ARTICLE IN REVIEW:

ViviGen® associated with consistently successful lumbar fusion among high-risk patients

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TITLE: Lumbar Spine Fusion Outcomes Using a Cellular Bone Allograft with Lineage-committed Bone-forming Cells in 96 Patients.[1]

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STUDY DESIGN: Retrospective review of data from 96 patients, single surgeon.

SUMMARY: Patients (mean age: 58.9 years, 53.1% female) underwent instrumented posterior lumbar fusion (IPLF) with (n = 83) and without (n = 13) transforaminal interbody fusion (TLIF) using ViviGen at a total of 222 levels (average 2.3 levels). Anteroposterior and lateral radiographs with computerized tomography (CT) scans were independently reviewed for assessment of fusion according to the Lenke grading scale.[2] Grades of A or B were considered fused, and Grades of C or D were considered not fused. Successful fusion (Lenke A or B) was reported for 88 of 96 patients (91.7%) overall, including in all IPLF-only patients. Of 22 patients with diabetes in the IPLF+TLIF group, fusion was reported in 20 patients (90.9%). In IPLF+TLIF patients currently using tobacco (n = 19), fusion was reported in 16 patients (84.3%), while in those with a history of tobacco use (n = 53), fusion was observed in 48 patients (90.6%). Successful fusion was reported in all 6 patients with previous pseudarthrosis at the same level. Patient-reported postoperative disability (average 18.0%) was significantly reduced versus preoperative (average 37.2%; P<0.0001), as was pain (average postoperative Visual Analog Scale (VAS) 4.4 vs preoperative VAS 7.6; P<0.0001). Finally, the average operating room (OR) time was 193 minutes, which represented a 42- to 55-minute reduction over that reported in the literature for other grafts.[3,4] The authors concluded that use of ViviGen yielded consistently successful fusion and significant decreases in patient-reported disability and pain, despite patient comorbidities and lifestyle risk factors that are known to negatively affect such bony healing.

Consistently successful lumbar fusion among high-risk patients:

Overall successful fusion of 91.7%, with similar rates among high-risk patients with obesity (91.3%), diabetes (91.7%), current tobacco use (85.7%), historical tobacco use (91.8%), or pseudarthrosis (100%; see figure).

Significant reductions in patient-reported pre- vs postoperative disability and pain:

Average 19.2% reduction in disability (P<0.0001) and 3.2-point-reduction in VAS (P<0.0001).

Substantial reductions in OR time over reported times with other grafts:

Average OR time was 193 minutes, which represents a 42- to 55-minute reduction from operative time reported in the literature for other grafts.[3,4]

References

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2. Lenke LG, Bridwell KH, Bullis D, Betz RR, Baldus C, Schoenecker PL. Results of in situ fusion for isthmic spondylolisthesis. J Spinal Disord. 1992;5(4):433-442.
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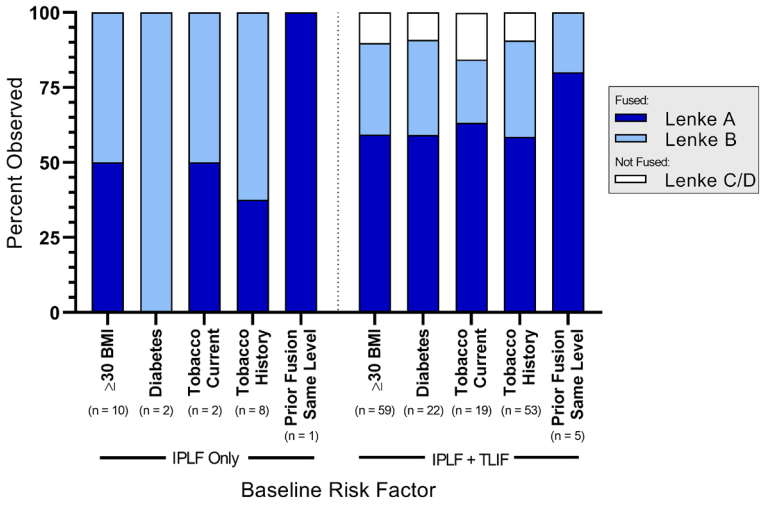
Consistently successful fusion among high-risk patients.

Fusion status by treatment and baseline risk factor as applicable for all levels treated. All percentages were based on the total number of patients within each category. Figure reproduced with permission under an open access license.[1]



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