Severe Impingement of Lumbar Disc Replacements Increases the Functional Biological Activity of Polyethylene Wear Debris

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Background: Wear, oxidation, and particularly rim impingement damage of ultra-high molecular weight polyethylene total disc replacement components have been observed following surgical revision. However, neither in vitro testing nor retrieval-based evidence has shown the effect(s) of impingement on the characteristics of polyethylene wear debris. Thus, we sought to determine (1) differences in polyethylene particle size, shape, number, or biological activity that correspond to mild or severe rim impingement and (2) in an analysis of all total disc replacements, regardless of impingement classification, whether there are correlations between the extent of regional damage and the characteristics of polyethylene wear debris.

Methods: The extent of dome and rim damage was characterized for eleven retrieved polyethylene cores obtained at revision surgery after an average duration of implantation of 9.7 years (range, 4.6 to 16.1 years). Polyethylene wear debris was isolated from periprosthetic tissues with use of nitric acid and was imaged with use of environmental scanning electron microscopy. Subsequently, particle size, shape, number, biological activity, and chronic inflammation scores were determined.

Results: Grouping of particles by size ranges that represented high biological relevance (<0.1 to 1-μm particles), intermediate biological relevance (1 to 10-μm particles), and low biological relevance (>10-μm particles) revealed an increased volume fraction of particles in the <0.1 to 1-μm and 1 to 10-μm size ranges in the mild-impingement cohort as compared with the severe-impingement cohort. The increased volume fractions resulted in a higher specific biological activity per unit particle volume in the mild-impingement cohort than in the severe-impingement cohort. However, functional biological activity, which is normalized by particle volume (mm^3/g of tissue), was significantly higher in the severe-impingement cohort. This increase was due to a larger volume of particles in all three size ranges. In both cohorts, the functional biological activity correlated with the chronic inflammatory response, and the extent of rim penetration positively correlated with increasing particle size, number, and functional biological activity.

Conclusions: The results of this study suggest that severe rim impingement increases the production of biologically relevant particles from motion-preserving lumbar total disc replacement components.

Level of Evidence: Prognostic Level IV. See Instructions for Authors for a complete description of levels of evidence.

Total disc replacement surgery is intended to both preserve motion and reduce pain in patients with severe lumbar disc degeneration[1,2]. Two lumbar total disc replacement devices have been approved for use in the United States: the Charité III (DePuy Spine, Raynham, Massachusetts) and the ProDisc (Synthes, West Chester, Pennsylvania). The Charité artificial disc is no longer used, but it has the longest clinical history, having been implanted in Europe since the 1980s; it consists of two CoCr end plates fixed to the adjacent vertebral bodies[1]. Between the end plates, a mobile, biconvex conventional ultra-high molecular weight polyethylene (hereafter referred to as *polyethylene*) core articulates against the concave bearing surfaces. Similar to hip and knee joint replacements, motion-preserving total disc replacements are

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TABLE I Summary of Clinical Information (Sorted by Increasing Implantation Time within Each Impingement Classification)

Case	Sample ID	Impingement Classification	Implantation Time *(yr)*	Revision Reason	Age at Implantation *(yr)*	Level
1	Maa003	Severe	6.24	Subsidence	46	L4-L5
2	Maa006	Severe	6.50	Grossly loose with osteolysis in sacrum	46	L5-S1
3	Maa002	Severe	9.18	Persistent pain in low back and both legs; flattening of polyethylene core; broken metal wire; subsidence	39	L5-S1
4*	Maa018	Severe	10.58	Persistent lumbar and right leg pain; disc degeneration at L3-L4, above a successful posterior fusion at L4-S1	33	L4-L5
5	Maa004	Severe	12.70	Anterior position of L4-L5 disc	32	L4-L5
6	Maa013	Severe	12.75	Instability—retrolisthesis at L1-L2 and L2-L3; pseudarthrosis at L4-L5; anterior position and possible wear	34	L3-L4
7	Maa019	Severe	16.10	Progressive anterior migration; pressure against aorta; back and leg pain	72	L4-L5
8	Maa023	Mild	4.61	Severe back and leg pain; multiple disc degeneration above prosthesis; lateral displacement of upper end plate	45	L5-S1
9	Maa010	Mild	8.47	Persisting pain after failed posterior fusion	34	L5-S1
10	Sal007	Mild	9.72	Faulty polyethylene	39	L5-S1
11	Maa009	Mild	10.21	Pain due to severe facet joint degeneration at L4-L5 and disc degeneration at L1-L2 and L3-L4	39	L4-L5

*Bisegmental Charité implants at L2-L3 and L4-L5.

prone to generate wear debris during a patient's daily activities[3-9]. The Charité, like the ProDisc, consists of two metallic end plates and a polyethylene core. However, the polyethylene core is firmly attached to the inferior end plate with the use of a locking mechanism. The superior surface of the core is dome-shaped and articulates against a concave superior metallic plate[10]. Until recently, published data on the role of polyethylene wear debris as a factor limiting the longevity of total disc replacements consisted of only a few case studies[11-13]. Additionally, the clinical implications of polyethylene debris in spine tissue are still poorly understood[6,14,15].

Polyethylene implant wear is affected by many variables, including surface roughness, cross-linking, wear path (distance, direction), and applied load[16-20]; however, the generation of wear debris can be attributed to four predominant wear modes[18]. Mode-1 wear occurs with articulation of intended bearing surfaces. Mode 2 occurs during articulation of a bearing and nonbearing surface, and Mode 3 occurs when abrasive third-body particles become entrapped between articulating surfaces. Finally, Mode 4 is the result of unintended articulation between nonbearing surfaces[18]. Impingement, typically ascribed to Mode-4 wear, is a source of concern in total hip and knee replacement.

The effects of impingement have been addressed by numerous studies of revised artificial hip, knee, and shoulder components[21-26]. Specifically, malfunctioning metal-on-metal[27-31] and ceramic-on-ceramic[32-37] hip bearings as well as rim fracture of highly cross-linked polyethylene liners[38,39] have been considered in the context of impingement. Recently, total disc replacement retrieval studies have also identified impingement patterns on the polyethylene core of Charité and ProDisc implants[13,40-43]. In the Charité implant, the kinematics of the superior bearing surface cause locking of the core, resulting in an accumulation of rim damage, radial cracking, and rim fracture[12,40,44].

While impingement remains a clinical concern in total disc replacement, the extent to which impingement affects polyethylene particle formation remains uncertain. Thus, we sought to determine (1) differences in polyethylene particle size, shape, number, or biological activity that correspond to mild or severe rim impingement and (2) in an analysis of all total disc replacements, regardless of impingement classification, whether there are correlations between the extent of regional damage and the characteristics of polyethylene wear debris.

Materials and Methods

Patient Selection

Forty-eight SB Charité III total disc replacements (Link, Hamburg, Germany) were retrieved during revision surgery, and analyzed between 2002 and 2008. Components were made of polyethylene GUR 412 resin and gamma-air sterilized or GUR 1020 resin and gamma-inert sterilized and polymer barrier packaged, which allowed exposure to air. We recently reported the clinical information, oxidative properties, and surface damage of this cohort[44,45]. In eleven of these forty-eight cases, periprosthetic tissue samples were retrieved as well. The revisions in these eleven patients was indicated at an average of 9.7 years (range, 4.6 to

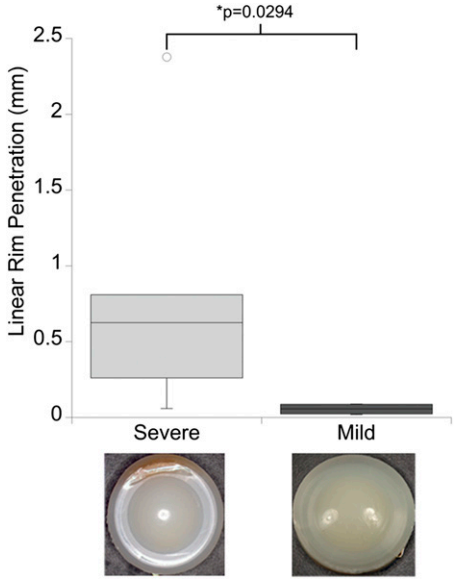

Fig. 1

Linear rim penetration was increased for retrieved Charité total disc replacement components exhibiting severe impingement. Provided are boxed ranges of the 25th to 75th percentile and whiskers showing the 1st and 4th quartiles. The length of the whiskers is equal to 1.5 times the box height; anything outside of this range is considered an outlier and is shown as an open circle. Representative images are also provided to illustrate both impingement classifications. A significant difference between impingement groups was determined with use of independent t tests.

16.1 years) because of persistent back and leg pain and, in one case, osteolysis (Table I). To confirm that the subset of total disc replacements was representative of the published collection, oxidation, the hydroperoxide index (see Appendix), and surface damage (see Appendix) were compared with those of all forty-eight total disc replacements; no significant differences were observed. The extent of rim impingement was determined on each device. Components with evidence of minimal rim contact (e.g., minor burnishing; Fig. 1, right) were considered to have mild impingement, whereas evidence of severe rim contact (e.g., large areas of burnishing, fatigue, and subsurface cracking; Fig. 1, left) was considered to indicate severe impingement. The frequency of severe impingement (seven of the eleven total disc replacement retrievals that included removal of tissue and thirty-seven of the forty-eight replacements overall) was higher than that of mild impingement (four of eleven and ten of forty-eight). One total disc replacement exhibiting signs of severe impingement was considered separately because of the presence of osteolysis.

Implant and Wear Particle Analyses

Wear particles from the eleven tissue specimens were isolated, imaged, and morphologically characterized. Their osteolytic potential was determined with use of modifications of the functional biological activity and specific biological activity indices described by Fisher et al. (see Appendix)[46,47]. Specific biological activity is the estimated biological activity (per unit volume) of wear debris based on particle sizes within three ranges—those that stimulate the highest inflammatory responses (<0.1 to 1-μm particles), those that stimulate an intermediate response (1 to 10-μm particles), and those that stimulate the lowest response (>10-μm particles). Functional biological activity is the product of the specific biological activity and total component-wear volume. This metric provides the weighted biological importance of wear debris by taking into account the total volume/number of particles, which directly reflects the amount of component wear.

Particle purity was validated by means of Fourier transform infrared spectroscopy (see Appendix). Tissue specimen inflammatory response was assessed histologically. Gross mechanical damage of the polyethylene cores (penetration depth) was measured with use of a calibrated micrometer. The cores' oxidation status was assessed (after lipid extraction) with Fourier transform infrared spectroscopy, as was hydroperoxide content. The technical details of these various protocols and indices are presented in the Appendix.

Statistical Analysis

It was determined that, with a statistical power of $p = 0.80$ and a significance level of $\alpha = 0.05$, ten total disc replacement samples were sufficient to detect a 1.5-fold change in functional biological activity between impingement groups. Distributions of particle morphological characteristics were assessed for normality with use of the Shapiro-Wilk test. For normally distributed data, differences between impingement groups were evaluated with use of independent t tests. For nonparametric data, Mann-Whitney U tests were used to evaluate differences in particle characteristics. Correlations between particle characteristics and inflammation, implantation time, penetration, and oxidation were determined with use of the Spearman rank correlation test.

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Results

Differences in Particle Characteristics and Inflammatory Responses Between Mild and Severe-Impingement Groups

No significant differences in mean particle size, shape, or number were observed on the basis of the total disc replacement-impingement classification. The mean particle size (equivalent circular diameter) was 0.56 ± 0.11 μm in the mild-impingement group compared with 0.81 ± 0.30 μm in the severe-impingement group ($p = 0.15$) (see Appendix). In both impingement groups, characterization of particle shapes revealed a combination of granular and, to a lesser extent, fibrillar morphologies (Fig. 2). The mean aspect ratio did not differ significantly between the mild and severe-impingement groups ($p = 0.77$) (see Appendix). Roundness values were also comparable between the groups ($p = 0.78$). Form factor was similar between the impingement groups as well ($p = 0.58$); however, in both groups, the form factor of the submicrometer particles was increased (more rounded) compared with that of the larger particles ($p < 0.01$). Finally, the mean particle number per gram did not differ significantly between the impingement groups ($p = 0.10$).

A chronic inflammatory response to the presence of wear particles was observed in all patients (see Appendix). The majority

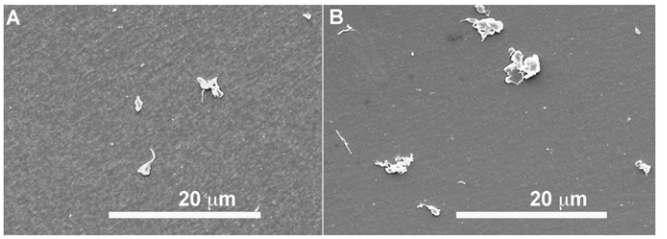

Fig. 2

Representative environmental scanning electron microscope images of polyethylene particles from Charité components with mild (**Fig. 2-A**) and severe (**Fig. 2-B**) impingement.

TABLE II Particle Sizes and Numbers for Individual Particle Size Ranges

Impingement Classification	Equivalent Circular Diameter (μm)			Particle Number		
	<0.1-1 μm	1-10 μm	>10 μm	<0.1-1 μm	1-10 μm	>10 μm
Severe*	0.42 ± 0.05	1.97 ± 0.21	18.70 ± 4.83	$1.95 \pm 0.52 \times 10^9$	$4.52 \pm 3.04 \times 10^7$	$3.17 \pm 2.98 \times 10^5$
Mild*	0.38 ± 0.08	1.91 ± 0.11	12.86 ± 3.35	$1.40 \pm 0.44 \times 10^9$	$1.13 \pm 0.73 \times 10^7$	$0.71 \pm 0.28 \times 10^5$
P value	0.26	0.54	0.03†	0.11	0.03†	0.07

*The values are given as the mean and standard deviation. †Significantly higher in the severe-impingement group. Significance was evaluated with use of Mann-Whitney U tests and set at $p < 0.05$.

of the inflammatory cells observed throughout the fibrous tissue were enlarged macrophages/histiocytes filled with small wear debris. Similarly, when large wear debris was present, giant cells surrounded the particles. The macrophage/histiocyte responses were similar in the severe and mild-impingement groups ($p = 0.75$), given the comparable volumes of particles in the <0.1 to 1-μm size range. However, there was a significant increase in giant cells ($p = 0.04$) associated with the increased volume of >10-μm particles in the severe-impingement group. The overall chronic inflammatory responses (combined macrophage and giant-cell scores) in the severe-impingement group tended to be higher than that in the mild group ($p = 0.08$), presumably as a result of the increased volume of particles of all three sizes.

We also evaluated particles according to size ranges with high biological relevance (<0.1 to 1-μm particles), intermediate biological relevance (1 to 10-μm particles), and low biological relevance (>10-μm particles). This analysis showed the mean equivalent circular diameter of the particles in the >10-μm range to be larger in the severe-impingement group ($p = 0.03$), and tissues from this group contained more particles in the 1 to 10-μm size range ($p = 0.03$) (Table II).

Differences in Biological Activity of Particles Between Mild and Severe-Impingement Groups

Significant increases in the volume fraction, V(r), of particles in the <0.1 to 1-μm and 1 to 10-μm size ranges were observed in the group of total disc replacements with mild impingement ($p = 0.04$ and $p = 0.03$, respectively, compared with the severe-impingement group), whereas the volume fraction of >10-μm particles was increased in the severe-impingement group ($p = 0.01$) (Fig. 3-A). After application of ranked biological activity scalars, B(r), particles from total disc replacements with mild impingement had increased specific biological activity compared with those in the severe-impingement group ($p = 0.02$) (Fig. 3-B).

The total particle volume (mm^3/g of tissue), with respect to both the 1 to 10-μm and the >10-μm size range ($p = 0.01$) and the cumulative value for all three size ranges ($p = 0.01$), was

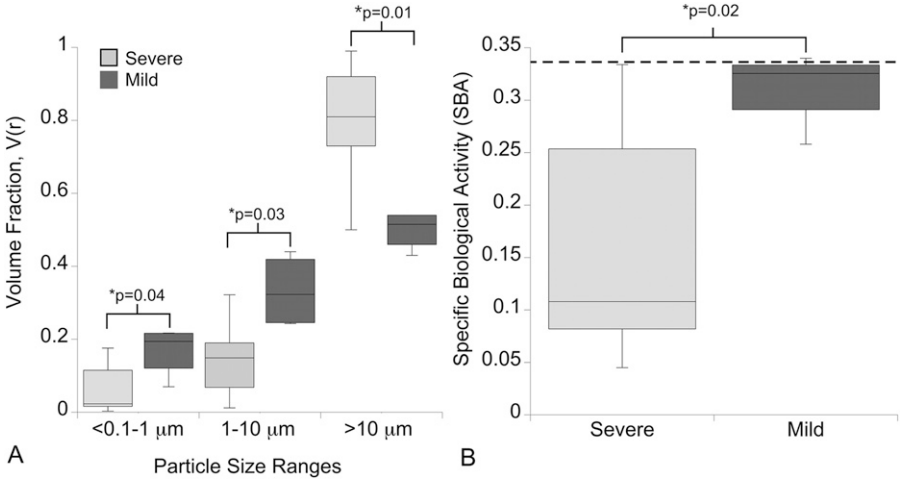

Fig. 3

Differences in volume fraction (V[r]) and specific biological activity were observed on the basis of impingement classification. **Fig. 3-A** Total disc replacements with mild impingement had an increase in the volume fraction of particles in the <0.1 to 1-μm and 1 to 10-μm-size ranges, whereas the severe-impingement group had an increase in the volume fraction of particles of >10 μm. **Fig. 3-B** As a result, specific biological activity was increased for the mild-impingement group. Provided are boxed ranges of the 25th to 75th percentile and whiskers showing the 10th and 90th percentiles. The dotted line represents the specific biological activity of polyethylene wear debris from the single total disc replacement revised because of osteolysis. Significant differences between impingement groups were determined with use of Mann-Whitney U tests.

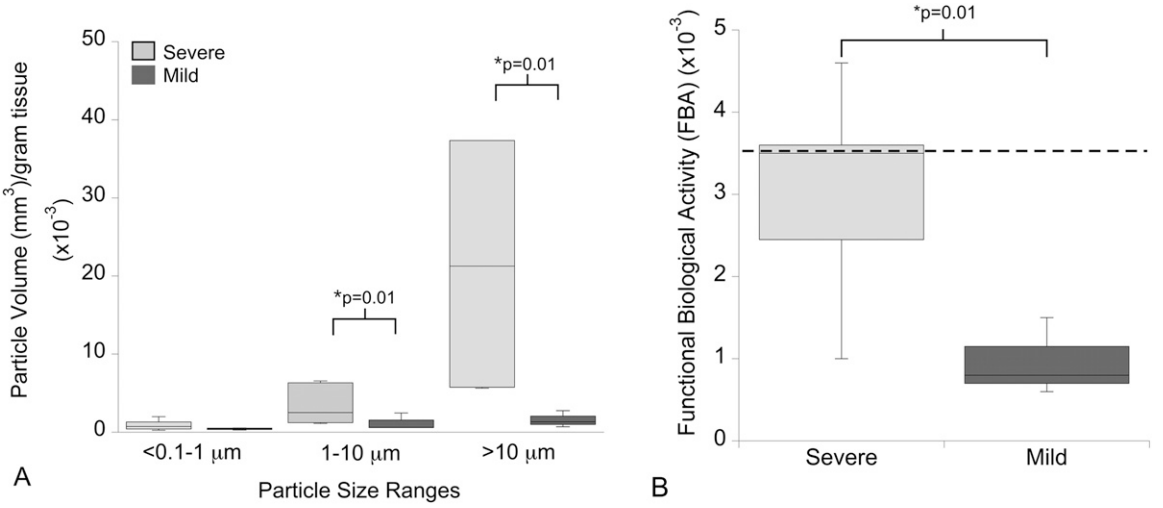

Fig. 4

Differences in the total particle volume and functional biological activity were observed on the basis of impingement classification. **Fig. 4-A** Total disc replacements with severe impingement had an increase in the volume of particles in the 1 to 10-μm and >10-μm size ranges as well as the cumulative value for particles in all three size ranges. **Fig. 4-B** Functional biological activity (specific biological activity normalized by particle volume [mm^3/g of tissue]) was increased in the severe-impingement group as compared with that in the mild-impingement group. Provided are boxed ranges of 25th to 75th percentile and whiskers showing the 10th and 90th percentiles. The dotted line represents the functional biological activity of polyethylene wear debris from the single total disc replacement revised because of osteolysis. Significant differences between impingement groups were determined with use of Mann-Whitney U tests.

significantly higher in the severe-impingement group than it was in the mild-impingement group (Fig. 4-A). As a result, functional biological activity (specific biological activity normalized by particle volume [mm^3/g of tissue]) was significantly higher in the severe-impingement group ($p = 0.01$) (Fig. 4-B). The single total disc replacement revised because of osteolysis had among the highest specific biological activity and functional biological activity values of any specimen in either impingement group.

When both groups were considered together, the functional biological activity showed a positive correlation with giant-cell number and the overall chronic inflammatory response (combined macrophage and giant-cell scores) ($\rho = 0.62$; $p = 0.04$) (see Appendix). However, there was no correlation, in either impingement group, between the functional biological activity and the level of implantation (Kruskal-Wallis test, $p = 0.76$).

Correlations Between Regional Total Disc Replacement Damage or Oxidation and the Characteristics of Polyethylene Wear Debris

Analysis of the retrieved total disc replacements revealed varying amounts of regional penetration, oxidation, and hydroperoxide (see Appendix). Neither oxidation nor hydroperoxide indices were correlated with particle morphology or calculated biological

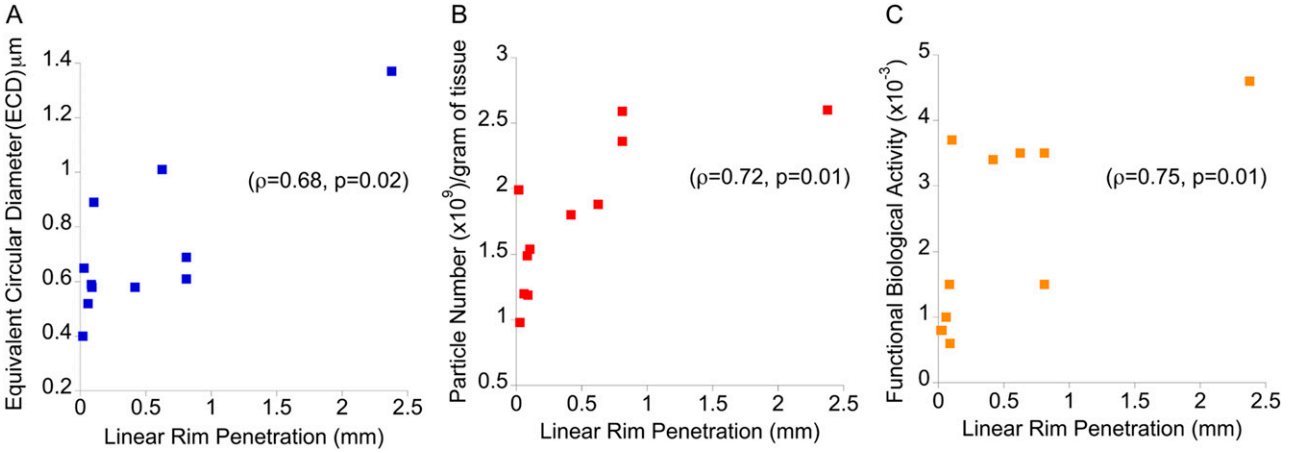

Fig. 5

Positive correlations were observed between increasing linear rim penetration (mm) and mean equivalent circular diameter (μm) (**Fig. 5-A**), polyethylene wear particle number (×10^9/g tissue) (**Fig. 5-B**), and functional biological activity (**Fig. 5-C**) with use of Spearman rank correlation. Shown are the ranked magnitudes of each variable.

activities. However, linear rim penetration was significantly increased in the severe-impingement group ($p = 0.03$) (Fig. 1). In addition, the extent of linear rim penetration was positively correlated with increasing particle size ($\rho = 0.68$, $p = 0.02$) and particle number ($\rho = 0.72$, $p = 0.01$) (Figs. 5-A and 5-B). Furthermore, linear rim penetration was positively correlated with increasing functional biological activity values ($\rho = 0.75$, $p = 0.01$) (Fig. 5-C).

Discussion

Collectively, to our knowledge, these data represent the largest characterization of submicrometer and micrometer-sized polyethylene debris from revised lumbar total disc replacements. In addition, this first implementation of biological activity to particles isolated from periprosthetic tissues highlights the differences in particle characteristics due to impingement. Specifically, this study shows that severe impingement exacerbates the production of biologically relevant polyethylene wear debris, which may represent a serious negative consequence of this unintended wear mode. Thus, the results of this study serve as an important benchmark both in terms of understanding the clinical relevance of polyethylene wear particles in the spine and for the future development of test methods to simulate total disc replacement rim impingement in vitro.

We acknowledge that this study had limitations. First, the number of tissue samples available for particle analysis was small. However, when we compared all forty-eight total disc replacements with the subset of eleven with available periprosthetic tissues, we observed no differences between measurements of oxidation or penetration[45]. Second, the lower cutoff of wear particle size was based on the 0.05-μm pore size of the polycarbonate membranes used to filter the samples. According to Scott et al.[48], this pore size is expected to exclude 2.8% of the total particle number, thereby having a negligible effect on the total particle volume. In addition, Richards et al.[49] showed that nanoparticles are rarely observed when a pore size of 0.017 μm is used, a finding that agrees with that of Lapcikova et al.[50], who observed nanoparticles in only two of 100 hip-tissue samples from patients. The biological activity of nanoparticles is currently under investigation[51-54]. A third limitation of our investigation was its focus on only one of the implant designs (the Charité device) currently approved by the FDA. This design was chosen because it has the longest clinical record and represented the largest cohort with retrieved tissue in our collection. While there are substantial differences between the ProDisc and Charité devices, both exhibit mainly adhesive/abrasive wear on the conforming dome region. Thus, impingement and its effect on wear debris remain a clinical concern for current and future Charité and ProDisc motion-preserving devices. Finally, the use of particle volume per gram of tissue to determine the functional biological activity differs from the original method of Fisher et al., who utilized component wear volume ($mm^3/10^6$ cycles)[46,47]. The volume of particles per gram of tissue depends on both the amount of tissue used and the tissue region[55]. While the implant volumetric wear rate is a direct measurement, this measurement was not possible in the present study because of the iatrogenic damage of the polyethylene cores. This damage manifested as deep, parallel scratches or complete tearing of the polyethylene core that appeared to have occurred during extraction. There is, however, a moderate positive correlation ($\rho = 0.55$) between functional biological activity based on particles isolated from hip tissues and functional biological activity based on hip implant volumetric wear (unpublished data). Therefore, the functional biological activity values in our study[56] are analogous to, but not directly comparable with, the results reported by Fisher's group[46].

Studies other than our own[6,57] focusing on the characteristics of polyethylene particles in the lumbar spine are, for the most part, limited to an in vitro study by Serhan et al.[58]. In their study, particle sizes visualized with an environmental scanning electron microscope ranged from submicrometer to >10 μm; however, the mean particle size (5 μm) was an order of magnitude larger than the mean particle size (0.72 μm) in the current study. Additionally, the total disc replacement components tested in that in vitro study were not loaded to induce rim impingement. Overall, the sizes of the particles from the total disc replacements with mild and severe impingement in our study were similar to those in previous studies of particles isolated from hip and knee tissues[59,60], and the particle number in our severe-impingement group was in the same range as particle loads found in hip implant tissues (2.3×10^9 particles in the size range of 0.05 to 2.0 μm)[57]. However, while the range of particle sizes observed in our patients with mild (0.40 to 0.65 μm) and severe (0.52 to 1.37 μm) impingement of the total disc replacement appeared to be influenced by differences in conformity and wear patterns, the mean particle size, shape, and number did not differ significantly between groups. Importantly, grouping of particles according to biologically relevant size ranges revealed differences. Specifically, particles from total disc replacements with evidence of severe impingement were larger and more numerous in the >10-μm and 1 to 10-μm size ranges, respectively. Thus, the use of mean particle characteristics alone as opposed to size range stratification is less sensitive in distinguishing differences associated with multiple modes of component wear.

In general, prevalent wear mechanisms affecting motion-preserving total disc replacements include adhesive/abrasive wear of the highly conforming dome region and predominantly fatigue wear at isolated points of rim contact[12,40,44]. In a radiographic study of sixty-six ProDisc total disc replacements, Käfer et al. found the prevalence of posterior component impingement to be 11% to 15% (depending on the lumbar level and/or extension angle) and that impingement was more frequently observed at the L4-L5 vertebral level and for bisegmental implants at the L4-L5 and L5-S1 levels[13]. Importantly, it was not possible to directly evaluate whether total disc replacement impingement affected wear particle characteristics in that in vivo study.

Our findings of correlations of increasing linear rim penetration with increasing particle size and number are also

supported by hip and knee retrieval studies. After both total hip arthroplasty and total knee arthroplasty, contact resulting from impingement contributes to localized cracking and fragmentation, to an increase in wear, and to an overall altered distribution of forces[24,39,61,62]. Rundell et al. observed similar findings using a validated computational model of mobile-bearing total disc replacements in the lumbar spine: they showed that peak contact stress significantly correlated with rim penetration rate (mm/yr) at the interface of the superior footplate and the central polyethylene core[41].

Since the original biological activity model was initially published, it has been implemented in simulator studies to investigate the effect of roughness[63,64], wear path complexity[65-69], polymer cross-linking[64,68-71], and/or type of material[72,73] on particle generation. On the basis of differences in the biomaterials and/or testing parameter(s) used in vitro, published values of specific biological activity have ranged from 0.08 to 0.94[46,70,74]. In the current study, specific biological activity values exhibited substantial variability, ranging from 0.05 to 0.34 as a result of changes in the particle volume fraction of each size range. In the mild-impingement group, the decreased mean particle size in the >10-μm range contributed to the lower volume fraction in that range and concurrently to the increased volume fraction in both the <0.1 to 1-μm and the 1 to 10-μm size ranges. In contrast, the decreased volume fraction of the <0.1 to 1-μm and 1 to 10-μm-sized particles from the total disc replacements with severe impingement resulted in reduced values of specific biological activity. To eliminate the volume-fraction bias, functional biological activity was implemented, to account for the overall volume of particles in each size range. Functional biological activity was increased in the severe-impingement group as a result of the increased volume of particles per gram of tissue across all size ranges. In the single case of osteolysis, the increases in both specific biological activity and functional biological activity were due to the large volume fraction of biologically relevant particles and a large overall volume of wear debris. However, given the similar levels of penetration at the dome and rim, it is unclear whether the particles originated during normal articulation at the dome or during severe impingement at the rim.

At present, the biological activity model does not include the contributions of pro-inflammatory factors in vivo (e.g., adsorption of endotoxin/protein[75-80] and/or the extent of polyethylene particle oxidation[81-83]), so further investigation of the inflammatory cytokine responses to wear debris in the spine is warranted. Nevertheless, these results lend support to the use of biological activity calculations in combination with particle size and number in individual size ranges to illustrate differences in total disc replacement wear modes. The effect of impingement on the overall biological activity potential highlights the importance of developing test methods that reproduce a comprehensive range of total disc replacement wear modes in vitro.

Appendix

eA Details of the methods for wear particle isolation, imaging, wear particle analysis, particle validation, inflammatory response evaluation, penetration analysis, and oxidation analysis; tables showing implant oxidation values, linear penetration values, equations and definitions of wear particle characteristics and biological activity indices, and values for particle size, shape, and number; and a figure demonstrating a comparison of the Fourier transform infrared spectroscopy findings with previous spectra are available with the online version of this article as a data supplement at jbjs.org. ■

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