



ASTM biomechanical study comparing the AxioMed lumbar viscoelastic disc to human lumbar disc data

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ABSTRACT

Background: 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 characterize native spinal biomechanics. To date, no in vitro study has directly compared the stiffness of a viscoelastic total disc replacement (VTDR) to that of the natural lumbar disc under physiologic conditions.

Methods: Ten AxioMed® lumbar VTDRs were tested using standardized ASTM protocols in a physiologic environment (PBS at $37 \pm 3^\circ\text{C}$). Axial compression, flexion-extension, axial rotation and compressive shear stiffness were measured using servohydraulic test systems. An additional five implants underwent static axial loading up to 20,000 N. All values were compared to published stiffness ranges for the healthy human lumbar disc.

Findings: Axial stiffness ranged from 2.56 to 3.48 kN/mm, overlapping the reported native range of 0.5 to 2.5 kN/mm. Flexion-extension stiffness (1.69–2.14 Nm/deg) matched the physiologic range (0.8–2.5 Nm/deg). Rotation stiffness (0.79–0.83 Nm/deg) was lower than native values (2.0–9.6 Nm/deg), resulting in greater rotational mobility. **Compressive shear stiffness (0.49–0.59 kN/mm) fell within the native lumbar disc range (0.4–0.7 kN/mm).** All implants withstood static compression to 20,000 N without structural failure.

Interpretation: These findings show that the AxioMed® VTDR reproduces lumbar disc stiffness more closely 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.

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

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segmental mobility while alleviating pain (Blumenthal et al., 2005; Li et al., 2020; Rao and Cao, 2014). However, early-generation articulating TDRs have shown limitations in replicating the full biomechanical behavior of the native intervertebral disc (Hsieh et al., 2023; Jung et al., 2013).

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 (Chen et al., 2009; Demetropoulos et al., 2010; Wilke et al., 2012). 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 do not fully replicate the native disc's natural shock absorption and load-sharing, which are essential for spinal stability and function (Chen et al., 2009; Demetropoulos et al., 2010; Wilke et al., 2012). In addition, clinical studies have reported device-related failures and variable patient-reported outcome measures (PROMs), highlighting the limitations of early-generation TDRs in achieving durable clinical success (Eskandar et al., 2024).

To address these shortcomings, viscoelastic total disc replacements (VTDRs) have been engineered to mimic the shock absorption and flexural stiffness of the natural disc (Lazennec, 2020; Lazennec et al., 2019). Unlike articulating ball-and-socket implants, VTDRs incorporate deformable polymer cores designed to replicate the nonlinear stiffness of the native disc, stiffening progressively under increasing loads while allowing controlled motion within physiological ranges. This viscoelastic behavior offers the potential to restore not only RoM but also the native disc's capacity for shock absorption and damping, thereby reducing stress on adjacent structures.

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

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

2. Methods

Biomechanical testing was performed in accordance with applicable American Society for Testing and Materials (ASTM) standards for total disc replacement (TDR) devices (F2346 AS, 2005; F2423 AS, 2005) (Fig. 1). All biomechanical testing was outsourced to independent facilities. In line with the guidelines for evaluating functional performance, kinematics, and wear 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 (Benzel et al., 2011). Mechanical failure referred to material-related damage, such as fatigue cracks or bonding failure, that may or may not result in



Fig. 1. Experimental setup for axial compression testing of the AxioMed® Freedom Lumbar Disc.

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 $\pm 6 \text{ Nm}$. Each implant underwent up to 190 loading cycles in compression and torsion. 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 $+8 \text{ Nm}$ (flexion) to -6 Nm (extension). **Flexion-extension testing consisted of 420 cycles.** 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.

Compressive shear testing was conducted on ten implants at a 45° orientation in accordance with ASTM F2346 protocols. Testing was

performed on an INSTRON 8872 or 8874 servohydraulic system (Instron, Norwood, MA, USA). Cyclic loads between 1200 and 2000 N were applied at a frequency of 3 Hz until either 10^6 cycles were completed or functional/mechanical failure occurred.

Compressive shear testing was also performed to characterize the FLD under combined compression–shear loading in accordance with ASTM F2346. This loading mode, while not physiologic, represents an extreme scenario that places the polymer core and bond interfaces under high tensile and shear stresses. Static tests were conducted on both the smallest (“worst case”) and largest sizes. Five of each device were tested. This approach provided a severe test of construct durability and bone strength at the implant–endplate interface.

RoM and stiffness data from the VTDR were subsequently compared to published cadaveric benchmarks of the native lumbar disc to evaluate the ability of the implant to replicate natural biomechanical performance (Berkson et al., 1979; Edwards et al., 1987; Eijkelkamp et al., 2001a; Schultz et al., 1979; White and Panjabi, 1990). Because native disc values were obtained from previously published literature as ranges rather than raw datasets, inferential statistical analyses (e.g., hypothesis testing) could not be conducted. Therefore, implant performance was evaluated using descriptive statistics and contextual comparison to published benchmarks.

3. Results

3.1. Stiffness and displacement

Under an axial compressive load of 2000 N, the axial displacement of the AxioMed® FLD ranged from 0.67 to 1.31 mm. The corresponding axial stiffness was measured between 2.56 and 3.48 kN/mm (in the range of 400 to 600 N), which falls within or slightly exceeds the reported stiffness range of native lumbar discs (0.5–2.5 kN/mm) (Berkson et al., 1979; Eijkelkamp et al., 2001b; Li et al., 1995; Tencer et al., 1982; White and Panjabi, 1990), 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 0.79 and 0.83 Nm/deg. This was lower than native lumbar disc stiffness, which typically ranges from 2.0 to 9.6 Nm/deg. (Eijkelkamp et al., 2001b; Schultz et al., 1979; White and Panjabi, 1990), 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 1.69 to 2.12 Nm/deg. (from 0 to 8 Nm), which overlaps with native lumbar discs reported to range from 0.8 to 2.5 Nm/deg. (Eijkelkamp et al., 2001b). Extension stiffness ranged from 1.74 to 2.14 Nm/deg. (from 0 to 6 Nm), slightly below the native disc value of 2.1 Nm/deg. (Eijkelkamp et al., 2001b), indicating comparable resistance to motion in both flexion and extension planes. As illustrated in Fig. 2, both the intact and FLD moment–angle curves demonstrated a compliant neutral zone followed by a progressive elastic zone. The close overlap between the curves indicates that the FLD closely reproduces the nonlinear dual-zone behavior of the native lumbar disc.

3.4. Static axial compression

During static compression testing, stiffness increased nonlinearly with increasing load. This nonlinear load–displacement response is qualitatively similar to that reported for human lumbar discs (Table 1), although direct equivalence could not be established since native controls were not tested under identical conditions. All devices remained

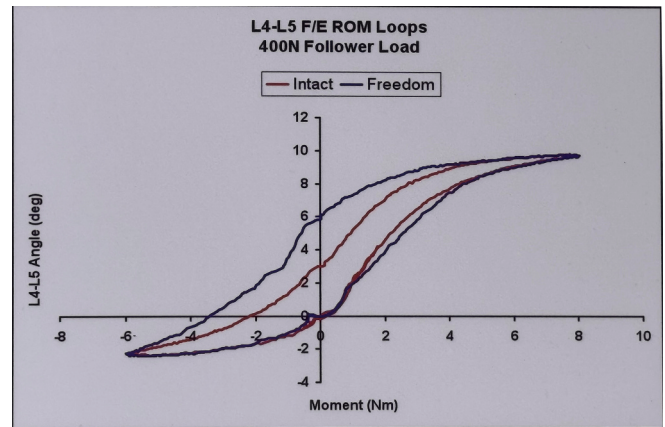


Fig. 2. Flexion-extension moment-angle relationship for the Freedom Lumbar Disc compared with a cadaveric intact lumbar segment at L4–5, tested under laboratory conditions with a 400 N follower load. Both curves demonstrate a compliant neutral zone and a progressively stiffening elastic zone, with close overlap indicating similar nonlinear responses. This comparison is provided as an illustration of how a viscoelastic disc can mimic the nonlinear mechanical profile of the native disc, but it should not be considered definitive evidence of biomechanical equivalence.

Table 1

Summary the range of stiffness parameters between AxioMed FLD and the native lumbar disc.

Parameter	AxioMed FLD	Native Lumbar Disc
Axial Compression Stiffness (kN/mm)	2.56–3.48	0.5–2.5 (Berkson et al., 1979; Eijkelkamp et al., 2001a; White and Panjabi, 1990)
Axial Rotational Stiffness (Nm/Deg)	0.79–0.83	2.0–9.6 (Eijkelkamp et al., 2001a; Schultz et al., 1979; White and Panjabi, 1990)
Compressive Shear (kN/mm)	0.49–0.59	0.4–0.6 (FSU) (Edwards et al., 1987)
Flexion Stiffness (Nm/deg)	1.69–2.12	0.7 (White and Panjabi, 1990)
Extension Stiffness (Nm/deg)	1.74–2.14	0.8–2.5 (Eijkelkamp et al., 2001a)
		2.1 (Eijkelkamp et al., 2001a)

FLD; Freedom Lumbar Disc. FSU; Functional Spinal Unit, two vertebrae and the intervertebral disc.

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.

3.5. Compressive shear stiffness

In compressive shear testing, the FLD demonstrated stiffness values between 0.49 (0.04) and 0.59 (0.02) kN/mm (Table 2). These values

Table 2

Summary of FLD static compressive shear test results.

AxioMed FLD Size	Stiffness from 300 to 1000 N (kN/mm)	Peak Load (kN)	Crosshead displacement at peak load (mm)
	Mean (Standard Deviation)		
L-261312 (Worse case)	0.59 (0.02)	5.32 (0.16)	12.38 (0.15)
L-261312 (Worst case) Post-validation	0.74 (0.02)	5.73 (0.08)	13.85 (0.44)
L-281612 (Largest)	0.49 (0.04)	3.51 (0.51)	11.15 (1.44)

FLD; Freedom Lumbar Disc.

overlap with published ranges for native lumbar discs (0.4–0.6 kN/mm for functional spinal units and up to 0.7 kN/mm in some reports), indicating physiologic performance under shear loading. All implants withstood cyclic loading up to 10^6 cycles at an anterior shear load of 1697 N without mechanical or functional failure.

A crosshead displacement of **11.15 to 13.85 mm** corresponds to a relative displacement of **15.8 to 19.6 mm** between retaining plates. In comparison, anterior/posterior (A/P) shear motion in the lumbar spine has been estimated at approximately 2.8 mm in the anterior direction and 1 mm in the posterior direction, with **4.5 mm of anterior shear considered a marker of instability**. Accordingly, the FLD tolerated displacements representing a **safety factor of 3.5 to 4.4 times** the threshold associated with instability.

Table 1 summarizes the range of stiffness parameters between Axiomed® FLD and the native lumbar disc, while Table 2 details the results of static compressive shear testing across three device sizes.

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 approximate the stiffness behavior of the natural lumbar disc.

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 the ranges reported for native lumbar discs in cadaveric studies (Berkson et al., 1979; Edwards et al., 1987; Eijkelkamp et al., 2001a; Schultz et al., 1979; White and Panjabi, 1990). In compressive shear, the FLD demonstrated stiffness between 0.49 and 0.59 kN/mm, overlapping with reported ranges for native lumbar discs (0.4–0.6 kN/mm for functional spinal units and up to 0.7 kN/mm in individual reports). These findings provide additional evidence that the device replicates native load–deformation behavior across multiple loading modes.

Importantly, the lower axial rotational stiffness suggests a propensity for greater segmental rotation, which may influence posterior element loading. While increased rotation could distribute motion more evenly across the motion segment, it may also elevate facet joint stresses in some conditions; therefore, its clinical relevance requires targeted investigation in specimens with intact posterior elements and, ultimately, in vivo. 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 (Chen et al., 2009).

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. Testing performed at the Musculoskeletal Biomechanics Laboratory at Loyola University Chicago Stritch School of Medicine provided supplemental FLD flexion–extension RoM loops at L4–5 that closely paralleled those of a cadaveric lumbar segment (Fig. 2). The cadaveric specimen was tested under laboratory conditions that typically include a 400 N follower load, consistent with established spine biomechanics protocols (Costi et al., 2021; Ha et al., 2009; Voronov et al., 2009). However, donor characteristics and the inclusion of posterior elements (facets and ligaments) were not reported. Only flexion–extension loops were available; no comparable curves in axial rotation or lateral bending were provided from this test. The close overlap of the two curves highlights similarity in moment–angle responses, though this comparison should be considered illustrative rather than definitive evidence of equivalence.

Other viscoelastic TDRs include the LP-ESP (Spineway, Lyon, France), which uses an elastomeric core with viscoelastic damping and six degrees of freedom, and the now-discontinued M6-L (Orthofix Medical Inc., Lewisville, TX, USA), which combined a polymer nucleus with a fiber annulus to mimic annular mechanics (Faulks et al., 2022; Lazennec, 2020; Lazennec et al., 2013). In contrast, the Axiomed® FLD employs a one-piece homogeneous viscoelastic core without fiber wrapping, representing a different strategy to replicate lumbar disc stiffness.

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. A particularly important limitation is that cadaveric lumbar disc values used for comparison were extracted from previously published literature rather than measured under identical experimental conditions in this study. This restricts the strength of our direct comparison claims, and findings should therefore be interpreted as contextual rather than definitive evidence of equivalence.

Rotational findings were generated without direct measurement of facet joint forces and in the absence of posterior ligaments and facets in the test construct, limiting our ability to interpret potential changes in facet loading or hypermobility risk. Another important limitation is the absence of inferential statistical testing, which was not possible given the reliance on literature-derived ranges rather than directly measured control values. Consequently, our comparisons should be interpreted as descriptive rather than definitive evidence of equivalence.

This study adhered to ASTM-recommended testing configurations for spinal disc prostheses, including stiffness evaluation in compression, compression–shear, flexion–extension, and torsion. At the time of testing, lateral bending was not part of the ASTM test matrix and was therefore not included in the independent laboratory's protocol. This was not due to technical limitations but reflected the scope of the original standardized testing campaign. As a result, while the present findings validate the device's stiffness behavior in the primary ASTM modes, they do not represent a complete biomechanical characterization of its viscoelastic properties. Future work should include dedicated testing of lateral bending and other physiologic loading modes, cadaveric testing with preserved facets and coupled loading, as well as clinical follow-up, to clarify the clinical relevance of the observed stiffness profile.

4.5. Clinical relevance

By replicating the stiffness and motion characteristics of the natural lumbar disc, the AxioMed® VTDR demonstrates promising biomechanical properties that could contribute to improved load sharing, segmental stability, and shock absorption. In addition, compressive shear testing showed that the FLD tolerated anterior/posterior displacements far exceeding physiologic thresholds, with displacement at failure corresponding to 3.5 to 4.4 times the anterior shear displacement associated with lumbar instability reported in the literature. However, these potential advantages have not yet been directly confirmed, and further cadaveric and clinical investigations will be required to validate their clinical significance. Its biomechanical profile supports consideration of its use in motion-preserving spine surgery as an alternative to fusion or commonly used TDRs, particularly in patients with high functional demands.

The VTDR's reduced rotational stiffness relative to native values indicates the potential for increased axial rotation under load. In theory, this could have bidirectional effects: (i) beneficial distribution of motion that limits stress concentrations within the implant–endplate construct, and (ii) a risk of increased facet joint loading or segmental hypermobility in select patients. Because our tests did not include intact posterior elements or direct facet load measurements, we cannot infer clinical risk or benefit from the present data. Cadaveric studies with preserved facets and coupled loading (including follower load) as well as prospective clinical follow-up are needed to determine whether the observed rotational profile is advantageous, neutral, or adverse in practice.

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.

Conflict of Interest Considerations. Some authors are current shareholders or employees of AxioMed®, the developer of the VTDR evaluated in this study. These relationships were established *after* the biomechanical testing described here was completed. No shareholders were involved in the study design, execution, or data collection, and the study is published for purely academic purposes. While these factors do not affect the integrity of the experimental methods or results, they are disclosed here in the interest of full transparency. Independent replication of these findings will nevertheless be important to confirm their broader applicability.

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 VTDR demonstrated physiologic stiffness and RoM in axial compression, flexion-extension, axial rotation and compression shear. Its dual-zone mechanical behavior, characterized by a compliant neutral zone and stiffening elastic zone, mirrors the natural stress-strain response of a healthy disc. **Its dual-zone mechanical behavior, characterized by a compliant neutral zone and stiffening elastic zone, was observed consistently across test modes and reflects features of the natural disc's stress-strain response, though broader validation is still required.**

These findings support the potential of this VTDR to restore natural spinal function, offering a promising alternative to both fusion and traditional TDR devices. However, because native disc benchmarks were drawn from literature rather than directly matched cadaveric controls, these results should be viewed as comparative rather than definitive evidence of equivalence. **Future work should include direct**

cadaveric testing under identical protocols, long-term fatigue and wear assessments, and clinical outcome studies to determine the implant's durability and real-world performance.

CRediT authorship contribution statement

Kingsley R. Chin: Writing – review & editing, Writing – original draft, Methodology, Conceptualization. **Sukanya Chebrolu:** Writing – original draft, Methodology. **Roger D. Sung:** Supervision, Resources. **Jeffrey R. Carlson:** Supervision, Resources. **Mark W. McFarland:** Supervision, Resources. **Erik Spayde:** Supervision, Resources. **William M. Costigan:** Supervision, Resources. **Sandra Thompson:** Supervision, Resources. **Vito Lore:** Supervision, Resources, Investigation. **Kari B. Zimmers:** Methodology, Investigation. **Hope Estevez:** Project administration. **Swapnil Pangarkar:** Resources, Project administration, Conceptualization. **Aditya Humad:** Resources, Project administration. **Chukwunonso C. Ilogu:** Writing – original draft, Visualization. **Jason A. Seale:** Writing – review & editing, Project administration.

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

The authors did not receive any funding, grants or financial support for the preparation of this manuscript. All biomechanical testing was performed independently by third-party laboratories, and the authors were not involved in the design, execution, or funding of the tests. Kingsley R Chin MD reports a relationship with KIC Ventures that includes: board membership and equity or stocks. Erik Spayde MD reports a relationship with KIC Ventures that includes: board membership and equity or stocks. William M Costigan MD reports a relationship with KIC Ventures that includes: board membership and equity or stocks. Sandra Thompson MD reports a relationship with KIC Ventures that includes: equity or stocks. Aditya Humad reports a relationship with KIC Ventures that includes: board membership and equity or stocks. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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