**FAILURE LOAD OF THE LUMBAR SPINOUS PROCESS**

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INTRODUCTION There are currently a number of spinal fixation systems designed to provide stability and/or promote fusion of the lumbar spine. These include interbody cages, pedicle screws, laminar hooks, and plates. Common points of fixation include the vertebral body, lamina, and pedicle. In the 1980’s Drummmond et al. reported on an interprocess spinal wiring technique developed to promote fusion, and recently, Papp et al. and Minns and Walsh described a flexible implant developed to stabilize the lumbar spine. Although several systems utilize the spinous processes as a fixation point, there are very few reports on the strength of the spinous processes in relation to the *in situ* loads applied by the implants.

The objective was to measure the *in situ* loads of a novel interspinous spacer and relate these implant loads to the failure loads of the spinous processes using a cadaver model. The spacers used in this study are designed to place an individual motion segment in slight flexion, and in turn, decrease the degree of stenosis at the pathologic level. The second objective was to relate the spinous process failure load to the bone mineral density (BMD) of each respective vertebra. The overall goal was to determine the level of safety for the spacer and the fracture risk for the spinous processes.

METHODS Eight L2-L5 human cadaver specimens were procured and cleaned of all muscle and adipose tissue. Each specimen was DEXA scanned as that of the instrumented spacer in the flexion/extension testing. Processes were loaded at 1 cm/min until fracture. Load and displacement were recorded at 20 Hz and fracture was denoted by a sharp decrease in load.

*In situ* spacer loads were calculated as a percentage of the spinous process failure load, and the failure loads were correlated to the individual vertebral BMD. Differences between the mean spinous process failure loads of L3 and L4 specimens were analyzed using a paired t-test with a level of significance of 0.05.

RESULTS The mean donor age was 60 years (range: 36 to 77) and the mean BMD for the L3 and L4 vertebra was 8.93 g/cm² and 8.95 g/cm² respectively. There was no significant difference between the BMD values of the L3 and L4 vertebra. Six specimens were implanted with 12 mm spacers, and two specimens were implanted with 10 mm spacers. The mean maximum load of all spacers occurred in extension (mean: 109.5 N, sd: 65.3 N, range: 43.4 to 214.0 N) the mean minimum load of all spacers resulted from flexion (mean: 45.0 N, sd: 39.0 N, range: 3.5 to 106.2 N). The mean failure strength of the L3 spinous processes (mean: 1033 N, sd: 505 N, range: 498 to 2095 N) was significantly greater than the mean failure strength of the L4 spinous processes (765 N, sd: 374 N, range: 379 to 1472 N).

During extension, the L3 spinous processes were loaded to a mean of 11.7% of their failure load (sd: 7.3%, range: 5.0 to 25.7%), and the L4 spinous processes were loaded to a mean of 16.3% of their failure load (sd: 11.4%, range: 4.7 to 40.7%). The difference between the L3 and L4 mean percent failure load of the L3 and L4 specimens were analyzed using a paired t-test with a level of significance of 0.05.

DISCUSSION The difference between the mean failure strength of the L3 and L4 spinous processes is likely due to the different loading directions, rather than the difference in specimens. Both groups of specimens had similar BMDs, but the L3 spinous processes were compressed on the cephalad surface while the L4 spinous processes were compressed on the caudal surface. The results suggest if spinous failure was to occur as a result of extreme extension, failure would likely originate within the most caudal spinous process. In addition, there was a significant positive relationship between the spinous process failure load and the BMD. This suggests that patients with low bone mineral density should be examined thoroughly before being selected for interspinous spacer surgery or any other surgery involving loading of the spinous processes. Finally, during extension the mean percent failure load of the L3 spinous processes was 11.7%, and 16.3% for the L4 spinous processes. Yet two of the specimens with the lowest BMD values and failure strengths were loaded above 20% of their failure strength. This again suggests that vertebral BMD is an important measure when considering fixation to the spinous process.

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