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Restoring lumbar spine stiffness using an interspinous implant in an ovine model of instability

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ABSTRACT

Background: The objective of this study was to determine the effect of an interspinous implant on lumbar spine stability and stiffness during dorsoventral loading.
Methods: Twelve Merino lambs were mechanically tested in vivo. Oscillatory (2 Hz) loads were applied to L2 under load control while displacements were monitored. Tri-axial accelerometers further quantified adjacent L3–L4 accelerations. Dorsoventral lumbar spine stiffness and L3 and L4 dorsoventral and axial displacements were determined over six trials of 20 cycles of loading. Four conditions were examined: 1) initial intact, 2) following destabilization at L3–L4, 3) following the insertion of an InSwing® interspinous device at L3–L4, and 4) with the implant secured with a tension band. Comparisons were performed using a one-way ANOVA with repeated measures and post-hoc Bonferroni correction.
Findings: Compared to the intact condition, destabilization significantly decreased lumbar stiffness by 4.5% ($P = .001$) which was only recovered by the interspinous device with tension band. The interspinous device caused a significant 9.75% ($P = .001$) increase in dorsoventral stiffness from destabilization that increased 14% with the tension band added ($P = .001$). The tension band was responsible for decreased displacements from the intact ($P = .038$), instability ($P = .001$), and interspinous device ($P = .005$) conditions. Dorsoventral L3–L4 motion significantly improved with the interspinous device ($P = .01$) and the addition of the tension band ($P = .001$). No significant differences in L3–L4 intersegmental stability were noted for axial motion in the sagittal plane.
Interpretation: This ovine model provided objective in vivo biomechanical evidence of lumbar instability and its restoration by means of an interspinous implant during dorsoventral spinal loading.

1. Introduction

Lumbar spinal stenosis (LSS) is characterized by a narrowing of the spinal canal with encroachment of the neural structures from degenerated or hypertrophied osteoligamentous structures. Decreased disk height, bulging of the posterior annulus and buckling of the ligamenta flava are among the most common viscoelastic structures contributing to LSS; while hypertrophic facet joints and laminar thickening are among the major osteogenic contributors to the narrowing of the spinal canal and neuroforamina. It is well established that the diameter of the spinal canal decreases during extension (Dai et al., 1989) which in turn amplifies stenotic conditions in the presence of degenerative changes (Penning and Wilmink, 1987). The patterns of sagittal motion are also disturbed during extension in stenotic patients (Szpalski et al., 1996). When these degenerative changes allow a forward displacement of the cranial vertebra, thus creating a clinical instability, the condition is referred to as degenerative spondylolisthesis.

The incidence and prevalence of LSS is rising with the aging of our populations, representing the most common reason for lumbar spine surgery in persons over 65 years of age (Weinstein et al., 2008). When standardized conservative treatment fails in LSS patients, the standard of care consists of surgical decompression. Of concern in decompressive

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lumbar spinal surgery is the creation of instability as a consequence of the degenerative nature of LSS (Fujiwara et al., 2000). Segmental instability is often considered a cause for low back pain (Nachemson, 1985) mostly related to degenerative processes (Mimura et al., 1994). Decompression in the presence of a degenerative spondylolisthesis can increase this effect. Subsequently, more invasive methods have been developed including rigid stabilization systems with pedicle screw fixation (Resnick et al., 2005). Some of these involve implants secured to the spine by pedicle screw fixation such as the Graf (Graf, 1992) and Dynesis (Stoll et al., 2002) systems. In spite of encouraging early results of pedicle–screw systems for flexible intervertebral stabilization (Freudiger et al., 1999; Grevitt et al., 1995), some long-term results were less optimistic (Grob et al., 2005; Rigby et al., 2001). Increased lumbar lordosis, stretching of the Dacron parts, mal-positioning, and/or loosening of pedicle screws have been reported as reasons for failure. Accelerated adjacent segment disk degeneration from abnormal load sharing is also a concern with implantation of rigid systems (Levin et al., 2007). As a result, dynamic stabilization systems have been developed to prevent overloading of adjacent spinal segments (Schmoelz et al., 2003). It has been proposed that, combined with a tension band, stabilization could also be obtained in flexion, thus avoiding the need for pedicle screw fixation (Senegas, 2002). Little biomechanical data exists to support these notions.

Interspinous implants have been developed to assist in providing dynamic spinal stabilization in order to avoid or supplement LSS decompression. Placing an implant between adjacent spinous processes avoids the capacity decreasing effect of sagittal extension. Interspinous implants are also thought to decrease intra-discal pressure (Swanson et al., 2003), unload the facet joints (Wiseman et al., 2005), restore foraminal height (Humke et al., 1996), provide improved spinal stability (especially in extension) (Kettler et al., 2008; Tsai et al., 2006), and offer the advantage of being minimally invasive. Several such implants have been developed, some connecting spinous processes and laminae (Leahy et al., 2000), others placed between two adjacent spinous processes with a spring (Laudet et al., 1993), one with a silicone implant (Minns and Walsh, 1997), another with a U-shaped device (Kong et al., 2007), and another called the X-stop interspinous process distraction system (Siddiqui et al., 2007; Zucherman et al., 2005). A different type of implant for non-rigid stabilization of lumbar segments uses polyetheretherketone (PEEK), an interspinous blocker fixed to the spine by two bands looped and tensioned around the adjacent spinous processes, termed the Wallis system (Senegas, 2002). The InSwing® system allows the controlled application of a set tension on the band. The principle of all these systems consists of inserting the spacer between the spinous processes at the stenotic level in order to increase the intervertebral space, stretch the ligamenta flava and posterior annular fibers, thus enlarging both the central canal and the neuroforamina (Bono and Vaccaro, 2007; Lindsey et al., 2003). Little is known however, about how these interspinous implants influence intersegmental instability and stiffness of the lumbar spine.

The purpose of this in vivo study was to investigate the effect of a less invasive interspinous implant, on instability and stiffness of the lumbar spine in an ovine model with a simulated, induced stenotic degenerative spondylolisthesis. We hypothesized that following insertion of the ISD and fastening with the tension band (ISD w/band), there would be a reduction in instability and restoration of the stiffness of the lumbar spine.

2. Methods

Merino lambs ($n = 12$, 6–8 months old, 25 kg) were examined using a research protocol approved by the Animal Ethics Committee of the Institute of Medical and Veterinary Science (Adelaide, South Australia). Following anesthesia, the animals were placed in a standardized prone-lying position with the abdomen and thorax supported by a rigid wooden platform and foam padding, respectively, thereby positioning the lumbar spine parallel to the operating table and load frame. With the animals in this standardized prone-lying position, a 1.5 cm region of the bony prominence of the L2 spinous process was exposed using electrocautery. A plain lateral X-ray film was taken to verify normal lumbar spine anatomy and positioning.

Each animal was mechanically tested in vivo using a validated computer controlled force apparatus designed to quantify dorsoventral (DV) stiffness. Complete details of the mechanical testing apparatus, including the validation, are presented elsewhere (Keller and Colloca, 2007) and are briefly summarized here. The mechanical testing apparatus was positioned over the trunk of the animal and rigidly fixed to its supporting table. The indenter stylus of the apparatus consisted of a 12.7 mm-diameter stainless-steel rod containing a slotted tip that cradled the exposed bone surface of the L2 spinous process of each animal. The stylus was equipped with a 750 N load cell (Transducer Techniques, Temecula, CA, USA) and a ± 25 mm linear variable displacement transducer (LVDT, model S1D, Instruments & Control, Inc., Branford, CT, USA) were used to control actuator force and measure displacement, respectively. In this fashion the mechanical apparatus was used to deliver oscillatory DV (2 Hz) loads (~5% of body weight) directly to the lumbar spine of each animal. Lumbar spine DV force and displacement at L2 were recorded using a 16-bit data acquisition system (Model MP150, Biopac Systems, Inc. Santa Barbara, CA, USA) at a sampling rate 2500 Hz. DV stiffness (load/deformation, N/mm) were determined over six trials of 20 cycles of loading, and averaged.

Following animal preparation, to quantify intersegmental displacements, 10-*g* piezoelectric tri-axial accelerometers (Crossbow Model CXL100HF3, Crossbow Technology, Inc., San Jose, CA, USA) were attached to intraosseous pins that were rigidly fixed to the L3 and L4 lumbar spinous processes under fluoroscopic guidance (Fig. 1). The accelerometers are high frequency vibration measurement devices comprised an advanced piezoelectric material integrated with signal conditioning (charge amp) and current regulation electronics. The sensors feature low noise (300-μg rms), wide bandwidth (.3–10,000 Hz) and low nonlinearity (<1% of full scale) and are precision calibrated by the manufacturer. The *x*-, *y*- and *z*-axes of the accelerometer were oriented with respect to the medial–lateral (ML), dorso-ventral (DV) and cranial–caudal or axial (AX) axes of the vertebrae. The in situ natural frequency of the pin and transducer was determined intraoperatively by "tapping" the pins in the ML, DV and AX axes, and was found to be greater than 80 Hz. This is approximately 20 times greater than the natural frequency of the ovine spine (12), which also exhibits significantly damped motion responses (increased stiffness) for oscillatory DV loads above 15 Hz (Keller and Colloca, 2007).

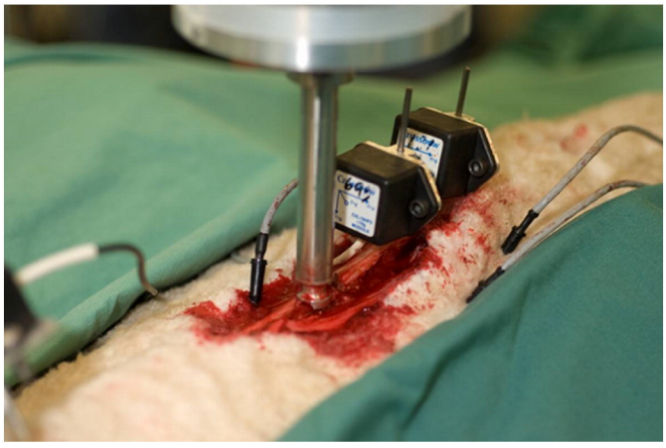

Fig. 1. The experimental setup shows stainless steel actuator positioned over the L2 spinous process with tri-axial accelerometers mounted to pins inserted into the L3 an L4 spinous processes in vivo. Needle electromyographic electrodes are also visualized whose data are presented elsewhere.