INTRODUCTION:
Anterior cervical discectomy and fusion (ACDF) is frequently performed to treat instability, disc herniations, and degenerative conditions in the cervical spine. Intervertebral motion must be minimized to obtain a solid bony union between adjacent vertebral, and various devices including plates, cages, and intervertebral spacers have been designed to achieve this goal. The incorporation of fixation screws into the graft itself may be a viable alternative to standard treatment options.

The purpose of this study was to evaluate the effects of incorporating fixation screws into a PEEK interbody cage in terms of immediate biomechanical rigidity using an in vitro cadaveric spine model. It was hypothesized that (1) standard and investigational fusion constructs would reduce motion in all directions, (2) the addition of fixation screws to a PEEK interbody cage would decrease motion of the fusion constructs, and (3) the PEEK interbody cage with screws would not be statistically different in range of motion from standard treatment options.

METHODS:
Twelve fresh-frozen human cadaveric cervical spines were acquired (age range 44 to 70 years) and scanned using DEXA in the AP direction. Spines were dissected of non-essential soft tissues, disarticulated into eleven C3-4 and eight C5-6 motion segments and potted in a urethane resin. The intact motions segments were tested to ± 2.5 Nm in flexion-extension, lateral bending, and axial torsion with a 25 N axial preload. All surgical procedures were performed by orthopaedic spine surgeons following the manufacturer’s recommendations. The investigational device, which consisted of a 2-hole stand-alone PEEK cervical interbody cage with integrated screws (PEEK Prevail, Medtronic, Memphis, TN) was then implanted into all specimens and tested both with (ID + 2 screws) and without screws (ID w/o screws). As a final test condition, specimens were divided into two groups that received either a threaded cage (n=10, Affinity, Medtronic, Memphis, TN) or an interbody graft (Cornerstone PSR, Memphis, TN) + 4-hole anterior plate (n=9, Zephir, Medtronic, Memphis, TN).

Tests were conducted by applying pure moments of ±2.5 Nm to the superior vertebral body using a hydraulically-actuated spinal loading fixture mounted to a servohydraulic load frame (MTS 858). Specimen motion was tracked using a non-contact motion measurement system (Vicon). Local coordinate systems were constructed for the cranial and cranial vertebral and Euler angle calculations were performed to determine specimen motion. Range of motion (ROM) was determined from each flexibility curve as the difference between the peak positive and negative rotations. The neutral zone, representing specimen motion in the low stiffness region, was calculated as the difference between the peak positive and negative low/high stiffness inflection points.

Paired t-tests were used for comparisons between the intact and all implanted states and between the investigational device with and without screws. A one-way ANOVA was used for statistical comparisons between the investigational device with two screws, threaded cages, and plate. Significant differences were defined as p ≤ 0.05.

RESULTS:
Compared to the intact condition, the investigational device with two screws reduced ROM only in lateral bending (p=0.012). There were no significant ROM differences between any of the implanted test groups, excluding the investigational device without screws, except in flexion-extension where ROM was significantly greater for the threaded cage vs. the graft + plate (p = 0.029). The addition of two screws to the investigational device significantly reduced motion in all directions.

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