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The biomechanics of a multilevel lumbar spine hybrid using nucleus replacement in conjunction with fusion

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Abstract

BACKGROUND CONTEXT: Degenerative disc disease is commonly a multilevel pathology with varying deterioration severity. The use of fusion on multiple levels can significantly affect functionality and has been linked to persistent adjacent disc degeneration. A hybrid approach of fusion and nucleus replacement (NR) has been suggested as a solution for mildly degenerated yet painful levels adjacent to fusion.

PURPOSE: To compare the biomechanical metrics of different hybrid implant constructs, hypothesizing that an NR+fusion hybrid would be similar to a single-level fusion and perform more naturally compared with a two-level fusion.

STUDY DESIGN: A cadaveric in vitro repeated-measures study was performed to evaluate a multilevel lumbar NR+fusion hybrid.

METHODS: Eight cadaveric spines (L3–S1) were tested in a Spine Kinetic Simulator (Instron, Norwood, MA, USA). Pure moments of 8 Nm were applied in flexion/extension, lateral bending, and axial rotation as well as compression loading. Specimens were tested intact; fused (using transforaminal lumbar interbody fusion instrumentation with posterior rods) at L5–S1; with a nuclectomy at L4–L5 including fusion at L5–S1; with NR at L4–L5 including fusion at L5–S1; and finally with a two-level fusion spanning L4–S1. Repeated-measures analysis of variance and corrected *t* tests were used to statistically compare outcomes.

RESULTS: The NR+fusion hybrid and single-level fusion exhibited no statistical differences for range of motion (ROM), stiffness, neutral zone, and intradiscal pressure in all loading directions. Compared with two-level fusion, the hybrid affords the construct 41.9% more ROM on average. Two-level fusion stiffness was statistically higher than all other constructs and resulted in significantly lower ROM in flexion, extension, and lateral bending. The hybrid construct produced approximately half of the L3–L4 adjacent-level pressures as the two-level fusion case while generating similar pressures to the single-level fusion case.

CONCLUSIONS: These data portend more natural functional outcomes and fewer adjacent disc complications for a multilevel NR+fusion hybrid compared with the classical two-level fusion.

Keywords: Nucleus replacement; Lumbar spine; Biomechanics; Intradiscal pressure; Disc arthroplasty

FDA device/drug status: Not approved for this indication (DASCOR Disc Arthroplasty System). Approved for this indication (PEEK TLIF cage with Click'X [Synthes, Paoli, PA, USA]).

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Introduction

More than 54 million Americans experience low back pain annually [1,2]. Most of these patients spontaneously recover within a short amount of time and do not receive medical care [3]. Of those seeking medical attention, a small subset is diagnosed with lumbar spine instability, deformity, trauma, degenerative disc disease, and spondylolisthesis—all of which may be addressed by spinal surgery including but not limited to arthrodesis procedures [4,5]. Lumbar spine arthrodesis (fusion) includes numerous procedural approaches and supplementary instrumentation, which attempt to off-load the afflicted spinal motion segment and relieve pain. The annual incidence of spinal fusion cases has increased 2.4-fold between 1998 and 2008 [5], in spite of evidence that suggests less than optimal outcomes for these patients [6]. Accelerated adjacent-level disc degeneration is one hypothesized issue that may decrease the long-term enthusiasm for lumbar spinal fusion [7–12]. Specifically, when an intervertebral disc adjacent to spinal fusion is already mildly or moderately degenerated, the stresses placed on this disc because of the stiffness of the fusion construct may potentially accelerate disc degeneration [13–22].

Devices to replace the intervertebral disc, developed since the 1950s, aim to retain the kinematic and kinetic functions of the spinal unit [23]. The objective of these disc arthroplasty devices is to replicate spinal mechanics and reduce the degenerative effects on adjacent spinal levels. Recently, nucleus replacements (NRs) have been introduced as a minimally invasive alternative to fusion and total disc arthroplasty, particularly in the case of mild-to-moderate degenerative disc disease [24–32]. Nucleus arthroplasty augments the existing annulus fibrosus by replacing the dysfunctional nucleus pulposus. The technology works in conjunction with the annulus to restore physiological loading and kinematics to alleviate pain and has shown initial clinical success out to 2 years in single-level implantation [24–26,28–30,33,34].

Often, patients presenting with the indications for spinal fusion also exhibit pathology at adjacent levels requiring attention. Multiple-level fusions may limit function and initiate adjacent-level disc disease [13–20]. A proposed alternative involves using the most biofidelic and anatomy-preserving treatment for each pathological level's need, formulating a hybrid construct, that is, various devices or procedures combined along multiple levels to provide a unique patient treatment. Benefits of this approach include the tailoring of surgical care to leave more invasive treatment options available in the future should the need arise [35–40]. This hybrid approach including arthrodesis and arthroplasty has been examined clinically in the lumbar spine with positive results [35–44]. Aunoble et al. [41] reported on a prospective study of 42 patients receiving a single-level arthroplasty adjacent to a single-level arthrodesis. They identified positive outcomes at the 2-year follow-up with decreased pain and increased Oswestry Disability Index scores. Bertagnoli et al. [40] performed a single-level arthroplasty on patients with preexisting fusions, creating a hybrid construct, which also revealed positive improvements in pain and Oswestry Disability Index scores without complications. The approaches to a hybrid spinal construct have included fusions with disc replacements [36–41,43] and posterior dynamic stabilization [42,44].

Unfortunately, few biomechanical studies have examined these hybrid spinal constructs for their efficacy [45–47]. These studies have all used repeated-measures study designs to evaluate different surgical configurations, including disc replacement with fusion [47] and posterior dynamic stabilization with fusion [45,46]. All these studies reported that the level adjacent to a fusion, when compared with intact, exhibited a similar range of motion (ROM) with arthroplasty techniques as compared with arthrodesis. The large number of reports on the clinical applications of hybrid constructs in the lumbar spine is incongruous with the supporting biomechanical data. Furthermore, to our knowledge, there is no literature on nucleus arthroplasty hybrid constructs. Thus, this in vitro study hypothesizes that an NR can function in conjunction with an inferiorly placed fusion in a manner similar to a natural disc adjacent to fusion and that this hybrid arrangement is mechanically more biofidelic than that of a two-level fusion construct.

Materials and methods

Specimen preparation

Eight cadaveric specimens L3–sacrum were obtained from the University of Minnesota Bequest Program for this institutional review board–approved study. The specimens had an equal gender distribution and average age of 61 years. The specimens were assessed manually and radiographically for gross deformity and segmental mobility. All specimens were dissected down to their osteoligamentous tissues and embedded in polymethylmethacrylate on their superior and inferior ends. The specimens were frozen at −20°C until use, at which time they were thawed and hydrated in a water bath.

Experimental testing

One specimen was tested per day, minimizing degradation by wrapping with moist paper towels and hydrating with a spray bottle. Specimens were attached to a custom six-axis Spine Kinetic Simulator (Model 8821 with BioPuls Multi-Axial Testing Unit; Instron, Norwood, MA, USA) capable of applying pure moments through a programmable control system and actuated upper and lower platens minimizing shear forces inferiorly (Fig. 1). The segmental displacements were recorded using a three-dimensional visual motion analysis 5-camera system (Vicon MX-F40NIR; Vicon Motion