Spinous Process Fractures after Placement of an Interspinous Process Spacer Device: Insight into the Mode of Action of an Interspinous Device

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Introduction: Interspinous devices may be less invasive to manage mild to moderate lumbar stenosis. Reports of spinous process fractures have found their rate to be 22% with much higher rates of 52% associated with spondylolysthesis. These high rates of spinous process fractures raise questions about the impact they have on patient outcomes. As the proposed mechanism of the device is to force the spinous processes apart and cause distraction, it would appear intuitive that patients would have poorer outcomes as the fracture reduces the ability of the implant to flex the vertebra forward. The purpose of this study was to determine the effect of a spinous process fracture on functional outcomes.

Methods: This was a prospective multicenter IDE study with patients aged 45 years or greater with moderate lumbar spinal stenosis looking at the Superion interspinous device (Vertiflex, San Clemente, CA) and comparing it in a non-inferiority study to the X-stop device (Medtronic, Minneapolis, MN). 344 subjects were randomized, enrolled with demographic and operative data collected. At each follow-up visit, subjects completed Zurich Claudication Questionnaire (ZCQ), Oswestry Disability (ODI), Visual Analog Scale (VAS), Short Form Health Survey (SF-12) and the VertiFlex Patient Satisfaction questionnaires to evaluate disability, function, pain, quality of life and satisfaction. Patients also underwent standing anterior/posterior, lateral and flexion/extension lateral lumbar spine views which were reviewed by an independent radiologist. A stepwise multivariate regression analysis was completed looking at factors affecting patient ODI at the one year follow-up. These identified factors were sub-examined in patients with and without postoperative spinous process fractures.

Results: 344 subjects were included in this study (263 subjects without fracture and 81 with fracture). After controlling for the effect of ODI preoperatively and after 6 weeks, the average ODI score at one year for subjects with fracture is 1.465 units more than for those patients without fracture, which was not statistically significant (p=0.403). For subjects without fracture, the ODI score at one year was significantly affected by foraminal height difference between week 6 and preoperatively (p=0.031), but not by flexion/extension (FE) motion at week 6 (p=0.800). For every 1mm increase of foraminal height, the ODI at one year decreased 3.455 units. However, for subjects with a spinous process fracture, the ODI at one year was more significantly affected by FE rotation at week 6 (p=0.007), but not by foraminal height increase between week 6 and pre-op (p=0.766). For every unit increase of FE rotation at week 6, the ODI at one year increased 2.725 units. The FE motion noted on the preoperative radiograph did not predict the occurrence of a spinous process fracture.

Discussion: Spinous process fractures after placement of interspinous process spacer devices are likely under recognized. Kim et al found lower functional outcome scores for patients, poorer outcomes on Zurich Claudication Questionnaire (ZCQ) and tended toward lower satisfaction rates at one year.
compared to patients without fracture. Our study found a much more robust outcome for patients with fracture. In examining factors that were associated with better outcome scores, it appears arresting spinal motion may represent a more plausible mode of action for these implants as opposed to foraminal distraction. Patients with a painful spinous fracture would likely also limit their lumbar range of motion; and thereby, limit their flexion and extension.

**Significance:** Our study determined the effect of spinous process fracture on functional outcomes and found that arresting spinal motion may represent more plausible mode of action for these implants compared to foraminal distraction.

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