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Comparative In Vitro Biomechanical Range Of Motion Study of A Viscoelastic Disc Versus Two Articulating Total Disc Replacements Versus The Native Lumbar Disc

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Corresponding Author:	Kingsley Richard Chin, MD Less Exposure Surgery (LESS) Clinic Fort Lauderdale, FI UNITED STATES
Corresponding Author E-Mail:	kingsleychin@lesclinic.com;kingsleychin@gmail.com
Corresponding Author Secondary Information:	
Corresponding Author's Institution:	Less Exposure Surgery (LESS) Clinic
Corresponding Author's Secondary Institution:	
First Author:	Kingsley Richard Chin, MD
First Author Secondary Information:	
Order of Authors (with Contributor Roles):	Kingsley Richard Chin, MD (Conceptualization; Methodology; Supervision; Writing – review & editing)
	Sukanya Chebrolu (Project administration; Writing – original draft)
	Roger D Sung, MD (Supervision)
	Jeffrey R Carlson, MD (Supervision)
	Mark W McFarland, DO (Supervision)
	Erik Spayde, MD (Methodology; Resources; Supervision)
	William M Costigan, MD (Conceptualization; Methodology; Resources; Supervision)
	Sandra Thompson, MD (Conceptualization; Resources; Supervision)
	Vito Lore, PE (Investigation; Resources; Writing – review & editing)
	Kari B Zimmers (Conceptualization; Supervision)
	Hope Estevez (Project administration; Resources)
	Swapnil Pangarkar (Project administration; Resources)
	Aditya Humad (Project administration; Resources)
	Chukwunonso C Ilogu, MD (Investigation; Project administration; Writing – original draft)
	Jason A Seale, MBBS (Project administration; Validation; Writing – review & editing)
Order of Authors Secondary Information:	
Additional Information:	

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Kingsley R Chin MD[1,2,3,4,5]
Sukanya Chebrolu[5]
Roger D Sung MD[6]
Jeffrey R Carlson MD[7]
Mark W McFarland DO[7]
Erik Spayde MD[8]
William M Costigan MD[9]
Sandra Thompson MD[10]
Vito Lore[5,11]
Kari B Zimmers[12]
Hope Estevez[1,5]
Swapnil Pangarkar[5]
Aditya Humad[5]
Chukwunonso C Ilogu MD[1,5]
Jason A Seale MBBS[1,5]

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

Background

Lumbar degenerative disc disease (DDD) is a major contributor to chronic low back pain and disability. Total disc replacement (TDR) offers a motion-preserving alternative to spinal fusion; however, articulating ball-and-socket designs, such as the unconstrained CHARITÉ and semi-constrained ProDisc-L, often fail to replicate the biomechanical properties of the native disc. This study presents the first in vitro range of motion (ROM) comparison of a viscoelastic TDR, the AxioMed® Freedom Lumbar Disc (FLD), to both legacy devices and cadaveric lumbar spine benchmarks.

Methods

The FLD underwent in vitro biomechanical testing under simulated physiologic loading to assess ROM in flexion-extension, lateral bending, and axial rotation. ROM values were compared to publicly available FDA Summary of Safety and Effectiveness Data for CHARITÉ and ProDisc-L, as well as published data from cadavers and healthy volunteered lumbar discs.

Results

The FLD demonstrated ROM values within native physiologic ranges: 3.0–5.3° (flexion), 1.9–5.0° (extension), ±4° (lateral bending), and 7.6–8.4° (axial rotation). In contrast, CHARITÉ and ProDisc-L exceeded native norms, with flexion up to 13° and lateral bending up to ±10°. Native cadaveric ranges typically span 5.4–13° flexion, 1–5° extension, ~4.3° lateral bending, and 1–5.8° axial rotation. The FLD more closely mirrored native biomechanics and demonstrated more controlled motion across all planes.

Conclusions

The AxioMed® FLD more accurately reproduces the native lumbar disc's multidirectional motion than traditional articulating ball-and-socket TDRs. Its viscoelastic, one-piece design

enables motion damping and physiologic mobility, suggesting improved biomechanical compatibility for lumbar disc arthroplasty. This is a controlled in vitro biomechanical study. Findings highlight the potential for viscoelastic TDRs to better restore native spinal kinematics, warranting further clinical investigation.

Clinical Relevance

These findings highlight the potential of viscoelastic TDRs to more closely replicate native spinal kinematics than traditional articulating designs, supporting the need for further clinical evaluation in patients with lumbar DDD.

Keywords: AxioMed® viscoelastic disc replacement; Biomechanical Study; In Vitro; Range of Motion (ROM); Lumbar Spine; Total disc replacement (TDR); Intervertebral Disc.

Introduction

Lumbar degenerative disc disease (DDD) is one of the most prevalent causes of chronic low back pain and disability worldwide, contributing significantly to reduced quality of life and economic burden [1]. DDD results from structural and biomechanical changes in the disc, often driven by aging but also influenced by factors such as genetics, obesity, smoking, trauma, and repetitive spinal loading, particularly in physically active populations [2-5]. While conservative management can alleviate symptoms in many patients, a subset with progressive structural degeneration requires surgical intervention. Spinal fusion remains the gold standard for such cases; however, it eliminates motion at the treated level and has been associated with adjacent segment degeneration (ASD) due to altered spinal biomechanics [6, 7].

Total disc replacement (TDR) emerged as a motion-preserving alternative to spinal fusion, aiming to maintain physiological segmental motion and reduce the risk of ASD. Randomized controlled trials and long-term follow-ups have demonstrated that articulating TDRs, such as the CHARITÉ (DePuy Synthes, Raynham, MA, USA) and ProDisc-L (Centinel Spine, West Chester, PA, USA), can yield clinical outcomes comparable to fusion in well-selected patients [8-10]. CHARITÉ is an unconstrained design, featuring a mobile ultra-high molecular weight polyethylene core that articulates freely between cobalt-chrome endplates [11]. In contrast, ProDisc-L is a semi-constrained design with a fixed polyethylene core that limits translation and permits primarily rotational motion. Both devices use a ball-and-socket articulation to enable flexion-extension, lateral bending, and axial rotation. However, their mechanical behavior deviates from the native intervertebral disc, particularly in terms of viscoelasticity and compressive deformation [12, 13].

Unlike the healthy lumbar disc, which exhibits nonlinear stiffness, energy damping, and time-dependent deformation (creep and stress relaxation), articulating TDRs lack true shock absorption. They do not replicate axial compressibility or restore physiological load sharing, which may contribute to increased facet joint stress, altered kinematics, and implant-related complications over time [14, 15]. Additional complications such as osteolysis, heterotopic ossification, device migration, and loss of sagittal balance have been associated with articulating TDRs [16-19].

Next-generation designs have sought to overcome these limitations. The AxioMed® Freedom Lumbar Disc (FLD) (AxioMed LLC, Burlington, MA, USA) is a one-piece, viscoelastic TDR (VTDR) implant comprising a thermoplastic elastomer core bonded chemically and mechanically to titanium alloy endplates. The design aims to restore the spine's native multidirectional motion while preserving its viscoelastic, load-bearing, and shock-absorbing properties [20]. A growing body of clinical studies supports the effectiveness of the AxioMed® VTDR [21-23]. Rischke et al. [22] reported significantly greater relief of leg and back pain following VTDR compared to anterior lumbar interbody fusion (ALIF).

Although prior mechanical studies have characterized the FLD's behavior under load [20, 24], few have directly compared its performance to both traditional articulating TDRs and cadaveric benchmarks of healthy lumbar segments. Such comparative analyses are essential to contextualize newer viscoelastic technologies within the broader evolution of spinal arthroplasty.

The aim of this in vitro biomechanical study was to compare the range of motion (ROM) of the AxioMed® FLD across multiple planes to established data for the CHARITÉ and ProDisc-L devices, as well as to cadaveric data representing the biomechanical norms of the native lumbar spine. We hypothesized that the FLD would more closely replicate native lumbar disc

biomechanics and provide more controlled motion than unconstrained and semi-constrained articulating TDRs.

Materials and Methods

Mechanical testing of the AxioMed® Freedom Lumbar Disc (FLD) was performed in accordance with ASTM F2346 and F2423 standards for evaluating the functional and kinematic properties of spinal total disc replacement (TDR) devices [20, 24-26]. All testing was conducted in a physiologically simulated environment using phosphate-buffered saline (PBS) at 37°C to approximate in vivo conditions. Testing was performed using INSTRON 8872/8874 and MTS 810 servohydraulic test systems. Range of motion (ROM) testing was conducted on ten FLD devices to evaluate performance under physiologic loads. Tests included flexion-extension (±8 Nm), lateral bending (±12 Nm), and axial rotation (±6 Nm). Motion endpoints were recorded to assess conformity to native disc kinematics.

For comparison, ROM data for the CHARITÉ and ProDisc-L devices were obtained from publicly available United States Food and Drug Administration (FDA) Summary of Safety and Effectiveness Data (SSED) and cadaveric studies [27-29]. Native lumbar disc ROM values were extracted from published cadaveric literature representing typical biomechanics. [27, 30-41].

Results

The AxioMed® FLD demonstrated ROM within physiologic limits observed in the human lumbar spine. Specifically, the FLD provided 3.0–5.3° of flexion at 8 Nm, 1.9–5.0° of extension at 6 Nm, ±4° of lateral bending at ±12 Nm, and 7.6–8.4° of axial rotation at ±6 Nm. In contrast, CHARITÉ and ProDisc-L showed higher ROM values, particularly in flexion and lateral

bending, up to 13° and ±10°, respectively. These values exceed typical cadaveric ranges and may increase the risk of hypermobility or facet joint overload. The FLD's motion more closely approximated native disc behavior, supporting its potential to restore segmental mobility while maintaining physiologic control [20].

Table 1 summarizes the comparative ROM data for the FLD, CHARITÉ, and ProDisc-L, alongside reference values for native lumbar discs.

Discussion

Key Findings

To our knowledge, this is the first in vitro biomechanical study to directly compare the range of motion of a viscoelastic lumbar disc replacement to both articulating TDRs and native lumbar disc values. This biomechanical study compares the range of motion (ROM) of the AxioMed® FLD, a viscoelastic total disc replacement (TDR), with articulating TDRs, CHARITÉ and ProDisc-L, to evaluate how closely each replicates native lumbar disc behavior. The FLD exhibited ROM values within physiologic limits, while CHARITÉ and ProDisc-L demonstrated excessive motion, particularly in flexion and lateral bending. These findings indicate that the FLD more closely approximates native lumbar kinematics and may help mitigate the biomechanical complications associated with traditional ball-and-socket designs.

Explanation of Findings

The exaggerated ROM observed in CHARITÉ and ProDisc-L supports the hypothesis that unconstrained or semi-constrained articulations permit non-physiologic motion, contributing to increased facet joint stress and degeneration. The FLD's one-piece viscoelastic design allows for multidirectional movement while offering intrinsic motion damping and axial compression. This

biomimetic behavior may protect against excessive motion and associated mechanical overload, offering a key functional distinction from articulating TDRs.

Strengths and Limitations

A major strength of this study is the controlled, standardized in vitro testing environment using ASTM protocols to assess ROM under simulated physiologic conditions for AxioMed®. Comparative data from FDA summaries and published cadaveric studies strengthen the external validity. However, limitations include the absence of direct mechanical testing for CHARITÉ and ProDisc-L under identical conditions. Literature-derived data introduce variability due to differences in methodology. Additionally, the use of synthetic test environments cannot account for biological responses such as inflammation, bone remodeling, and implant-bone interface changes seen in vivo.

Comparison with Similar Research

Previous investigations into articulating ball-and-socket TDRs have reported increased ROM and elevated loading at the index level, often accompanied by reduced mobility at adjacent segments [42]. The degree of constraint inherent to articulating disc designs has been shown to influence postoperative spinal kinematics and load transmission [43]. Notably, biomechanical analyses have demonstrated that the geometric configuration of ball-and-socket implants significantly impacts segmental motion, facet joint contact forces, and stresses within the cancellous bone. These effects may be further amplified by anatomical variability between patients, suggesting that the traditional articulating ball-and-socket architecture may not be optimal for all individuals [44].

Additional studies have raised concerns about increased facet joint loading following TDR, particularly with unconstrained or semi-constrained devices. Narendran et al.[45] observed

higher rates of facet joint interventions in TDR patients compared to those treated with fusion. Lemaire et al.[46] showed facet loading in torsion with CHARITÉ was 2.5 times that of intact discs. Multiple studies have demonstrated the impact of implant placement and ligament injury on facet forces [23, 47, 48]. Retrospective imaging studies have further corroborated these findings. Shim et al.[14] and Park et al.[49] reported significant postoperative progression of facet arthrosis in CHARITÉ and ProDisc-L patients. More recently, Furunes et al.[50] reported a 36% progression of facet degeneration at 8-year follow-up.

Implications and Actions Needed

These findings support the FLD's potential role as a motion-preserving alternative for treating lumbar degenerative disc disease, with improved biomechanical fidelity to the native disc. Future studies should focus on direct comparative testing between devices using uniform methods, as well as long-term clinical outcomes evaluating adjacent segment degeneration, facet arthrosis, and device survivorship.

Conclusion

This in vitro biomechanical study is the first to compare the range of motion of a viscoelastic total disc replacement, the AxioMed® Freedom Lumbar Disc (FLD), with both articulating TDRs, CHARITÉ and ProDisc-L, and native lumbar disc benchmarks. The FLD demonstrated a range of motion that remained within physiologic limits and more closely matched native disc behavior than the excessive mobility observed in the CHARITÉ and ProDisc-L designs. Its viscoelastic architecture, which allows for motion damping and axial compression, may offer advantages in minimizing facet joint stress and preserving adjacent segment function. These findings support the FLD as a next-generation, motion-preserving solution for lumbar disc

arthroplasty. Future clinical studies are warranted to validate these biomechanical advantages in vivo and assess long-term patient outcomes.

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Figure Legend

Figure 1: AxioMed Freedom Lumbar Disc (FLD) one-piece viscoelastic design.

Figure 2: Range of motion in flexion: AxioMed versus Native Lumbar Disc.

Figure 3: Range of motion in flexion: AxioMed versus Native Lumbar Disc.

Figure 1

Figure 2

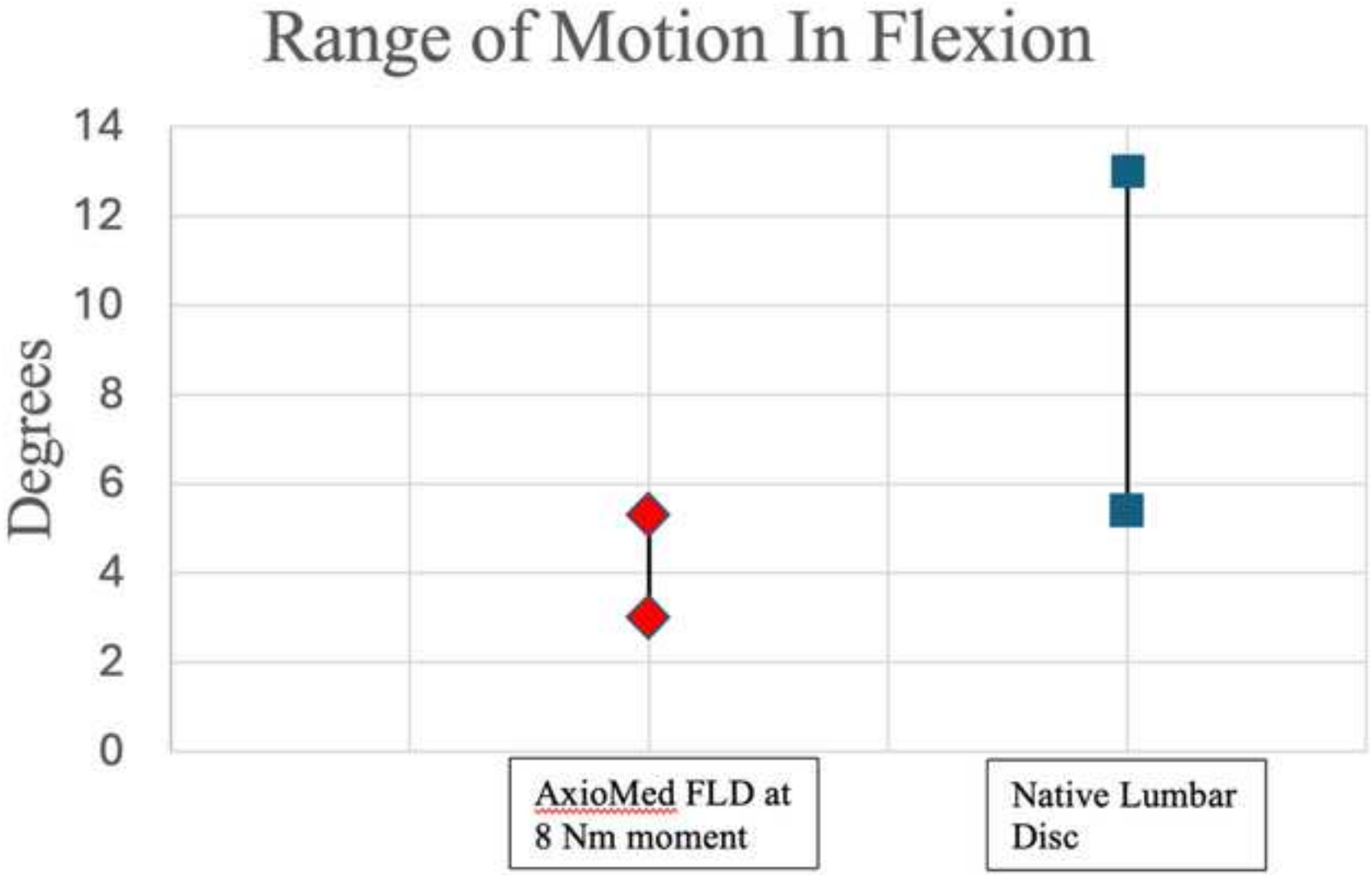
Range of Motion In Flexion
Degrees
14
12
10
8
6
4
2
0
AxioMed FLD at 8 Nm moment
Native Lumbar Disc

Figure 3

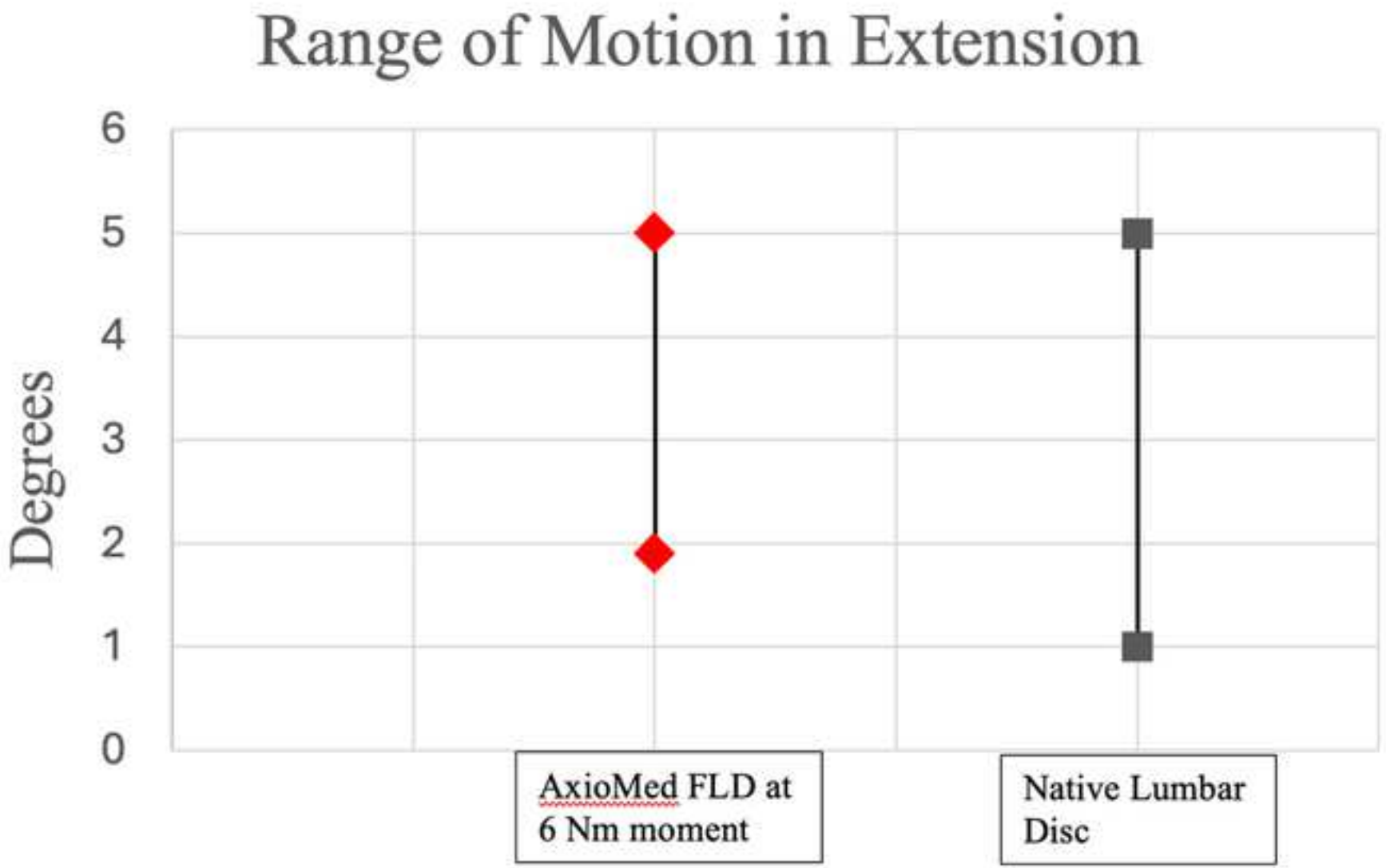
Range of Motion in Extension
Degrees
6
5
4
3
2
1
0
AxioMed FLD at 6 Nm moment
Native Lumbar Disc

Table 1. Comparative Range Of Motion Data of AxioMed FLD, CHARITÉ, ProDisc-L, and Native Lumbar Disc

Parameter	AxioMed FLD [20]	CHARITÉ [27]	ProDisc-L [29]	Native Lumbar Disc
Design Type	One-piece viscoelastic	Articulating Ball-and-socket (unconstrained)	Articulating Ball-and-socket (semi-constrained)	Healthy volunteers & cadavers
Flexion ROM (°)	3.0–5.3	8.11	13	5.40-13 [27, 37, 40, 41]
Extension ROM (°)	1.9–5.0	4.67	7	1-5 [27, 37, 40, 41]
Axial Rotation ROM (°)	7.6–8.4	8.39	±3	1-5.8 [27, 30, 38, 39]
Lateral Bending ROM (°)	±4	12.9	±10	4.34 [27]
Shock Absorption	Yes	No	No	Yes

FLD, Freedom Lumbar Disc; ROM, Range Of Motion.