Outcomes Following Lumbar Interbody Fusion with a Novel Cellular Bone Allograft: A Matched-Cohort Analysis

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INTRODUCTION: Lumbar interbody fusion is a commonly performed procedure to stabilize the spine and reduce pain by achieving bony union. Biologic augmentation has been developed to improve fusion rates, with recombinant human bone morphogenetic protein-2 (rhBMP-2) and cellular bone allografts (CBAs) representing leading options. Although rhBMP-2 provides strong osteoinductive potential, its use is limited by complications & high cost. Conversely, CBAs may enhance efficacy by integrating all three components of the bone remodeling triad: osteoconduction, osteoinduction, and osteogenicity. Yet, comparative clinical evidence for CBA use with rhBMP-2 in lumbar interbody fusion remains limited. This study addresses this gap by comparing outcomes in patients undergoing transforaminal (TLIF) or posterior lumbar interbody fusion (PLIF) with rhBMP-2 alone versus rhBMP-2 combined with a novel CBA.

METHODS: We conducted a retrospective matched-cohort analysis of TLIF/PLIF patients (2017–2022) at a single center. Groups were rhBMP-2 alone (Infuse™, Medtronic) versus rhBMP-2 plus CBA (PrimaGen Advanced Allograft™, Zimmer Biomet; hereafter CBA-P). Rate of interbody fusion at 12 and 24 months was the primary outcomes, defined as ≤2° intersegmental angular motion at operative levels on flexion–extension radiographs assessed via SpineCamp™ [Medical Metrics]. Secondary outcomes included revisions, complications, and PROs. Statistical analysis included chi-square or Fisher's exact tests for categorical variables and t-tests for continuous variables, with $p<0.05$ considered significant. Multivariable adjustments were performed to account for baseline differences between cohorts. Institutional review board approval was obtained from the Colorado Multiple Institutional Review Board.

RESULTS: Each cohort included 50 patients: Control (mean age 63.1 ± 10.2 years; 32 females, 18 males) and Experimental (mean age 61.7 ± 11.6 years; 31 females, 19 males). Baseline differences were noted, with Controls having significantly higher BMI ($p=0.02$), greater tobacco use ($p=0.03$), and a higher prevalence of diabetes mellitus ($p=0.04$). Fusion rates were high in both groups—89.1% (Control) vs 95.7% (Experimental) at 12 months and 89.5% vs 100.0% at 24 months—with no statistically significant differences [Figure 1]. Estimated blood loss was greater in the Experimental cohort (364.4 ± 311.3 cc) compared with Control (232.9 ± 218.9 cc; $p=0.0006$), but intraoperative, perioperative, and postoperative complication rates were otherwise similar. Patient-reported pain scores and revision rates at 24 months were likewise comparable [Table 1]. Attrition was substantial, with 66% of patients lost to follow-up at 24 months.

Exploratory confounder analyses were conducted to ensure baseline imbalances did not bias interpretation of study outcomes. Current smokers were fund to have higher complication rates than former or nonsmokers at 6 and 12 months ($p<0.01$). Patients with obesity (BMI ≥30) demonstrated increased complications at 12 and 24 months ($p<0.02$), and diabetic patients experienced greater perioperative blood loss ($p=0.05$). However, after adjustment, none of these factors significantly influenced cohort-level outcomes with fusion, complication rates, and patient-reported pain remaining comparable between groups.

DISCUSSION: In this first clinical evaluation of CBA-P in lumbar interbody fusion, the addition of CBA-P to rhBMP-2 did not improve fusion rates, reduce complications, or enhance pain outcomes. Although EBL was higher in the CBA-P cohort, this difference did not translate into worse perioperative or long-term outcomes. Importantly, despite baseline imbalances in BMI, diabetes, & tobacco use, these factors did not alter cohort-level results, supporting the robustness of the findings. Taken together, these results suggest that routine use of CBA-P as an adjunct to rhBMP-2 in short-segment lumbar interbody fusion may not be warranted. However, high attrition at 24 months and baseline cohort imbalances limit the interpretation of these findings.

SIGNIFICANCE/CLINICAL RELEVANCE: Despite its novel biologic design, CBA-P did not demonstrate measurable clinical benefit when added to rhBMP-2 in lumbar interbody fusion. As surgical decision-making increasingly incorporates both outcomes and value, these findings highlight the need for broader, prospective trials to validate the clinical utility of cellular bone allografts before wider adoption in interbody fusion.

IMAGES AND TABLES:

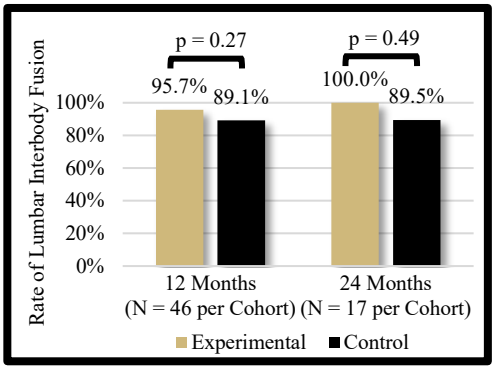

Figure 1 - Lumbar Interbody Fusion Rates at 12 and 24 Months Post-Operation: This figure illustrates the percentage of patients achieving successful lumbar interbody fusion in the Experimental (CBA-P + rhBMP-2) and Control (rhBMP-2 alone) study cohorts at 12 months & 24 months postoperatively. A p-value ≤ 0.05 indicates statistical significance (**).

Table 1 - Intraoperative, Perioperative, and Postoperative Complications: This table presents the number of intraoperative, perioperative, and postoperative complications of the Experimental (CBA-P + rhBMP-2) and Control (rhBMP-2 alone) study cohorts. Values are reported as mean (SD) for continuous variables and N (%) for categorical variables. A p-value ≤ 0.05 indicates statistical significance (**).

Complications		Statistical Index	Study Cohorts		P-Value
			Experimental [N = 50]	Control [N = 50]	
Estimated Blood Loss (cc)		*Mean (SD)*	364.4 (311.3)	232.9 (218.9)	<0.001**
Number of Intraoperative Complications	*Yes*	*N (%)*	0 (0)	0 (0)	1.00
	No		50 (100)	50 (100)	
Number of Perioperative Complications	*Yes*	*No*	16 (32.0)	9 (18.0)	0.16
	No		34 (68.0)	41 (82.0)	
Number of Postoperative Complications at 6 Weeks	*Yes*	*N (%)*	3 (6.0)	2 (4.6)	1.00
	No		47 (94.0)	42 (95.5)	
Number of Postoperative Complications at 6 Months	*Yes*	*N (%)*	6 (22.2)	5 (12.8)	0.33
	No		21 (77.8)	34 (87.2)	
Number of Postoperative Complications at 12 Months	*Yes*	*N (%)*	10 (21.3)	10 (23.3)	1.00
	No		37 (78.7)	33 (76.7)	
Number of Postoperative Complications at 24 Months	*Yes*	*N (%)*	7 (41.2)	11 (64.7)	0.32
	No		10 (58.8)	6 (35.3)	
Revision Surgery within 24 Months Post-Operation	*Yes*	*N (%)*	9 (18.0)	5 (10.0)	0.38
	No		41 (82.0)	45 (90.0)	