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Biomechanical comparison of an interspinous fusion device and bilateral pedicle screw system as additional fixation for lateral lumbar interbody fusion

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ABSTRACT

Background: This investigation compares an interspinous fusion device with posterior pedicle screw system in a lateral lumbar interbody lumbar fusion.
Methods: We biomechanically tested six cadaveric lumbar segments (L1–L2) under an axial preload of 50 N and torque of 5 Nm in flexion–extension, lateral bending and axial rotation directions. We quantified range of motion, neutral zone/elastic zone stiffness in the following conditions: intact, lateral discectomy, lateral cage, cage with interspinous fusion, and cage with pedicle screws.
Findings: A complete lateral discectomy and annulectomy increased motion in all directions compared to all other conditions. The lateral cage reduced motion in lateral bending and flexion/extension with respect to the intact and discectomy conditions, but had minimal effect on extension stiffness. Posterior instrumentation reduced motion, excluding interspinous augmentation in axial rotation with respect to the cage condition. Interspinous fusion significantly increased flexion and extension stiffness, while pedicle screws increased flexion/extension and lateral bending stiffness, with respect to the cage condition. Both posterior augmentations performed equivalently throughout the tests except in lateral bending stiffness where pedicle screws were stiffer in the neutral zone.
Interpretation: A lateral discectomy and annulectomy generates immediate instability. Stand-alone lateral cages restore a limited amount of immediate stability, but posterior supplemental fixation increases stability. Both augmentations are similar in a single level lateral fusion in-vitro model, but pedicle screws are more equipped for coronal stability. An interspinous fusion is a less invasive alternative than pedicle screws and is potentially a conservative option for various interbody cage scenarios.

1. Introduction

Interbody fusion has become a common practice in spine surgery. Among different surgical interbody fusion techniques, the transpsoas approach or lateral lumbar interbody fusion (LLIF) has gradually gained popularity during the last decade (Isaacs et al., 1976; Le Huec et al., 2002; Ozgur et al., 2006; Rodgers et al., 2010; Simpson et al., 2011). The LLIF involves a minimally invasive retroperitoneal transpsoas approach that makes it an attractive option. Unlike anterior and posterior approaches, risk of major vessel injury (Ozgur et al., 2006) and neurological complications (Simpson et al., 2011) are reduced in a LLIF procedure. Nevertheless, a common clinical question is whether to implant a LLIF as stand-alone instrumentation or augment the cage with posterior instrumentation.

Bilateral pedicle screw stabilization (BPSS) is currently considered the "gold standard" in posterior lumbar stabilization (Isaacs et al., 1976; Slucky et al., 2006), but this all-encompassing technique comes at costs of invasiveness, surgical time, radiation exposure, risk of pedicle screw breach and potential nerve root injury (Kaibara et al., 2010; Karahalios et al., 2010). These complications can prevent surgeons from supporting anterior hardware, so developing minimally invasive procedures, testing alternative devices, reducing complications of actual procedures, and proposing new treatments that provide similar stabilization to BPSS are of interest in spine research.

A LLIF cage is implanted while the patient is in a lateral decubitus position (Ozgur et al., 2006). Implantation of percutaneous pedicle screws requires patient manipulation to a prone position (Ozgur et al., 2006) with two lateral incisions. Conversely, surgeons can implant an

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interspinous fusion device (IFD) without position manipulation with a midline incision (Zucherman et al., 2004). Thus, if the two posterior devices have comparable performance in certain scenarios, such as in LLIF, then IFD may be a suitable alternative to BPSS.

Historically, surgeons have employed interspinous stabilization as a treatment for spinal stenosis, which is one of the most common age-related diseases of the spine (Sobottke et al., 2009). More recently, surgeons use interspinous fusion devices (IFD) to aid in spinal fusion and stability. The results of previous IFD investigations are promising in posterior lumbar interbody fusion models compared to select cases of BPSS (Kim et al., 2012). Furthermore, in vitro biomechanical data suggest that both BPSS and IFD provide equivalent flexion–extension and axial rotation stability in a posterior lumbar interbody fusion model with posterior or expandable cages (Gonzalez-Blohm et al., 2013).

Our goal in this study was to explore, via in vitro biomechanical testing, if an IFD provides immediate similar (non-inferior) rigidity to the current gold standard technique (BPSS).

2. Methods

2.1. Specimen preparation

Six cadaveric lumbar spines, five males and one female (average age −56 years, range 45–60 years), were dissected into L1–L2 segments and proper care was taken to preserve all synovial capsules and ligaments. L1–L2 segments were selected due to (1) their participation in previous interspinous (Lazaro et al., 2010) and interbody (Ploumis et al., 2010) biomechanical investigations and (2) availability. Furthermore, similar biomechanical data has been reported between L1–L2 and other segments so specimen selection was considered acceptable for an exploratory study (Posner et al., 1982). Specimens were thawed overnight in a refrigerator (4 °C), prior to dissection/testing and were out of a frozen environment for a maximum of 48 h. The specimens had 4″ × 4″ gauze sponges, moistened with 0.9% NaCl solution, wrapped around all exposed tissue, when specimens were not in the testing machine, to maintain hydration.

The specimens had six self-tapping screws (2 in. long) installed into the superior (L1) and inferior (L2) vertebral bodies, and the superior L1 and inferior L2 articular processes, to act as anchors for the mold. A mold medium of polyester resin (Bondo, Bondo Corp, Atlanta, GA, USA) anchored the specimen into the frame and ensured that the testing machine would properly transmit forces to the specimen.

Various qualitative protocols ensured accurate vertebral body location, level superior and inferior frames and correct sagittal/coronal/axial alignment during the potting procedure. These included: using a level to ensure that the top and bottom frames were parallel; inspecting the anatomy to ensure that the center of rotation in each axial plane lined up with the center of the machine frames (and mirrored anatomical positions);verifying that the disk was in the mid axial plane of the frames; and ensuring that the approximate center of rotation of each anatomical plane was located in the frames center of rotation.

2.2. Biomechanical testing

A servo hydraulic testing apparatus performed biomechanical testing (MTS 858 MiniBionix Eden Prairie, MN USA modified with an Instron controller Grove City, PA), which previous works describe (Doulgeris et al., 2013; Gonzalez-Blohm et al., 2013, 2014). The four degrees of freedom apparatus allowed three anatomical degrees of freedom: (1) flexion/extension (FE) or lateral bending (LB), (2) axial rotation (AR), and (3) axial displacement. The servo hydraulic machine delivered AR and axial displacements to the superior frame, while the inferior frame remained constrained from these motions. Conversely, the frames permitted FE or LB motions on both superior and inferior frames.

Specimens were placed under a constant 50 N axial pre-load followed by 5 Nm torques in the FE, LB and AR directions (Brodke et al., 2001; Doulgeris et al., 2013). This protocol was chosen to be similar to previously published interspinous investigations. A series of pulleys and weights delivered pure torques in FE and LB loads in a manual quasi-static fashion (3 cycles at 0.03 Hz) while the servo hydraulic motors delivered axial rotation loads in an automated dynamic fashion (6 cycles at 0.125 Hz). The analysis used the last collected cycle and all previous cycles preconditioned the segment. The delivery method and motion direction determined the number of cycles selected, which was described in previous works (Doulgeris et al., 2013). The preload was delivered axially to the L1 vertebra to apply some compression, ensuring frame-specimen contact throughout the tests. The eccentric loading moments were considered negligible since the magnitude of the load was considered small and applied to single functional spinal units (i.e. spinal curvature is minimal).

The machine applied controlled-torque to each specimen and the resulting displacement (degree) was opto-electronically tracked by sensors located at the superior and inferior frames, via an Optotrak Certus System (Optotrak 3020, Northern Digital, Inc., Waterloo, Canada, precision 0.1 degree). A data acquisition unit acquired all measurements at a rate of 10 Hz for all testing conditions.

The machine tested each specimen under the following conditions: (1) intact, (2) discectomy, (3) lateral cage (LC), (4,5) lateral cage with bilateral pedicle screw system (LC + BPSS), and (4,5) lateral cage with interspinous fusion device (LC + IFD). The first condition tested was the intact (control) model, which created a baseline for all other conditions. Secondly, a surgeon performed a lateral discectomy and contralateral annulotomy on a dissection table using standard transpsoas techniques and then returned the specimen so the machine could perform the tests. Thirdly, the surgeon placed the specimen on the dissection table and implanted a PEEK lateral cage (Axis-Spine, 18 mm-width, 50–55 mm-length, 10–12 mm-height) into the disk space; afterwards, the machine performed testing on the lateral cage condition (LC). Subsequently, the surgeon augmented the LC condition with bilateral pedicle screws and rods (Titanium Fortex System, X-Spine System Inc., Miamisburg, Ohio, screws 6.5–6.5 mm-diameter × 40–50 mm-lenght, rods 5.5 mm-diameter) and the machine performed testing (LC + BPSS —Fig. 1A). Lastly, the surgeon removed the rods and screws and augmented the LC condition with an interspinous fusion device with titanium inserts (Axle™ Interspinous Fusion System, X-Spine Systems Inc., Miamisburg, Ohio, 36–40 mm-width × 8–14 mm-height) and then the machine performed the fifth test (LC + IFD—Fig. 1B). The protocol implemented randomized orders of the last two conditions (LC + IFD and LC + BPSS) to reduce order bias. Fluoroscopy confirmed the mid-disk location of the discectomy and the accuracy of the hardware placement in each case.

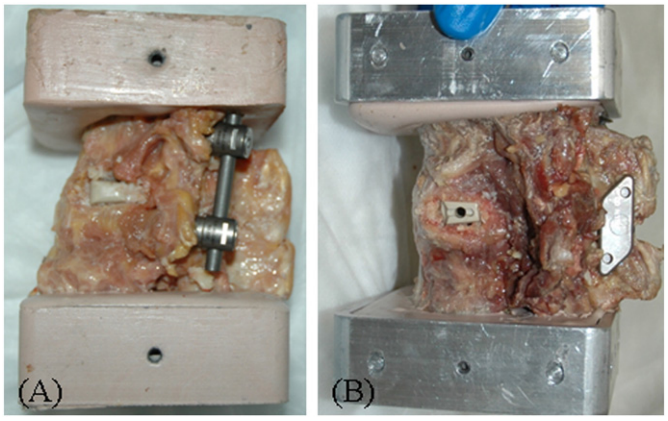

Fig. 1. Lateral view of L1–L2 spinal segments under: (A) lateral cage with bilateral pedicle screw (LC + BPSS) condition and (B) lateral cage with interspinous fusion device (LC + IFD) condition.