Rate of Fusion Using Novel Synthetic Bone Graft Mixed with Allograft Stem Cell Product in Lumbar Interbody Fusions

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Background

- Over 400,000 interbody fusions performed annually in the US with 75% involving lumbar region[1]
- Indicated treatment for multiple orthopedic conditions[2]
- Iliac crest autograft has been considered the "gold standard" for bone grafting during lumbar fusions, but it has several morbidities including numbness and pain at harvest site which can lead to disability[1,3]
- Vimax®, a cellular bone matrix produced by SurGenTec, is an allograft combined with stem cells and growth factors that is processed in a manner that allows it to be osteogenic, osteoconductive, and osteoinductive[4,5,6]
- OsteoFlo® by SurGenTec is a bone graft putty with a quadphasic resorption profile and nanotopography which allows for quicker bone growth over previous putty products[6]
- This study observes the rate of arthrodesis when combining Vimax® and OsteoFlo® to observe its efficacy as an iliac crest autograft substitute in lumbar fusions

Hypothesis & Objectives

Hypothesis

- The rate of fusion using Vimax® and OsteoFlo® will provide an acceptable arthrodesis rate

Objectives

- Determine arthrodesis rate of Vimax® and OsteoFlo® in lumbar interbody fusions
- Observe changes in spinal measurements and alignment after using allograft mixture in spinal fusions

Materials & Methods

- Retrospective chart review of patients that received lumbar interbody fusion with Vimax® and OsteoFlo® from 5/26/21 to 6/27/22 at a single institution
- 96 patients, 146 interbody fusions
- Patients were included that had a lumbar interbody fusion with pre-op and at least one post-op radiograph. Patients under the age of 21 at the time of surgery were excluded.
- Demographics, comorbidities, and surgery details were collected from the EMR
- Interbody fusion grades were assigned via the Bridwell Grading System to the 2-week, 6-week, 3-month, 6-month, and 1-year post-op radiographs
- Lumbar and segmental lordosis, anterior and posterior disc height, foraminal height, pelvic incidence, pelvic tilt, PI-LL mismatch were measured on pre- and post-op X-rays
- Statistical significance calculated using Kruskal-Wallis for Bridwell grades and Unpaired T-Test for measurements

Results

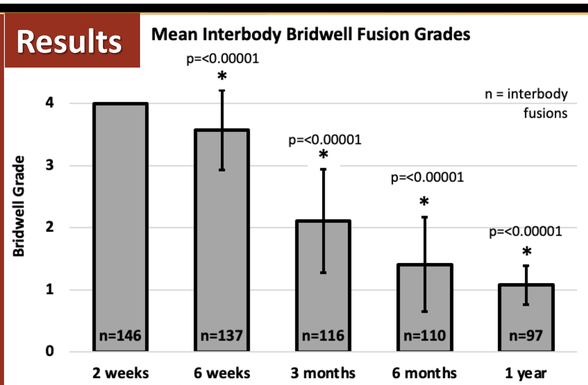

Figure 1. Mean Bridwell grades of all interbody fusions at each follow up

Fusions	2 weeks	6 weeks	3months	6 months	1 year
Fraction Fused	0/146	1/137	27/116	78/110	90/97
Percent Fused	0	0.7	23.3	70.9	92.8

Table 1. Percent of grafts fused at each follow up

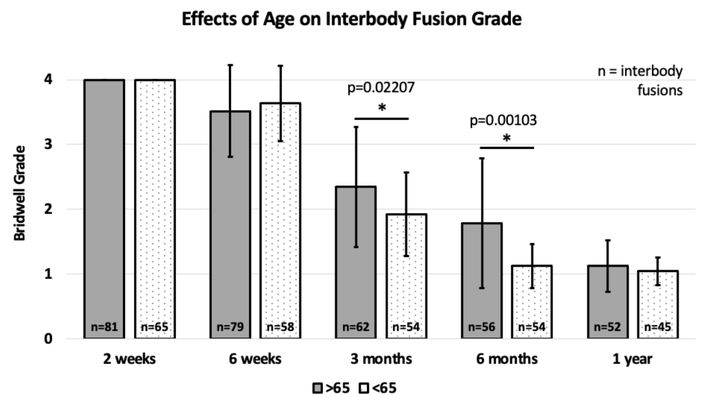

Figure 2. Effect of Age on Interbody Fusion Grade. Sex and BMI had significance at 3 month follow up with females and BMI >35 less fused

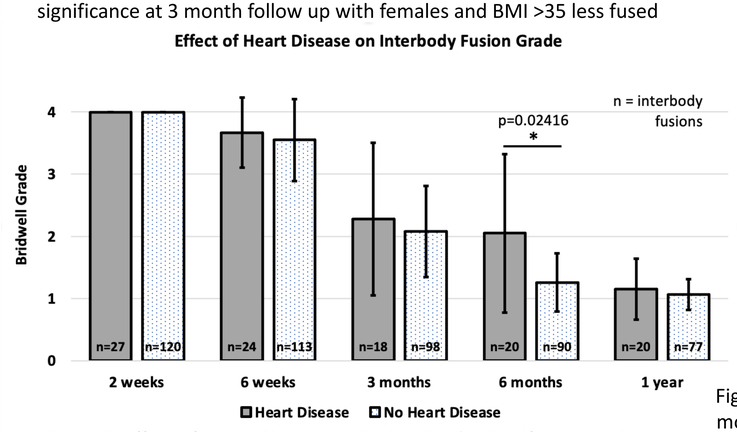

Figure 3. Effect of Heart Disease on Fusion Grade. Significance at 6 month follow up for being less fused

Grade	Description
I	Fused with remodeling and trabeculae present
II	Graft intact, not fully remodeled and incorporated, but no lucency present
III	Graft intact, but a potential lucency at the top or bottom of the graft
IV	Fusion absent with collapse/resorption of graft

Table 2. Bridwell Interbody Fusion Grading Scale used to assess radiographs

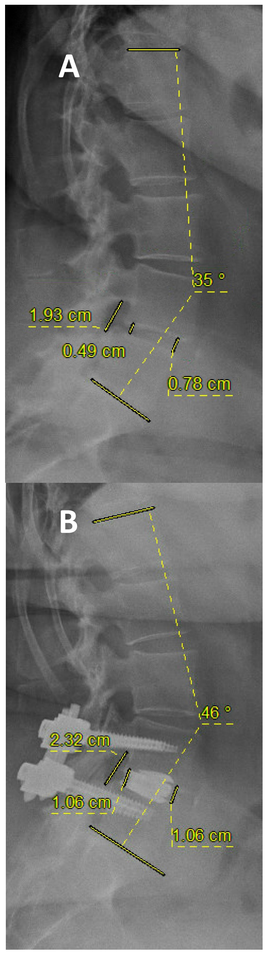

Figure 4. L4/L5 MIS ALIF pre-op (A) and 6-month post-op (B) radiographs. Diagnosis of stenosis and anterolisthesis. Bridwell grade 1 at 6 months

Measurement	Pre-op	2 weeks	6 weeks	3 months	6 months	1 year
Lumbar Lordosis (degrees)	51.6	48.0*	48.6	48.7	48.8	50.4
Spondylolisthesis (mm)	7.7	4.3***	4.3***	4.2***	3.4***	4.1***
Ant. Disc Height (mm)	8.6	12.7***	12.9***	12.7***	12.2***	12.3***
Post. Disc Height (mm)	6.9	10.5***	10.6***	10.5***	10.2***	10.0***
Foraminal Height (mm)	19.6	22.0***	21.9***	21.4**	21.2***	21.3***
Pelvic Incidence (degrees)	56.9	56.3	57.3	57.7	56.4	59.4
Pelvic Tilt (degrees)	20.4	21.3	21.3	22.0	21.5	22.5
PI-LL Mismatch (degrees)	5.3	8.3	8.7	9.0	7.9	9.0

Figure 5. Effect of interbody fusion on anterior disc height. Posterior disc height and foraminal height had similar significance. Spondylolisthesis had significance with decreasing measurements post-op

Conclusions

- 70.9% arthrodesis by 6 months and 92.8% by 1 year
- Age over 65, female sex, and BMI >35 showed slower arthrodesis on 3- and/or 6-month follow up radiographs, but all had over 90% Bridwell grade 1 on 1-year post-op radiograph
- Comorbidities of heart disease and hypertension displayed delayed arthrodesis rate at 6 months and 3 months, respectively. However, both had over 90% Bridwell Grade 1 at 1-year post-op
- No significant difference was noted for surgical approach or other comorbidities such as diabetes mellitus, and renal disease
- Lumbar lordosis had significant decrease 2 weeks post-op but at no other timepoint
- Segmental lordosis, pelvic tilt, pelvic incidence, and PI-LL mismatch had no significance post-op compared to pre-op
- Anterior and posterior disc height and foraminal height increased significantly while spondylolisthesis decreased significantly
- Lateral mass fusions were also studied and yielded similar results
- Interbody fusions were significantly more fused than lateral mass fusions at 3-months, 6-months, and 1-year
- Vimax® and OsteoFlo® demonstrated effectiveness as an iliac crest autograft substitute

References

1. Reisener MJ, et al. Trends in lumbar spinal fusion-a literature review. J Spine Surg. 2020;6(4):752-761.
2. Lopez CD, et al. Recent trends in Medicare utilization and reimbursement for lumbar spine fusion and discectomy procedures. *The Spine Journal*. 2020;20(10):1586-1594.
3. Kim DH, et al. Prospective study of iliac crest bone graft harvest site pain and morbidity. Spine J Off J North Am Spine Soc. 2009 Nov;9(11):886–92.
4. Khan SN, et al. The Biology of Bone Grafting. JAAOS - J Am Acad Orthop Surg. 2005 Feb;13(1):77–86.
5. Loiselle AE, et al. Specific biomimetic hydroxyapatite nanotopographies enhance osteoblastic differentiation and bone graft osteointegration. Tissue Eng Part A. 2013;19(15-16):1704-1712.
6. Surgentec Graftgun®: Bone Graft Delivery Systems. SurGenTec Graftgun® - Bone Graft Delivery Systems. Accessed June 20, 2023. https://www.surgentec.com/.

Acknowledgements

Student Education and Research Fellowship Program, Orthopaedics Northeast – ONE, Parkview Mirro Center for Research and Innovation. Project partially funded by SurGenTec, Indiana Clinical and Translational Sciences Institute, and UL1TR002529 from the National Institute of Health. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Health