CHARACTERIZING SPINOUS PROCESS STRENGTH: IMPLICATIONS FOR INTERSPINOUS DEVICE DESIGN

INTRODUCTION

Interspinous devices are a relatively new class of less-invasive, motion-preserving devices that reduce spinal instability by restricting flexion-extension range of motion between adjacent lumbar vertebrae [1]. These devices mount directly to the spinous process and impose point loads in either the caudal or cranial direction depending on device design and spinal motion. Because the spinous process normally experiences distributed tensile loads from the interspinous ligaments [2], these new devices may substantially alter the mechanical demands placed on this structure and place the bone at risk of fracture under normal activities of daily living. In order to evaluate and improve upon product safety, we sought to characterize spinous process strength under loading conditions similar to those imposed by the current class of interspinous devices. We conducted biomechanical experiments to focus on three different points of clinical interest: 1) most likely fracture location, 2) differences in spinous process strength cranial vs. caudally-directed loads, and 3) strength sensitivity to bone mineral density (BMD).

METHODS

Two interrelated biomechanical experiments were conducted for this study. First, “in situ” tests were conducted on whole spinal sections to determine fracture location with ligamentous structures intact (Figure 1, left). Fresh-frozen, three-bone thoracolumbar spinal sections (N=3, T12-L2) were harvested from human donors (3 male, 62-77 y.o.). Specimens were cleaned of muscle tissue, with care taken to preserve all posterior ligaments. The anterior aspect of the spine was potted in the neutral position in a metal cup using a quick-set polymer (Smooth Cast 300, Smooth-On). Potting was performed to within 5 mm of the anterior aspect of the spinal canal, leaving the posterior elements completely exposed. The specimen was attached to an x-y-table on the base of an industrial hydraulic press (858 Mini-Bionix, MTS), instrumented with a load cell (MC5-6-5000, AMTI) and an in-built LVDT. A uniform incision was made in the L1-L2 interspinous ligament, and a 1 cm wide polyaaxial strap was looped through the incision and rigidly held in a vice (Advantage™ Wedge Grip Assembly, MTS) attached to the actuator. The spinous process was loaded cranially at the quasi-static rate of 1 mm/min. Post-test x-rays were taken to determine the exact site of fracture (BV Pulsera, Philips).

RESULTS

For all in situ test specimens, fractures induced by interspinous device loading were localized to the spinous process (Figure 2). Bony failure occurred via compaction directly under the loading strap. The adjacent regions of the spinous process, as well as the pedicles and lamina, were unaffected.

Figure 2: Post-test x-rays of two in situ test specimens showing fractures in the L1 spinous process (arrow).

Spinous process strength in the caudal direction was significantly greater than the cranial direction (902±142 N vs. 687±173 N, respectively; p<0.05 for t-test; Figure 3). There was no statistically significant relationship between spinous process strength in either loading direction and bone mineral density as measured by DEXA T-score (p>0.05 for linear regression).

Figure 3: Spinous process strength for different loading directions. *p<0.05 for paired t-test.

CONCLUSIONS

The results of our study have several important implications in interspinous device design and efficacy testing. First, we found that spinous process is the most likely site of fracture from an interspinous device. When the posterior ligamentous structures are intact, overload causes bony compaction directly at the loading site, rather than fracture through the pedicle, as observed in previous studies using isolated vertebrae [3]. Risk of fracture localized to the spinous process should be considered in evaluating the safety of current and future interspinous device designs. Second, we found that the spinous process is approximately 30% stronger when loaded caudally, as with a flexion-limiting strap, than cranially, as would occur with an extension-limiting spacer. We believe that this difference is due to the natural concavity of the caudal surface of the spinous process, which may act as a stress concentration under the tensile loads induced by an extension-limiting device. Lastly, we found that spinous process strength in either loading direction was not dependent on DEXA-BMD, which contrasts a previous study that found a significant BMD-strength correlation [3]. This discrepancy may be due to differences in experimental methods, and future work by our group will focus on increasing the sample size of this study to better elucidate whether interspinous devices may be safely used in low BMD patients without cement augmentation.

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REFERENCES