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Novel Total Nucleus Replacement Using Spherical Magnetic Beads: A Biomechanical Study

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Abstract

Objective: Lumbar Degenerative Disc Disease is a potential cause of spinal instability. Surgical techniques such as arthrodesis or arthroplasty are implemented to restore the stability to the spine. Both a fusion and a disc replacement are substantially invasive. A lumbar disk replacement is typically done via retroperitoneal or Trans peritoneal approach. With increasing number of symptomatic levels, the disk replacement becomes incrementally more invasive, with a potential for a significant blood loss, injury to great vessels, injury to abdominal viscera, weakening of abdominal wall, etc. There is no minimally invasive way to perform a disk replacement either at one or multiple levels. Our goal was to evaluate the feasibility of a novel and less invasive total nucleus replacement using magnetic spherical beads in a cadaver-based multidirectional bending flexibility model. We aimed to assess the ability of the beads to restore stability to a spine segment. We hypothesized that the beads would increase stability during flexion and extension motions.

Methods: Three fresh-frozen, human cadaveric L2-L3 segments were used. We performed multidirectional flexibility tests in six directions, under intact, nucleotomy and bead insertion conditions. We measured the ranges of motions, the neutral zone and the elastic zone.

Results: There was statistically significantly more flexion-extension range of motion, neutral zone and elastic zone observed upon nucleotomy than during intact condition. Bead insertion statistically significantly reduced the neutral zone observed after nucleotomy, during flexion and extension loading.

Conclusion: We conclude that our novel total nucleus replacement is capable of restoring the stability to spine motion segments during flexion and extension motions, by means of adjustments to their neutral zones.

Keywords: Biomechanics • Spine • Arthroplasty • Intervertebral disc

Introduction

Degenerative Disc Disease (DDD) is a ubiquitous diagnosis in the aging population. It is a major cause of pain and disability world-wide. DDD may be accompanied by axial pain, radiculopathy, myelopathy, spinal instability, deformity and specific imaging findings [1]. DDD often results in the development of debilitating back pain. This leads to patients' activity levels becoming pain-limited, contributing to the development of comorbidities, including weight gain, diabetes, heart disease, and dependence on pain medication.

Surgical approaches to DDD include spinal decompression, discectomy, fusion, or disc replacement. The current standard of care, spinal fusion across two or more vertebrae, prevents motion, increases stability and is theorized to decrease pain. Major criticisms to spinal fusion surgery include accelerated degeneration of discs above or below the level of fusion [2-4] as well as alteration of kinematics at adjacent segments [5]. Therefore, there is a need for a device or a method to restore function and normal spine kinematics.

For years, disc replacements have been proposed and studied as a potential solution. Total disc replacement procedures involve the complete removal of the intervertebral disc to replace with an artificial disc. This attempts to maintain and/or restore disc height, retain the motion between the vertebrae and indirectly decompress the neural elements by the restoring the disk height and indirectly decompressing the neuroforamina [6,7]. While a total disc replacement surgery allows for the motion between vertebrae, this may cause abnormal motion and stress to the posterior elements at the treated levels, especially with the older ball-and-socket designs [8]. Total nuclear replacements have been developed as an alternative less invasive procedure seeking to correct the effects of DDD with less change to the biomechanics of the spinal column. Rather than replacing the entire disc, a nuclear replacement selectively replaces the nucleus pulposus. Maintaining the annulus fibrosus provides a structural support for the injected biomaterials, however, the defect created in the annulus during the implantation procedures provides a possible site for the biomaterial extrusion. The challenges of current total nucleus replacement, often known as partial disc replacement, include migration or expulsion of the implant, and subsidence [7].

In our study, we introduce a novel Total Nucleus Replacement (TNR) to address the limitations of the previous biomaterial implantation options. We look to develop a proof of concept utilizing metallic, magnetic spherical beads as TNR. In this study, functional biomechanical testing is carried out to establish how well this type of construct maintains the motion characteristics of the native disc. We hypothesized that the implanted beads would increase stability during flexion and extension; evident in range of motion values after bead insertion being comparable to intact values.

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Materials and Methods

Three frozen cadaveric spinal segments were harvested for this study. The specimens were grossly examined for the absence of spinal pathology before inclusion. After examination, the L2-L3 spinal segments were isolated and stripped of the soft tissue, leaving ligamentous structures, facet structures, the nucleus pulposus and annulus fibrosus intact. The L2-L3 levels were chosen due to the specimen availability. The specimens were then frozen until potting for testing.

Specimen preparation

Before potting, the specimens had wood screws inserted to increase adherence to the epoxy. 3 to 4 wood screws were drilled halfway into the cranial and caudal aspects of the L2 and L3 vertebral bodies, respectively. The specimen was then potted using epoxy in a large silicone fixture for the caudal aspect and in a smaller metallic fixture for the cranial aspect. The specimens were aligned using the cylindrical shape of the spine to fit the cylindrical shape of the fixture. The shelves of the potting were not parallel since the lumbar region of the spine from which the specimens were harvested has a natural lordotic curvature.

The floating moment ring, which is used to impart pure moment forces on the specimens, was attached cranially with screws, and the base was secured to linear bearings situated on the test frame using cap screws. Two pedicle screws were attached to the anterior aspect of the vertebral bodies, with one screw per spinal level to later mount optical tracking markers. The screws were placed on opposite sides. During testing, specimens were covered with wetted gauze applied around the circumference of the intervertebral disc.

Optical motion tracking

Two triangular test frame markers (Optotrak marker triads) were attached to the specimen, one per pedicle screw, facing laterally and with their LEDs facing the camera. The movement of the markers was captured by an optoelectronic system (Optotrak 3020; Northern Digital, Inc.). The accuracy of the Optotrak 3020 optical active-marker system has been reported to have a bias of 0.05° and 0.03 mm, with repeatability limits of 0.67° and 0.29 mm [9].

Biomechanical testing

The biomechanical test and Optotrak calibration were run through the MFlexWin software. All specimens underwent a low-speed lumbar spine test in three planes: flexion/extension, axial rotation, and lateral bending. The ranges of motion were recorded in flexion and extension, left and right lateral bending, as well as left and right axial rotation.

For each condition, the loading was applied to a single functional spinal unit in the superior-inferior orientation. Loading was applied via a servo-hydraulic test frame (858 Mini Bionix II; MTS) through a custom fixture for pure moment loading attached to the superior L2 vertebra (Figure 1). A preload of 7.5 Nm was applied three times for 45 seconds with 15 seconds of rest in between preloads for each specimen. During testing, each specimen underwent steadily increasing load from 0-7.5 Nm with 1.5 Nm increment increases every 45 seconds. Data was collected through the MFlexWin (custom) software and stored on a personal computer before being run through the DextrWin (custom) software to extract axis of rotation and translational data. Specimens were tested in the following conditions: intact, after nucleotomy, and after bead insertion.

Creation of nucleotomy specimens, and bead insertion

After intact testing, a nucleotomy was performed on intact specimens. A 5 mm incision was made posterolaterally along the annulus fibrosus. Rongeurs and curettes were inserted through the incision to remove about 2 grams of the nucleus pulposus. After nucleotomy testing, a 5 mm hollow cannula and non-magnetic rod were used to push 80 magnetic neodymium spheres into the nuclear space for the treatment testing (Figures 2 and 3).

Data analysis

Range of Motion (ROM), Elastic Zone (EZ), and Neutral Zone (NZ) were calculated for each specimen at each condition. Neutral zone was defined as the difference in degrees in the zero-load state between each paired moment, after three cycles of preconditioning for each load (ie, flexion-extension,

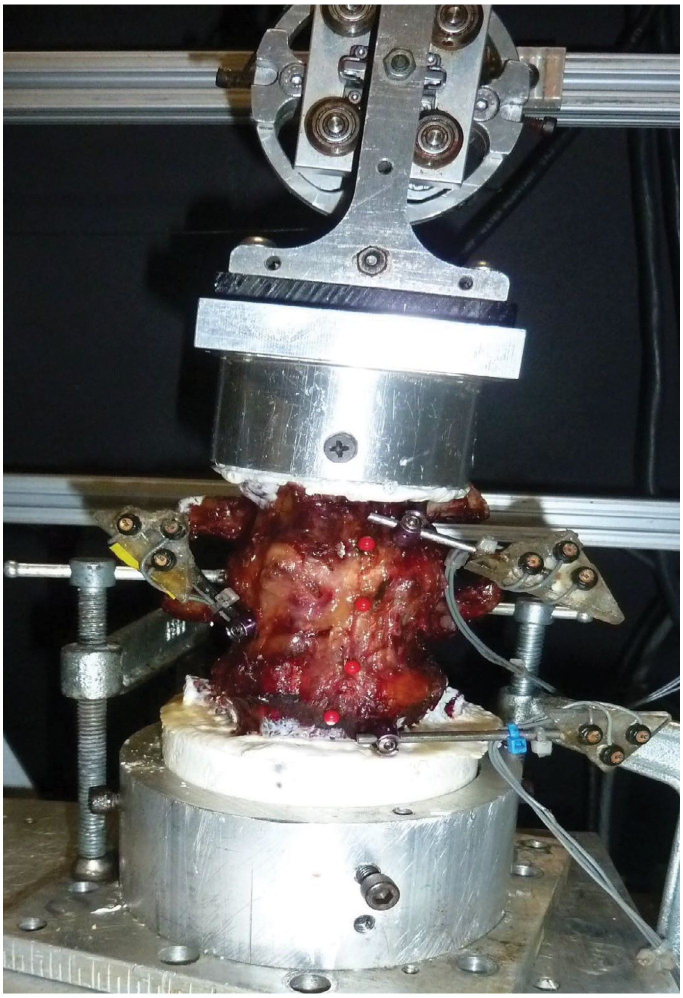

Figure 1. Biomechanical setup showing potted lumbar segments, test frame markers and pure moment loading fixture.

Figure 2. Magnetic spherical nucleus replacement being delivered *via* a tubular cannula through a small defect in the annulus fibrosus.

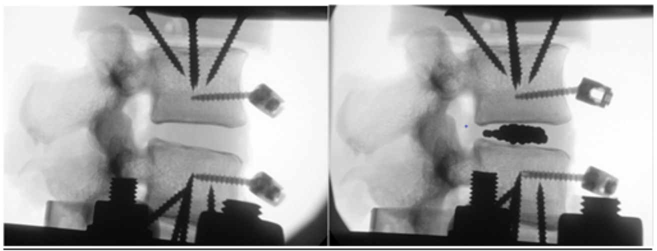

Figure 3. Fluoroscopic lateral image of intact specimen (left) and after total nucleus replacement using magnetic spherical implants (right).

right-left axial, right-left lateral) [10]. The range of motion was defined as the displacement in degrees from the maximum moment to respective the maximum moment for the paired load taken at the final loading cycle. The elastic zone was defined as the range of motion minus the neutral zone.

The intact data was analyzed using paired t-tests between the intact specimens in flexion/extension, lateral bending, and axial rotation. The data comparing between treatment conditions was analyzed using a one-way analysis of variance (ANOVA) with post-hoc comparisons using Tukey-Kramer HSD (JMP, Version 15. SAS Institute Inc., Cary, NC, 1989-2021). For statistical purposes, the data population being sampled from was assumed to be normal; however, with only three samples normality is unlikely, thus, results should not be taken as proof of statistical significance, but a trend towards significance. Data for each functional spinal unit was compared between the 3 conditions (intact, nucleotomy, bead insertion) for each pure moment. P-values less than 0.05 were considered statistically significant. All data is displayed as mean ± standard deviation unless otherwise stated.

Results

Three specimens aged 52-57 from two female and one male cadaver underwent the above-mentioned testing (Table 1). The ranges of rotational motion in each of the three anatomical planes as well as their neutral and elastic zones are displayed in Figure 4. Axial rotation generated the lowest range of motion in all study groups (intact 1.96° ± 0.86°, nucleotomy 3.75° ± 0.79°, replacement 2.82° ± 1.13°, $p \leq 0.028$), and there were no significant differences in range of motion between flexion-extension (intact 4.83° ± 0.62°, nucleotomy 9.72° ± 1.53°, replacement 8.61° ± 1.76°) and lateral bending motions (intact 6.59° ± 1.76°, nucleotomy 10.04° ± 1.20°, replacement 9.48° ± 2.36°) ($p \geq 0.220$). When compared against the intact condition, nucleotomy generated significant range of motion increase during flexion-extension (intact 4.83° ± 0.62° *vs* nucleotomy 9.72° ± 1.53°, p=0.012), there was also similar increase during lateral bending (intact 6.59° ± 1.76° *vs* nucleotomy 10.04° ± 1.20°, p=0.132), and axial rotation (intact 1.96° ± 0.86° *vs* nucleotomy 3.75° ± 0.79°, p=0.128), but these were not significant. The neutral zone was also increased in all loading planes, although only flexion-extension (intact 0.37° ± 0.33° *vs* nucleotomy 2.82° ± 0.67°, p=0.006) was statistically significant. In all loading planes, the elastic zone increased upon nucleotomy, but was only statistically significant during flexion-extension (intact 4.56° ± 0.62° *vs* nucleotomy 6.90° ± 0.99°, p=0.050).

Upon nucleus replacement after nucleotomy, range of motion decreased in flexion/extension (nucleotomy 9.72° ± 1.53° *vs* replacement 8.61° ± 1.76°, p=0.617) and axial rotation (nucleotomy 3.75° ± 0.79° *vs* replacement 2.82° ± 1.13°, p=0.493) across all specimens, although these reductions were not statistically significant. Reduction was seen in the neutral zone in flexion/extension (nucleotomy 2.82° ± 0.67° *vs* replacement 1.06° ± 0.73°, p=0.027) which was statistically significant, as well as axial rotation, although this was not statistically significant (nucleotomy 0.41° ± 0.23° *vs* replacement 0.23° ± 0.10°, p=0.392). Across all specimens, the elastic zone increased during flexion/extension (nucleotomy 6.90° ± 0.99° *vs* replacement 7.55° ± 1.12°, p=0.687), but reduced during axial rotation (nucleotomy 3.34° ± 0.57° *vs* replacement 2.59° ± 1.04°, p=0.533), none of these changes were statistically significant.

Discussion

Research has been continuous regarding the ideal materials and methods of nucleus replacement in patients with DDD as the perfect solution to current nucleus replacement complications has yet to be determined. With the available nucleus replacement options, subsidence through the endplates, extrusion through annular defects, and adjacent segment changes remain recurrent complications. With our novel total nucleus replacement, we aimed to address these concerns by introducing the proof of concept of utilizing neodymium magnetic balls as a nucleus implant prototype. Our novel method increased spinal stability during flexion/extension as indicated by the significant reduction in the neutral zone upon nucleus replacement [11-13].

Improved upon the original single Fernstrom Ball technique [14], our lab has used multiple 3 mm neodymium magnetic balls to increase the surface area where the implant construct contacts the endplates. In theory, this physiologic distribution of load and contact pressure could prevent endplate changes and avoid subsidence. The fluidity of the balls allows them to conform to the dead space created by the removal of nucleus pulposus and to distribute themselves as needed throughout the space. With movement, the localized pressure points between the implant and endplates will change, preventing areas of bone yielding or bone resorption in high strain and lower strain areas, respectively [15]. By design, the ultimate construct of the magnetic balls is customizable by altering the number of balls implanted as well as the size of the individual balls themselves. This theoretically allows the surgeon to calculate the required number and diameter of balls based on both the amount of nucleus pulposus removed and targeted disc height restoration. By continuing to collect data on the resulting outcome measures of ROM, NZ, and EZ based on these input variables, we aim to standardize the calculation to determine the optimal implant construct.

Both stainless steel and cobalt-chromium balls have been used in previous literature with similar goals in mind [16]. Neodymium magnetic balls have the added benefit of drawing together, potentially preventing extrusion through the defect in the annulus fibrosus created during implantation. Preceding studies indicate that the success rate of repairs of the annulus fibrosus by means of adhesive bonding or sutures has been minimal [17,18] though some find the use of Annular Closure Devices (ACD) more promising [19-21]. Our study removes the hurdle of ineffective annulus repair; the attraction between the balls keeps them within the target area while allowing the rearrangement among them required during range of motion of the spinal column.

To similarly address complications from extrusion through the annular defect, Zengerle et al. [19] implemented the use of an ACD in conjunction with a novel collagen-based nucleus implant. Like our study, they were able to perform comparable cyclic loading tests without evidence of implant extrusion from within the annulus fibrosus. Our study was able to accomplish this without the longer procedure time and device-related complications of the additional step of ACD implementation [22]. Other studies utilized finite element analyses to test their implant concept properties, but without comparable cadaveric testing, it is difficult to compare outcomes [17-23]. Reitmaier et al. [24] discusses the importance of restoring the interface between the nucleus implant and the surrounding structures for proper restoration of the native biomechanical function. Unlike typical hydrogel nucleus replacements, our novel design does not allow for interdigitation of the magnetic balls with the adjacent annulus and endplates as their macroscopic size does not provide ideal conditions for facilitating a cellular migration.

As with all studies, our study had limitations involved in the process. Due

Table 1. Specimen summary.

Current State	Gender	Age	Height (inches)	Weight (lbs)	BMI
L2-L3	F	52	64	130	22
L2-L3	M	52	76	265	32.3
L2-L3	F	57	62	185	33.8

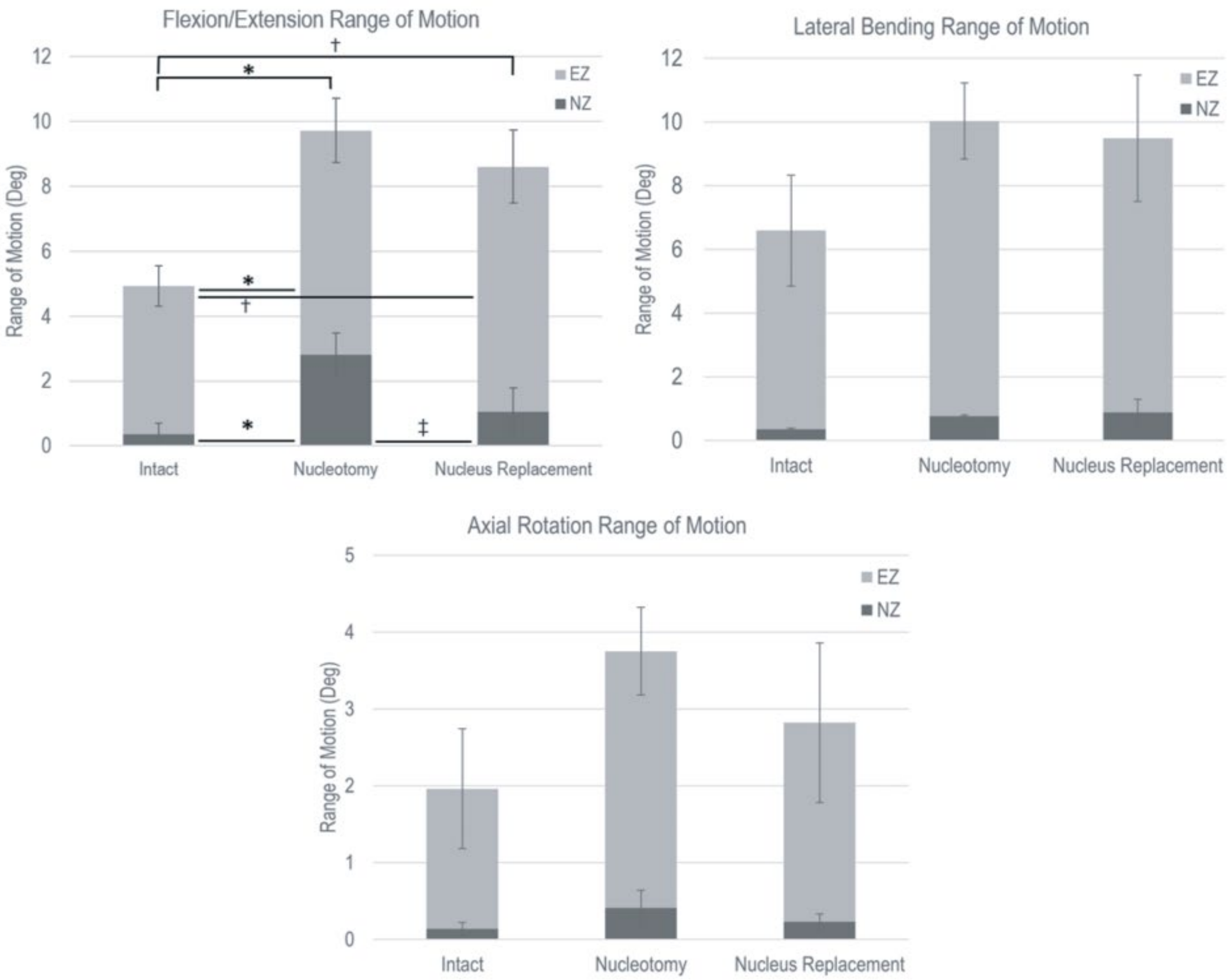

Table. Multidirectional Bending Flexibility Results

Loading	Range of Motion (Deg)	Neutral Zone (Deg)	Elastic Zone (Deg)
Flexion/Extension			
Intact	4.83 ± 0.62*,†	0.37 ± 0.33*	4.56 ± 0.62*,†
Nucleotomy	9.72 ± 1.53*	2.82 ± 0.67*,‡	6.90 ± 0.99*
80 Replacement Beads	8.61 ± 1.76†	1.06 ± 0.73‡	7.55 ± 1.12†
Left/Right Axial Rotation			
Intact	1.96 ± 0.86	0.14 ± 0.08	1.82 ± 0.78
Nucleotomy	3.75 ± 0.79	0.41 ± 0.23	3.34 ± 0.57
80 Replacement Beads	2.82 ± 1.13	0.23 ± 0.10	2.59 ±1.04
Left/Right Lateral Bending			
Intact	6.59 ± 1.76	0.36 0.03	6.23 ± 1.74
Nucleotomy	10.04 ± 1.20	0.77 ± 0.03	9.26 ± 1.19
80 Replacement Beads	9.48 ± 2.36	0.89 ± 0.40	8.60 ± 1.98

Figure 4. Multidirectional bending flexibility results of our L2/L3 specimens for each study group in three planes of rotation motion. All data are displayed as mean ± one standard deviation. Range of motion was defined as the motion between the extents of loading in both directions. Neutral zone is the amount of displacement during passive resistance to loading and elastic zone is the displacement during active resistance. The asterisk or note mark (*, †, ‡) indicates statistically significantly differences between the designated pair for the given loading condition at $p < 0.05$.

to cost and availability of cadaver specimens, only three specimens were tested, leading to low power. Restoration of the disc height and intradiscal pressure was not measured outcomes; thus, we are unable to comment on the efficacy of the implant strategy regarding these outcomes. Bone quality of the donor vertebrae was not measured, thus we cannot comment on how the outcomes change for osteopenia or osteoporosis. Future studies are required to determine the ratio of amount of nucleus pulposus removed vs. number of magnetic balls implanted, ideal size of individual magnetic balls, and how best to customize these properties to optimize the stiffness of the implant construct. While there was no observed migration or expulsion over the course of our testing, further tests are required to definitively assess this.

Conclusion

This study utilized a cadaver-based biomechanical model to evaluate the potential viability of a novel and less invasive total nucleus replacement using magnetic spherical beads. The aim was to assess the ability of the beads to restore stability to the spine segment. It was hypothesized that the beads would increase stability during flexion and extension; evident in range of motion values after bead insertion being comparable to intact values. Bead insertion statistically significantly reduced the neutral zone observed after nucleotomy, during flexion and extension loading. These initial results suggest that magnetic spherical beads may be a suitable replacement of the nucleus pulposus.

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