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Comparative In Vitro Biomechanical Stiffness Study of A Viscoelastic Disc Versus The Native Lumbar Disc --Manuscript Draft--

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Corresponding Author:	Kingsley R Chin, M.D Less Exposure Surgery Specialists Institute (LESS Institute) HOLLYWOOD, FL UNITED STATES
First Author:	Kingsley R Chin, M.D
Order of Authors:	Kingsley R Chin, M.D Sukanya Chebrolu, MS Roger D Sung, MD Jeffrey R Carlson, MD Mark W McFarland, DO Erik Spayde, MD William M Costigan, MD Sandra Thompson, MD Vito Lore, PE Kari B Zimmers Hope Estevez Swapnil Pangarkar Aditya Humad Chukwunonso C Ilogu, MD Jason A Seale, MBBS
Abstract:	<p>Background</p> <p>Artificial disc replacements aim to preserve motion in patients with lumbar disc degeneration, but most do not replicate the natural stiffness of the healthy human lumbar disc. Existing ball-and-socket designs often permit excessive motion and fail to provide the nonlinear, load-dependent stiffness that is characteristic of native spinal biomechanics. To date, no in vitro study has directly compared the stiffness of a viscoelastic disc implant to that of the natural lumbar disc under physiologic conditions.</p> <p>Methods</p> <p>Ten viscoelastic disc implants were tested using standardized protocols in a physiologic environment (phosphate-buffered saline at 37±3°C). Axial compression, flexion-extension, and axial rotation stiffness were measured using servohydraulic test systems. An additional five implants underwent static axial loading up to 20,000 newtons. All values were compared to published stiffness ranges for the healthy human lumbar disc.</p> <p>Findings</p>

1 **Highlights**

- 2 • Viscoelastic disc implant mimics native lumbar stiffness across key loading modes
- 3 • Axial, flexion-extension stiffness matched healthy disc; rotation was more flexible
- 4 • Static tests confirmed durability up to 20,000 newtons without mechanical failure
- 5 • Load-displacement loops reproduced physiologic neutral and elastic zones
- 6 • First in vitro stiffness comparison of viscoelastic disc to native human lumbar disc

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Kingsley R Chin MD^{1,2,3,4,5}

Sukanya Chebrolu MS⁵

Roger D Sung MD⁶

Jeffrey R Carlson MD⁷

Mark W McFarland DO⁷

Erik Spayde MD⁸

William M Costigan MD⁹

Sandra Thompson MD¹⁰

Vito Lore^{5,11}

Kari B Zimmers¹²

Hope Estevez^{1,5}

Swapnil Pangarkar⁵

Aditya Humad⁵

Chukwunonso C Ilogu MD^{1,5}

Jason A Seale MBBS^{1,5}

¹Less Exposure Spine Surgery Institute (LESS Institute aka LESS Clinic), Fort Lauderdale, Florida, USA; ²LESS Institute of Jamaica, Kingston, St. Andrew, Jamaica, West Indies; ³Department of Orthopedics, Herbert Wertheim College of Medicine at Florida International University, Miami, Florida, USA; ⁴Faculty of Science and Sports, University of Technology, Kingston, St. Andrew, Jamaica; ⁵Less Exposure Spine Surgery (LESS) Society 501©(3), Fort Lauderdale, Florida, USA; ⁶Colorado Springs Orthopaedic Group, Colorado Springs, CO, USA; ⁷Orthopaedic and Spine Center, Newport News, VA, USA; ⁸St. Charles Spine Institute, Thousand Oaks, CA, USA; ⁹Congress Orthopaedic Associates, Pasadena, CA, USA; ¹⁰The Pain Center, Boise, ID, USA; ¹¹LESSpine, Burlington, MA, USA; ¹²AxioMed LLC, Burlington, MA, USA.

Corresponding Author:

Kingsley R. Chin, MD, MBA

Less Exposure Surgery Specialists Institute (LESS Institute aka LESS Clinic), 6550 N Federal Hwy, Suite 510, Fort Lauderdale, Florida, 33308.

Email: kingsleychin@thelessinstitute.com

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1 **Structured Abstract**

2 *Background*

3 Artificial disc replacements aim to preserve motion in patients with lumbar disc degeneration,
4 but most do not replicate the natural stiffness of the healthy human lumbar disc. Existing ball-
5 and-socket designs often permit excessive motion and fail to provide the nonlinear, load-
6 dependent stiffness that is characteristic of native spinal biomechanics. To date, no in vitro study
7 has directly compared the stiffness of a viscoelastic disc implant to that of the natural lumbar
8 disc under physiologic conditions.

9 *Methods*

10 Ten viscoelastic disc implants were tested using standardized protocols in a physiologic
11 environment (phosphate-buffered saline at $37 \pm 3^\circ\text{C}$). Axial compression, flexion-extension, and
12 axial rotation stiffness were measured using servohydraulic test systems. An additional five
13 implants underwent static axial loading up to 20,000 newtons. All values were compared to
14 published stiffness ranges for the healthy human lumbar disc.

15 *Findings*

16 Axial stiffness ranged from 1.55 to 3.48 kN/mm, overlapping the reported native range of 0.5 to
17 2.5 kN/mm. Flexion-extension stiffness (1.4–2.14 Nm/deg) matched the physiologic range (0.8–
18 2.5 Nm/deg). Rotation stiffness (0.72–0.83 Nm/deg) was lower than native values (2.0–9.6
19 Nm/deg), resulting in greater rotational mobility. All implants withstood static compression to
20 20,000 newtons without structural failure.

21 *Interpretation*

22 These findings show that this viscoelastic disc implant more closely reproduces the stiffness of
23 the natural lumbar disc than prior designs. The ability to replicate both compliant and stiff

loading zones suggests improved biomechanical performance and segmental stability, supporting its use as a potential alternative to spinal fusion.

Keywords: Lumbar Spine, Total Disc Replacement, AxioMed® Viscoelastic Disc, Spinal Biomechanics, Stiffness, In Vitro Testing

1 Introduction

Lumbar degenerative disc disease (DDD) is a major cause of chronic low back pain and disability, often requiring surgical intervention when conservative treatments fail. Total disc replacement (TDR) has emerged as a motion-preserving alternative to spinal fusion, aiming to maintain segmental mobility while alleviating pain [1-3]. However, early-generation articulating TDRs have shown limitations in replicating the full biomechanical behavior of the native intervertebral disc[4, 5].

Charité (DePuy Synthes, Raynham, MA, USA) and ProDisc-L (Centinel Spine, West Chester, PA, USA) are two widely used articulating TDR systems designed to mimic the mechanical function of the lumbar disc. Charité features an unconstrained design, while ProDisc-L employs a semi-constrained ball-and-socket configuration. While both devices preserve motion, biomechanical studies indicate that they do not fully replicate the stiffness and segmental mechanics of the native disc. These implants have been shown to significantly increase range of motion (RoM) and segmental lordosis compared to intact lumbar segments, particularly in flexion-extension and axial rotation [6-8]. These mechanical differences may impact adjacent segment health and contribute to long-term complications.

Importantly, while articulating TDRs maintain or enhance motion, the flexibility they introduce is not necessarily physiologic. The increased mobility and changes in contact mechanics suggest a less stiff, more compliant segment than intended, especially in the absence of annular structures. Though effective in reducing pain and restoring mobility, these devices may deviate from the native disc's natural shock absorption and load-sharing characteristics, which are critical to spinal stability and function [6-8].

1 To address these shortcomings, viscoelastic total disc replacements (VTDRs) have been
2 engineered to mimic the shock absorption and flexural stiffness of the natural disc [9, 10]. Unlike
3 articulating ball-and-socket implants, VTDRs incorporate deformable polymer cores designed to
4 replicate the nonlinear stiffness of the native disc, stiffening progressively under increasing loads
5 while allowing controlled motion within physiological ranges. This viscoelastic behavior offers
6 the potential to restore not only RoM but also the native disc's capacity for shock absorption and
7 damping, thereby reducing stress on adjacent structures.

8 Despite these advancements, there remains limited published data directly comparing the
9 stiffness of a VTDR to that of the native lumbar disc under physiologic loading. To our
10 knowledge, this is the first in vitro study to quantify the stiffness behavior of a viscoelastic
11 lumbar disc across axial compression, flexion-extension, and axial rotation, and to compare these
12 values to reported benchmarks for healthy discs.

13 The objective of this study is to evaluate whether a VTDR can replicate the biomechanical
14 stiffness of the native lumbar disc in clinically relevant loading modes. By addressing this
15 knowledge gap, we aim to provide biomechanical validation for VTDRs as next-generation
16 implants capable of restoring natural spinal function more effectively than legacy articulating
17 designs.

18 19 **2 Methods**

20 Biomechanical testing was performed in accordance with applicable American Society for
21 Testing and Materials (ASTM) standards for total disc replacement (TDR) devices [11, 12]. In
22 line with the guidelines for evaluating functional performance, kinematics, and wear
23 characteristics of TDRs, functional failure was defined as any permanent deformation or wear

that impairs the implant's ability to sustain normal loads or intended motion [13]. Mechanical failure referred to material-related damage, such as fatigue cracks or bonding failure, that may or may not result in functional impairment. Testing focused on the smallest available disc size ($26 \times 36 \text{ mm}^2$, 13 mm height, 12° lordotic angle) to represent the “worst-case scenario” for mechanical durability. To capture the full performance range, range of motion (RoM) testing was also performed on the largest available size at the time ($28 \times 38 \text{ mm}^2$, 16 mm height, 12° lordotic angle). The AxioMed® Freedom Lumbar Disc (FLD) (AxioMed LLC, Burlington, MA, USA) VTDR implants were preconditioned in phosphate-buffered saline (PBS) at $37 \pm 3^\circ\text{C}$ for a minimum of three days prior to testing, and all evaluations were conducted in a physiologic temperature-controlled PBS environment. Each implant was mounted within custom steel fixtures and subjected to load using a servohydraulic testing system. An MTS 810 system (MTS, Eden Prairie, MN, USA) was used for flexion-extension testing, while an INSTRON 8874 system (INSTRON, Norwood, MA, USA) was utilized for compression and torsion. RoM testing in axial compression and torsion was carried out on ten implants using quasi-static and cyclic loading protocols. Compressive loads ranged from 400 to 2000 N, while torsional loads were applied up to $\pm 6 \text{ Nm}$. Key outcome measures included RoM, static stiffness (calculated over the 400–600 N range for compression and at 4 Nm for torsion), dynamic stiffness (from a single cycle and averaged over the final five cycles), and hysteresis (recorded at the 90th and 190th cycles for compression and torsion, respectively). For flexion-extension testing, ten implants were subjected to loads ranging from +8 Nm (flexion) to –6 Nm (extension). Metrics included RoM, static and dynamic stiffness (from cycles 380 to 420), and hysteresis (measured at the 400th cycle). All data were captured under closed-loop control to ensure consistency.

Static axial compression testing followed ASTM F2346 standards to assess construct stiffness and failure thresholds. Five implants of the smallest size were tested under displacement control at a rate of 0.2 mm/s until reaching a 20,000 N force limit. Collected data included peak load, displacement at peak load, physiologic-range stiffness, and mode of failure. RoM and stiffness data from the viscoelastic disc were subsequently compared to published cadaveric benchmarks of the native lumbar disc to evaluate the ability of the viscoelastic implant to replicate natural biomechanical performance.

3 Results

3.1 Stiffness and Displacement

Under an axial compressive load of 2000 N, the axial displacement of the AxioMed® FLD ranged from 0.7 to 1.3 mm. The corresponding axial stiffness was measured between 1.55 and 3.48 kN/mm, which falls within or slightly exceeds the reported stiffness range of native lumbar discs (0.5–2.5 kN/mm) [14-18], indicating appropriate load-sharing capacity and resistance to deformation under physiologic conditions.

3.2 Rotational Stiffness

In axial rotation, the FLD demonstrated stiffness values between 0.72 and 0.83 Nm/deg. This was lower than native lumbar disc stiffness, which typically ranges from 2.0 to 9.6 Nm/deg [16, 17, 19], suggesting the device allows greater rotational motion than the natural disc under similar loading.

3.3 Flexion and Extension Stiffness

Flexion stiffness values for the FLD ranged from 1.4 to 2.12 Nm/deg, which overlaps with native lumbar discs reported to range from 0.8 to 2.5 Nm/deg [17]. Extension stiffness ranged from 1.4

to 2.14 Nm/deg, slightly below the native disc value of 2.1 Nm/deg [17], indicating comparable resistance to motion in both flexion and extension planes.

3.4 Range of Motion (RoM)

RoM testing across all mechanical modes demonstrated that the viscoelastic disc maintains a motion profile comparable to that of the human lumbar disc. No mechanical or functional failures were observed in any of the tested implant sizes throughout ROM assessments.

3.5 Static Axial Compression

During static compression testing, stiffness increased nonlinearly with increasing load. All devices remained structurally intact up to the 20,000 N load limit of the testing machine. The average displacement at peak load was 3.36 mm, and no device exhibited signs of mechanical or functional compromise under high-load conditions.

Table 1 summarizes the stiffness parameters between AxioMed® FLD and the native lumbar disc.

4 Discussion

4.1 Brief Summary

This study evaluated the in vitro biomechanical performance of a AxioMed® VTDR device and compared its mechanical stiffness and RoM to that of the native human lumbar disc. While earlier-generation TDRs often prioritized motion preservation without fully replicating physiologic biomechanics, this study addresses the gap in comparative stiffness data by directly measuring the mechanical response of a VTDR designed to simulate the natural disc's shock absorption and load distribution characteristics.

4.2 Key Findings

The VTDR device demonstrated axial compression stiffness values ranging from 1.55 to 3.48 kN/mm, consistent with or slightly exceeding native disc stiffness values reported in the literature (0.5–2.5 kN/mm). These higher values, particularly in compression, the spine's primary load-bearing direction, may confer improved implant stability and durability. In flexion and extension, the VTDR stiffness (1.4–2.14 Nm/deg) closely matched native values (0.8–2.5 Nm/deg), further supporting its capacity to preserve physiologic motion. Although the device showed lower stiffness in axial rotation (0.72–0.83 Nm/deg) than native discs (2.0–9.6 Nm/deg), this resulted in increased RoM, which still fell within a functional, physiologic range. No functional or mechanical failures were observed, and nonlinear load-displacement curves in static compression confirmed the presence of both neutral and elastic zones, replicating native disc mechanics.

4.3 Comparison with Similar Research

Previous TDR designs, particularly early-generation articulating devices, often failed to restore the viscoelastic behavior of the intervertebral disc, resulting in excessive motion and low resistance across the full RoM. In cadaveric and finite element studies, ProDisc-L has demonstrated up to a 91.4% increase in extension RoM and more than 150% increase in facet joint loading, indicating altered load transfer and segmental stiffness [8].

In contrast, the VTDR evaluated in this study reproduced both the compliant neutral zone and the stiffening elastic zone seen in healthy discs, a feature rarely achieved in mechanical disc replacements. A study at the Musculoskeletal Biomechanics Laboratory at Loyola University Chicago Stritch School of Medicine illustrated how closely the FLD implant closely mirrored the native disc at L4-5 in flexion-extension RoM loops (Figure 1).

4.4 Limitations

This study was limited to in vitro testing using standardized fixtures and physiologic loading conditions. While this approach enables consistent comparison of device mechanics, it does not account for biological factors such as bone-implant interface behavior, tissue remodeling, or wear particle response. Additionally, cadaveric lumbar disc values used for comparison were extracted from previously published literature rather than directly measured under identical testing conditions.

4.5 Clinical Relevance

By replicating the stiffness and motion characteristics of the natural lumbar disc, this VTDR may offer advantages in load sharing, segmental stability, and shock absorption, critical elements for reducing adjacent segment degeneration and improving long-term outcomes. Its biomechanical profile supports its use in motion-preserving spine surgery as an alternative to fusion or legacy TDRs, particularly in patients with high functional demands.

4.6 Implications for Further Research

Future studies should include cadaveric comparative testing under identical protocols, long-term fatigue testing, and in vivo studies evaluating clinical outcomes, implant stability, and wear behavior. Additionally, analysis of kinematic coupling and segmental alignment over time will be critical to validate this VTDR's functional durability and its effect on global spine biomechanics.

5 Conclusion

This in vitro investigation is the first to directly evaluate and compare the stiffness of a viscoelastic total disc replacement to published values for the native human lumbar disc. The

1 VTDR demonstrated physiologic stiffness and RoM in axial compression, flexion-extension, and
2 axial rotation. Its dual-zone mechanical behavior, characterized by a compliant neutral zone and
3 stiffening elastic zone, mirrors the natural stress-strain response of a healthy disc. These findings
4 support the potential of this VTDR to restore natural spinal function, offering a promising
5 alternative to both fusion and traditional TDR devices.

6

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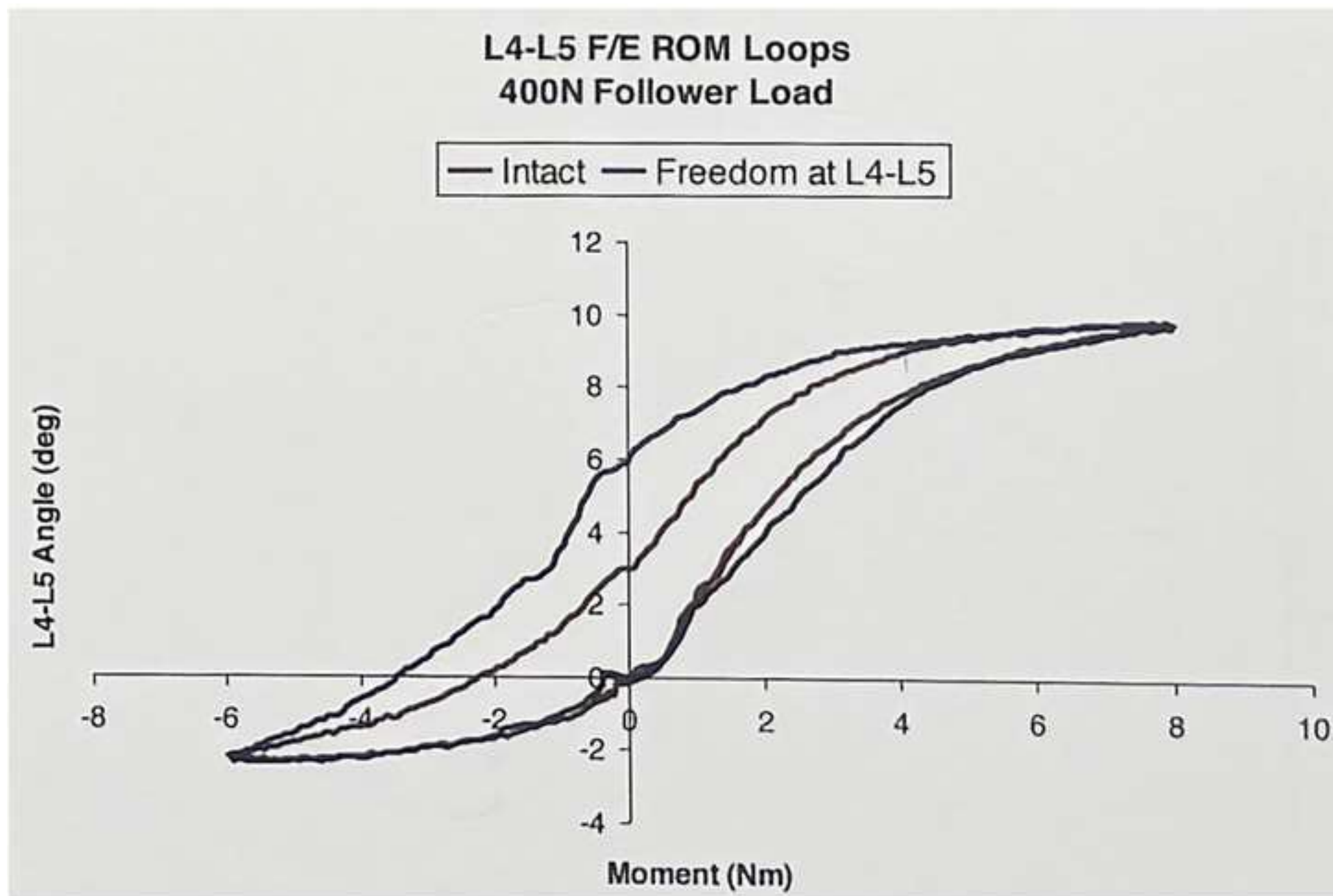
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1 **Figure Legend**

2 Figure 1: Moment versus Angel of the Freedom Lumbar Disc Compared To the Native Lumbar

3 Disc.

4



1 Table 1 summarizes the stiffness parameters between AxioMed FLD and the native lumbar disc.

Parameter	AxioMed FLD	Native Lumbar Disc
Axial Compression Stiffness (kN/mm)	1.55-3.48	0.5-2.5
Axial Rotational Stiffness (Nm/Deg)	0.72-0.83	2.0-9.6
Flexion Stiffness (Nm/deg)	1.4-2.12	0.8-2.5
Extension Stiffness (Nm/deg)	1.4-2.14	2.1

2