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Comparative In Vitro Analysis of Wear Particles in A Viscoelastic Disc Versus Two Articulating Total Disc Replacements

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Structured Abstract

Background

Wear debris is a known contributor to implant failure in orthopedic devices, particularly in joint arthroplasty. Although spinal total disc replacements (TDRs) are increasingly used, less is known about their wear characteristics. Compared to knee implants, spinal TDRs operate under complex multidirectional loads and have been shown to produce wear particles that trigger a stronger immune response. Submicron debris, in particular, is associated with osteolysis and implant loosening. Viscoelastic TDR (VTDR) devices have emerged to address these risks by reducing particle generation and improving biocompatibility.

Methods

Six AxioMed® Freedom Lumbar Disc (FLD) devices underwent 30 million cycles of multidirectional wear testing using an MTS servohydraulic system in phosphate-buffered saline at 37°C. Wear fluid samples were collected every 5 million cycles and analyzed using scanning electron microscopy and laser diffraction. Wear rates were calculated in mg per million cycles. Comparative data for CHARITÉ and ProDisc-L were obtained from FDA Summary of Safety and Effectiveness Data.

Results

The VTDR showed a mean wear rate of 1.70 mg per million cycles, lower than ProDisc-L (5.73 mg/MC) and comparable to CHARITÉ (0.11 mg/MC). The number-average particle size was 1.9 μm, with a volume-average of 48.66 μm, significantly larger than those produced by CHARITÉ (0.2 μm) and ProDisc-L (0.44 μm). No mechanical failures were observed during the 30 million cycles. Larger particles (>1.0 μm) are less likely to induce inflammatory responses.

Conclusion

The AxioMed® one-piece VTDR demonstrated lower wear and larger, less biologically reactive particles compared to articulating TDRs, suggesting a reduced risk of osteolysis and longer implant lifespan.

Clinical Relevance

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

Keywords:

Total Disc Replacement, Wear Particles, Osteolysis, Viscoelastic Disc, CHARITÉ, Prodisc-L, AxioMed®

Introduction

Degenerative disc disease (DDD) remains a leading cause of chronic low back pain and disability worldwide [1-5]. While many patients achieve relief through conservative management, a significant proportion continues to experience 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]. Despite its biomechanical advantages, concerns have emerged regarding wear debris generated by TDR implants, particularly polymer and metal particles produced through articulation or surface degradation. Extensive orthopedic literature in hip and knee arthroplasty has established the role of submicron wear particles in driving adverse biological responses, including 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 TNF-α and IL-1β [19-21]. While such mechanisms have been well documented in large joint replacements, the biological consequences of wear particles from spinal implants remain comparatively under-investigated.

Historically, spinal implants were not believed to produce clinically significant wear debris due to the absence of synovial joints and lower perceived motion. However, this assumption has been challenged by increasing evidence showing periprosthetic inflammation, pseudotumor formation, metallosis, and even neural cell toxicity in response to wear particles from spinal devices [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 implants have shown revision rates exceeding 30% within 10 years, with wear-related complications being a primary contributor in late failures [29, 30]. Particles generated from TDRs may originate 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 TDR patients [35, 36]. These ions and particles have been retrieved from distant tissues such as lymph nodes and liver, suggesting the potential for systemic dissemination [37].

In response to these risks, newer TDR systems have shifted toward viscoelastic, non-articulating designs that eliminate metal-on-metal or polymer-on-metal interfaces. The AxioMed® Freedom Lumbar Disc (FLD) (AxioMed LLC, Burlington, MA, USA) (Figure 1) features a one-piece viscoelastic core that enables motion through internal deformation rather than articulation. This architecture is intended to reduce particle generation, particularly submicron debris, and produce larger, potentially less bioactive wear particles. Importantly, to date, no cases of osteolysis have been reported with this device [38-40].

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. A deeper understanding of these factors is essential for optimizing long-term outcomes and informing regulatory and clinical decision-making.

The purpose of this study is to perform a comparative in vitro analysis of wear debris generated by a viscoelastic total disc replacement (VTDR) and two established articulating TDRs; and two established articulating TDR systems: CHARITÉ (DePuy Synthes, Raynham, MA, USA) and ProDisc-L (Centinel Spine, West Chester, PA, USA). We hypothesize that the viscoelastic design will exhibit a lower wear rate and generate larger wear particles (>1 μm), which may translate to a reduced risk of osteolysis and other biologic complications. This work seeks to bridge the existing knowledge gap and contribute to the design of safer, more durable spinal implants that better replicate natural disc function while minimizing long-term complications related to wear.

Methods

Device Preparation

Six AxioMed® VTDR devices and two controls were selected for in vitro wear testing [41]. All samples were fully hydrated in phosphate-buffered saline (PBS) 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 1200 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 system (MTS, Eden Prairie, MN), configured to simulate coupled spinal motion (Figure 2), in accordance with previously established test protocols [42]. Each VTDR device was subjected to 30 million

loading cycles under physiological conditions. Testing included three principal motions: flexion-extension under ±10 Nm torque with a constant axial compressive load of 1200 N; lateral bending under ±12 Nm torque control; and axial rotation at ±3° under angle control. 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.

Fluid Sampling and Debris Collection

Wear fluid samples were collected from each device at intervals of 5 million cycles, resulting in a total of 20 samples across the study. All samples were shipped to BioEngineering Solutions Inc. (Oak Park, IL, USA) 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 Morphology 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, though it is inherently biased toward smaller particles due to magnification effects. For mass-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 were reported as equivalent spherical diameters, and wear rate was calculated as the average mass loss in milligrams per million cycles.

Comparative Data Sources

To contextualize the wear behavior of the VTDR, comparative data were extracted from publicly available United States Food and Drug Administration (FDA) Summary of Safety and Effectiveness Data (SSED) for the CHARITÉ [43] and ProDisc-L [44] devices.

Results

Device Integrity and Functional Performance

All six VTDR devices successfully completed 30 million wear cycles, comprising 10 million cycles each in flexion-extension, lateral bending, and axial rotation, under a constant axial compressive loading of 1200 N. No mechanical or structural failures were observed throughout the testing protocol.

After 10 million cycles in multidirectional loading (±10 Nm) (Figure 3), which corresponds to approximately 80 years of significant bending motions based on estimated annual activity levels in the lumbar spine, localized wear was noted on the posterior aspect of the polymer core. This wear was minor and limited to the area 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 cycling 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. These results suggest strong long-term mechanical reliability in simulated in vivo conditions.

Mass and Dimensional Changes

Following the completion of 30 million cycles, the average weight loss across the VTDR specimens was 0.07 grams per device. Dimensional analysis showed minor changes in disc geometry. On average, the anterior height decreased by 0.31 mm, and the posterior height decreased by 0.24 mm. In contrast, peripheral expansion was observed, with lateral dimensions increasing by 0.83 mm and anterior-posterior width increasing by 0.64 mm.

Wear Rate and Particle Size Distribution

The mean wear rate of the VTDR was calculated to be 1.70 mg per million cycles. Wear particle analysis, based on 20 PBS solution samples, revealed a number-average particle diameter of 1.90 μm (range: 0.80–6.92 μm) and a mass-average particle diameter of 48.66 μm (range: 23–76 μm).

Comparative Particle Size Analysis

When compared to the two articulating ball-and-socket TDRs, the VTDR generated substantially larger wear particles (>0.1 μm). Reported number-average particle sizes for CHARITÉ and ProDisc-L are approximately 0.2 μm and 0.44 μm, respectively [43, 44]. In contrast, the VTDR's average particle size exceeded 1.0 μm, which may reflect a reduced risk of wear-induced osteolysis and macrophage-driven inflammatory responses, as submicron particles have been more strongly associated with adverse biological effects [18]. Additionally, in terms of fatigue endurance and wear rate, the VTDR performed favorably relative to both comparator devices. A comprehensive comparison of design type, fatigue limits, wear rates, and particle sizes for AxioMed® FLD, CHARITÉ, and ProDisc-L is provided in Table 1.

Discussion

Brief Summary

This study evaluated the wear characteristics and particle profiles of a viscoelastic total disc replacement (VTDR) in vitro and compared the results to published data for two widely used articulating total disc replacements, CHARITÉ and ProDisc-L. Prior research has primarily focused on articulating ball-and-socket TDRs, with limited comparative data on viscoelastic, one-piece designs. This study addresses a key research gap by analyzing wear particle size and morphology, which are known to influence biological response and long-term implant performance.

Key Findings

The VTDR demonstrated a favorable wear profile, with a mean wear rate of 1.70 mg per million cycles, markedly lower than that reported for ProDisc-L (5.73 mg/MC). The average particle size of 1.9 μm was also significantly larger than those reported for CHARITÉ (0.2 μm) and ProDisc-L (0.44 μm), supporting the hypothesis that the one-piece viscoelastic design reduces the generation of submicron debris associated with inflammatory responses and osteolysis.

All five VTDR devices completed 30 million cycles of multidirectional loading, including flexion-extension, lateral bending, and axial rotation, under a constant axial compressive load of 1200 N, without any structural or functional failures. Notably, after 10 million flexion-extension cycles (±10 Nm), equivalent to approximately 80 years of significant lumbar bending, only minor surface wear was observed on the posterior region of the polymer core near the flash ring, a non-load-bearing manufacturing feature. These changes were superficial and non-progressive, with no signs of delamination, cracking, or deformation, and did not compromise device performance.

These results emphasize the mechanical durability and dimensional stability of the viscoelastic design under physiologic and extreme cyclic loading, further supporting its potential for long-

term in vivo reliability. Together, the low wear rate, favorable particle morphology, and sustained mechanical integrity highlight the promise of this design in improving TDR longevity and reducing biologically mediated complications.

Comparison with Similar Researches

Compared to previous studies on CHARITÉ and ProDisc-L, the VTDR generated larger and fewer wear particles, which is considered a favorable outcome due to the well-established link between smaller 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 total disc replacements. Specifically, osteolysis has been observed in a range of 8–64% of patients following cervical total disc replacement, often as a delayed complication triggered by particulate debris [45].

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 [46]. Failures in containing wear debris, such as those seen with the polymer sheath in the M6-C^{TM} device (Orthofix, Lewisville, TX, USA), have led to soft tissue infiltration and granulation at the bone-implant interface, with associated clinical consequences [47].

Limitations

This study was limited by its small sample size (n=6) and in vitro nature, which does not replicate the full complexity of the in vivo spinal environment. Variables such as patient-specific biomechanics, implant positioning, bone quality, and biological response are not fully captured in bench testing. Additionally, particle analysis was based on simulated wear, and real-world

histologic effects were not evaluated. Differences in testing protocols and lubricants used across studies further limit direct comparisons.

Clinical Relevance

The reduced wear rate and larger particle size produced by the VTDR suggest a lower risk of biologically induced osteolysis, which has been a complication in other articulating TDR systems. The one-piece viscoelastic design, which mimics the natural disc's shock absorption and motion constraint, may improve long-term implant survivorship by avoiding excessive micromotion and particulate debris. These characteristics could offer clinical advantages in reducing revision surgery risk, particularly in younger or more active patients.

Implications for Further Research

Future investigations should include long-term clinical follow-up to confirm whether the favorable in vitro findings of the VTDR correlate with reduced osteolysis and implant loosening in patients. Additional retrieval studies, in vivo animal models, and histological analyses are needed to assess tissue response to viscoelastic wear debris. Comparative randomized controlled trials between VTDRs and articulating TDRs would provide further insight into patient outcomes, revision rates, and cost-effectiveness. Biomarker studies may also help detect early inflammatory responses related to particle exposure.

Conclusion

This in vitro study demonstrates that the viscoelastic total disc replacement (VTDR) exhibits a favorable wear profile compared to traditional articulating lumbar disc replacements. With a significantly lower wear rate and larger average particle size, the VTDR may offer a reduced risk of biologically driven complications such as osteolysis and implant loosening. The one-piece,

non-articulating design appears to minimize particulate generation while maintaining structural integrity under high-cycle, multidirectional loading. Although further clinical validation is needed, these results suggest that viscoelastic TDR technology represents a promising advancement in motion-preserving spinal implants, potentially improving long-term outcomes for patients requiring lumbar disc arthroplasty.

References:

1. Hoy D, Bain C, Williams G, March L, Brooks P, Blyth F, et al. A systematic review of the global prevalence of low back pain. Arthritis Rheum. 2012;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;31(3):185-91.
3. Battie MC, Joshi AB, Gibbons LE, Group IDSP. Degenerative Disc Disease: What is in a Name? Spine. 2019;44(21):1523-9.
4. Wu A, March L, Zheng X, Huang J, Wang X, Zhao J, et al. 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;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;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. Journal of neurosurgery Spine. 2005;2(5):515-20, discussion 3-4.
7. Pennicooke B, Moriguchi Y, Hussain I, Bonssar L, Hartl R. Biological Treatment Approaches for Degenerative Disc Disease: A Review of Clinical Trials and Future Directions. Cureus. 2016;8(11):e892.
8. Buttermann GR. The effect of spinal steroid injections for degenerative disc disease. The spine journal : official journal of the North American Spine Society. 2004;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;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;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. 2013;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. 2008;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? The spine journal : official journal of the North American Spine Society. 2004;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. 2013;38(7):E409-22.
15. Vital JM, Boissière L. Total disc replacement. Orthopaedics & Traumatology: Surgery & Research. 2014;100(1, Supplement):S1-S14.
16. Song G, Qian Z, Wang K, Liu J, Wei Y, Galbusera F, et al. Total disc replacement devices: Structure, material, fabrication, and properties. Progress in Materials Science. 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;19(8):1262-80.
18. Ganko R, Madhavan A, Hamouda W, Muthu S, Jain A, Yoon ST, et al. Spinal implant wear particles: Generation, characterization, biological impacts, and future considerations. iScience. 2025;28(4):112193.
19. Behl B, Papageorgiou I, Brown C, Hall R, Tipper JL, Fisher J, et al. Biological effects of cobalt-chromium nanoparticles and ions on dural fibroblasts and dural epithelial cells. Biomaterials. 2013;34(14):3547-58.
20. Bladen CL, Teramura S, Russell SL, Fujiwara K, Fisher J, Ingham E, et al. 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;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, et al. Are periprosthetic tissue reactions observed after revision of total disc replacement comparable to the reactions observed after total hip or knee revision surgery? Spine. 2012;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;29(11):2701-12.
24. Yoshihara H. Rods in spinal surgery: a review of the literature. The spine journal : official journal of the North American Spine Society. 2013;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;102(7):1496-505.
26. Hallab NJ. A review of the biologic effects of spine implant debris: Fact from fiction. SAS J. 2009;3(4):143-60.
27. Couto M, Vasconcelos DP, Sousa DM, Sousa B, Conceição F, Neto E, et al. The Mechanisms Underlying the Biological Response to Wear Debris in Periprosthetic Inflammation. Frontiers in Materials. 2020;Volume 7 - 2020.
28. Purdue PE, Koulouvaris P, Nestor BJ, Sculco TP. The central role of wear debris in periprosthetic osteolysis. HSS J. 2006;2(2):102-13.
29. Melcher C, Paulus AC, Roßbach BP, Gülecyüz MF, Birkenmaier C, Schulze-Pellengahr CV, et al. 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. 2007;32(2):223-9.
31. Gierzyńska-Dolna M, Lijewski M, Mróz A, Brytsko AA, Anosov VS. Tribological examination of lumbar intervertebral disc implants. Journal of Friction and Wear. 2013;34(4):253-61.
32. Kurtz SM, Steinbeck M, Ianuzzi A, van Ooij A, Punt IM, Isaza J, et al. Retrieval analysis of motion preserving spinal devices and periprosthetic tissues. SAS J. 2009;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;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. 2007;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;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;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;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;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(1)-(7).
42. F2423 AS. “Standard Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses,” ASTM International, West Conshohocken, PA. 2005.
43. FDA. CHARITÉ Artificial Disc. Summary of safety and effectiveness. PMA Number P040006. October 26, 2004. 2004 [cited 2025 April]. Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf4/P040006B.pdf.
44. FDA. PRODISC-L Total Disc Replacement. Summary of safety and effectiveness data. PMA number P050010. August 14, 2006. 2006 [cited 2025 April]. Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050010B.pdf.
45. Joaquim AF, Lee NJ, Lehman RA, Jr., Tumialan LM, Riew KD. Osteolysis after cervical disc arthroplasty. Eur Spine J. 2020;29(11):2723-33.
46. Hackel S, Gaff J, Pabbruwe M, Celenza A, Kern M, Taylor P, et al. Heterotopic ossification, osteolysis and implant failure following cervical total disc replacement with the M6-C artificial disc. Eur Spine J. 2024;33(3):1292-9.

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

Figure Legend:

Figure 1: Lordotic AxioMed® Freedom Lumbar Viscoelastic Disc

Figure 2: Coupled Motion Test Rig

Figure 3: After 10 million cycles of flexion/extension (±10Nm) under a compressive load of 1,200 N

Figure

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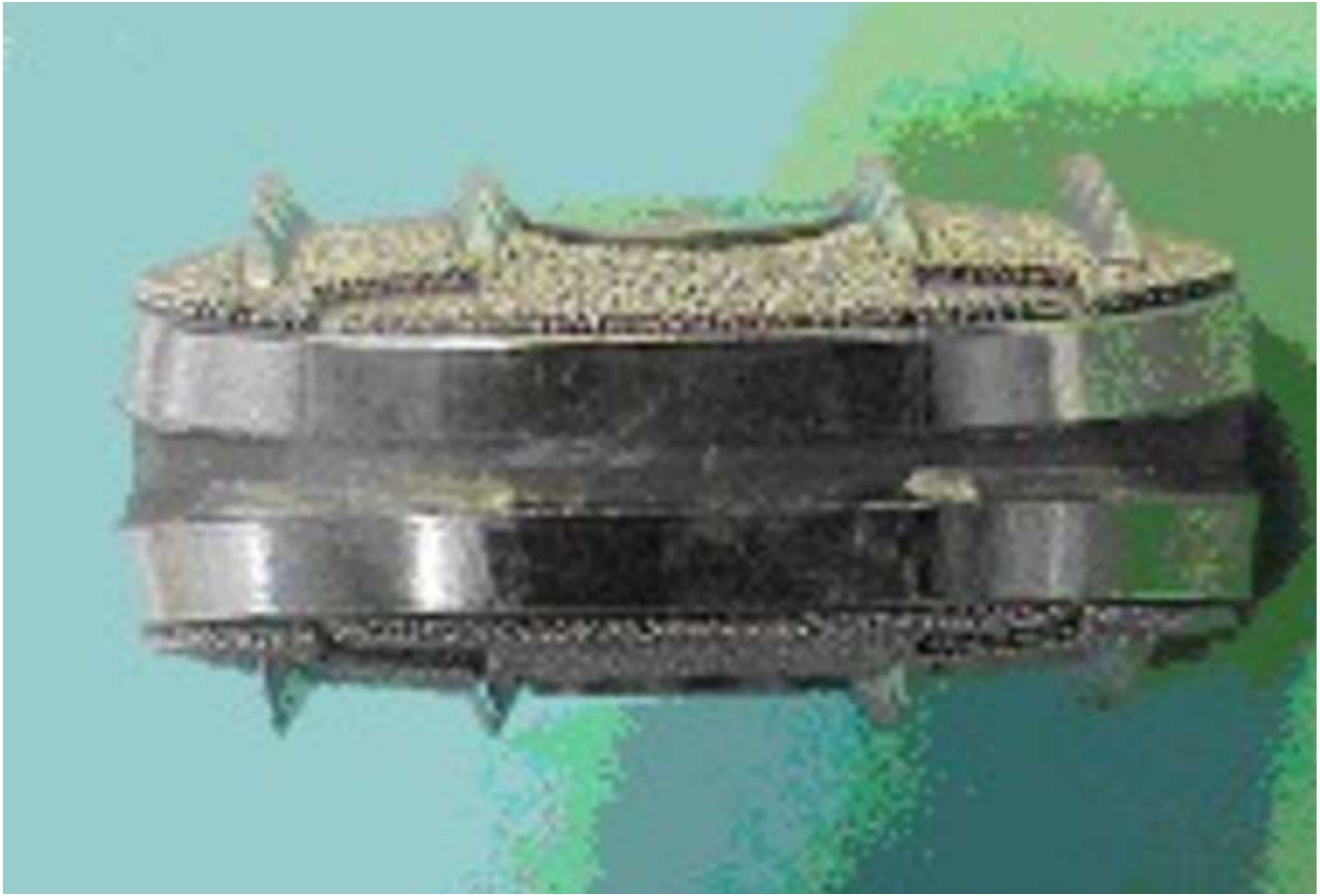

Table

Table 1: Comparative Wear Data of AxioMed® FLD, CHARITÉ and ProDisc-L

Parameter	AxioMed® **FLD [41]**	**CHARITÉ [43]**	**ProDisc-L [44]**
Design Type	One-piece viscoelastic	Ball-and-socket (mobile core)	Ball-and-socket (fixed core)
Fatigue Limit	50M cycles @ 2400 N	20M cycles	30M cycles
Wear Rate (mg/MC)	1.70	0.11 @ 20M	5.73 @ 30M
Particle Size (µm)	>1.0 1.9	<1.0 0.2	<1.0 0.44

FLD, Freedom Lumbar Disc; M, Million.