Use of a Novel Allograft in Single- and Two-Level Posterolateral Lumbar Spinal Fusion: 2-Year Clinical and Radiographic Results from a Prospective Multicenter Study

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PURPOSE: The purpose of this study was to compare 2-year clinical and radiographic outcomes of OSTEOAMP and iliac crest bone graft (ICBG) in single- and 2-level posterolateral lumbar fusion (PLF).

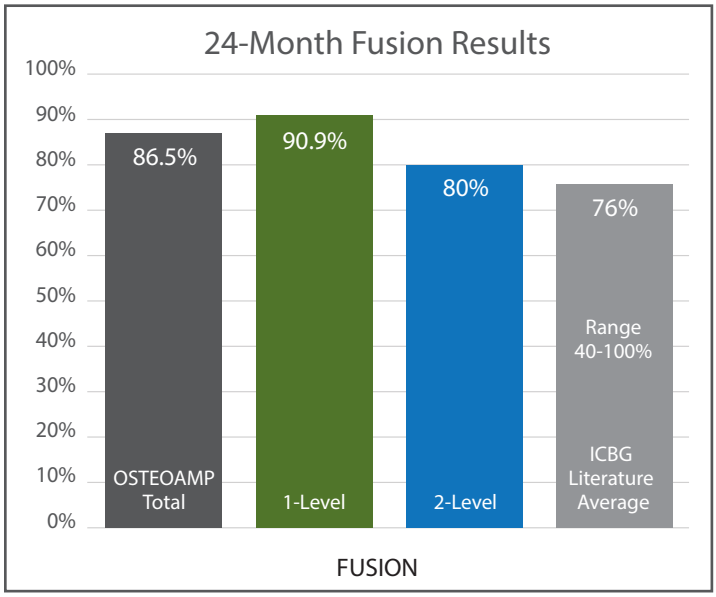
STUDY DESIGN: This was a prospective multicenter cohort study (level 2 evidence) involving nine centers in the United States.

PATIENT SAMPLE: 42 patients with Oswestry Disability Index (ODI) score of at least 30 at baseline were prospectively enrolled and underwent a single- (N=26) or two-level (N=16) PLF utilizing OSTEOAMP. 38/42 (90.5%) and 32/42 (76.2%) subjects attended 12- and 24-month follow-ups, respectively.

OUTCOME MEASURES: ODI, back and leg pain, SF-36 MCS and SF-36 PCS.

METHODS: Data was obtained preoperatively and at 1.5, 3, 6, 12, and 24 months. Radiographic studies were assessed by an independent core lab for evidence of bridging bone and lack of segmental angular (<5°) and translational (≤3 mm) motion. Missing 24-month follow-up observations were populated using 12-month values. Clinical outcomes were evaluated with mixed model for repeated measures analysis adjusting for baseline differences in the scores.

RESULTS: The two-year fusion rate for OSTEOAMP was 32/37 (86.5%) compared to the literature average of 76% (range 40%-100%) for ICBG. The fusion rate was 90.9% (20/22) in single- and 80% (12/15) in 2-level PLF (p=0.377). While ODI improved in both groups, the improvement was larger in single- than in 2-level subjects (p=0.058). At 24 months, the improvement in ODI was 33.5 and 25.9 in single- and 2-level subjects, respectively. There was a tendency for greater improvements at 24 months in single-level compared to 2-level PLF in SF-36 PCS (15.4 vs 12.5) and SF-36 MCS (7.9 vs 5.6), but these differences did not reach statistical significance. Improvements in pain at back (4.8 vs 4.6) and pain at leg (4.8 vs 4.3) were similar in single- and 2-level surgeries. One secondary surgery was performed at 3 months postoperatively for a symptomatic screw in a single-level subject. No product-related treatment complications were reported.



24-MONTH OUTCOMES

	1-Level	2-Level	*p*-value
Fusion Rate	90.9%	80%	0.377 Not significant
ODI Improvement	33.5	25.9	0.058
SF-36 PCS Improvement	15.4	12.5	Not significant
SF-36 MCS Improvement	7.9	5.6	Not significant
VAS Back Pain Improvement	4.8	4.6	Not significant
VAS Leg Pain Improvement	4.8	4.3	Not significant

CONCLUSIONS: OSTEOAMP is safe and effective for use in posterolateral spinal fusion as evidenced by fusion rates higher than for ICBG, good clinical outcomes, and freedom from serious product-related complications. One-level PLF is associated with better ODI but similar pain outcomes compared to two-level PLF.

INDICATIONS: OSTEOAMP may be used in situations where an autograft is appropriate. It should be restricted to homologous use for the repair, replacement, or reconstruction of musculoskeletal defects.

STUDY LIMITATIONS: The study had a relatively small sample size.

A Novel Bone Graft Has Higher Fusion Rate Than Local Autologous Bone in Stand-alone Posterolateral Fusion: A Propensity Score Adjusted Analysis

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PURPOSE: To compare radiologic and patient outcomes following stand-alone posterolateral fusion (PLF) that used a novel bone graft substitute, OSTEOAMP, vs local autologous bone (LAB).

STUDY DESIGN: A propensity score-adjusted non-concurrent multicenter prospective cohort study.

PATIENT SAMPLE: Patients undergoing PLF with either OSTEOAMP or LAB. The OSTEOAMP group underwent a 1- or 2-level procedure and the LAB group underwent a 1-level procedure.

OUTCOME MEASURES: Fusion, Oswestry Disability Index (ODI), back and leg pain, Short Form-36 (SF-36) physical component summary (PCS) and mental component summary (MCS) scores at 12 months.

METHODS: Clinical and patient outcomes for PLF using OSTEOAMP (N=38 patients) or LAB (control, N=104 patients) from two prospective studies were compared utilizing a propensity score approach to reduce selection bias in baseline characteristics. After application of propensity score region, 38 OSTEOAMP and 82 LAB patients were included in the analysis. The weighted analysis was performed using propensity scores as weights. Fusion was defined as uni- or bilateral bridging bone on CT scans and an absence of angular and translational motion (<5 degrees angular motion and ≤3 mm translational motion) on flexion-extension radiographs.

PATIENT COMPARISON AFTER PROPENSITY SCORING

	OSTEOAMP (N=38)	Local Autologous Bone (N=82)	*p*-value
Gender (Female)	22 (57.9%)	47 (57.3%)	0.9527
Race (White)	35 (92.1%)	73 (89.0%)	0.6023
Age (Years)	67.1 (10.2)	63.5 (11.1)	0.0905
Body Mass Index (kg/m^2)	30.3 (4.4)	30.6 (5.6)	0.7584
Underweight	0 (0.0%)	0 (0.0%)	0.5799
Normal Weight	5 (13.2%)	13 (15.9%)	
Overweight	12 (31.6%)	28 (34.1%)	
Obese	21 (55.3%)	41 (50.0%)	
Tobacco Use			0.9844
Never	18 (47.7%)	39 (47.6%)	
Former / Current	20 (52.6%)	43 (52.4%)	
SF-36 Physical Component Score	30.6 (6.2)	29.9 (7.5)	0.6024
Oswestry Disability Index (ODI)	52.5 (18.0)	50.1 (13.5)	0.4663
Back Pain (0-10)	6.4 (2.0)	7.0 (2.5)	0.2251
Leg Pain (0-10)	6.6 (3.0)	7.3 (2.4)	0.1708

12-MONTH OUTCOMES

	OSTEOAMP	LAB	*p*-value
Fusion	**84%**	**61%**	**0.028 (RR 1.4)**
ODI Score (Improvement)	20.3 (31.5)	18.8 (30.5)	0.7585
SF-36 PCS Improvement	15.4	13.1	0.1642
SF-36 MCS Improvement	7.1	7.6	0.175

CI = 95%
p-value < 0.05 = statistical significance

RESULTS: The fusion rate was 84% and 61% in the OSTEOAMP and LAB groups, respectively (p=0.028, RR = 1.4 (95% C.I. = 1.0 to 1.9)). At 12-month follow-up, both groups showed statistically significant improvements in all outcomes. There was no difference in ODI outcomes between the groups. The average ODI score at 12 months was 20.3 (31.5-point improvement) and 18.8 (30.5-point improvement) in the OSTEOAMP and LAB subjects, respectively. There was a marked and significant improvement in SF-36 PCS in both groups (15.4 and 13.1 in OSTEOAMP and LAB groups, respectively, n.s.). SF-36 MCS improved in both groups (7.1 and 7.6 in OSTEOAMP and LAB groups, respectively, n.s.). Both groups experienced similar improvements in back pain and leg pain. Safety outcomes were similar between the groups.

CONCLUSIONS: OSTEOAMP is a viable replacement for local autologous bone and achieves better radiologic fusion rates and similar patient outcomes in stand-alone PLF.

STUDY LIMITATIONS: Some 2-level cases were included in the OSTEOAMP group which likely underestimated the true fusion rate. The study had a relatively small sample size, but propensity scoring reduces selection bias. OSTEOAMP was not compared to the "gold standard" ICBG, but local autologous bone represents a more viable and common application.

OSTEOAMP may be used in situations where an autograft is appropriate. It should be restricted to homologous use for the repair, replacement, or reconstruction of musculoskeletal defects.

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