

6-1-2006

# Explant Analysis of Total Disc Replacement

Paul A. Anderson  
*University of Wisconsin*

Steven M. Kurtz  
*Drexel University*

Jeffrey M. Toth  
*Marquette University, jeffrey.toth@marquette.edu*

Marquette University

**e-Publications@Marquette**

***Biomedical Engineering Faculty Research and Publications/College of Engineering***

***This paper is NOT THE PUBLISHED VERSION; but the author's final, peer-reviewed manuscript.*** The published version may be accessed by following the link in the citation below.

*Seminars in Spine Surgery*, Vol. 18, No. 2 (June, 2006): 109-116. [DOI](#). This article is © Elsevier (WB Saunders) and permission has been granted for this version to appear in [e-Publications@Marquette](#). Elsevier (WB Saunders) does not grant permission for this article to be further copied/distributed or hosted elsewhere without the express permission from Elsevier (WB Saunders).

## Explant Analysis of Total Disc Replacement

**Paul A. Anderson**

Department of Orthopedic Surgery and Rehabilitation and Department of Neurologic Surgery, University Of Wisconsin, Madison, WI

**Steven M. Kurtz**

Exponent, Inc., Philadelphia, PA

Implant Research Center, School of Biomedical Engineering, Science, and Health Systems and Department of Materials Engineering, Drexel University, Philadelphia, PA

**Jeffrey M. Toth**

Department of Orthopaedic Surgery, The Medical College of Wisconsin, Milwaukee, WI

Keywords

intervertebral disc arthroplasty, wear, bone in-growth, explant analysis

[Explant](#) analysis of human disc [prostheses](#) allow early evaluation of the [host response](#) to the prosthesis and the response of the prosthesis from the host. Furthermore, early predictions of failure and wear can be obtained. Thus far, about 2-3% of disc prostheses have been removed. Observed wear patterns are similar to that of appendicular prostheses including abrasions/scratching, burnishing, surface deformation, [fatigue](#), and embedded debris. Chemically the polymeric components have shown little degradation in short-term implantation. In metal on metal prostheses the histologic responses consist of large numbers of metallic particles with occasional [macrophages](#) and giant cells. Only rare cases of significant inflammatory response from polymeric debris have been seen.

Retrieval analyses of disc replacements in the peer-reviewed literature have thus far been limited to isolated case studies.<sup>1, 2, 3</sup> However, larger series of retrieved implants have been discussed at recent national meetings.<sup>4</sup> Although the published literature regarding retrievals is currently limited, the state of knowledge is expanding rapidly. Retrieved disc replacement components—whether metal-on-polyethylene or metal-on-metal (MOM)—should be evaluated both macroscopically and microscopically for the presence of damage modes typically observed in large joint arthroplasty components (eg, burnishing, abrasion, scratching, pitting, plastic deformation, fracture, fatigue damage, and embedded debris). Additionally the host response should be analyzed using standard as well as special histologic methods. This article is intended to provide the surgeon with a concise summary of the techniques of retrieval analyses and of the most relevant wear and fatigue damage modes that may be encountered, and the results of recent case series of retrievals of total disc replacement components.

## Retrieval Analysis

### What Is Retrieval Analysis?

Implants and medical devices may be retrieved (removed) from humans and analyzed for a number of reasons. These might include (1) dislodgment or movement of the device; (2) mechanical failure, or impending failure; (3) painful or dysfunctional performance; and/or (4) temporary devices removed in the normal course of treatment. Retrieval analysis seeks to obtain information on the biological performance of the implanted devices by analyzing the retrieved device and peri-prosthetic tissues. Biological performance includes information on the materials response (the response of the implant or device to the physiologic environment or mechanical loading) and the host response (the local and systemic response of the host to the implanted material). Examples of materials response would include evidence of creep, wear, fracture, craze lines, or other material degradation processes. Examples of host responses would include evidence of a chronic inflammatory response to wear debris in peri-prosthetic tissues, evidence of an overt or subclinical infection in peri-prosthetic tissues, sequestration of ions or particulate debris in remote organs, immune responses to antigenic substances, acute inflammatory responses to toxic degradation products, or other inflammatory events. Note that while retrieval analysis might completely document the materials response, only local host responses are likely to be found in peri-prosthetic tissues, and the systemic component of host responses may be missed.

## Why Perform Retrieval Analysis?

There are many reasons device retrieval analysis should be conducted. First, preclinical testing may not reveal all material or design defects. In a few cases, preclinical studies have not identified or elucidated device-related complications found later in clinical trials or, worse, after general market release. This might be due to misleading results from preclinical studies. It might occur if an animal model that mimics the human situation is inadequate. For example, preclinical testing of prototype devices in a healthy animal model that does not imitate human motion may yield results that cannot be directly extrapolated to humans. In describing the need for clinical trials, Dr. Jonathon Black indicates, "The most exhaustive engineering and biological tests of a new biomaterial can do no more than to remove the risk of gross adverse biological response in clinical application."<sup>5</sup> Retrieval analysis should be a valuable component of clinical trials for the following reasons. Data obtained from retrieval analysis during a clinical trial can be used to supplement the data on biological performance (materials and host response) gained from preclinical testing. Retrieval analysis performed during a clinical trial has the potential to answer important questions. Does the host response found in peri-prosthetic tissues correlate with the host response as characterized in preclinical biocompatibility tests? Is the materials response similar? Is the wear debris the same? Are there similar wear patterns on the devices?

Second, data from clinical trials may only involve a limited number of patients (perhaps 100 to 200), a short follow-up (perhaps 2 years or less), select surgeons, and uniform patient conditions. Retrieval analysis can shed light on device performance after general market release subsequent to the clinical trial. Retrieval analysis has the potential to answer many questions. Compared with the results obtained by select surgeons in the clinical trial, does the device performance change when others use the device? Does the device performance change when the device is used for other conditions or off-label use? Finally, only careful epidemiological studies (of normal and implant populations) can reveal cause-and-effect relationships between implants and pathologies. Histological analysis during retrieval analysis has yielded information on the association of implants with host response to biomaterials.

Third, and perhaps most importantly, retrieval analysis may provide valuable information on the material's response, the host response, the device design, and device performance that can be used as an iterative step in the device design process. That is, retrieval analysis might shed light on material selection, implant design, or surgical technique that may be used to improve the "next generation" of devices. This idea is perhaps best presented by Dr. Jonathon Black, who indicates, "From modest beginnings, the use of orthopaedic implants has grown to enormous proportions. Between 5 and 10 million metallic, polymeric, or ceramic parts are implanted each year; perhaps as many as 100 million parts have been used and millions remain in patients permanently, either by design or by chance. A vast experiment has been undertaken, involving millions of subjects and lasting far beyond the lifetimes of those who started it. The present situation is fairly described as experimental since it is widely accepted that there are uncertainties in predicting the performance of present devices and both medical and engineering deficiencies in many of them. In the normal course of such a widespread application of technology, we would expect a continual feedback from the user to the developer and the manufacturer that would lead to an evolutionary improvement and

convergence of design and practice.”<sup>6</sup> Data obtained from retrieval analysis provides useful information in the design and perhaps revisions to design of implants.

Finally, some authors have made the argument that clinicians have an ethical obligation to see that retrieval analysis is conducted, as it is a valuable source of information on patient care. Fielder proposes, “Removed organs are studied, not for their religious significance, but because they provide potentially valuable insights into their pathology. Retrieved implants have a similar significance, even though they are manufactured rather than natural parts of the body. A clinician who ignores a significant source of information—whether it is diseased organs or broken implants—fails to give the patient the benefit of the knowledge it can provide. This is an ethical failure, for it denies patients, present and future a known source of information relevant to their treatment. Thus, clinicians have an ethical obligation to gather as much information as possible from retrieved implants, just as they would for body tissues and organs.”<sup>7</sup>

## Mechanism of Wear

Many mechanisms are present that lead to wear and eventual failure of prosthetic devices containing articulations. These include abrasion and scratching, burnishing, surface deformation, fatigue, embedded debris, and chemical changes. Examination of explants can gain insights into these processes and validate predictions from simulators.

### Abrasion and Scratching

Abrasive wear, evidenced by scratching, is common to both metallic and polymeric components for total disc replacement. Abrasion may occur macroscopically and be apparent to the naked eye, or it may only be apparent when viewed using microscopy. Abrasive wear occurs when microscopic surface irregularities (also referred to as “asperities”) in one implant scratch the surface of the opposing counterface. In the case of metal-on-polyethylene, the asperities on the metallic implant produce scratches in the softer polymeric implant. In the case of CoCr alloy or stainless steel MOM implants, abrasive wear is produced by locally stiffer asperities, such as carbides, plowing through the relatively softer cobalt alloy matrix. During retrieval analysis, the pattern of scratches on an implant, whether macroscopic or microscopic, provide clues to the kinematics (motion) of the surfaces while they were in contact in vivo.

### Burnishing

Typically encountered with polyethylene disc components, burnishing gives the polymer surface a polished, glossy appearance. At a microscopic length scale, burnishing is associated with an adhesive wear mechanism, whereby the polyethylene surface wear occurs by adhesion to the metallic counterface. Highly magnified images of a burnished wear zone from a retrieved total disc replacement are shown in [Figure 1](#), and as noted, also show evidence of scratching, which denotes the presence of abrasion. For this reason, the dominant wear mechanism in metal-on-polyethylene articulations is considered to be a combination of adhesion and abrasion, as seen in total joint replacements.<sup>8, 9</sup>

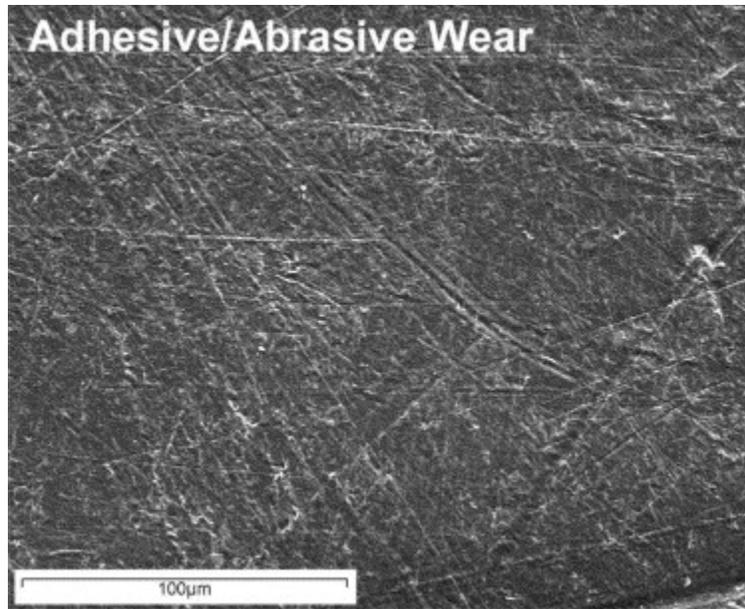


Figure 1. Adhesive/abrasive wear in a retrieved polyethylene artificial disc component (6 years in vivo) near the center of the dome. The scanning [electron microscope](#) image was taken at  $\times 500$  magnification.

#### Surface Deformation

Surface deformation, sometimes referred to plastic deformation or creep, corresponds to permanent changes in the shape or geometry of a total disc replacement, without the loss of material. Although surface deformation is not considered a wear mechanism, it does represent an undesirable damage mode. When permanent changes in the geometry of a device compromise its in vivo function or kinematics, surface deformation is considered a failure mode for the implant.

Surface deformation at a macroscopic level, visible to the naked eye, has thus far been observed at the rim of retrieved polyethylene total disc replacements ([Fig. 2](#)). As illustrated in [Figure 2](#), permanent deformation of the thin polyethylene rim can also be associated with burnishing and fracture caused by impingement of the metallic endplates. In MOM disc replacements, on the other hand, surface deformation has been observed to occur on a microscopic level and is typically only visible at high magnification using a scanning electron microscope (SEM).

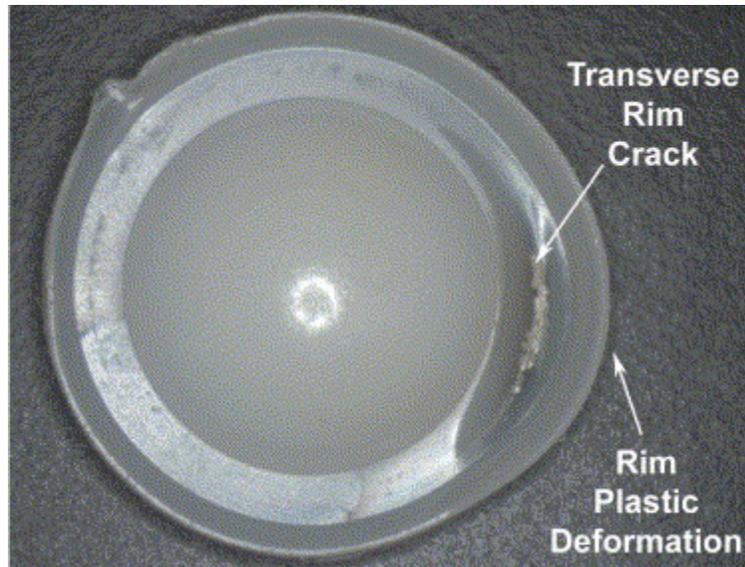


Figure 2. Plastic deformation and transverse rim fracture in a CHARITÉ disc replacement retrieved after 5 years [in vivo](#). (Color version of figure is available online.)

### Fatigue Wear and Fracture

Fatigue wear and fracture, especially of the rim, are a concern with polyethylene total disc replacements ([Fig. 2](#)). The etiology and incidence of fatigue wear and fracture in total disc replacement remains unclear, as it may require many years for progressive fracture mechanisms in a particular design to result in clinical symptoms. It is further unknown what role gamma sterilization in air, or in a low oxygen environment, has on the fracture mechanisms in disc replacement. These research topics are currently under investigation at our institution.

There have been no reports of fracture of a MOM disc replacement component in the literature. Similarly, implant fracture has not been a clinical concern for contemporary MOM-bearing surfaces in hip prostheses.

### Embedded Debris

Embedded debris is an unusual but noteworthy damage mode for disc replacements. We have observed embedded debris in two cases thus far, in which a fractured radiographic wire marker became trapped between the polyethylene core and a metallic endplate. The clinical significance of this wear mode is unknown at the present time. In large total joints, embedded debris is a potential roughening mechanism for the metallic component, which can result in accelerated wear. Additional retrievals are necessary to better understand the incidence and clinical significance (if any) of embedded debris in total disc replacements. Although metallic surfaces are also theoretically susceptible to embedded debris, including third-body scratching by the radiopacifiers contained in bone cement for total joint applications, there are no reports yet in the literature of third-body wear being observed in MOM disc replacements.

## Chemical Changes In Vivo

Although characterization of wear and damage mechanisms is perhaps one of the most fruitful goals of retrieval analysis, it is also equally important to investigate whether the biological environment has resulted in any long-term chemical changes to the implant material, whether it be composed of polymer, metal, or ceramic. With polyethylene components, in vivo oxidation may be a potential long-term damage mechanism for artificial discs.<sup>2</sup> However, in vivo chemical changes to implants may be incidental and unrelated to clinical performance. For polyethylene acetabular components, for example, severe rim oxidation has been shown to occur after 10 years in vivo, but the clinical relevance is unclear because these implants do not normally articulate at the rim.<sup>10</sup> With polyethylene total disc replacement components, rim failure has been observed to occur in vivo, but it is unclear if oxidation is the driving mechanism in all of these cases, or whether impingement alone may be sufficient to generate the types of fractures that have been documented to occur clinically.<sup>4</sup>

In vivo changes in chemistry may also occur with metallic components. In MOM hip implants fabricated from CoCr alloys, tribochemical deposits have been observed on the surface of retrieved implants.<sup>11</sup> These carbon- and oxygen-rich surface layers, which have a smoky or hazy appearance, are attributed to joint fluids, which become fused to the bearing surface. The biofilms are thought to have a beneficial effect, by providing a solid lubricant for the articulating surface. We have observed comparable biofilms on retrieved CoCr alloy, MOM disc replacement components, suggesting that a similar mechanism may be occurring.<sup>12</sup>

## Techniques of Retrieval Analyses

The goals of retrieval analyses are to evaluate the reaction of prostheses to the host and the host to the prosthesis. Thus it is essential during the early use of new devices that explanted cases be critically examined and the prostheses undergo critical examination. This will include analyses of peri-prosthetic tissues, and qualitative and quantitative examination of the explants themselves. The most useful document on how to conduct retrieval analysis is the American Society for Testing and Materials (ASTM) standard F561-05.<sup>13</sup> This standard practice covers “recommendations for the retrieval, handling, and analysis of implanted medical devices and associated specimens that are removed from patients during revision surgery, at postmortem, or as part of animal studies.”<sup>13</sup> This practice discusses the selections of tests for evaluation of the host and materials responses associated with retrieved implants. Testing can be customized based on the biomaterial used in the implant and the type of implant. For the analyses described below, institutional review board approvals were obtained before initiation of explant analysis. (Pertinent approval numbers include the following: University of Wisconsin [HSC 2002-326] and The Medical College of Wisconsin [HRRC 239-03]).

## Histologic Principles

In addition to routine H&E staining, several special stains can be used to evaluate the cellular and histological response to the device and particulate debris in peri-prosthetic tissues. These staining protocols included Mallory’s aniline blue connective tissue stain, Wright–Giemsa,

Toluidine Blue-O, and Oil Red-O/hematoxylin stain. The Mallory stain is an aniline blue connective tissue stain that stains bone purple to red based on maturity of the bone. Cartilage is stained pale to sky blue. Red blood cells are stained red orange. The Wright–Giemsa stain is also useful as a differential stain in serial sections, particularly for nuclear detail. Toluidine Blue-O is a metachromatic dye that stains viable bone light blue, while autograft and allograft is stained dark blue. This stain is widely used to determine bone ingrowth into porous coatings of prostheses. Toluidine Blue-O also is an excellent nuclear stain. All of these stains provide for differentiation of tissue type found in peri-prosthetic tissue samples adjacent to the device. These stains can also be used to characterize the host response in tissues adjacent to the devices by identifying and characterizing the cell type and population of cells in peri-explant tissues. [Table 1](#) of the ASTM F981-04 standard can then be used to quantify the cytological response found in peri-prosthetic tissues.<sup>14</sup> The result is a rating of 0, 0.5, 1, 2, or 3.0 for all inflammatory cells on a scale of 0 to 3.0. The ASTM standard also provides an interpretation of the host response (none, very slight, mild, moderate, marked) based on the inflammatory response in peri-prosthetic tissues.<sup>14</sup> The Oil Red-O protocol is ideal for the staining and recognition of polymeric wear debris (not all polymers are stained by this protocol) in peri-explant tissues.<sup>15</sup> Finally, the presence of birefringent polymeric debris is easily recognizable by polarized light microscopy. Polarized light microscopy is indispensable for the recognition of microscopic unstained birefringent polymeric debris that is not stained with routine or special staining.

Table 1. Reoperation Rates after Anterior Cervical Fusion or [Arthroplasty](#)

	<b>Reoperation Rate</b> <sup>□</sup>	<b>Same level</b>	<b>Adjacent Level</b> <sup>□</sup>
Arthroplasty	649 22 (3.4%)	16 (2.5%)	5 (0.8%)
Fusion	580 332 (5.5%)	16 (2.8%)	16 (2.8%)

Results are from 1229 patients enrolled in prospective investigations evaluating arthroplasty and fusion devices. Studies include the European Bryan and Prestige Disc, FDA Bryan and Prestige randomized controlled studies comparing arthroplasty to fusion, and control group from the Affinity cage fusion study.

Statistically significant  $P < 0.05$ .

### Polymeric Components

A wide range of well-established techniques has been developed to assess chemical changes in polyethylene and metallic components for disc replacement; a comprehensive list is provided by ASTM F561.<sup>13</sup> With polyethylene components, the preferred methods include characterization of crystalline content using differential scanning calorimetry, measurement of oxidation using Fourier transform infrared spectroscopy (FTIR), and measurement of mechanical properties using the small punch test (ASTM F 2183-02). Gel permeation chromatography is a method that measures molecular weights of polymers. In previous case studies of polyethylene disc replacements, FTIR, the small punch test, and GPC have been successfully employed.

## Metal on Metal

For metallic components, electron dispersive X-ray spectroscopy (EDS), in combination with SEM, is useful for characterizing the chemistry of the alloys and biological surface layers. As previously alluded to, we have successfully employed EDS to analyze biofilms on the surface of retrieved MOM implants fabricated from CoCr alloys.<sup>12</sup> These EDS analyses have enabled us to confirm that carbon- and oxygen-rich tribochemical reactions can occur on both the concave and the convex sides of MOM articulations in the spine. Further studies with an additional number of retrieved implants are necessary to determine the incidence of biofilms on CoCr alloy implants, as well as for disc replacements produced from stainless steel or metalloceramic alloy composites.

## Cervical Disc Replacement

Reoperation, and therefore, explantation of prosthetic cervical discs has occurred despite the relatively short-term follow-up. However, reoperations in fusion patients occur more frequently than in arthroplasty patients. Anderson and coworkers reviewed 1254 patients enrolled in prospective studies of fusion devices or in randomized controlled studies comparing fusion to disc replacement.<sup>16</sup> The etiology and incidence of reoperation were determined ([Table 1](#)). Overall, the follow-up was slightly longer in fused patients than arthroplasty. Reoperation in fusion patients compared with arthroplasty was significantly greater at 5.5 to 3.4%, respectively. This difference was statistically significant. More interesting was that the etiology for reoperation for adjacent segment diseases was 2.8% in fusions compared with 0.8% in arthroplasty. Although early in the follow-up period, this statistically significant difference implies validation of the fundamental hypothesis, leading to development of cervical arthroplasty: prevention of adjacent segment degeneration.

## Bryan Cervical Disc Explants

The Bryan Cervical Disc (Medtronic, Memphis, TN) is composed of titanium alloy shells or simulated endplates with a nuclear core of polyurethane. The prosthesis is covered with a polyurethane sheath and is lubricated by saline. Since this is a three-piece design, there are two bearing surfaces. The surface adjacent to the bone is dome-shaped, covered with titanium shards for bone ingrowth, and fits in specially milled cavities in the vertebral endplates. Over 10,000 have been implanted worldwide since 2000 and only about 20 have been known to be explanted.

Anderson and coworkers examined retrievals from 11 humans that were explanted 4 to 16 months following surgery.<sup>3</sup> Seven patients had revision for persistent pain and four had revision because of infection. The explants were analyzed by weight, size, surface condition by light microscopy, and chemically using FTIR spectroscopy and GPC. Peri-prosthetic tissues were stained with H&E and Oil Red-O (used to recognize polymeric debris) and analyzed using transmitted and polarized light microscopy.

The explanted Bryan disc prostheses revealed no wear or damage as compared with the metallic components. The polymeric nucleus appeared more yellow in color but had no other visible signs of damage. On histologic analysis of peri-prosthetic tissue no metallic debris was found. No inflammatory response was seen in most fields, which showed normal connective tissue. [Figure 3A](#) and [B](#) shows no inflammatory response adjacent to the birefringent polymeric debris in cartilage and fibrous tissues adjacent to the Bryan device. In a few sections near the prosthesis, polymeric debris was observed with occasional foreign body giant cells and macrophages in a chronic inflammatory response. In some cases there was no cellular response in relation to the debris.

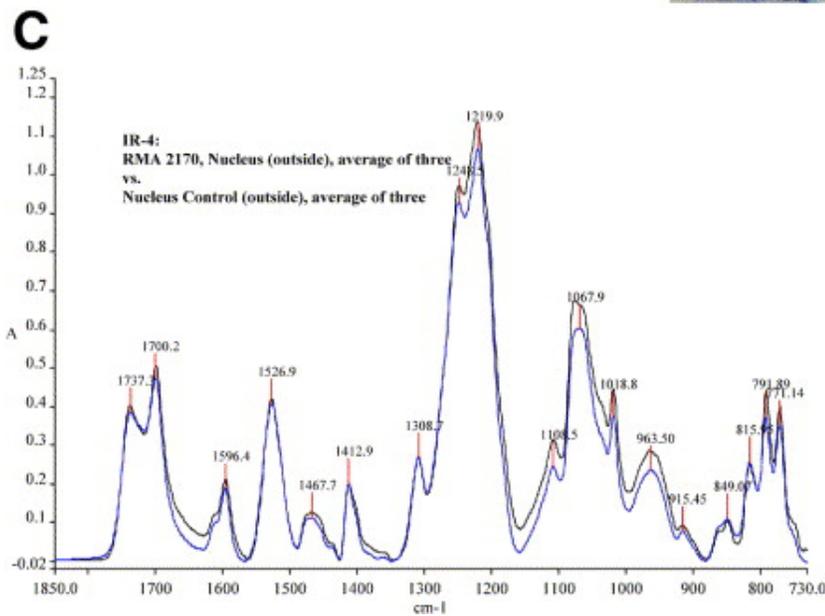
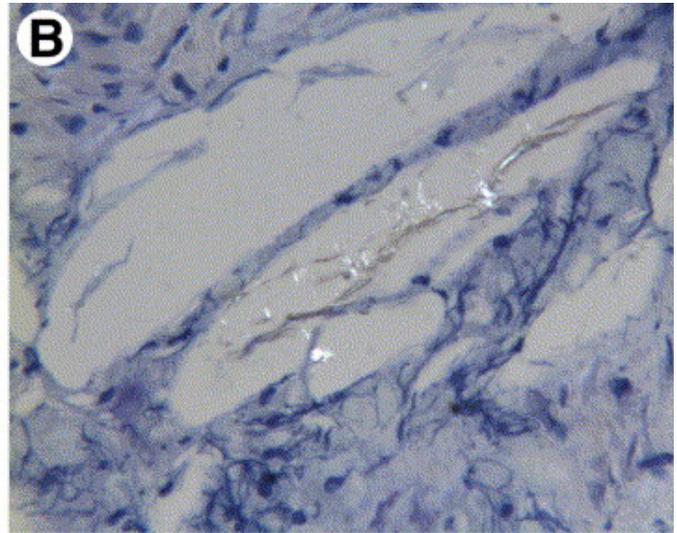
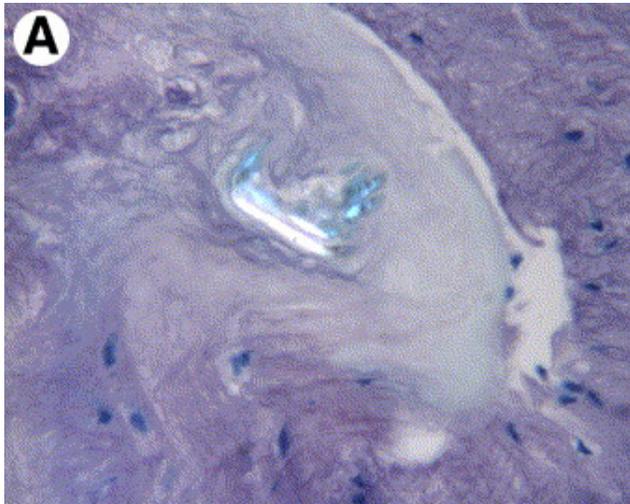


Figure 3. (A) Photomicrograph of [peri-prosthetic](#) tissues obtained from a Bryan disc. Polymeric particles were found in approximately 0.5 to 1% of the microscopic fields. In this field, no inflammatory response is seen adjacent to the birefringent polymeric debris. Both cartilage and fibrous tissues are seen in the microscopic field adjacent to the Bryan device. Polarized light,

[Wright–Giemsa stain](#), ×313. (B) Photomicrograph of peri-prosthetic tissues obtained from a Bryan disc approximately 18 months postoperatively. Polymeric particles were found in approximately 0.5 to 1% of the microscopic fields. In this field, no inflammatory response is seen adjacent to the birefringent polymeric debris. Fibrous tissues are seen in the microscopic field adjacent to the Bryan device. Polarized light, Wright–Giemsa stain, ×500. (C) [FTIR](#) spectroscopy of explanted Bryan disc and control from same manufactured lot. No difference is seen and no spikes indicating oxidation are present.

The polyurethane nuclear components were optically scanned for dimension and all were well within specifications. Since the prostheses were not initially measured and the dimensions change over time as a result of hydration and loading, an exact dimensional comparison to before implantation is not feasible. However, all retrieved specimens met specifications, which indicated they are greater than the minimal size that could be implanted, indicating that wear did not decrease beyond these limits.

FTIR spectroscopy demonstrated excellent correlation of explants to controls ([Fig. 3C](#)). No evidence of oxidation or other degradation processes were noted. Similarly GPC showed the molecular weight of the polymer was unchanged compared with controls, indicating no fragmentation.

Bone ingrowth into two explanted prostheses (at 3 and 8 months) was evaluated by sectioning the shells and staining with toluidine blue and measuring the ratio of bone to fibrous tissue in the porous surface using light microscopy.<sup>17</sup> Bone ingrowth averaged 32% and was distributed into all areas of the convex surface. This amount of ingrowth is slightly greater than that seen in total knee and hip replacements.<sup>17</sup>

## Prestige SS

The Prestige Stainless Steel (Medtronic, Memphis, TN) is a two-part prosthesis with a ball and trough-bearing surface. The device has flanges along the anterior vertebral cortices and is fixed by two screws. Two explants were available for analysis. Testing included peri-prosthetic histology and examination of the bearing surfaces using SEM. The devices were explanted at 18 and 38 months, one for infection and one to treat adjacent segment degeneration. An explanted Prestige cervical disc showing articulating surfaces of both device components is seen in [Figure 4A](#).

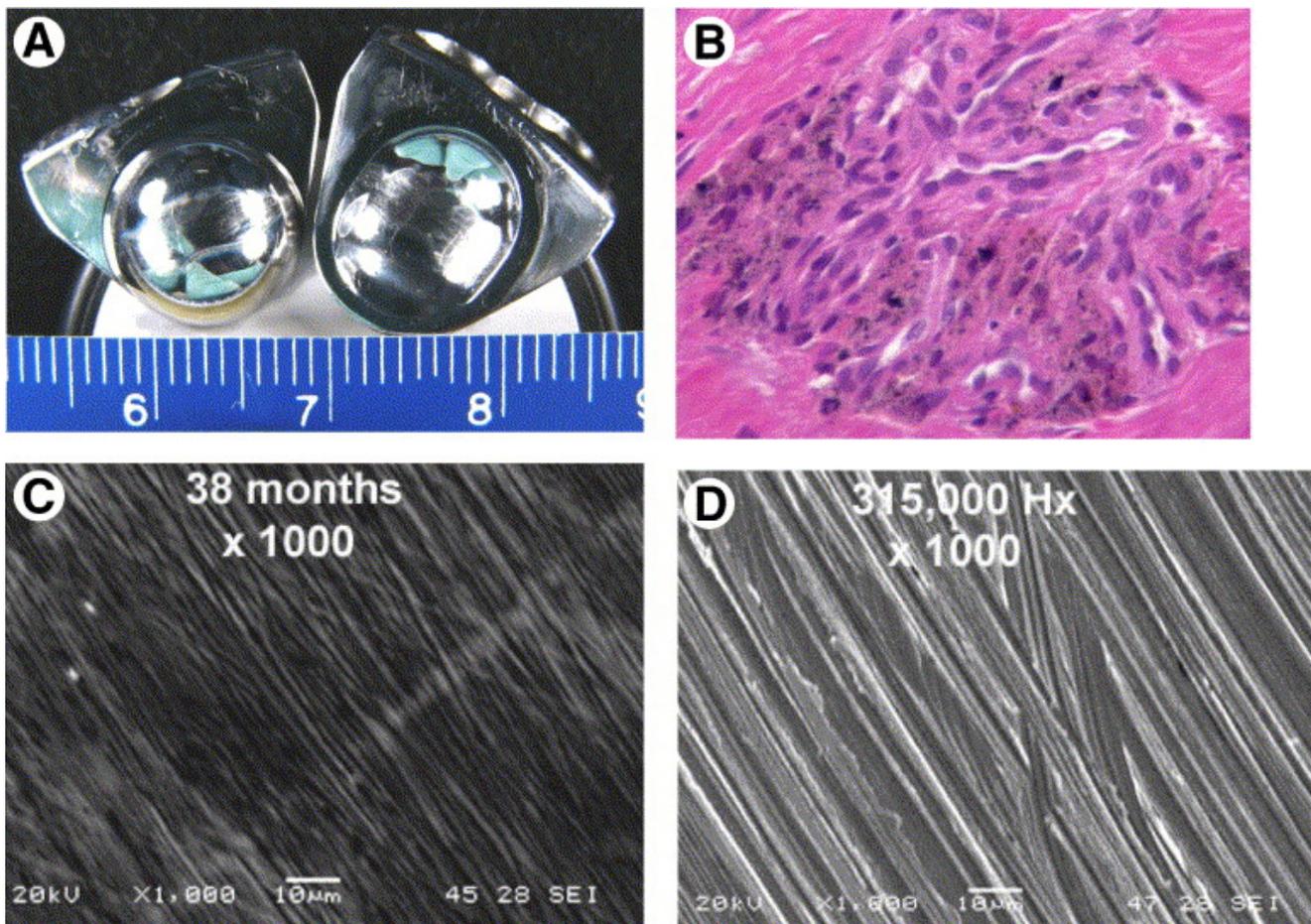


Figure 4. (A) Explanted Prestige Cervical Disc showing articulating surfaces of both device components. (B) Photomicrograph demonstrating fine metallic debris and chronic inflammatory response consisting of [macrophages](#) in [peri-prosthetic](#) tissues adjacent to Prestige Cervical Disc. H&E,  $\times 400$ . (C) High power  $\times 1000$  of wear patterns in explanted Prestige SS device at 38 months. Note the shallow depth of scars. (D) High power  $\times 1000$  of wear patterns in explanted Prestige SS device after 315,000 cycles of wear. The scar depth is far wider and deeper than [explant](#), indicating that the explant wear is significantly less than predicted by simulation.

Local fretting corrosion was noted at the screw heads. Metallic debris was found in all peri-prosthetic tissue samples. Macrophage and foreign body giant cells were seen in areas of metallic debris ([Fig. 4B](#) and C). However no osteoclastic response was observed. Metallic debris was seen more frequently anterior to the device than posterior.

SEM of the bearing surface demonstrated wear patterns similar to that observed in simulators. However the degree of wear as measured by the width and depth of scratches was significantly less than that seen in the wear simulators. The explant removed at 39 months and one after testing in a simulator for 315,000 cycles (less than 1 year) is shown in [Figure 4A](#) and D, respectively. The wear was significantly greater in the simulator despite being theoretically of a much shorter duration (less than 6 months) than seen in the explant (39 months).

## Conclusion on Cervical Explants

Two types of cervical devices, metal-on-polymer and metal-on-metal, were analyzed. The metal-on-polymer showed that wear occurred to the polymer but that a minimum tissue reaction was observed. Polyurethane appeared durable and did not elicit inflammatory response. The metal-on-metal device also demonstrated wear with production of metallic debris with a host response. However, no osteolysis was observed. The wear was similar in pattern to that predicted by simulators but significantly less wear was observed. This indicated that the simulations are very conservative and probably significantly overestimate in situ wear.

## Lumbar Disc Replacement

### SB CHARITÉ III

The CHARITÉ Total Disc Replacement (Depuy, Raynham, MA) is composed of two CoCrMo alloy endplates and a central core of ultrahigh molecular weight polyethylene. The device is unconstrained and has two bearing surfaces. Fixation is by small teeth projecting into the vertebral body and the surface of the approved device in the United States is currently smooth and without capacity for bone ingrowth. The current version of the device, the SB CHARITÉ III, has been implanted in Europe since the 1980s and has recently been approved for use in the United States. Textured endplates for this device have been available in Europe since 1997 and are expected to be approved for use in the United States in 2006.

David reported a case in which the entire rim of a disc replacement fractured from the central body of the core after 9.5 years in vivo.<sup>1</sup> This case of rim failure was attributed to severe oxidation degradation following gamma sterilization in air.

Kurtz and colleagues examined a single explant case of a CHARITÉ prosthesis removed for continuing pain 35 months after initial surgery and after a failed posterior fusion attempt using pedicular fixation.<sup>2</sup> The operative procedure of explantation was difficult due to scarring of the great vessels. The metal endplates were found to be loose and easily separated from bone. The polyethylene core was found to have an imperceptible transverse crack and only a small amount of surface damage. Histologically mild inflammation was present with foreign body cell reaction. Chemically only minimal oxidation of the polymer core was present and normal mechanics by the small punch test was observed.

Kurtz and coworkers performed an analysis of 14 CHARITÉ retrievals including the one case described above.<sup>4</sup> The severity and clinical manifestation of fatigue-related rim damage in the CHARITÉ design varied widely, ranging from full-thickness rim fracture ([Fig. 2](#)) to more benign radial crack formation. Radial cracks were observed in 8 of 14 and transverse cracks in 6 of 14 retrieved explants. Fatigue fracture was generally related to impingement by the metallic endplates.

Microscopic multidirectional scratches and crisscrossing wear paths at the dome of a retrieved lumbar, polyethylene TDR ([Fig. 1](#)), were seen and are consistent with microscopic abrasive wear mechanisms previously observed in retrieved hip replacement components.<sup>8, 9</sup> By

matching comparable regions of damage on two opposing bearing surfaces, it is further possible to infer the orientation of the components while they were in contact. These observations are consistent with wear patterns in the dome region of the core typical for total hip prosthesis and rim failure consistent with impingement or oxidation.

## Maverick

The Maverick (Medtronic, Memphis, TN) is a two-part MOM prosthesis with a ball and trough-bearing surface. Retrieval analyses have been reported for two explants.<sup>12</sup> The devices were implanted in two female 43-year-old patients at the L5/S1 level and were removed after 12 months or less for nerve root impingement and a metal allergy, respectively.

Retrieval analysis included the examination of the bearing surfaces using white light interferometry and SEM coupled with EDS to evaluate the wear mechanisms and analyze tribochemical deposits. Microscopic evidence of wear was found on both sets of components. The primary wear mechanism was microabrasion, which was evident by microscopic scratching of the articulating surfaces. Focal microplasticity was also observed at the apex of the dome and the A/P vertices of the cupped components. Surface deposits, manifested as a smoky or hazy discoloration, were observed on both sets of components. Using EDS, these deposits were confirmed to be carbon- and oxygen-rich films comparable in composition to those films previously observed in MOM hip joints.

## Conclusions

This section has summarized the methods and findings from retrieval analysis of explanted total disc replacements. Retrieval analysis of disc arthroplasty is still in its early stages, but the majority of the characterization techniques from hip and knee arthroplasty have been shown to be readily adapted for total disc replacements.

## Acknowledgments

The authors acknowledge Medtronic Sofamor Danek for research contracts to the Medical College of Wisconsin in support of this study. The authors also acknowledge and thank Amy Rizzo, MT(ASCP), for technical expertise in histological processing of the tissues.

## References

- 1** T. David, **Revision of a Charite artificial disc 9.5 years in vivo to a new Charite artificial disc: case report and explant analysis**, *Eur Spine J*, 14 (2005), pp. 507-511.
- 2** S.M. Kurtz, J. Pelozo, R. Siskey, *et al.*, **Analysis of a retrieved polyethylene total disc replacement component**, *Spine J*, 5 (2005), pp. 344-350.

- [3](#) P.A. Anderson, J.P. Rouleau, J.M. Toth, *et al.*, **A comparison of simulator-tested and -retrieved cervical disc prostheses. Invited submission from the Joint Section Meeting on Disorders of the Spine and Peripheral Nerves, March 2004**, J Neurosurg Spine, 1 (2) (2004), pp. 202-210.
- [4](#) S.M. Kurtz, A. van Ooij, J.P. Pelozo, *et al.*, Central core and rim damage in retrieved polyethylene total disc replacement components (2005), p. 17, Proceedings of the NASS 20th Annual Meeting, September 28, 2005. Philadelphia, PA.
- [5](#) J. Black, Orthopaedic Biomaterials in Research and Practice, Churchill Livingstone, New York, NY (1988), p. 314.
- [6](#) J. Black, Orthopaedic Biomaterials in Research and Practice, Churchill Livingstone, New York, NY (1988), p. 320.
- [7](#) J. Fielder **Issues in ethics**, IEEE Eng Med Biol, 11 (1992), p. 75.
- [8](#) H.A. McKellop, P. Campbell, S.H. Park, *et al.*, **The origin of submicron polyethylene wear debris in total hip arthroplasty**, Clinical Orthopaed Relat Res, 311 (1995), pp. 3-20.
- [9](#) A. Wang, A. Essner, V.K. Polineni, *et al.*, **Lubrication and wear of ultra-high molecular weight polyethylene in total joint replacements**, Tribol Int, 31 (1998), pp. 17-33.
- [10](#) S.M. Kurtz, C.M. Rimnac, W.J. Hozack, *et al.*, **In vivo degradation of polyethylene liners after gamma sterilization in air**, J Bone Joint Surg, 87A (2005), pp. 815-823.
- [11](#) R. Buscher, G. Tager, W. Dudzinski, *et al.*, **Subsurface microstructure of metal-on-metal hip joints and its relationship to wear particle generation**, J Biomed Mater Res B Appl Biomater, 72 (2005), pp. 206-214.
- [12](#) S.M. Kurtz, P. McCombe, L. Ciccarelli, *et al.*, In vivo wear mechanisms of a retrieved metal-on-metal total disc replacement. (2005), 12th International Meeting on Advanced Spine Techniques (IMAST), Banff, Alberta, Canada, July 7-9.
- [13](#) American Society for Testing and Materials (ASTM) standard F561-05, Standard Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids. Annual Book of ASTM Standards, ASTM International, West Conshohocken, PA (2005), pp. 136-151.
- [14](#) American Society for Testing and Materials (ASTM) standard F981-04, Standard Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone. Annual Book of ASTM Standards, ASTM International, West Conshohocken, PA (2005), pp. 378-382.
- [15](#) T.P. Schmalzried, M. Jasty, A. Rosenberg, *et al.*, **Histologic identification of polyethylene wear debris using Oil Red O stain**, J Appl Biomater, 4 (1993), pp. 119-125.

[16](#) Anderson PA, Sasso RC, Metcalf N, et al: Reoperation Rates for Cervical Arthroplasty vs. Arthrodesis Read at the 32nd Annual Meeting Cervical Spine Research Society, San Diego, CA, December 1, 2005.

[17](#) W.K. Jensen, P.A. Anderson, L. Nel, *et al.*, **Bone ingrowth in retrieved Bryan Cervical Disc prostheses**, Spine, 30 (22) (2005), pp. 2497-2502.

Disclosure: The author's institutions received research funding from Medtronic Sofamor Danek in support of the explant analysis described in the article.