CLINICAL STUDY PROTOCOL FUSION SCALE

THE STABILITY STUDY: FUNCTIONAL MOTION OUTCOMES IN PATIENTS TREATED WITH AN INTERSPINOUS FUSION DEVICE FOR DEGENERATIVE CONDITIONS OF THE LUMBAR SPINE

Brief Title:	STABILITY
Protocol Number:	PDPROJ-4-TP-001-23
Sponsor Name:	Spinal Simplicity 6363 College Blvd Suite 320 Overland Park, KS 66211
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Grade	Interspinous Fusion Grades (New)
1	*Definitely Fused* – Clear evidence of bridging bone through and/or around the device, no noticeable lucencies or areas of concern
2	*Probably Fused* – Evidence of bridging bone through and/or around the device (50-75% at least), but there may be minor lucencies or areas of incomplete bone bridging
3	*Probably Not Fused* – Minor evidence of bone formation within a portion of the device but may not fully extend through the device (<50%), there may be lucency around a portion of the device
4	*Definitely Not Fused* – No clear evidence that appreciable bone formation has occurred and/or major lucencies indicating the device is not solidly anchored in bone

Table 1

Novel Interspinous Fusion Grading Scale

(Instrumented Posterior Arthrodesis of the Lumbar Spine: Prospective Study Evaluating Fusion Outcomes in Patients Receiving an Interspinous Fixation Device for the Treatment of Degenerative Spine Diseases, 2023)

Currently, there is no gold standard fusion grading metric for posterior interspinous fusions. As such, the authors have reviewed the existing literature assessing other lumbar fusion constructs to develop a reasonable, clinically relevant fusion grading scale that can be applied to all interspinous fixation devices. Bridwell et al13 defined a 4-point grading scale for lumbar spine fusions that has been widely cited in the literature. Bridwell's team investigated anterior interbody and posterior pedicle-based instrumentation used to correct adult deformity conditions. The Bridwell scale for anterior and posterior fusion grading is presented in Table 1 along with the newly developed criteria to grade interspinous fusion.

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Their anterior grading scale conveys generally recognized degrees of successful or unsuccessful bony fusion, while the posterior scale is more specific to grading fusions around pedicle-based posterior constructs. Two other papers provide fusion characteristics scales specifically for interspinous fixation devices. Vokshoor et al14 graded interspinous fusions following implantation of the Zimmer Biomet Aspen interspinous fixation device according to a similar, but reversed, 4 grade scale, with the 4 grades distinguished by: small islands of bone, larger islands of coalescence with bridging to surrounding anatomy, some solid incorporation and bridging bone, and solid fusion with incorporation and obvious stability and maturity. They considered constructs exhibiting either Grade 3 or Grade 4 characteristics to be fused and reported a 94% interspinous fusion rate with the Aspen interspinous device in a 50 data point cohort assessed using CT imaging. Postacchini et al15 graded interspinous fusions after placement of the Nuvasive Affix interspinous device according to a more basic “Certain”, “Incomplete”, or “Absent” fusion definition scale. In their study, a total of 25 fusion assessments were made with CT imaging and 21 of 25 (84%) were reported as “Certain”, 1 of the 25 (4%) was “Incomplete”, and 3 of the 25 (12%) were reported as “Absent.” Since the Bridwell scale is specific to pedicle-based posterior fusion constructs, and not spinous process fixation devices like the device being evaluated in this study, the present study scoring system modified the Bridwell fusion grading scale taking into account the design intent and location for a posterior interspinous fusion with the device. The present study’s proposed scale also considers the 4-point fusion definition scale previously used by Vokshoor et al and Postacchini et al. The new fusion grading scale for interspinous fixation devices is presented in Table 1