

Vertebral Body Splitting Fractures Following ProDisc-L™ Implantation

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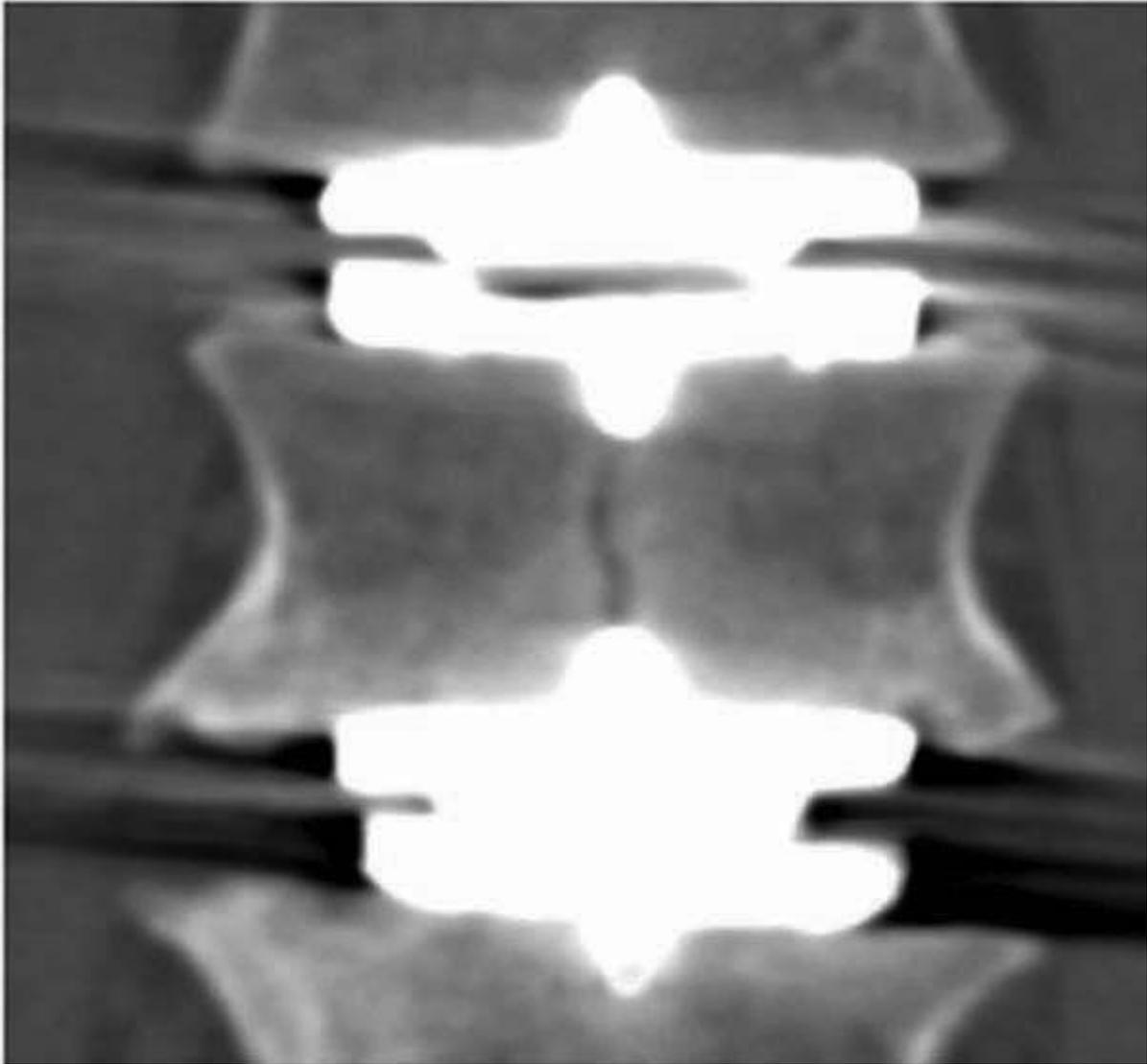
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Purpose: To document the occurrence of vertebral body splitting fractures (VB-SF) after ProDisc-L (PDL™) implantation, to compare the standard U.S. surgical technique to newly developed transitional and modified surgical techniques designed to prevent VB-SFs, to evaluate potential risk factors for VB-SF, and to determine the evolution of VB-SFs over time.

Methods: Computed tomography (CT) scans were examined for VB-SFs in Group I (14 standard-technique single-level cases, 4 standard-technique hybrid cases, 5 standard-technique multilevel cases and 1 transitional-technique multi-level case), as well as in Group II (15 modified-technique multi-level cases). Patients with fractures were followed with CT for 5 to 13 months. Demographic and clinical data were collected to identify risk factors for VB-SF.

Results: No VB-SFs were observed in the 14 standard-technique single-levels, 4 standard-technique hybrids, or the only transitional-technique multi-level. There were VB-SFs in 4 of 5 interposed vertebral bodies (IVBs) in standard-technique multi-levels. The remaining patient had an anterior keel cut to anterior keel cut fracture which did not transect the vertebral body. In the lone transitional-technique multi-level, 1 of the 2 IVBs had a VB-SF. No VB-SFs were noted in the 15 (17 IVBs) modified-technique multi-levels. The reduction in VB-SFs associated with the modified surgical technique was highly statistically significant ($p < .001$). The vertebral body height (VBH) of the standard-technique multi-levels was on average 2.9 mm smaller than the VBH of the modified-technique multi-levels ($p < .001$). However, there was a small VBH subset within the modified-technique multi-levels which did not differ in VBH from the VBH of the standard-technique multi-levels. These small vertebral body modified-technique multi-levels did not have VB-SFs. No other clinical or demographic feature could account for the absence of VB-SF association with the modified surgical technique. A 2-level patient may have suffered an adverse outcome as a result of VB-SF separation and implant dislocation due to trauma 10 days post-operatively. Follow-up CT scans indicated that VB-SFs did not bridge with bone, instead formed sclerotic margins around the fracture. Sclerosis was noted in relationship to the keel in non-fractured vertebral bodies.

Conclusions: VB-SFs are rare in single-level PDL™ cases and may be under reported in multi-level applications. VB-SFs tend not to bridge with bone, with sclerotic margins forming around the VB-SF. In the immediate post-operative period, VB-SF in combination with trauma may increase the risk of additional bony injury and implant dislocation. VB-SFs may be prevented by the modified surgical technique reported here.



[Fig1]



[Fig2]