Failure strength of lumbar spinous processes loaded in a tension band model

Laboratory investigation

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Object. There has been increasing interest in spine process tension band devices, as distinct from spineous process spacers and plates. The purpose of this study was to load spineous processes caudally at L-4 and cranially at L-5 parallel to the long axis of the spine in a biomechanical model of tension band loading. The goal was to provide normative data for the design of a spineous process tension band device after varying degrees of surgical decompression and across varying bone mineral densities (BMDs).

Methods. Fresh-frozen L-4–5 lumbar vertebrae pairs were divided into 3 surgical groups: intact, midline-sparing decompression (laminotomy and medial facetectomy), and midline decompression with foraminotomy (one-half of spineous process resected, laminotomy, and medial facetectomy). After decompression, specimens were disarticulated into isolated L-4 and L-5 vertebrae. Each vertebra was loaded to failure in a caudal (L-4) or cranial (L-5) direction parallel to the long axis of the spine via a 6-mm-wide strap looped around the spineous process. Failure strength and mode were recorded.

Results. Seventeen L-4 and L-5 lumbar vertebrae were tested from 17 cadavers. There were 10 male (59%) and 7 female (41%) cadavers, with a mean age of 66.6 ± 16.5 years (range 41–100 years) and a mean BMD of 1 ± 0.23 g/cm² (range 0.66–1.34 g/cm²); the mean is expressed ± SD throughout. For data analysis, specimens were grouped into those with no or midline-sparing decompression (Group 1: 11 of 17) and those with midline decompression (Group 2: 6 of 17). At L-4, the mean failure strength for Group 1 was 453 ± 162 N, and for Group 2 it was 264 ± 99 N (p = 0.02; Cohen’s d = 1.4). At L-5, the mean failure strength for Group 1 was 517 ± 190 N, and for Group 2 it was 269 ± 184 N (p = 0.02; Cohen’s d = 1.3). There was no significant difference in failure strength between the intact and midline-sparing decompression groups at L-4 (p = 0.91) or L-5 (p = 0.41).

Conclusions. Across specimens with a wide range of BMDs, midline-sparing decompression was not found to decrease the mean failure strength of the L-4 and L-5 spineous processes (453 and 517 N, respectively), whereas midline surgical decompression decreased the failure strength of these processes (264 and 269 N, respectively) in a biomechanical model of tension band loading relevant to the design of a tension band device.

(key words • spineous process • tension band • load • failure strength • lumbar vertebra)

There has been increasing interest in instrumentation of the lumbar spine processes.2 The majority of devices are spineous process spacers that distract the posterior elements of the spine; however, spineous process plates,12 fusion devices (see http://clinicaltrials.gov/ct2/show/NCT01019057), and tension band devices2 have also been developed. Recently, tension band devices have received increased attention in clinical studies.8,10 The focus of the present study is to gather normative data in a biomechanical model of tension band loading relevant to the design of spineous process tension band devices.

Abbreviation used in this paper: BMD = bone mineral density.
765 N at L-4, although measurement was made by strain gauges in a metal cylinder, emulating an interspinous process spacer and not a tension band.

The aim of the present study was to measure the failure strength of spinous processes in a manner specific to the design of a tension band device. In this paradigm, paired vertebrae from a single spinal motion segment are tested, although each vertebra is tested separately in a jig. The cephalad vertebra (L-4) is loaded with a caudally directed force, and the caudal vertebra (L-5) is loaded with a cephalad directed force parallel to the long axis of the spine. This emulates the loads expected in a spinous process tension band device in a controlled way, without requiring testing of a specific device or design. Another aim was to perform testing with varying degrees of surgical decompression, to emulate the clinical situation. Our hypothesis was that the failure strength of the spinous processes would depend on the degree of surgical decompression and the BMD at both lumbar levels.

Methods

Cadaveric Specimens

Fresh-frozen human cadaveric motion segments at L4–5 were obtained. The specimens were thawed and stripped of soft tissues, then subjected to dual-energy x-ray absorptiometry scanning at L-4. The motion segments were divided into 3 study groups: intact; midline-sparing decompression (laminotomy and medial facetectomy); and midline decompression (one-half of spinous process resected, laminotomy, and medial facetectomy). For each specimen requiring decompression, surgical decompression was undertaken using a standard technique by the senior author (T.F.A.). Figure 1 illustrates the degree of surgical decompression undertaken.

Failure Strength Testing

The L-4 and L-5 vertebrae were disarticulated and isolated to obtain matched pairs from a single cadaver. Isolated vertebrae were potted in epoxy resin and fixed on a servohydraulic machine. Specimens were loaded in a caudal (L-4) or cranial (L-5) direction by using a 6-mm-wide strap looped around the spinous process in a direction parallel to the long axis of the spine. The strap was placed midway on the spinous process between the lamina and the tip of the process. Figure 2 illustrates the testing configuration. Specimens were preconditioned to 20 N to remove slack and tested to failure at 1 mm/minute. Pretest and posttest radiographs were obtained to determine failure modes. The radiographs and gross specimens were inspected and categorized into 3 failure modes by the senior author: through the spinous process, through the pedicles, or complex failure through several structures.

Data Analysis

Data were analyzed by t-test, multivariate ANOVA, and Fisher exact test. A priori power analysis was performed. The power of t-tests was 82% for 17 pairs of specimens, with an alpha value of 0.05 assuming a very large effect size (Cohen’s d = 1.5). The mean is expressed ± SD.

Results

Seventeen pairs of L4–5 lumbar vertebrae were tested. These were obtained in 10 male (59%) and 7 female (41%) cadavers with a mean age of 66.6 ± 16.5 years (range 41–100 years). According to dual-energy x-ray absorptiometry scanning, the mean BMD was 1 ± 0.23 g/cm² (range 0.66–1.34 g/cm²). The mean T-score was –1.2 ± 2.0 (range –4.1 to 1.7), with 4 specimens (24%) being osteopenic and 5 (29%) being osteoporotic. The mean failure strength at L-4 was 386 ± 168 N (range 107–745 N) and at L-5 it was 429 ± 219 N (range 120–1006 N), including intact and surgically decompressed specimens.

Specimen pairs were categorized into 2 groups: Group 1 included those with no or midline-sparing decompression (11 of 17), and Group 2 included those with midline decompression (6 of 17). At L-4, the mean failure strength for Group 1 was 453 ± 162 N, and for Group 2 it was decreased to 264 ± 99 N, which was significant according to the t-test (p = 0.02). The effect size of midline decompression at L-4 was large (Cohen’s d = 1.4). At L-5, the mean failure strength for Group 1 was 517 ± 190 N, and for Group 2 it was decreased to 269 ± 184 N, which was also significant according to the t-test (p = 0.02). The effect size of midline decompression at L-5 was large (Cohen’s d = 1.3). Figure 3 summarizes these results.

The effect of midline decompression on failure strength at L-4 and L-5 jointly was significant by mul-
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Failure modes were categorized as through the spinous process, through the pedicles, or as complex failure through several structures. The results are summarized in Table 1. The effects of spinal level, degree of decompression, sex of the donor, or BMD status on failure mode were not significant according to the Fisher exact test (p > 0.05).

**Discussion**

Our study measures the failure strength of spinous processes loaded in along the long axis of the spine in a caudal (L-4) or cranial (L-5) direction by using a strap looped around the spinous processes. Strength was measured after varying degrees of surgical decompression and across a range of BMDs. The goal was to assess the ability of spinous processes to sustain loads generated by a tension band device. This is the only investigation into the role of different surgical decompressions in the setting of tension band loading with the goal of providing normative data for the design of tension band devices. The principal finding of the study is that the failure strength is not significantly reduced by a surgical decompression that spares the midline structures, whereas it is significantly reduced by resection of one-half of the spinous process. The merits of the study include the use of a well-defined biomechanical protocol, the use of vertebrae from both male and female cadavers of varying ages and BMDs, and the use of matched sets of L-4 and L-5 vertebrae from the same specimen to allow matched data analysis.

These findings may affect the design of tension band devices for instrumenting the spinous processes, because normative data improve understanding of loading safety margins. The spinous processes were completely stripped of soft tissue so that they did not benefit from any support from the adjacent midline connective structures, such as the L4–5 supraspinous ligament. This implies that the failure loads seen in this study may underestimate the actual failure loads in vivo.

There has been increasing interest in instrumentation of the lumbar spinous processes.1,4 Spacers for the spinous process are in wide clinical use, and spinous process plates and fusion devices are commercially available and undergoing clinical trials (see http://clinicaltrials.gov/ct2/show/NCT01019057). Spinous process instrumentation with wires and cables has a long history in spine surgery.2 More recently, spinous process tension band devices have been developed, and these are the principal focus of the present study. Garner et al.2 tested an early design involving a braided polyethylene band. They concluded that polyethylene bands have higher fatigue strength and...
similar creep to metal cables with a crimp, but articulate with the bony anatomy to avoid early loosening. Papp et al.\textsuperscript{9} and Leahy and colleagues\textsuperscript{6,7} described several generations of a tension band design that includes spinous process hooks and laminar hooks connected by a polyester loop that is tensioned with metal crimps. These investigators described incremental improvements to the hooks and crimping devices to address failures occurring within the device components on mechanical testing.

With regard to clinical studies of tension band devices, Lee et al.\textsuperscript{3} retrospectively compared outcomes in 45 patients with stenosis and Grade I spondylolisthesis treated with decompression followed by instrumented fusion versus interspinous tension band at a mean 76-month follow-up. They found clinical improvement in Oswestry Disability Index scores for both groups, with no significant difference between groups. Postoperative sagittal alignment was compared with preoperative alignment. In the tension band group these investigators noted pelvic anteverision with an increase in sacral slope, but in the fusion group they noted pelvic retroversion with a decrease in sacral slope. Pflugmacher et al.\textsuperscript{10} reported on 22 patients with spinal stenosis and neurogenic claudication treated with decompression followed by a tension band device at a minimum 3-month follow-up. They reported statistically and clinically significant improvements in back pain, leg pain, and Oswestry Disability Index score. There was no increase in segmental instability assessed by flexion-extension radiographs. There was no control group in their study.

Despite the increase in implant development, only a few studies of the strength of lumbar spinous processes have appeared. Our study is most consistent with both the methodology and findings of Shepherd et al.,\textsuperscript{11} who loaded cadaveric lumbar spinous processes with a custom jig and a hook around the spinous process. These investigators found a mean failure strength of 339 N at L-3 and L-4 together, which compares with 453 N in our study for an L-4 that was intact or with minimal decompression. Similarly, Wenger et al.\textsuperscript{12} found a mean failure strength of 405 N in earlier work. In contrast, Yerby et al.\textsuperscript{13} found a higher mean failure strength of 1033 N at L-3 and 765 N at L-4. The methodology used by Yerby et al. was meant to emulate a spinous process spacer as opposed to a tension band, and measurement was made by strain gauges in a metal cylinder. Although some spinous process spacers contain a band to secure the device in place,\textsuperscript{5} this is distinct from a device designed to limit flexion by the tension band effect, although some devices aim to do both.

In all spinous process device applications, the ability of the spinous process to sustain applied loads is a potential concern. Idler et al.\textsuperscript{1} studied a technique for the injection of cement into spinous processes for use with an interspinous spacer, and demonstrated increased stiffness and failure strength. Spinous process spacers load the spinous processes in compression, and bear axial compressive loads. One study reported an average maximum load of > 390 N over multiple implant sizes from 8 to 14 mm (Kohm A, Malandain H, Schwartj J, presentation to the International Meeting on Advanced Spine Techniques [IMAST], 2007). The loads that spinous process tension band devices place on the spinous processes have not been reported, but they may be significantly less than those due to spacers because tension bands do not bear axial compressive loads. Obtaining normative spinous process strength values relevant to tension band devices over a range of BMDs is one of the motivations behind the present study.

Several anatomical considerations are important, including issues involving the spinous processes, supraspinous and interspinous ligaments, and neural foramina. It is worth noting that the results of a study probably depend on the location in which the strap is placed on the spinous process. In our study, the strap was placed midway on the spinous process between the lamina and the tip of the process, in an attempt to find the most stable position that would allow tensioning and prevent slipping of the strap. In our experience, this is the simplest and most stable configuration in which to place the strap. However, placing the strap more ventral (toward the lamina) or dorsal (toward the tip) may alter the results. In addition, spinous processes vary considerably in morphological features between patients in terms of both size and the degree of caudal angulation, and this small number of cadaveric specimens is unlikely to capture all possible variability. Regarding the ligaments, the supraspinous and interspinous ligaments were resected in this study, because the goal was to load individual vertebrae, which were paired but were not tested as a single motion segment. The presence of retained ligaments may affect the behavior and loads of intact motion segments. Regarding the biomechanics, we view the ultimate goal of a tension band in this setting as control of sagittal plane motion, because tension bands have been historically limited in controlling rotation and in fusion applications without interbody support. That said, any tension band construct has the potential to decrease the caliber of the neural foramina by placing the motion segment in relative extension. In clinical use, careful foraminotomies would be required, and exploration of the foramina after tension band application would be needed to assure that neuroforaminal stenosis was not induced.

Of note, this study was conducted to be independent of any specific device design. The testing apparatus contained a strap only, with no additional device complexity such as a tensioning mechanism, a locking mechanism, or instruments for implantation. Our goal was to provide normative data on how much load the bony elements can withstand in tension, because these data can inform such design considerations for any group interested in tension band applications.

The current study has several limitations. Human cadaveric data only represent an approximation of the in vivo scenario. A limited number of specimens minimizes the conclusions that can be drawn from subset and multivariate analyses, for example analysis of BMD or sex of the cadaver. This results in a power limitation, because power is calculated for the primary hypothesis. Therefore, our inability to show a significant effect of osteopenia or osteoporosis may represent a type II error. An alternative interpretation is that the study relies on the strength of cortical bone, whereas osteopenia affects primary can-
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cellous bone. In addition, we tested only the L4–5 level, to study a level with high clinical interest and to achieve a homogeneous study group; however, other levels may have distinct values. Our goal was to provide normative strength data, although this is only one factor in determining the biomechanical properties of a clinically useful implant designed in reference to these data.

Conclusions

Midline-sparing decompression does not decrease the mean failure strength of the L-4 and L-5 spinous processes (453 N and 517 N), but midline surgical decompression decreases the failure strength of the L-4 and L-5 spinous processes (264 N and 269 N) when loaded to failure in a biomechanical model of a tension band construct.

Disclosure

Dr. Golish is a consultant to the Medical Devices Advisory Committee of the US FDA, a member of the Biomedical Engineering Committee of the American Academy of Orthopaedic Surgery (AAOS), a Section Editor for the journal Orthopaedic Knowledge Online (OKO) from the AAOS, and a member of the Medical and Surgical Materials and Devices Committee (F04) of the American Society for the Testing of Materials International. Dr. Alamin and Mr. Fielding are employees or stockholders of Simpirica Spine. Drs. Agarwal and Buckley have no relevant disclosures that represent a potential conflict of interest.

Author contributions to the study and manuscript preparation include the following. Conception and design: Buckley, Alamin. Acquisition of data: Fielding, Agarwal, Buckley. Analysis and interpretation of data: all authors. Drafting the article: Golish, Fielding, Agarwal, Alamin. Critically revising the article: all authors. Approved the final version of the manuscript: all authors. Reviewed submitted version of manuscript: all authors.

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