INTRODUCTION
The goal of lumbar spinal fusion is to limit pain by decompression and removal of soft tissues, followed by the formation of a rigid bony union between adjacent vertebrae. The general consensus for a rigid fusion construct requires careful preparation of the intervertebral space and the creation of a rigid fusion construct. Anterior lumbar interbody fusion (ALIF) provides good access to the intervertebral space and has been shown to yield excellent fusion results, especially with supplemental posterior fixation. However, supplemental posterior fixation requires a secondary procedure and is associated with additional complications. Threaded interbody cages provide one stand-alone alternative, but have issues including imaging limitations and subsidence risks. A PEEK interbody cage has been developed with incorporated screws so that additional fixation and resistance to graft extrusion could be provided without the use of blocking screws, plates, or pedicular fixation.

The hypothesis of this study was (1) that the stand-alone device would provide increased rigidity compared to the intact state in all anatomic directions and (2) such fixation would be similar to that obtained with threaded cages. It was also hypothesized that the investigational device would have a significantly greater resistance to pullout forces when compared to a stand-alone interbody cage.

METHODS
Eleven cadaveric lumbar spines with a mean (±SD) age of 60 ± 8 years (range 48-72) were acquired and scanned using DEXA. Twenty L2-3 and L4-5 vertebra-disc-vertebra motion segments were prepared and potted in urethane resin.

Specimens were tested intact using moments of 7.5 Nm in flexion, extension, bilateral lateral bending and bilateral axial torsion. A 100 N preload was applied coincident with the long axis of the inferior vertebrae to maintain compression. Pure moments were applied to the superior vertebral body using a hydraulically-actuated gimbal mounted on a load frame. A 6 DOF load cell attached to the lower end of the gimbal was used to measure the loads and moments applied to the superior vertebrae. The inferior vertebral body was allowed unconstrained movement on an X-Y table, and the test frame was allowed to float in the vertical direction. Two cycles were used to precondition the specimen and data were collected on a third test cycle.

Specimens were randomized into two groups (n=10 ea.). Group 1 was tested with the investigational device (ID) with and without the integrated screws (Intrepid, Medtronic, Memphis, TN) followed by dual-threaded interbody cages (LT-Cage, Medtronic, Memphis, TN). Group 2 was tested with a structural interbody graft and an anteriorly-placed plate (Pyramid+4, Medtronic, Memphis, TN), a graft plus pedicle screws (PS) (Legacy, Medtronic, Memphis, TN), and with the ID. Flexibility testing was performed for each construct.

The prescribed test order resulted in the dual-threaded cage and investigational device with screws tested as the last states. After flexibility testing, these devices were pulled out in an anterior direction at 0.1 mm/sec under a constant 400N compressive load. Vertebrae were allowed to rotate during the pullout tests.

Data reduction included calculation of the total range of motion (ROM) and neutral zone (difference in rotation after release of maximum moments in both directions) from flexibility tests. Peak extraction loads, resistance to pullout (slope of load-displacement curve), and work to initiate pullout (area under curve) were calculated for the pullout tests.

RESULTS
Compared to the intact state, all devices reduced the range of motion in all directions (p<0.006) except torsion, where neither the ID without screws nor the cage significantly reduced the range of motion (p > 1.0, Power=0.3). The addition of the screws to the ID significantly reduced the ROM in all directions vs. without screws (p<0.001). The graft with PS had statistically smaller ROM compared to the ID with screws and with cages in flexion-extension and lateral bending (p<0.05). The ID with screws also had a significantly greater range of motion in flexion-extension vs. the plate (p<0.05); the cage tended to have a similar range of motion vs. the ID with screws.

DISCUSSION
In this in vitro study, the addition of integrated fixation screws significantly reduced the interbody motion of simulated stand-alone ALIF constructs (i.e., the ID without screws), most notably in torsion. The investigational device constructs had a degree of motion similar to that of stand-alone threaded cage constructs, but their resistance to pullout was greater. The investigational PEEK interbody spacer with integrated fixation screws may be a suitable replacement for threaded cages or blocking screws when some additional rigidity and resistance to backout vs. a stand-alone spacer is desired.

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