PRESTIGE[®] I cervical artificial disc (Medtronic) was initiated in Europe during 1998. Although the anterior flange of the prosthesis was redesigned in 1999 (PRESTIGE[®] II) and 2002 (PRESTIGE[®]), the bearing surface articulation was unchanged in these subsequent design iterations. One of the design changes was the introduction of a locking screw in the anterior flange, to prevent backing out of the bone screws. A more detailed chronology of the PRESTIGE[®] design history has been

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summarized in a recent monograph.⁶ A prospective randomized trial was conducted for an Investigational Device Exemption (IDE) study for the PRESTIGE[®] design. On the basis of 2-year clinical data for the PRESTIGE[®] Cervical Disc,⁷ the Food and Drug Administration Panel recommended conditional approval in September 2006 and final approval in July 2007.

Although the stainless-steel ball-in-trough cervical disc arthroplasty has been in clinical use for nearly a decade, relatively little is known about its wear performance *in vivo*. In a previous study, Anderson et al.⁸ examined 2 PRESTIGE[®] explants (retrieved after 18 months and 39 months, respectively) and compared them with 3 components that had been tested on a wear simulator for up to 15 million cycles (MC). The dominant wear direction for the explants was noted to be in the coronal plane, and the authors suggested that the wear magnitude appeared to be less than that of the wear-tested devices. Fretting was observed between the screw heads and the anterior flanges of 1 set of retrieved components. Though noteworthy, these observations were based on a limited number of retrieved and wear-tested components.

Since the publication of the study of Anderson et al.,⁸ the collection of PRESTIGE[®] Cervical Disc explants available for detailed examination has expanded, and further wear tests have been performed. The main objective of our study was to update previous research with the current tribological findings of the PRESTIGE[®] Cervical Disc. Consequently, this study characterized the *in vivo* wear patterns of re-

trieved cervical discs and tested the hypothesis that the total disc replacements (TDRs) exhibited similar surface morphology and wear patterns *in vitro* as *in vivo*. In addition, the hypothesis that the wear testing protocol would influence the surface morphology and wear rates of the metal-on-metal cervical disc replacement was investigated.

Methods

In vitro wear tests

Two 15 MC series of wear tests were performed on a custom-built, multistation apparatus (Laveen Machine, Burnsville, Minnesota) (Fig. 1). The protocol for the first series of wear tests with 3 specimens has been described previously,⁸ consisting of 5 MC of coupled lateral bending ($\pm 4.7^\circ$) and axial rotation ($\pm 3.8^\circ$), followed by 10 MC of flexion-extension ($\pm 9.7^\circ$) (Fig. 2). There was no axial rotation during the flexion-extension phase of the test. The motions were all performed at a rate of 2 Hz. Static preloads of 49 N and 148 N were applied during the coupled motion and flexion-extension stages of the test, respectively. An additional 3 specimens underwent wear tests where the sequential order of the coupled motion and flexion-extension was reversed; none of the other test parameters were altered. All the testing was performed at body temperature ($37^\circ\text{C} \pm 3^\circ\text{C}$) using Alpha Calf Fraction (HyClone, Logan, Utah) at a concentration of 25% (protein concentration of approximately 11.5 g/L) as the lubricant. Sodium Azide



Fig. 1. Laveen wear test machine.

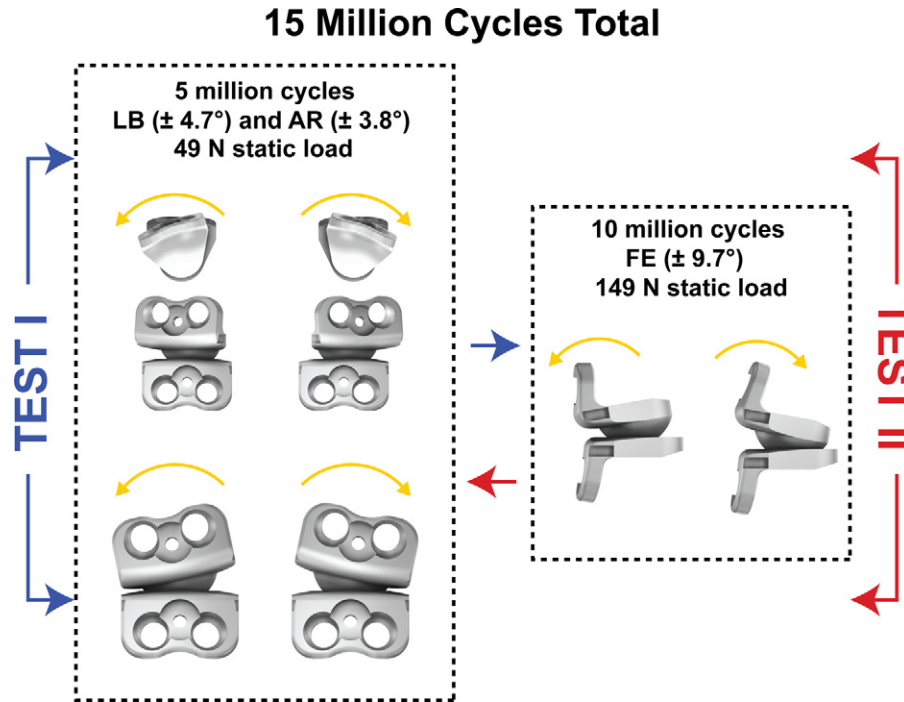


Fig. 2. Schematic of the wear tests. Wear test I was conducted with 5 MC of coupled lateral bending (LB) and axial rotation (AR), followed by 10 MC of flexion-extension (FE). Wear test II was performed in the reverse order, with 10 MC of FE, followed by 5 MC of coupled motion.

(Mallinckrodt, Phillipsburg, New Jersey) was added to the lubricant to prevent bacterial and fungal growth. The wear protocol was similar but not identical to that described in the American Society for Testing and Materials (ASTM) F2423-05 standard guide,⁹ which had not yet been published when the testing was performed. Specifically, the rotations and loads used during testing are described in Table 1, and the motions and loads described in ASTM F2423 have been provided for comparison.

Throughout the test, the components were removed from the testing apparatus, cleaned, photodocumented, and weighed in a microgram balance (Mettler AX205-I; Mettler-Toledo Inc., Toledo, Ohio). The implants were dried with an inert gas and placed in a vacuum with a desiccant at 16 inches Hg for 30 minutes. Wear rates were calculated for each phase of the test by linear regression. The changes in mass of the samples were converted to volumetric wear using the known density of 316L stainless steel (ASTM F138) of 7.95 g/cm³. No load soak correction was needed because the metallic implants were known to be nonabsorbent.

Table 1
Comparison of motion and loading profiles used and final consensus motions and loading published in ASTM F2423-05

	Flexion-extension	Lateral bending	Axial rotation	Axial load
ASTM F2423-05 Profile I (5 MC)	$\pm 7.5^\circ$	$\pm 6.0^\circ$	$\pm 6.0^\circ$	100 N
Profile II (10 MC)	$\pm 9.7^\circ$	$\pm 4.7^\circ$	$\pm 3.8^\circ$	49 N
				148 N

A comparison between the wear rates in coupled motion and flexion-extension was performed. In addition, wear rates as a function of the order of testing were compared, to determine whether the testing methodology influenced the wear rate. Because of the small sample sizes, a nonparametric Wilcoxon test was conducted to determine statistical significance. $P < 0.05$ was considered significant.

At the conclusion of all the wear tests, the surfaces were characterized by optical microscopy, white-light interferometry (WLI), and scanning electron microscopy (SEM). Wear maps were created from calibrated digital optical micrographs to compare the shape and extent of the wear scar on the components. A detailed description and validation of the photogrammetric wear-mapping technique have been published previously for total knee replacement retrievals,¹⁰ but the adaptation of the methodology for the total disc components is summarized in brief here. Wear scars were individually outlined on the digital micrographs and scaled appropriately for the size of the wear-tested superior and inferior components. This process was repeated for each set of bearings. The individual wear maps were then superimposed by use of Adobe Photoshop (Adobe Systems, San Jose, California) to create a composite image of wear scars for all the wear-tested superior and inferior components. This technique permits direct visualization of the overlapping shapes and sizes of the wear scars.

WLI was performed with a NewView 5000 Model 5032 equipped with advanced texture analysis software, Metro-Pro 7.7.0 (Zygo, Middlefield, Connecticut). An overview of

this technique has already been described for total disc replacements.¹¹ WLI measurements were taken by use of both low and high fast Fourier transfer filter wavelengths fixed at 200 μm and 5 μm , respectively. The low and high filter frequencies were 0.005 μm^{-1} and 0.200 μm^{-1} , respectively. The average waviness (W_a), representing the texture of the low-frequency features, and the average roughness (R_a), representing the average roughness of the high-frequency features, were calculated for 10 to 12 fields of view per component, sampled in both the worn and unworn regions of the component. The average roughness and average waviness values in the worn regions of the wear-tested and retrieved components were compared statistically by use of an analysis of variance (JMP 8; SAS Institute, Cary, North Carolina), and $P < 0.05$ was considered significant.

Because the surface morphology of the wear surfaces appeared qualitatively similar under optical microscopy and WLI, SEM by use of secondary electron mode was performed on a single set of wear-tested components and 3 sets of retrieved components. An analytic scanning electron microscope (JEOL 6400 SEM; Oxford Instruments, England) fitted with an Inca X-Sight electron-dispersive spectroscopy detector (Oxford Instruments, England) was used for this analysis.

Retrieval analysis

We analyzed 10 implants from 9 patients (2 implants from women and 8 from men) undergoing cervical TDR revision surgery. The mean patient age was 36 years, with a range of 25 to 43 years. The artificial discs were either PRESTIGE[®] I ($n = 2$), PRESTIGE[®] II ($n = 2$), or PRESTIGE[®] Cervical Disc ($n = 6$). Of the 10 implants, 6 (all PRESTIGE[®] Cervical Discs) were retrieved in the United States, and the remainder were from Europe or Australia. Of the 6 retrievals in the United States, 5 took place during the 2-year IDE prospective randomized trial. One retrieval was part of the continued-access study completed after all patients were enrolled for the IDE trial. Implants were removed because of neck pain or radiculopathy and infection (Table 2).

Explant analysis included evaluation of clinical data and assessment of the extent of wear on the articulating surfaces. Components were initially visually examined under a stereomicroscope for evidence of wear and/or macrofatigue or microfatigue damage. The screws and screw holes were examined in all cases for evidence of fretting, corrosion, or fracture. An abbreviated variant of the Hood method was used to evaluate each face of the components for the presence/absence of damage modes typically observed in orthopedic implants.¹² For metal-on-metal articulating surfaces, the predominant damage modes were expected to include scratching, pitting, and third-body damage. Each damage mode was graded on a 0 to 3 scale: 0 corresponded to the absence of the damage mode; 1 corresponded to less than 10% coverage of the wear surface by the damage mode; 2

corresponded to 10% to 50% coverage by the damage mode; and 3 corresponded to greater than 50% coverage.

Preliminary analysis showed that the wear surface of the retrievals was characterized by a worn region generated by microabrasion. Therefore the same wear-mapping technique for the explants as was used for the wear-tested implants was adopted. The surfaces of 9 explants were further characterized by use of WLI, as described previously for the wear-tested components.

The bearing surfaces for all the explants were examined using SEM. Electron-dispersive spectroscopy was also performed at 5 kV to visualize and analyze biofilm deposits on the surface of the explants.

The anterior portions of the components were evaluated for evidence of impingement. Impingement was distinguished from iatrogenic damage if a similarly shaped and oriented wear scar was present on both the superior and inferior rim faces.

Results

Each wear-tested component exhibited a slightly discolored, macroscopically visible wear scar, which was apparent within the first 0.5 MC of testing and appeared to grow in size as the test progressed (Fig. 3). In both the early and later phases of the test, the wear scar was dominated by curvilinear scratches, characteristic of an abrasive wear process (Fig. 3). Thus the wear mechanisms evident on the final wear-tested components were consistent throughout the test.

Regardless, the wear rate was significantly influenced by the kinematics of the duty cycle. The wear rate was an order of magnitude higher during the coupled-motion phase of the test ($n = 6$, $0.74 \pm 0.30 \text{ mm}^3/\text{MC}$) when compared with the rate during flexion-extension ($n = 6$, $0.03 \pm 0.03 \text{ mm}^3/\text{MC}$) ($P = 0.004$). No significant difference was observed in the wear rate under coupled motion as a function of its order in the test sequence. In contrast, the wear rate during flexion-extension was higher when it was conducted in the second phase of testing after coupled motion ($n = 3$, $0.059 \pm 0.009 \text{ mm}^3/\text{MC}$) compared with tests ordering flexion-extension during the first phase of testing ($n = 3$, $0.004 \pm 0.003 \text{ mm}^3/\text{MC}$) ($P = 0.0495$). Results of the wear tests are shown in Figs. 4 and 5.

The explants also generally exhibited a slightly discolored wear region of varying dimension and location (Figs. 6 and 7). A summary of the wear and surface damage observations for the retrievals is presented in Table 3. Abrasive wear was found to be the dominant in vivo wear mechanism, with microscopic scratches generally oriented in the medial-lateral direction. All retrievals showed evidence of an abrasive wear mechanism on the bearing surface. The wear maps for the retrievals showed that the most frequently worn location was at the center of the trough and ball but that in several cases the worn area also extended into the posterior region of the bearing (Fig. 8). The anterior bearing surface of the explants was less frequently worn. These

Table 2
Clinical information for retrieved PRESTIGE® components

Implant	Implant design	Age at implantation (y)	Gender	Primary diagnosis	Level	Year of index surgery	Year of removal surgery	Implantation time (y)	Revision reason	Revision reason category
PRESTIGE 1	PRESTIGE	25	F	Disc herniation	C6/C7	2003	2004	0.8	Pain in the neck, right shoulder, and right arm accompanied by decreased sensation in the right little finger; revised to anterior cervical fusion at C5 through C7; symptoms resolved	Neck pain
PRESTIGE 2	PRESTIGE	41	M	Left C6/C7 disc herniation; left C6 radiculopathy	C6/C7	2003	2004	1.2	C6 radiculopathy; removal for adjacent-level fusion; revised to anterior cervical fusion; symptoms unresolved	Radiculopathy
PRESTIGE 3	PRESTIGE II	38	M	Unknown	C5/C6	2002	2003	1.8	Deep infection; revised to fusion with iliac crest bone; symptoms resolved	Infection
PRESTIGE 4	PRESTIGE I	31	F	Unknown	C5/C6	1998	1999	1.2	Unresolved neck pain; revised to fusion with iliac crest bone; symptoms unresolved	Neck pain
PRESTIGE 5	PRESTIGE I	42	M	Unknown	C6/C7	1998	2001	3.3	Disc removed to facilitate fusion at adjacent level (C5/C6); revised with Brantigan cage fusion and Codman plating from C5 through C7; symptoms resolved	None
PRESTIGE 6	PRESTIGE II	43	M	Unknown	C6/C7	2001	2001	0.3	Unresolved neck pain and posterior rigidity; improper device placement; revised to fusion with anterior cervical cage; outcome unknown	Neck pain
PRESTIGE 7	PRESTIGE	29	M	HNP	C6/C7	2004	2005	0.7	Unresolved neck pain and headache; revised to anterior fusion; symptoms unresolved	Neck pain
PRESTIGE 8	PRESTIGE	39	M	Disc herniation	C5/C6	2003	2005	2.3	Continued symptoms (neck and arm pain with radiculopathy); revised to anterior cervical fusion at C4 through C7; outcome unknown	Neck pain and radiculopathy; continued symptoms
PRESTIGE 9	PRESTIGE	35	M	Cervical spondylosis	C5/C6	2004	2006	2.2	Neck pain; sporting injury resulting in HNP at C6/C7; revised to anterior cervical fusion at C5 through C7; outcome unknown	Neck pain
PRESTIGE 10	PRESTIGE	32	M	Disc degeneration	C5/C6	2004	2009	4.1	Neck pain	Neck pain

Abbreviations: F, female; M, male; HNP, herniated nucleus pulposus.

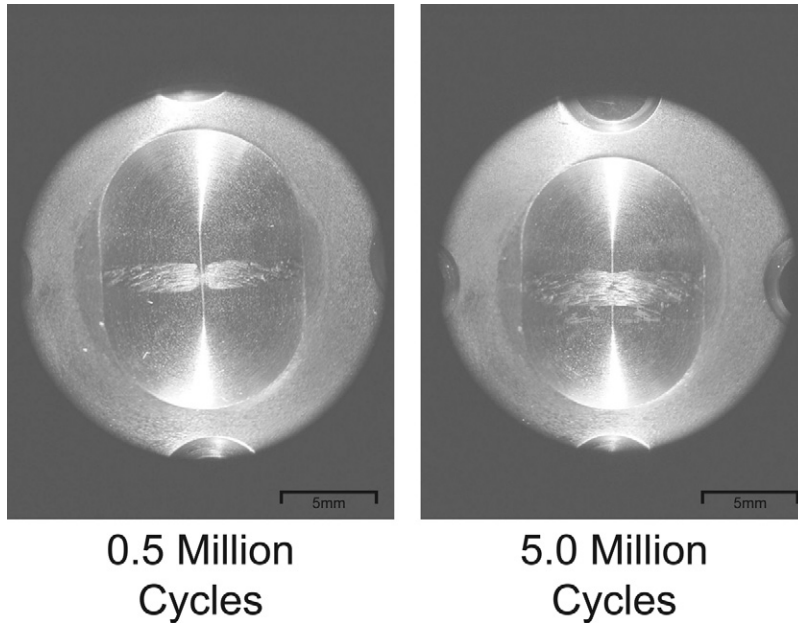


Fig. 3. Photomicrograph of inferior (trough) component after 0.5 and 5.0 MC of in vitro wear testing in coupled motion.

findings are consistent with the intended neutral-zone placement of the device, in which the superior ball is placed in the posterior region of the inferior trough. Although variability was also observed in the mapping of the wear-tested discs, the worn locations were more frequently located near the center of the bearing. None of the wear-tested devices had posteriorly biased wear scars.

Although the wear mechanisms from the explants were similar to those of the simulator-tested devices, the in vitro protocol resulted in more severe abrasion than observed in vivo (Figs. 8 and 9). The relative severity of the in vitro protocol was apparent on both optical microscopy and SEM (Fig. 9) and further quantified by WLI. The average surface roughness within the wear scar of the wear-tested components ($1.4 \pm 1.0 \mu\text{m}$) was found to be significantly greater than the average surface roughness of the retrieved explanted artificial discs ($0.12 \pm 0.10 \mu\text{m}$) ($P < 0.0001$). Similarly, the average surface waviness within the wear scar of the wear-tested components was found to be significantly greater ($0.54 \pm 0.47 \mu\text{m}$ for wear-tested components and $0.10 \pm 0.10 \mu\text{m}$ for retrieved explanted artificial discs). A summary of different metrics of the wear surface is summarized in Table 3.

Evidence of localized screw hole fretting and fretting near the heads of bone screws was noted in all cases (Fig. 10). SEM confirmed the presence of biological deposits and ruled out corrosive material removal at these locations. No fractures of any of the bone screws used for fixation were observed in this collection.

Evidence of anterior impingement was noted in 5 of the cases. Anterior impingement typically resulted in minor scratching or discoloration (Fig. 11). One explant, revised after 2.2 years because of neck pain after a sporting injury, showed evidence of moderate anterior impingement of the

superior and inferior endplate rims. Interestingly, the bearing also showed evidence of 2 regions of wear (Fig. 7E), suggesting that it operated in 2 separate configurations for a prolonged duration and consistent with subsidence. Evaluation of the radiographs confirmed posterior subsidence of the superior endplate in this case. The head of the locking screw of the superior component was fractured, with the remaining portion of the screw still within the hole. Examination of these parts under SEM showed a damage mechanism consistent with a fatigue crack propagation caused by the impingement of the head of the locking screw and the rim of the inferior endplate.

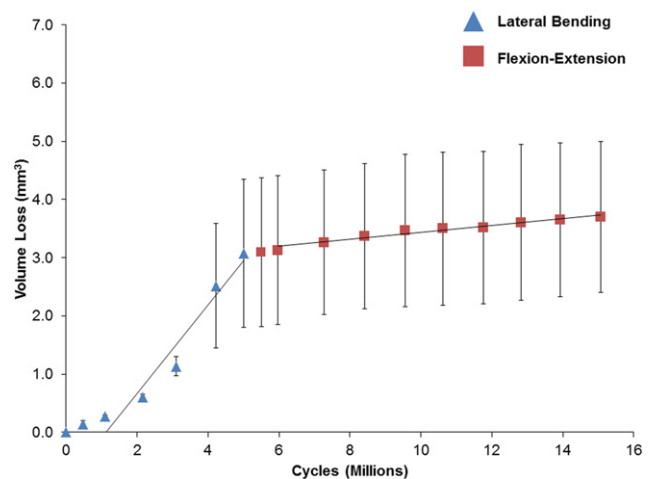


Fig. 4. Mean volume loss (in cubic millimeters) as a function of the number of cycles for samples undergoing lateral bending and axial rotation followed by flexion-extension ($n = 3$ samples). The wear rate for lateral bending and axial rotation was $0.760 \text{ mm}^3/\text{MC}$ ($R^2 = 0.95$), and the wear rate for flexion-extension was $0.059 \text{ mm}^3/\text{MC}$ ($R^2 = 0.96$).

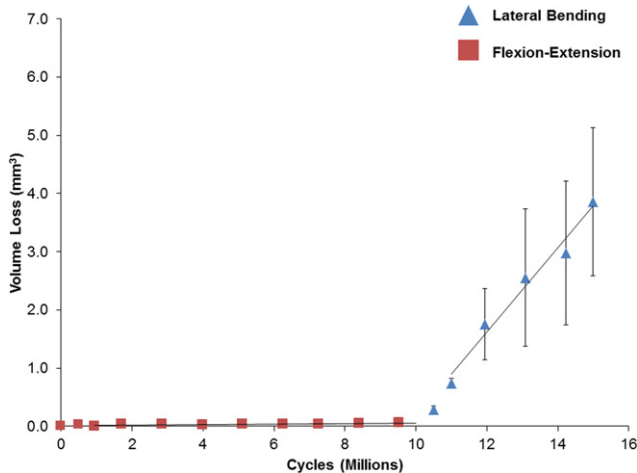


Fig. 5. Mean volume loss (in cubic millimeters) as a function of the number of cycles for samples undergoing flexion-extension followed by lateral bending and axial rotation ($n = 3$ samples). The wear rate for flexion-extension was $0.004 \text{ mm}^3/\text{MC}$ ($R^2 = 0.64$), and the wear rate for lateral bending and axial rotation was $0.720 \text{ mm}^3/\text{MC}$ ($R^2 = 0.97$).

Discussion

The results of this study strongly support the hypothesis that the abrasive wear mechanism observed in vivo is qualitatively replicated by the in vitro wear tests of the PRESTIGE® Cervical Disc. However, as evidenced by the deeper scratches and higher surface roughness of the wear-tested components, the in vitro tribological conditions appeared more severe than those occurring in vivo. These results also document the variability in the extent and location of the wear scars of the retrievals, which was also reflected in the wear-tested components. Overall, these retrieval data corroborate and build upon the previously published findings from 2 explants.⁸

An interesting and novel finding of this study was that the sequential ordering of the test sequences influenced the wear rates during the flexion-extension sequence of the

testing but not during the higher-wearing mode of coupled motion. These observations are consistent with the ball-in-trough design of the bearing surface, which is more conforming in the coronal plane than in the sagittal plane. Thus the higher wear rates during coupled lateral bending and axial rotation motions are likely due to the predominance of sliding, whereas during flexion-extension, the lower wear rate is attributed to the predominance of rolling contact. When flexion-extension was performed as the first test sequence, both bearing surfaces were in their smooth, as-manufactured configuration; hence the lowest wear occurred during this scenario. When flexion-extension was performed after coupled motion, the surfaces of both components had already become roughened by abrasive wear oriented in the curvilinear direction of coupled motion. Under flexion-extension, the articulating surfaces became polished, resulting in an increased wear rate. Thus the difference in wear rates under flexion-extension was attributed to the surface roughness at the initiation of the test sequence. Our data show that the wear rate of the PRESTIGE® Cervical Disc design in the simulator is governed by its response to lateral bending and axial rotation, rather than flexion-extension.

The morphology of retrieved wear surfaces confirmed that the surface damage was mostly produced during coupled motion in vivo, as opposed to flexion-extension. Specifically, the wear surfaces of the retrieved components were, at a microscopic level, dominated by parallel curvilinear scratches (Fig. 9B), which was remarkably similar to the wear-tested components. These findings differ substantially from the appearance of multidirectional, criss-crossing scratches on the wear surfaces of retrieved lumbar total disc replacements in previous studies.^{11,13} Because of the wear testing results, it is believed that the difference in surface morphology between the PRESTIGE® and previous lumbar retrievals is more likely due to the differing geometries of their respective bearing surfaces rather than reflecting fundamental differences in kinematics between the lum-

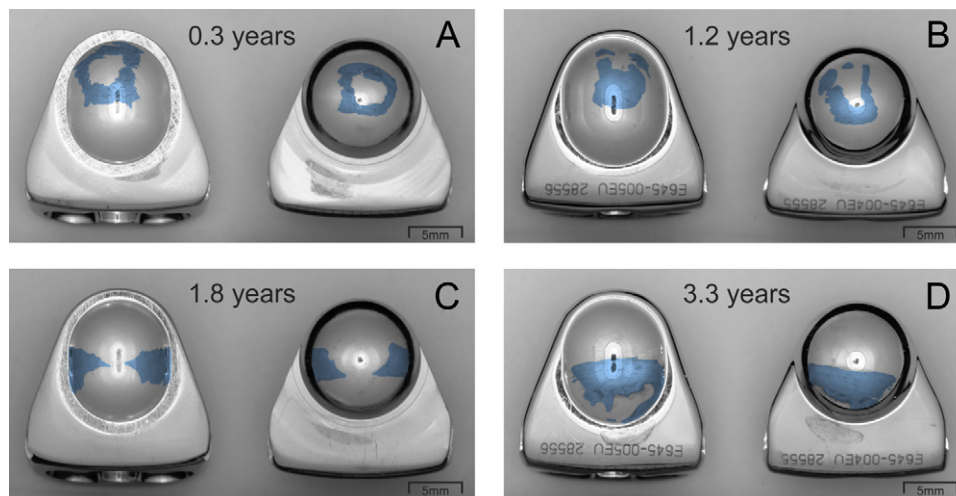


Fig. 6. Photomicrographs of PRESTIGE® I and II retrievals. The wear scar on the bearing surface has been highlighted in blue for each retrieval.

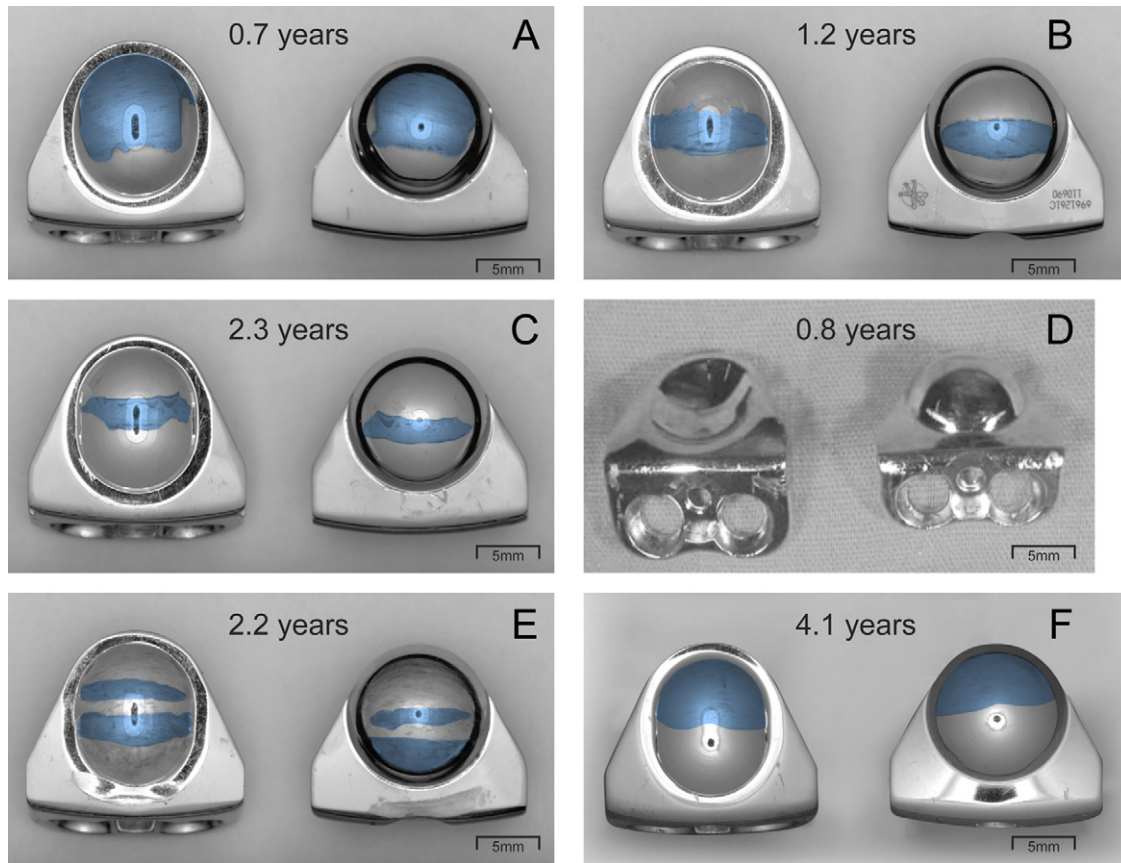


Fig. 7. Photomicrographs of PRESTIGE® retrievals. The wear scar on the bearing surface has been highlighted in blue for each retrieval, when discernible.

bar and cervical spine. Clinical radiographic studies clearly show motion of the endplate during flexion-extension.^{7,14} If the device were designed with a more conforming ball-in-socket articulation that prevented rolling contact, like the lumbar disc replacements, one would expect that the wear surfaces would show greater evidence of multidirectional scratching.

Given the microscopic nature of the *in vivo* wear, coupled with the comparatively greater uncertainty of the as-

manufactured surfaces, we were unable to measure the clinical wear rate for the device using only the retrieved components. It is clearly desirable to associate the number of cycles of simulator testing with the number of loading cycles that will be subjected to the implant per year. With wear simulators intended to replicate the forces and motions of the hip, 1 MC of testing is considered to replicate about 1 year of *in vivo* use.¹⁵ However, an analogous correlation

Table 3
Wear surface characteristics for retrieved PRESTIGE® components

Implant	Inferior damage score	Superior damage score	Total damage score	Screw fretting	Impingement	Superior wear scar (mean ± SD) (μm)		Inferior wear scar (mean ± SD) (μm)	
						R _a	W _a	R _a	W _a
PRESTIGE 1	Unknown	Unknown	Unknown	Unknown	Unknown	NA	NA	NA	NA
PRESTIGE 2	2	2	4	Yes	No	0.06 ± 0.01	0.02 ± 0.01	0.12 ± 0.04	0.05 ± 0.02
PRESTIGE 3	2	1	3	Yes	Yes	0.12 ± 0.02	0.03 ± 0.01	0.09 ± 0.03	0.03 ± 0.01
PRESTIGE 4	2	2	4	Yes	No	0.20 ± 0.18	0.06 ± 0.08	0.07 ± 0.03	0.01 ± 0.01
PRESTIGE 5	2	2	4	Yes	Yes	0.11 ± 0.02	0.03 ± 0.01	0.13 ± 0.10	0.09 ± 0.08
PRESTIGE 6	2	2	4	Yes	Yes	0.17 ± 0.04	0.06 ± 0.03	0.25 ± 0.11	0.08 ± 0.07
PRESTIGE 7	3	2	5	Yes	No	0.05 ± 0.04	0.02 ± 0.02	0.04 ± 0.02	0.01 ± 0.00
PRESTIGE 8	1	1	2	Yes	Yes	0.15 ± 0.07	0.08 ± 0.04	0.05 ± 0.00	0.02 ± 0.01
PRESTIGE 9	2	2	4	Yes	Yes	0.13 ± 0.04	0.08 ± 0.00	0.13 ± 0.03	0.10 ± 0.06
PRESTIGE 10	2	2	4	Yes	No	0.17 ± 0.04	0.16 ± 0.19	0.10 ± 0.05	0.11 ± 0.08

Abbreviations: NA, not available; R_a, average roughness; W_a, average waviness.

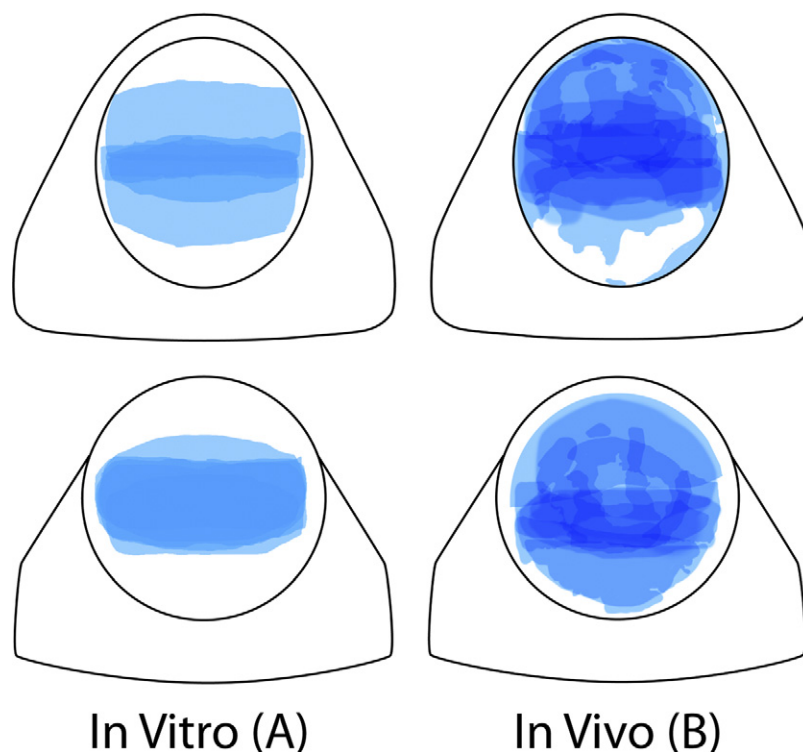


Fig. 8. Composite wear maps of the inferior and superior components, illustrating the variability in the size and extent of the wear scar for (A) in vitro wear-tested components ($n = 3$) at 15 MC after wear test I (Fig. 1) and (B) explanted components ($n = 10$).

between spine wear simulator cycles and the implantation time for the retrievals is not possible at this time. As illustrated in Fig. 3, as early as after 500,000 cycles of testing, the abrasive wear scars of the simulator-tested components already appeared harsher than those retrieved from patients after up to 4.1 years. Additional retrievals, with longer implantation times and greater magnitudes of clinical wear, will be needed to more clearly establish the association between time in the simulator and the implantation time within patients.

Metal ion studies of the PRESTIGE[®] TDR in patients may provide an indirect way of putting the simulator wear rates into clinical perspective by comparison with the established body of data in the literature for metal-on-metal total hip replacements. When performed with the appropriate procedures in a prospective longitudinal clinical study, changes in the metal ion levels in the blood and urine of patients are now accepted as providing an indication of the in vivo performance of metal-on-metal bearings.^{16,17} In the simulator, the wear rate of the PRESTIGE[®] device in lateral bending ($0.74 \pm 0.30 \text{ mm}^3/\text{MC}$) is comparable to the run-in wear rates of 0.2 to 0.8 mm^3/MC documented in the first million cycles of simulator studies for metal-on-metal total hip replacements.¹⁸ On the other hand, the available short-term clinical data indicate chromium and nickel metal ion levels that are an order of magnitude lower than those in patients with metal-on-metal hip replacements.¹⁹ Thus the available clinical data further support the current retrieval findings, which would also suggest that the “million cycles–

per-year” analogy for total hip replacements cannot be applied to the target patient population of the PRESTIGE[®] device. As a greater body of longer-term metal ion data become available, it may be possible to more precisely refine the clinically relevant timescale by which to interpret the simulator wear rates for cervical disc replacement.

Few detailed wear studies of total disc replacements have been published in the literature, making comparisons with previous studies difficult. Furthermore, international standards for wear testing, such as the ASTM F2423-05 standard guide,⁹ have been in use now for well over 5 years with few to no peer-reviewed data available for comparison to retrievals. Only minor differences between the reported protocol and the wear testing conditions recommended by ASTM F2423-05 were noted, which recommends a 100 N axial preload, $\pm 7.5^\circ$ of flexion/extension, and $\pm 6^\circ$ in both lateral bending and axial rotation. A greater axial load (148 N) and a higher range of motion ($\pm 9.7^\circ$) during flexion-extension than suggested in the ASTM standard were used, but because the test results for the PRESTIGE[®] device proved to be insensitive to this phase of the wear test, it is unlikely that adopting the testing ASTM protocol would influence these results. During the coupled-motion phase of the test, a lower axial load (49 N) and lower range of motion ($\pm 4.7^\circ$ in lateral bending and $\pm 3.8^\circ$ in axial rotation) were used than suggested by the standard. Had the ASTM recommended test parameters been adopted, the wear results would likely have been more severe than observed during testing. However, as underscored by the retrieval results, the

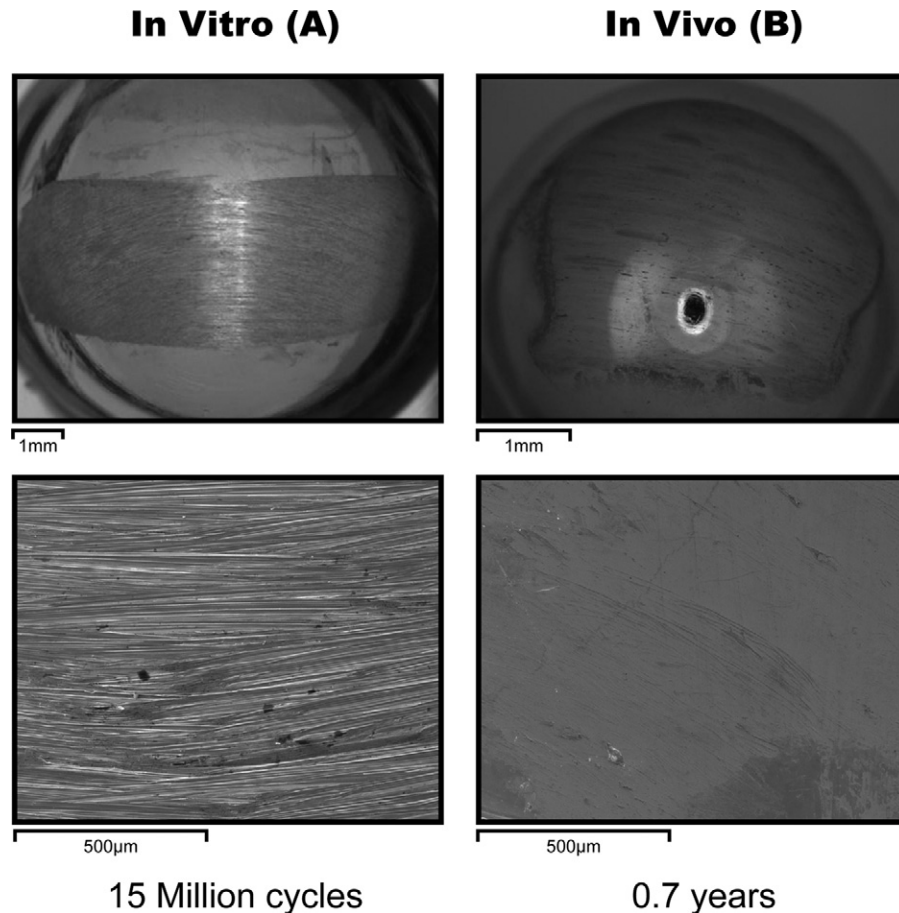


Fig. 9. (A) Photomicrographs and SEM micrographs of the superior (spherical) component at 15 MC after wear test I (Fig. 1). (B) Photomicrographs and SEM micrographs of an explanted, superior (spherical) component after 0.7 years in vivo.

chosen parameters produced abraded wear surfaces in the tested components that appeared similar in mechanism but more severe in magnitude than the observed wear patterns on the retrievals. Therefore, although the methods used are not identical to ASTM F2423, the explant data strongly support the validity and clinical relevance of the wear mechanisms generated by the motion and loading profile used. Furthermore, in vitro testing is not intended to perfectly reproduce the in vivo kinematics experienced by the device. Bench testing is not indicative of clinical performance.

Several of the retrievals in this study showed evidence of fretting between the bone screws and the screw holes in the anterior flange of the endplates. Similar observations were made during the previous analysis for 1 of 2 explants.⁸ Bone plates and fusion instrumentation using screw fixation and modular connections frequently show signs of fretting damage and/or corrosion.^{20,21} Therefore, given its occurrence with the current standard of care, the evidence of similar mechanisms occurring at the screw–screw hole interface of the design is not unexpected.

Mild to moderate impingement was observed in certain retrievals but not with the simulator components. The simulator testing was intended to replicate articulation after implantation in accordance with the manufacturer's instruc-

tions for use. Under these conditions, the endplates do not contact one another. In all the retrievals examined, impingement was an incidental finding, unrelated to the reason for revision. Impingement was typically associated with abrasive wear at the location of contact, similar to that at the bearing surface. Although moderate impingement was observed in 1 case and was associated with fracture of a locking screw, there was no evidence of fatigue or fracture damage to the bone screws or the metallic endplates.

Impingement has frequently been observed in retrieved acetabular components for total hip replacement,^{22–25} as well as in other retrieved artificial discs of different designs.^{11,26,27} Impingement in total hip replacements has been identified as an undesirable mechanism contributing to increased wear^{23,25} but is not necessarily the reason for revision. Many of the findings related to impingement in hip replacement, as in disc replacement, are based on observations of clinically failed and revised prostheses. It is often not straightforward to extrapolate the retrieval findings to the general patient population with well-functioning prostheses.^{11,19} Although it is clear that retrieved devices exhibit impingement, the frequency and relevance of this observation remain unclear. In the context of the successful prospective randomized IDE study,⁷ a single case of impinge-

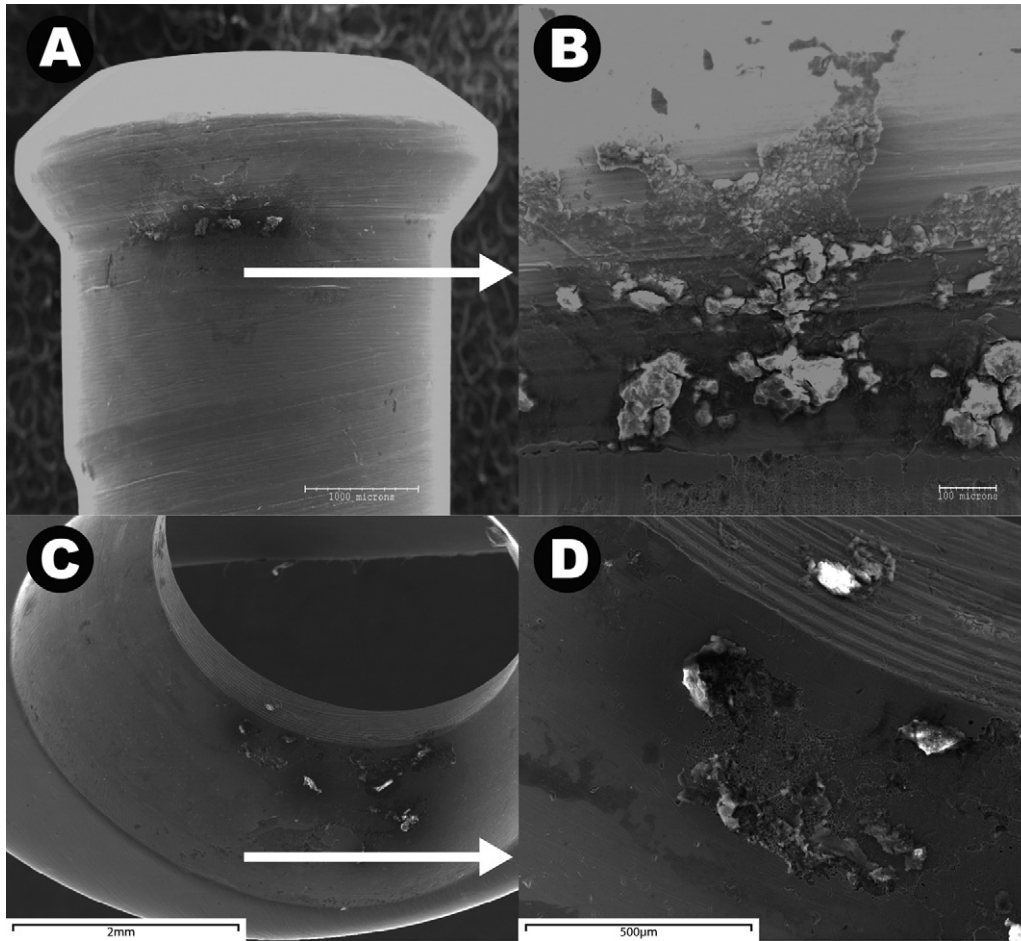


Fig. 10. Scanning electron microscopy of surface deposits on a retrieved screw head and screw hole: (A) screw head (20× magnification), (B) screw head (100× magnification), (C) screw hole (20× magnification), (D) screw hole (100× magnification).

ment was reported. Furthermore, clinical data show that, at least in the short-term, the serum metal ion levels in patients implanted with the PRESTIGE® artificial disc are an order of magnitude lower than those in metal-on-metal hip prostheses.¹⁹ Although impingement appears to be a clinically

rare event, its rarity in no way diminishes the importance of better understanding the clinical causes of impingement and its implications for both the device and the patient. The objective of the *in vitro* wear testing used for the device was to characterize the wear of the bearing surfaces only. No

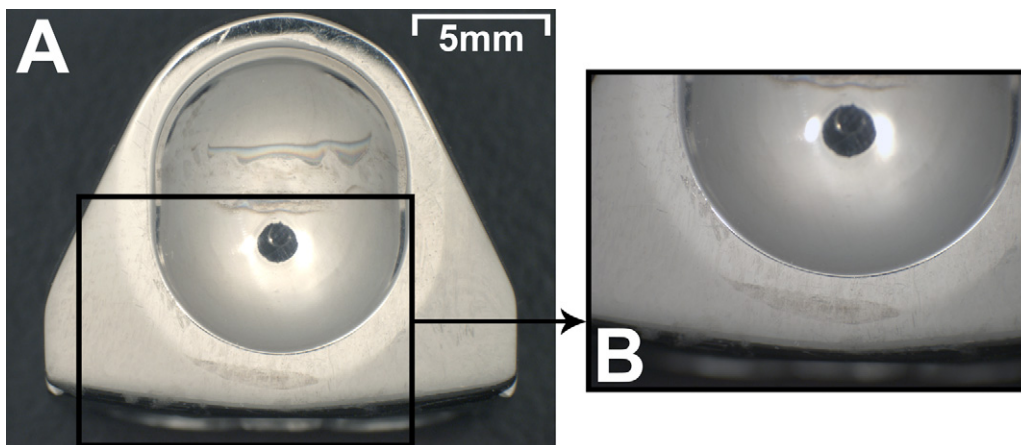


Fig. 11. Anterior impingement in a component retrieved after 2.3 years *in vivo*. (A) Photomicrograph of entire component. (B) Detail of impingement region.

impingement was observed on the devices tested in vitro. The observation of impingement further emphasizes the need for an in vitro test method to replicate and study this adverse mode of wear.

In summary, this study documented remarkable similarity between the wear mechanisms of components tested in vitro and explanted PRESTIGE® Cervical Discs after revision surgery. The curvilinear scratch patterns on both the wear-tested and retrieved components were consistent with the dominant coupled motions of lateral bending and axial rotation. Flexion-extension produced wear that was an order of magnitude lower in the simulator, because of rolling contact, as opposed to sliding. Despite the similarities in wear mechanisms, the severity of wear was found to be much greater during the in vitro test when compared with all the retrievals, regardless of their implantation time (range, 0.3–4 years).

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