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Comparative in Vitro Analysis of Wear Particles Generated by a Viscoelastic Disc Versus 2 Articulating Total Disc Replacements

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Background: Wear debris is a known contributor to orthopaedic implant failure, particularly in joint arthroplasty. The wear characteristics of spinal total disc replacement (TDR) remain under-investigated. Spinal TDRs have been shown to produce wear particles that elicit strong inflammatory reactions. Submicron debris, in particular, is associated with osteolysis and implant loosening. Viscoelastic TDR (VTDR) devices have emerged to address these risks.

Methods: Five AxioMed Freedom Lumbar Disc (FLD) devices underwent 30 million cycles (10 million each in flexion-extension, lateral bending, and axial rotation) of wear testing in phosphate-buffered saline solution at 37°C using an MTS servohydraulic system. Wear fluid samples were collected every 5 million cycles and analyzed using scanning electron microscopy and laser diffraction. A 30-million device cycle count simulates 240 years of lumbar bending. Wear rates were calculated in milligrams per million cycles (mg/MC). Comparative data for CHARITÉ (DePuy Synthes) and prodisc L (Centinel Spine) discs were obtained from the United States Food and Drug Administration (FDA) Summary of Safety and Effectiveness Data.

Results: The AxioMed device showed a mean wear rate of 1.7 mg/MC, in comparison to 5.7 mg/MC for the prodisc L. The number-average particle diameter was 1.9 μm, with a mass-average particle diameter of 49 μm, which was notably larger than those reportedly produced by the CHARITÉ (0.2 μm) and prodisc L (0.4 μm) devices, which is promising because larger particles (>1.0 μm) are less likely to induce inflammatory responses. No mechanical failures were observed during the 30 million cycles.

Conclusions: The AxioMed 1-piece VTDR device demonstrated a lower wear rate and larger, less biologically reactive, particles compared with articulating TDRs, suggesting a reduced risk of osteolysis and longer implant lifespan. No mechanical failures were observed, even after each 10-million-cycle interval, which simulates approximately 80 years of lumbar-bending motions. This study focused on particle size; further work is warranted to characterize composition and particle burden.

Clinical Relevance: This 1-piece VTDR may offer a safer and more durable alternative for motion-preserving lumbar spine surgery. Further clinical and retrieval studies are warranted.

Degenerative disc disease remains a leading cause of chronic low back pain and disability worldwide[1-5]. While many patients achieve relief through nonoperative management, a substantial proportion experiences persistent symptoms requiring surgical intervention[6-8]. Spinal fusion has traditionally been the surgical standard; however, it eliminates motion at the treated segment and may accelerate adjacent-segment degeneration due to altered biomechanics[9-14]. In response, articulating ball-and-socket total disc replacement (TDR) was introduced to preserve motion and better mimic native spinal kinematics[15-17].

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Despite the biomechanical advantages of TDR devices, concerns have emerged regarding wear debris, particularly polymer and metal particles produced through articulation or surface degradation. Submicron wear particles from joint arthroplasties have been linked to osteolysis, inflammatory cytokine release, tissue necrosis, and implant loosening[18]. These effects are largely mediated through macrophage activation and the release of pro-inflammatory mediators, such as tumor necrosis factor-alpha (TNF-α) and interleukin-1 beta (IL-1β)[19-21]. While such mechanisms have been well documented in large joint replacements, the biological consequences of wear particles from TDRs remain comparatively under-investigated.

Earlier assumptions that TDRs would not generate clinically notable wear debris have been challenged by increasing evidence showing periprosthetic inflammation, pseudotumor formation, metallosis, and even neural cell toxicity[22-28]. Comparisons of periprosthetic tissues from total knee replacements and lumbar TDRs have revealed similar particle-size ranges, but a higher concentration of macrophages and foreign-body giant cells surrounding spinal implants[22]. This may be attributed to the complex mechanical environment of the spine, which endures multidirectional loading, higher localized stresses, and diverse implant-tissue interfaces.

Moreover, some spinal arthroplasties have shown revision rates exceeding 30% within 10 years, with wear-related complications being a primary contributor to mid-to-long-term failure[29,30]. Particles generated from TDRs are hypothesized to arise from various mechanisms, including abrasive, adhesive, surface-fatigue, and tribochemical reactions, particularly in metal-on-metal or metal-on-polymer constructs[31-34]. Corrosion, often at modular interfaces, also contributes to systemic metal ion release, with elevated serum levels of titanium, cobalt, and chromium detected in patients who have undergone TDR[35,36]. These ions and particles have been retrieved from distant tissues, such as lymph nodes and the liver, suggesting the potential for systemic dissemination[37].

In response to these risks, newer TDR systems have shifted toward viscoelastic, nonarticulating designs that eliminate metal-on-metal or polymer-on-metal interfaces. The Freedom Lumbar Disc (FLD) developed by AxioMed (Fig. 1) features a 1-piece viscoelastic core that enables motion through internal deformation rather than articulation. The viscoelastic polymer core is composed of thermoplastic silicone polycarbonate urethane (CarboSil; The Polymer Technology Group), which is mechanically and chemically bonded to the retaining plates. This architecture is intended to eliminate the generation of particles, particularly submicron debris, from bearing surfaces and to produce larger, potentially less bioactive, wear particles. Viscoelastic TDR (VTDR) data are limited, but to our knowledge, there have been no published reports to date of clinically substantial osteolysis associated with the AxioMed VTDR device[38-40].

> *The AxioMed 1-piece VTDR device demonstrated a lower wear rate and larger, less biologically reactive, particles compared with articulating TDRs, suggesting a reduced risk of osteolysis and longer implant lifespan.*

Despite these innovations, comparative studies evaluating wear profiles across different TDR systems remain limited. The relationship between device design, material composition, particle size, and biological reactivity is not yet fully understood in the context of spinal arthroplasty.

The purpose of the present study was to perform a comparative in vitro analysis of wear debris generated by a VTDR and 2 established articulating TDR systems: CHARITÉ (DePuy Synthes) and prodisc L (Centinel Spine). We hypothesize that the viscoelastic design would exhibit a lower wear rate and generate larger wear particles (>1 μm), which may translate to a reduced risk of osteolysis and other biological complications.

Fig. 1
Lordotic AxioMed Freedom Lumbar viscoelastic disc.

Materials and Methods

Device Preparation

Six AxioMed VTDR devices and 2 controls were selected for in vitro wear testing[41]. However, 1 test device was lost because of part damage caused by a power outage. The remaining 5 VTDR devices completed full testing.

All samples were fully hydrated in phosphate-buffered saline (PBS) solution before testing commenced. Baseline dimensional measurements, including anterior and posterior heights as well as anterior-posterior and lateral lengths, were recorded for each specimen and repeated immediately before testing to ensure accuracy. Prior to dynamic testing, all specimens were preconditioned by applying a constant axial load of 1,200 N for a minimum of 3 hours in PBS to simulate physiological loading conditions.

Wear Testing Protocol

Wear testing was performed using an MTS servohydraulic closed-loop material testing system, configured to simulate coupled spinal motion (Fig. 2), in accordance with ASTM International F2423 and F2346 standards for the assessment of disc protheses[42,43]. Testing included 3 principal motions: flexion-extension under ±10 Nm of torque with a constant axial compressive load of 1,200 N; lateral bending under ±12 Nm of torque control; and axial rotation of ±3° under angular control. Each of the 5 VTDR devices was subjected to 30 million device cycles (10 million flexion-extension + 10 million lateral bending + 10 million axial rotation). This can also be described as a total of 20 million machine cycles (10 million flexion-extension + 10 million lateral bending/rotation). A 30-million device cycle count corresponds to 240 years of lumbar bending. All tests were conducted at a frequency of 2 Hz, with the temperature maintained at 37°C in a PBS solution to replicate in vivo conditions. We used PBS in order to provide a consistent and controlled environment for assessing mechanical wear and durability.

Fig. 2
Test setup rig for simulating coupled spinal motion.

Fluid Sampling and Debris Collection

Solution was collected by MAR-TEST from each device every 5 million cycles throughout testing, for a total of 20 solution samples across the study. All samples were shipped to Bio-Engineering Solutions for particle analysis. Processing was conducted in a Class-II sterile environment. Each sample was filtered through a 0.2-μm membrane to isolate particulate matter, centrifuged to concentrate sediment, and ultrasonicated to disaggregate particle clusters prior to analysis.

Particle Size and Morphological Analysis

Particle size and morphology were characterized using both number-based and volume-based techniques. Number-based analysis was conducted using scanning electron microscopy (SEM) paired with energy-dispersive x-ray analysis (EDXA). This method provided insights into particle shape (e.g., aspect ratio) and numerical distributions, although it is inherently biased toward smaller particles because of magnification effects. For volume-based evaluation, low-angle laser light scattering (LALLS), also known as laser diffraction particle analysis, was employed. This method is capable of analyzing millions to billions of particles simultaneously, offering a statistically robust assessment of volume-weighted particle-size distribution.

All results are reported as equivalent spherical diameters, and wear rate was calculated as the mean mass loss in milligrams per million cycles (mg/MC).

Comparative Data Sources

To contextualize the wear behavior of the AxioMed VTDR device, comparative data were extracted from the publicly available United States Food and Drug Administration (FDA) Summary of Safety and Effectiveness Data (SSED) for the CHARITÉ[44] and prodisc L[45] devices.

Results

Device Integrity and Functional Performance

All 5 VTDR devices successfully completed 30 million multidirectional device cycles, comprising 10 million cycles each in flexion-extension, lateral bending, and axial rotation, under a constant axial compressive load of 1,200 N. No mechanical or structural failures were observed throughout the testing protocol.

After 10 million cycles of flexion-extension, which corresponds to approximately 80 years of bending motions based on estimated annual activity levels in the lumbar spine, localized wear was noted on the posterior aspect of the polymer core (Fig. 3). This wear was minor and limited to the area

Fig. 3
After 10 million cycles of flexion-extension under ±10 Nm of torque with a 1,200-N compressive load, the tested AxioMed viscoelastic device showed localized wear on the posterior aspect of the polymer core.

near the center, adjacent to the flash ring, a peripheral feature formed during the molding process. The flash ring exhibited minor smoothing, but no signs of cracking, delamination, or deformation were present. Importantly, these surface observations did not progress with additional loading cycles and did not impact device integrity or function.

Across all loading modes, the VTDR devices maintained dimensional stability and demonstrated durability under extreme, multidirectional physiological loads.

Mass and Dimensional Changes

Following the completion of 30 million cycles, the mean weight loss across the VTDR specimens was 0.07 g per device. Dimensional analysis showed minor changes in disc geometry. On average, the anterior height decreased by 0.3 mm and the posterior height decreased by 0.2 mm. In contrast, peripheral expansion was observed, with lateral dimensions increasing by 0.8 mm and anterior-posterior width increasing by 0.6 mm.

Wear Rate and Particle-Size Distribution

The mean wear rate of the VTDR devices was calculated to be 1.7 mg/MC. Wear particle analysis, based on 20 PBS solution samples, revealed a number-average particle diameter of 1.9 μm (range, 0.8 to 6.9 μm) and a mass-average particle diameter of 49 μm (range, 23 to 76 μm).

Comparative Particle-Size Analysis

In contrast to the articulating CHARITÉ and prodisc L discs, which have been reported to produce mean particle sizes of approximately 0.2 and 0.4 μm, respectively[44,45], the VTDR devices produced particles with a mean size that exceeded 1.0 μm. Device design, fatigue limits, wear rates, and particle sizes for all 3 types of TDRs are summarized in Table 1.

Discussion

Key Findings

The VTDR device demonstrated a favorable wear profile, with a mean wear rate of 1.7 mg/MC, approximately 3.4-times lower than that of the prodisc L device (5.7 mg/MC) (Table 1). Although the CHARITÉ and prodisc L devices produced some large particles (up to 16.3 and 2.3 μm, respectively), both generated predominantly submicron particles, as reflected in their low mean sizes. However, the VTDR device generated larger particles, on average (1.9 μm), with far fewer submicron particles. This distinction is notable, as submicron debris is strongly linked to macrophage-driven inflammation and osteolysis[18]. These findings support the hypothesis that the VTDR device may reduce the biological risks associated with wear debris, while also demonstrating strong wear resistance and durability relative to both comparator devices.

The minor surface wear observed on the posterior region of the viscoelastic core near the flash ring (Fig. 3) suggests that particle generation in the VTDR device may result not from articulation, but from micromotions occurring at the periphery of the device, particularly at the interfaces between the viscoelastic core and the implant-end plate or adjacent bone. While the VTDR device maintained integrity over 30 million cycles, viscoelastic materials may exhibit time-dependent fatigue degradation not

Table 1. Comparative Wear Data of AxioMed Freedom Lumbar Disc (FLD), CHARITÉ, and prodisc L Devices*

Parameter	AxioMed FLD	CHARITÉ	prodisc L
Design type	1-piece viscoelastic	Ball-and-socket (mobile core)	Ball-and-socket (fixed core)
No. of cycles of testing *(MC)*	30	10	30
Mean wear rate *(mg/MC)*	1.7	0.1	5.7
Number-average particle diameter† *(μm)*	1.9 (0.80-6.92)	0.2 (0.08-16.3)	0.44 (0.08-2.29)

*MC = million cycles. †The values are given as the mean (range). Note that the mean particle size was >1.0 μm for the AxioMed FLD and <1.0 μm for the CHARITÉ and prodisc L devices.

captured by wear testing alone. Future studies should evaluate these properties under dedicated fatigue protocols.

Comparison with Similar Research

Compared with previous studies on the CHARITÉ and prodisc L devices, the VTDR device generated larger and fewer wear particles, which is considered a favorable outcome because of the well-established link between submicron debris and adverse biological responses, such as macrophage activation, inflammation, and osteolysis[18]. This association has been well documented in articulating ball-and-socket TDRs. Specifically, osteolysis has been observed in 8% to 64% of patients following cervical TDR, often as a delayed complication triggered by particulate debris[46].

Mechanistically, wear debris from polyethylene or polycarbonate-urethane components can activate a foreign-body response, involving phagocytosis by macrophages and the release of pro-inflammatory cytokines, which promotes bone resorption and implant instability[47]. TDR failure when wear debris is not contained, as has been seen with the polymer sheath in the M6-C device (Orthofix), has led to soft-tissue infiltration and granulation at the bone-implant interface, with associated clinical consequences[48].

Limitations

This study was limited by its small sample size (n = 5) and in vitro nature, which does not replicate the full complexity of the in vivo spinal environment, including patient-specific biomechanics, implant positioning, and bone quality. The use of PBS solution instead of a protein-containing medium such as bovine serum may have influenced wear behavior, limiting direct comparisons to the CHARITÉ and prodisc L devices.

While we have characterized particle size and morphology, we did not directly quantify the particle number or perform compositional analysis of the wear debris. As biological responses are dose-dependent and influenced by particle composition, future studies should include particle counting and biochemical characterization to better assess biological reactivity. Full size distributions by number or volume were not reported, which constrains the assessment of osteolytic risk.

Fatigue testing specific to the viscoelastic core was not performed, and long-term material behavior under cyclic loading remains to be evaluated. In addition, comparator data were drawn from literature sources without variability metrics, such as the standard deviation, so without access to their raw data, statistical comparisons with the results from our study could not be performed.

Overall, these limitations highlight the need for additional studies, including clinical follow-up, retrieval analysis, fatigue testing, serum-based wear testing, and comprehensive particle analysis, to fully assess the long-term performance and biological safety of the VTDR device.

Clinical Relevance

The VTDR device's lower wear rate and larger particle size suggest a reduced risk of osteolysis, a known complication in articulating TDRs. Its 1-piece viscoelastic design mimics natural disc motion and shock absorption, potentially improving long-term implant survivorship by limiting excessive micromotion and particulate debris. These features may reduce revision risk, particularly in younger or more active patients, although clinical validation is necessary.

Implications for Further Research

Long-term clinical follow-up is needed to determine whether the in vitro findings translate to reduced osteolysis and implant loosening. Retrieval and histological studies could provide further insight into tissue response to viscoelastic wear debris. Comparative trials between VTDR and articulating TDR devices may clarify differences in outcomes and cost-effectiveness. Biomarker studies may also help detect early inflammatory reactions.

Conclusions

This in vitro study demonstrated that the VTDR device exhibits a favorable wear profile compared with traditional articulating lumbar disc replacements. The VTDR device exhibited a lower wear rate and produced larger particles, both of which are associated with reduced biologically driven complications such as osteolysis. Its 1-piece, nonarticulating design may help minimize particulate generation while preserving structural integrity under high-cycle, multidirectional loading. While further clinical validation is necessary, these results suggest that VTDR technology may provide a durable and biocompatible solution for motion-preserving spinal implants. ■

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References

1. Hoy D, Bain C, Williams G, March L, Brooks P, Blyth F, Woolf A, Vos T, Buchbinder R. A systematic review of the global prevalence of low back pain. Arthritis Rheum. 2012 Jun;64(6):2028-37.
2. Hemanta D, Jiang XX, Feng ZZ, Chen ZX, Cao YW. Etiology for Degenerative Disc Disease. Chin Med Sci J. 2016 Sep 20;31(3):185-91.
3. Battié MC, Joshi AB, Gibbons LE; ISSLS Degenerative Spinal Phenotypes Group. Degenerative Disc Disease: What is in a Name? Spine (Phila Pa 1976). 2019 Nov 1;44(21):1523-9.
4. Wu A, March L, Zheng X, Huang J, Wang X, Zhao J, Blyth FM, Smith E, Buchbinder R, Hoy D. Global low back pain prevalence and years lived with disability from 1990 to 2017: estimates from the Global Burden of Disease Study 2017. Ann Transl Med. 2020 Mar;8(6):299.
5. Walker BF. The prevalence of low back pain: a systematic review of the literature from 1966 to 1998. J Spinal Disord. 2000 Jun;13(3):205-17.
6. Wenger M, Markwalder TM. A novel surgical treatment of lumbar disc herniation in patients with long-standing degenerative disc disease. J Neurosurg Spine. 2005 May;2(5):515-20, discussion 513-4.
7. Pennicooke B, Moriguchi Y, Hussain I, Bonssar L, Härtl R. Biological Treatment Approaches for Degenerative Disc Disease: A Review of Clinical Trials and Future Directions. Cureus. 2016 Nov 22;8(11):e892.
8. Buttermann GR. The effect of spinal steroid injections for degenerative disc disease. Spine J. 2004 Sep-Oct;4(5):495-505.
9. Anandjiwala J, Seo JY, Ha KY, Oh IS, Shin DC. Adjacent segment degeneration after instrumented posterolateral lumbar fusion: a prospective cohort study with a minimum five-year follow-up. Eur Spine J. 2011 Nov;20(11):1951-60.
10. Cho KS, Kang SG, Yoo DS, Huh PW, Kim DS, Lee SB. Risk factors and surgical treatment for symptomatic adjacent segment degeneration after lumbar spine fusion. J Korean Neurosurg Soc. 2009 Nov;46(5):425-30.
11. Xia XP, Chen HL, Cheng HB. Prevalence of adjacent segment degeneration after spine surgery: a systematic review and meta-analysis. Spine (Phila Pa 1976). 2013 Apr 1;38(7):597-608.
12. Yang JY, Lee JK, Song HS. The impact of adjacent segment degeneration on the clinical outcome after lumbar spinal fusion. Spine (Phila Pa 1976). 2008 Mar 1;33(5):503-7.
13. Lee CK, Langrana NA. A review of spinal fusion for degenerative disc disease: need for alternative treatment approach of disc arthroplasty? Spine J. 2004 Nov-Dec;4(6)(Suppl):173S-6S.
14. Phillips FM, Slosar PJ, Youssef JA, Andersson G, Papatheofanis F. Lumbar spine fusion for chronic low back pain due to degenerative disc disease: a systematic review. Spine (Phila Pa 1976). 2013 Apr 1;38(7):E409-22.
15. Vital JM, Boissière L. Total disc replacement. Orthop Traumatol Surg Res. 2014 Feb;100(1)(Suppl):S1-14.
16. Song G, Qian Z, Wang K, Liu J, Wei Y, Galbusera F, et al Total disc replacement devices: Structure, material, fabrication, and properties. Prog Mater Sci. 2023; 140:101189.
17. van den Eerenbeemt KD, Ostelo RW, van Royen BJ, Peul WC, van Tulder MW. Total disc replacement surgery for symptomatic degenerative lumbar disc disease: a systematic review of the literature. Eur Spine J. 2010 Aug;19(8): 1262-80.
18. Ganko R, Madhavan A, Hamouda W, Muthu S, Jain A, Yoon ST, El-Rozz H, Cyril D, Pabbruwe M, Tipper JL, Tavakoli J. Spinal implant wear particles: Generation, characterization, biological impacts, and future considerations. iScience. 2025 Mar 11;28(4):112193.
19. Behl B, Papageorgiou I, Brown C, Hall R, Tipper JL, Fisher J, Ingham E. Biological effects of cobalt-chromium nanoparticles and ions on dural fibroblasts and dural epithelial cells. Biomaterials. 2013 May;34(14):3547-58.
20. Bladen CL, Teramura S, Russell SL, Fujiwara K, Fisher J, Ingham E, Tomita N, Tipper JL. Analysis of wear, wear particles, and reduced inflammatory potential of vitamin E ultrahigh-molecular-weight polyethylene for use in total joint replacement. J Biomed Mater Res B Appl Biomater. 2013 Apr; 101(3):458-66.
21. Williams S, Tipper JL, Ingham E, Stone MH, Fisher J. In vitro analysis of the wear, wear debris and biological activity of surface-engineered coatings for use in metal-on-metal total hip replacements. Proc Inst Mech Eng H. 2003; 217(3):155-63.
22. Punt IM, Austen S, Cleutjens JP, Kurtz SM, ten Broeke RH, van Rhijn LW, Willems PC, van Ooij A. Are periprosthetic tissue reactions observed after revision of total disc replacement comparable to the reactions observed after total hip or knee revision surgery? Spine (Phila Pa 1976). 2012 Jan 15;37(2): 150-9.
23. Lee H, Phillips JB, Hall RM, Tipper JL. Neural cell responses to wear debris from metal-on-metal total disc replacements. Eur Spine J. 2020 Nov;29(11):2701-12.
24. Yoshihara H. Rods in spinal surgery: a review of the literature. Spine J. 2013 Oct;13(10):1350-8.
25. Papageorgiou I, Marsh R, Tipper JL, Hall RM, Fisher J, Ingham E. Interaction of micron and nano-sized particles with cells of the dura mater. J Biomed Mater Res B Appl Biomater. 2014 Oct;102(7):1496-505.
26. Hallab NJ. A review of the biologic effects of spine implant debris: Fact from fiction. SAS J. 2009 Dec 1;3(4):143-60.
27. Couto M, Vasconcelos DP, Sousa DM, Sousa B, Conceição F, Neto E, Lamghari M, Alves CJ. The Mechanisms Underlying the Biological Response to Wear Debris in Periprosthetic Inflammation. Front Mater. 2020 Aug; 7:274(1-13).
28. Purdue PE, Koulouvaris P, Nestor BJ, Sculco TP. The central role of wear debris in periprosthetic osteolysis. HSS J. 2006 Sep;2(2):102-13.
29. Melcher C, Paulus AC, Roßbach BP, Gülecyüz MF, Birkenmaier C, Schulze-Pellengahr CV, Teske W, Wegener B. Lumbar spinal stenosis - surgical outcome and the odds of revision-surgery: Is it all due to the surgeon? Technol Health Care. 2022;30(6):1423-34.
30. van Ooij A, Kurtz SM, Stessels F, Noten H, van Rhijn L. Polyethylene wear debris and long-term clinical failure of the Charité disc prosthesis: a study of 4 patients. Spine (Phila Pa 1976). 2007 Jan 15;32(2):223-9.
31. Gierzyńska-Dolna M, Lijewski M, Mróz A, Brytsko AA, Anosov VS. Tribological examination of lumbar intervertebral disc implants. J Frict Wear. 2013;34(4): 253-61.
32. Kurtz SM, Steinbeck M, Ianuzzi A, van Ooij A, Punt IM, Isaza J, Ross ER. Retrieval analysis of motion preserving spinal devices and periprosthetic tissues. SAS J. 2009 Dec 1;3(4):161-77.
33. Paré PE, Chan FW, Powell ML. Wear characterization of the A-MAV™ anterior motion replacement using a spine wear simulator. Wear. 2007;263(7):1055-9.
34. Reeks J, Liang H. Materials and Their Failure Mechanisms in Total Disc Replacement. Lubricants. 2015;3(2):346-64.
35. Cundy WJ, Mascarenhas AR, Antoniou G, Freeman BJ, Cundy PJ. Local and systemic metal ion release occurs intraoperatively during correction and instrumented spinal fusion for scoliosis. J Child Orthop. 2015 Feb;9(1):39-43.
36. Zeh A, Planert M, Siegert G, Lattke P, Held A, Hein W. Release of cobalt and chromium ions into the serum following implantation of the metal-on-metal Maverick-type artificial lumbar disc (Medtronic Sofamor Danek). Spine (Phila Pa 1976). 2007 Feb 1;32(3):348-52.
37. Urban RM, Jacobs JJ, Tomlinson MJ, Gavrilovic J, Black J, Peoc'h M. Dissemination of wear particles to the liver, spleen, and abdominal lymph nodes of patients with hip or knee replacement. J Bone Joint Surg Am. 2000 Apr;82(4):457-76.
38. Rischke B, Ross RS, Jollenbeck BA, Zimmers KB, Defibaugh ND. Preclinical and clinical experience with a viscoelastic total disc replacement. SAS J. 2011 Dec 1;5(4):97-107.
39. Rischke B, Zimmers KB, Smith E. Viscoelastic Disc Arthroplasty Provides Superior Back and Leg Pain Relief in Patients with Lumbar Disc Degeneration Compared to Anterior Lumbar Interbody Fusion. Int J Spine Surg. 2015 Jul 1;9:26.

40. Chin KR, Lubinski JR, Zimmers KB, Sands BE, Pencle F. Clinical experience and two-year follow-up with a one-piece viscoelastic cervical total disc replacement. J Spine Surg. 2017 Dec;3(4):630-40.

41. Benzel EC, Lieberman IH, Ross ER, Linovitz RJ, Kuras J, Zimmers K. Mechanical Characterization of a Viscoelastic Disc for Lumbar Total Disc Replacement. J Med Devices. 2011;5(1):011005.

42. Standard Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses. West Conshohocken: ASTM International; 2005.

43. Standard Test Methods for Static and Dynamic Characterization of Spinal Artificial Discs. West Conshohocken: ASTM International; 2005.

44. CHARITÉ Artificial Disc. Summary of safety and effectiveness. 2004 Oct 26. Accessed 2025 Apr. https://www.accessdata.fda.gov/cdrh_docs/pdf4/P040006B.pdf

45. PRODISC-L Total Disc Replacement. Summary of safety and effectiveness data. 2006 Aug 14. Accessed 2025 Apr. https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050010B.pdf

46. Joaquim AF, Lee NJ, Lehman RA Jr, Tumialán LM, Riew KD. Osteolysis after cervical disc arthroplasty. Eur Spine J. 2020 Nov;29(11):2723-33.

47. Häckel S, Gaff J, Pabbruwe M, Celenza A, Kern M, Taylor P, Miles A, Cunningham G. Heterotopic ossification, osteolysis and implant failure following cervical total disc replacement with the M6-C™ artificial disc. Eur Spine J. 2024 Mar;33(3):1292-9.

48. Silva Tavares JM, Jácome Morgado DM, Seromenho Santos Nora A, Lopes Luís AI. Osteolysis after cervical disc arthroplasty with artificial cervical disc. Eur Spine J. 2025 Jan;34(1):64-8.