Introduction:
Lumbar spinal stenosis is a progressive degenerative condition due to arthritic facet joints. Arthritic facets become inflamed and often develop osteophytes, leading to nerve compression and persistent severe back pain. When conservative treatment fails to reduce pain, surgical management may be pursued to improve the patient's quality of life. Spinal compression and fusion is one of the most common surgical procedures for treatment of spinal stenosis. However, fusion may result in accelerated degeneration of the adjacent motion segments and morbidity. Motion preservation instrumentation is being developed to preserve motion at the involved and adjacent segments, as opposed to fusion procedure. In this study, we used experimental and finite element (FE) techniques to assess and compare the biomechanics of intact and spine implanted with a novel posterior dynamic stabilizer device (PDS). The effects on the adjacent segment, including motion and intra-discal pressure, were analyzed.

Methods:
A cadaveric experiment using six fresh-frozen, healthy L1–S1 ligamentous spine segments was conducted to analyze spine biomechanics under various conditions. The specimens were thawed, and the tissue surrounding the spine, except the ligaments and disc, were carefully removed. The specimens were radiographed for any anomalies or fractures. Each spine was potted using Bondo (a 2-part epoxy resin) cranially at L1 and caudally at S1 (Fig. 1). The base was bolted to a test frame located in the field of view of an Optotrak Motion Measuring System (Northern Digital, Waterloo, Ontario, Canada). The vertebral bodies were affixed with a set of three LEDs each for recording the spatial locations in response to the applied load using the Optotrak system. The IDP sensors were placed at various places within the nucleus of implanted and adjacent segment to record the changes in the nucleus pressure (IDP) during testing. Each specimen was tested in intact and following PDS implant.

A pair of PDS was placed at the L4–L5 level using pedicle screws. The PDS device included a set of curved male-female parts with restricted sliding motion imposed by stoppers attached to springs inside the vertebral bodies affixed with a set of three LEDs each for recording the spatial locations in response to the applied load using the Optotrak system. The IDP sensors were placed at various places within the nucleus of implanted and adjacent segment to record the changes in the nucleus pressure (IDP) during testing. Each specimen was tested in intact and following PDS implant.

A 3D experimentally validated nonlinear FE model of L3/S1 spine [1] was used to simulate intact and PDS implanted conditions. In order to simulate the implant, a 3D model of PDS was meshed and placed at L4–L5 level of intact model. The Cobalt-Chrome material properties were used to define PDS and a frictionless contact pattern was defined between articulation/sliding surfaces within the implant assembly. The implanted and intact models were loaded with 400 N of follower load and 10 Nm of moment in various loading modes. FE model predictions were compared with cadaver data and then used to predict other parameters like maximum stress across the pedicle screws. These were compared with stresses in screws of an existing single level fusion model with similar loading configurations.

Results:
In the in vitro study, placement of the PDS didn’t alter the motion of the adjacent segment (P>0.5 in all loading cases). The FE model had similar prediction with motions of 4.9°, 2.3°, 4.7° and 2.6° in Flex, Ext, RB/LB and LR/RR respectively which were close to average and within 1 SD of the in vitro data (Fig. 2A).

At the index level, placement of implant decreased the motion in all specimens for all loading cases (P<0.02). The motions in the FE model (within 1 SD of cadaveric data) were 5.1°, 2.9°, 4.5° and 2.6° in intact versus 2.4°, 1.2°, 1° and 1.1° in PDS model for Flex, Ext, RB/LB and LR/RR respectively.

The IDP followed the observed/predicted changes in motion. The IDP values did not have significant changes at the adjacent segment in the implanted conditions for both FE and cadaveric experiments with P values ranging from 0.36 to 0.9 for all loading cases in cadaveric experiments. However, there was a significant reduction (P<0.03), except in Ext (P=0.07) in the IDP compared to intact conditions at the implanted segment. In FE models there were no notable IDP changes for the implanted segment, compared to the intact.

The stresses at pedicle screws at both L4 and L5 levels were less in PDS model (L4: 69-127MPa, L5: 67-77MPa) versus fusion (L4: 102-163MPa, L5: 120-100MPa) in all loading cases (Fig. 2B).

Discussion:
Fusion systems are commonly used for the treatment of spinal stenosis by stabilization of the degenerated segments. A common long term complication of fusion devices is the degenerative effect the systems may have on the adjacent segment. Dynamic stabilization devices are designed to provide controlled flexibility to the implanted level, avoid disc degeneration, and preserve the biomechanics of adjacent segments.

In this study, both cadaveric experiments and FE simulations demonstrated that the PDS provides some degrees of flexibility to the implanted segment in all loading conditions. This is unlike some spring based dynamic devices, which do not provide stability at the implanted segment in lateral bending and axial rotations. Also the PDS allows for constrained angular motion and shear stability of the implanted level. Thus, the PDS may be a good alternative to current surgical techniques for treatment of spinal stenosis and facet arthrosis. The reduction in screw stresses in PDS versus fusion may reduce the risk of screw loosening/failure. The validated FE model can be further used to compare other biomechanical parameters such as stress distribution across various spine and implant components as well as biomechanical effects of different settings of implant such as misalignment, etc.

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References: