

High Fusion Rates Using Trinity Elite Cellular Bone Allograft in High-Risk Patients

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Keywords

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Abstract

Introduction: Solid fusion is critical for successful spine and foot and ankle arthrodesis. Risk factors including smoking, obesity, diabetes, osteoporosis, and multilevel surgery elevate the risk of non-union. Cellular bone allografts (CBAs) have emerged as alternatives to autograft, but outcomes in high-risk populations remain insufficiently characterized.

Methods: This review examines a cellular bone allograft (TE-CBA) in spine and foot and ankle fusion procedures, with a particular emphasis on outcomes in patients with risk factors for non-union. Clinical endpoints included fusion success, patient-reported outcomes, complication rates, and the influence of patient risk profiles. Only studies that included high-risk populations were analyzed. The included studies were primarily Level IV evidence (prospective/retrospective with comparisons to previously published outcomes).

Results: In the lumbar spine, TE-CBA achieved a 90.5% fusion rate at 12 months and 95.3% at 24 months, with significant improvements in pain and function, even among high-risk patients. In ACDF procedures up to four levels, TE-CBA achieved a 97.4% fusion rate at 12 months, including 100% in one, two, and four-level procedures. In foot and ankle arthrodesis, 95.5% of patients achieved fusion within 12 months, with an average time to union of 6 months across patients with major risk factors. Studies employed strict fusion criteria, including combined motion analysis and CT-confirmed bridging bone.

Conclusion: TE-CBA demonstrated consistently high fusion success across anatomical sites in cohorts that included patients at high risk for non-union. Further controlled trials and mechanistic studies are needed to elucidate how CBAs might mitigate biologically impaired bone healing environments.

Introduction

Spinal fusion and foot and ankle arthrodesis are procedures frequently performed to manage degenerative, traumatic, and deformity-related conditions¹⁻⁴, with success heavily dependent on achieving solid bony fusion^{5,6}. Several risk factors are linked to reduced fusion success and less favorable patient outcomes. In the lumbar spine, advanced age, obesity, diabetes, smoking history, osteoporosis, or multilevel surgical indications predispose patients to nonunion and postoperative complications⁷⁻¹⁰. Lumbar pseudarthrosis rates can exceed 20% in these populations, with higher biomechanical demands of the region and impaired bone healing further contributing to substantial morbidity and increased revision burden². Similar challenges exist in cervical spine and foot and ankle procedures^{6,11,12}, with osteoporosis and smoking as key risk factors associated with increased complications, bone loss, and lower cervical fusion success¹³. While many surgeons avoid

elective reconstruction in smokers and diabetics, operating on high-risk patients is sometimes unavoidable due to severity of pathology. Bone graft selection is a modifiable factor that is critical for improving fusion success in high-risk patients¹. While autograft remains the gold standard, its use is limited by donor site morbidity, insufficient graft volume, and compromised quality in older or comorbid patients¹⁴⁻¹⁶.

Cellular bone allografts (CBAs) have emerged as an innovative alternative, providing structural scaffolds with physiological osteoinductive signals and native osteogenic cells to enhance fusion without the downsides of autograft harvest¹⁷. CBAs have been shown to achieve similar or better fusion outcomes to those reported for autograft, with an established clinical safety profile¹⁸⁻³⁵. However, despite their growing adoption in spine and orthopedics applications³⁶, the effectiveness of CBAs in patients at higher risk for non-union and complications remains underexplored.

The objective of this review was to examine the clinical evidence supporting the use of Trinity Elite cellular bone allograft (TE-CBA), in spine and orthopedic surgery, with a focus on assessing its performance in patients with elevated risk for non-union. Only studies with TE-CBA as the primary graft that included high-risk patients were included. Clinical and patient-reported outcomes across lumbar, cervical, and foot and ankle fusion procedures were reviewed. Study design, procedural context, and fusion criteria were also discussed to highlight the strengths and limitations of the studies to inform evidence-based graft selection.

TE-CBA in Lumbar Spine Fusion

Analyses from a prospective, multicenter (9 sites) clinical study demonstrated high fusion success and meaningful clinical improvements with TE-CBA in high-risk patients undergoing posterolateral fusion (1-4 levels) or interbody fusion (1-2 levels) in the lumbar spine^{26-28,31} (Tables 1-3). Of the 274 enrolled subjects, 51.1% (n = 140) were at high-risk of non-union, defined as having > 1 risk factor, including BMI >30kg/m², smoking, age >65, diabetes, osteoporosis, multi-level surgery and the existence of multiple risk factors.

In the 12-month analysis by Wind et al., fusion was achieved in 90.5% of the 201 analyzed patients (Table 1), alongside significant improvements in Oswestry Disability Index (ODI), and visual analog scale (VAS) scores for back and leg pain (all p < 0.001, Table 2)²⁷. Park et al. reported 24-month outcomes in a subset of these patients (n = 86), showing fusion success in 95.3% of cases and sustained clinical outcomes (Table 1). At final follow-up, patients experienced a 46.3% reduction in ODI, a 75.5% reduction in VAS-back pain, and an 80.0% reduction in VAS-leg pain compared to baseline. The small group of patients who did

not achieve fusion (n = 4) reported improvements across all domains, with ODI improving by 82.4%, VAS-Back by 85.5%, and VAS-Leg by 95.8% (Table 2)²⁸.

Russo et al. stratified outcomes by patient risk profile and found that TE-CBA achieved similarly high fusion rates in both high-risk (93.9%) and low-risk (90.0%) cohorts (p > 0.05) at 24 months. Notably, 100.0% fusion was achieved in patients with multi-level disease, high BMI, nicotine use, diabetes, osteoporosis and multiple risk factors (Table 1). Quality of life improved in both cohorts, with EQ-5D scores rising from 0.61 to 0.83 in low-risk and from 0.60 to 0.76 in high-risk patients. While baseline values were similar, the low-risk group showed significantly greater improvement at 6 weeks (p = 0.046), 12 months (p = 0.0005), and 24 months (p = 0.002). Baseline ODI scores differed significantly (p = 0.02) between the groups, but both showed significant improvement over time, with no differences at 24 months. Low-risk patients demonstrated greater absolute reductions in ODI (41.1% vs. 29.5%), VAS-Back (79.9% vs. 78.3%), and VAS-Leg (86.8% vs. 80.9%), with statistically greater improvements in VAS-Back (p = 0.04) and VAS-Leg (p = 0.045) at 24 months (Table 3)²⁶.

Lansford et al. analyzed outcomes by surgical approach and reported high fusion success across all groups, with fusion rates ranging from 89.5% (anterior) to 100% (posterior and lateral) at 24 months (Table 1). Quality of life, assessed by EQ-5D, improved significantly in all groups; at 24 months, posterior fusion showed the greatest improvement (0.83 ± 0.16), which was significantly higher than both anterior (0.80 ± 0.18; p = 0.04) and lateral (0.72 ± 0.17; p < 0.001) approaches. All groups demonstrated significant improvements in ODI, VAS-Back, and VAS-Leg scores through final follow-up (p < 0.0001). The posterior approach was associated with the greatest improvement in ODI (41.0%), which was significantly greater than the lateral group at 6, 12, and 24 months (p ≤ 0.015). The lateral group showed the greatest improvement in VAS-Back (89.2%), with greater early reduction in back pain compared to the anterior group (p = 0.0058), though differences at 24 months were not significant. VAS-Leg scores improved similarly across groups (Table 3)³¹.

A 2022 systematic review and meta-analysis of fusion outcomes in the lumbar spine detailed a range of fusion rates with local bone (95.3%), autologous iliac crest (88.6%), allograft (87.8%), and alloplastic materials including hydroxyapatite and recombinant BMPs (85.8%)³⁷. This analysis did not focus on high-risk patients or isolate outcomes with CBAs. Within this context, TE-CBA fusion results represent a highly successful fusion performance, inclusive of high-risk patients and various surgical approaches. In the reviewed studies, TE-CBA was the primary graft material (≥50% by volume), with optional augmentation with up to 50%

locally harvested autograft or cancellous allograft chips with no other graft substitutes permitted. Therefore, the fusion outcomes cannot be attributed to TE-CBA alone. The surgical approach, technique, and placement/location of the bone graft was determined at the discretion of the treating surgeon, and included anterior, lateral and posterior interbody fusions, as well as posterolateral lumbar fusion. A key strength was the fusion assessment, which was independently evaluated at 12 and 24 months using strict dual criteria: (1) <3° angular and <3 mm translational motion on Quantitative Motion Analysis (QMA), and (2) evidence of bridging bone on thin-cut CT. All levels had to meet both criteria to be considered fused in multi-level procedures. This fusion criterion represents a more stringent standard than standalone use of bony bridging and angular motion that is most consistently used in published lumbar clinical³⁸.

Table 1: Fusion success in lumbar spine by patient risk factor and surgical approach with TE-CBA. Fusion was defined as both bridging bone on CT and <3°/<3 mm motion on flexion-extension radiographs. Data summarized from Wind et al.²⁷ & Park et al.²⁸

	12 Months		24 Months	
	Subjects	Successful Fusion	Subjects	Successful Fusion
Overall	201	90.5%	86	95.3%
One-Level	141	90.8%	64	93.7%
Risk Factor				
2+ Levels	60	90.0%	22	100.0%
Age 65+	84	88.1%	29	96.6%
BMI >30	107	93.4%	40	100.0%
Nicotine Use	31	87.1%	12	100.0%
Diabetes	41	85.3%	17	100.0%
Osteoporosis	15	80.0%	8	100.0%
Multiple Risk Factors 2+	106	90.5%	38	100.0%
Surgical Approach				
ALIF	49	81.6%	19	89.5%
TLIF, MIS-TLIF, PLIF	86	93.0%	35	94.3%
OLIF/XLIF/LLIF/DLIF	53	94.3%	21	100.0%
PLF	13	92.3%	11	100.0%

ALIF (anterior lumbar interbody fusion), DLIF (direct lateral lumbar interbody fusion), LLIF (lateral lumbar interbody fusion), MIS-TLIF (minimally invasive transforaminal lumbar interbody fusion), OLIF (oblique lateral interbody fusion), PLIF (posterior lumbar interbody fusion), PLF (posterolateral lumbar fusion), TLIF (transforaminal lumbar interbody fusion), XLIF (extreme lateral interbody fusion)

Table 2: Clinical outcomes in lumbar Spine with TE-CBA. Data summarized from Wind et al.²⁷ & Park et al.²⁸

		ODI	VAS – Back	VAS – Leg
12 Months				
Overall (N=201)	Baseline	44.9 ± 17.1	56.5 ± 28.4	37.9 ± 25.6
	Follow-up	21.9 ± 18.5	17.3 ± 23.6	10.4 ± 16.9
	Improvement (%)	51.2%	69.4%	72.6%
Not Fused (N=19)	Baseline	41.5 ± 14.1	50.0 ± 34.2	33.7 ± 31.8
	Follow-up	14.4 ± 16.6	13.0 ± 16.4	7.2 ± 12.4
	Improvement (%)	65.3%	74.0%	78.6%
24 Months				
Overall (N=86)	Baseline	44.7 ± 18.4	53.9 ± 28.6	34.5 ± 25.9
	Follow-up	24.0 ± 21.2	13.2 ± 23.3	6.9 ± 15.6
	Improvement (%)	46.3%	75.5%	80.0%
Not Fused (N=4)	Baseline	37.0 ± 7.4	55.3 ± 29.8	26.4 ± 13.3
	Follow-up	6.5 ± 11.7	8.0 ± 14.1	1.1 ± 1.3
	Improvement (%)	82.4%	85.5%	95.8%

Values are (Mean ± SD)

Table 3: Clinical outcomes in lumbar spine by patient risk factor and surgical approach with TE-CBA. Data summarized from Russo et al.²⁶ & Lansford et al.³¹

Risk Factor		ODI	VAS – Back	VAS – Leg
Low-Risk	Baseline	63.8 ± 16.4	57.3 ± 27.5	36.5 ± 23.0
	24 Mo	37.6 ± 18.5	11.5 ± 20.8	4.8 ± 12.0
	Improvement (%)	41.1%	79.9%	86.8%
High-Risk	Baseline	67.9 ± 16.8	57.6 ± 12.5	40.3 ± 36.5
	24 Mo	47.9 ± 20.5	12.5 ± 20.8	7.7 ± 15.6
	Improvement (%)	29.5%	78.3%	80.9%
Surgical Approach				
Anterior	Baseline	65.51 ± 14.68	61.03 ± 24.87	35.21 ± 25.26
	24 Mo	43.53 ± 21.67	15.90 ± 22.72	7.97 ± 15.73
	Improvement (%)	33.6%	73.9%	77.4%
Lateral	Baseline	69.10 ± 17.60	59.82 ± 28.38	42.94 ± 28.51
	24 Mo	50.87 ± 18.29	6.46 ± 12.50	3.86 ± 7.81
	Improvement (%)	26.4%	89.2%	91.0%
Posterior	Baseline	64.21 ± 16.89	56.23 ± 29.92	38.50 ± 24.93
	24 Mo	37.89 ± 17.81	12.17 ± 21.36	5.72 ± 12.92
	Improvement (%)	41.0%	78.4%	85.1%

Values are (Mean ± SD)

TE-CBA in Cervical Spine Fusion

A recent retrospective study by Goldman et al. is the first independent evaluation of the safety and efficacy of TE-CBA in anterior cervical discectomy and fusion (ACDF) at up to 4 levels²⁴. The 73-patient cohort had a mean age of 54.6 years and included a high proportion of multilevel cases (74% total, 2-level 32%, 3-level 34%, and 4-level 8%) with 37% of patients classified as obese and 35.6% as current or former smokers.

At 12 months, the fusion rate was 97.4%, including 100% fusion in one-, two-, and four-level cases, and 92.3% in three-level procedures (Figure 1). The lower-bound effective fusion rate, assuming non-completers remained unfused at 6 months, was 71%, still within the range of historical autograft performance. No cases of cage migration, graft-related complications, or graft removal were reported. Two patients (2.7%) required supplemental fixation due to traumatic falls post-operatively, and both ultimately achieved successful fusion.

These results align with or exceed fusion rates previously reported for autograft (83–99%) and other CBAs (87–94%), which decline significantly in multilevel constructs²⁴. While this study did not include patient-reported outcome measures (PROMs), complication rates were low. Dysphagia occurred in 1.4% of patients at 12 months, which is below reported rates of up to 30% in four-level ACDFs^{39–41}. At 15 months post-operatively, unresolved pain and sensory symptoms declined and there were no cases of chronic dysphagia. Notably, TE-CBA achieved these results without graft-related complications, migration, or removal. This contrasts with BMP-2, which, while effective for multilevel ACDF⁴², has been linked to serious complications including life-threatening cervical edema, prompting an FDA black box warning⁴³. Here, fusion

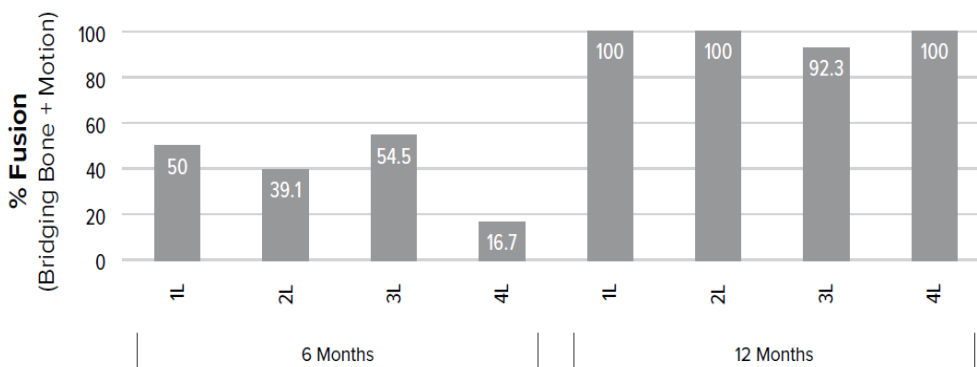


Figure 1: Fusion outcomes in cervical spine by number of levels with TE-CBA. Percentage of fused patients at 6 (n = 69) and 12 (n = 39) months postoperatively, with fusion was defined as both bridging bone on CT and <3°/<2 mm motion on flexion-extension radiographs. Data adapted from Goldman et al.²⁴

was assessed radiographically based on bridging bone on CT and <3° angular, and <2 mm translational motion on dynamic radiographs, representing a more stringent fusion assessment criteria than reported in ACDF literature⁴⁴.

TE-CBA in Foot & Ankle Arthrodesis

Donaghue et al. conducted a retrospective, single-site study evaluating the safety and efficacy of TE-CBA in foot and ankle arthrodesis among patients with high risk for non-union²⁵. The study included 22 patients (29 joints), nearly all of whom had at least one risk factor for impaired bone healing (nicotine use, diabetes, osteoporosis, neuropathy, or a history of failed fusion). Procedures included single-, double-, and triple-joint fusions in tibiotalar, subtalar, calcaneocuboid, and talonavicular joints. Fusion was determined successful with presence of bridging bone in three views of standard radiographs (AP, lateral, and oblique) or a CT scan.

Radiographic fusion was achieved in 95% of patients (21 of 22) within 12 months, with an average time to union of 6 months (Figure 2). Notably, 100% of patients with diabetes, nicotine use, osteoporosis, or prior non-union achieved successful fusion (Table 4). No statistically significant differences in time to fusion were observed between patients with fewer (≤1) versus multiple (≥2) risk factors, nor between obese and non-obese, smokers and non-smokers, or younger and older patients.

The fusion rates reported here are consistent with, or exceed, fusion rates reported for autograft and other cellular bone allografts (CBAs), which range from 78.8%–97% in similar surgical contexts with higher failure rates and longer time to fusion (7.5-9 months) observed in older adults or those with comorbidities⁴⁵⁻⁴⁷. While the study was limited by its retrospective design and small sample size, it provides early support for the use of CBAs in high-risk foot and ankle fusion, where achieving union is both critical and challenging.

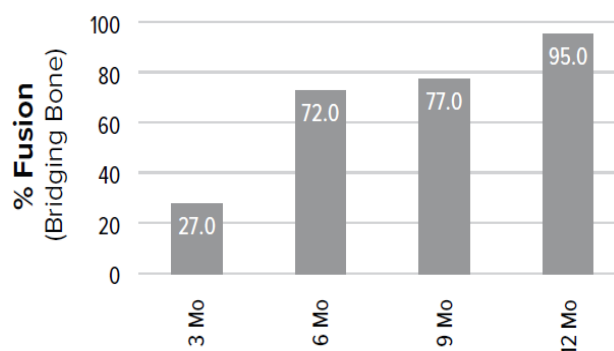


Figure 2: Cumulative fusion rates over time in patients undergoing foot and ankle arthrodesis with TE-CBA. Bridging bone was observed in 27% of joints at 3 months, increasing to 95% by 12 months postoperatively, as assessed by bridging bone in CT or standard radiographs. Data adapted from Donaghue et al.²⁵

Table 4: Fusion outcomes by risk factor in foot and ankle arthrodesis using TE-CBA. Data summarized from Donaghue et al.²⁵

	Subjects	Fusion %	Time to Fusion
Overall	22	95%	Mean: 6 months
Risk Factor			
Diabetes	4	100%	By 6 months
Nicotine Use	7	100%	By 6 months
Revision Surgery	3	100%	By 6 months
Osteoporosis	3	100%	By 12 months
Number of joint >1	4	75% (3/4)	By 12 months

Conclusion

Advancements in surgical techniques and perioperative care have enabled increasingly complex spinal fusion procedures in patients with elevated risk profiles who remain vulnerable to higher complication rates. Across lumbar and cervical spine and foot and ankle fusion procedures, TE-CBA has demonstrated high rates of radiographic fusion and clinically meaningful improvements in pain, disability, and quality of life among

patients with risk factors traditionally associated with impaired healing. These findings are consistent with or exceed reported outcomes for autograft, other CBAs, and rh-BMP-2, particularly in multilevel and high-risk surgical contexts. While the absence of a control arm limits direct comparisons with alternative grafting materials, the consistency of results across anatomical sites supports the use of TE-CBA in a variety of fusion settings.

Importantly, multi-level ACDF fusion rates with TE-CBA in the independent study reviewed here²⁴ were consistent with, or higher than, those reported for rh-BMP-2⁴⁸, with no graft-related complications. This is in contrast to BMP-2's history of elevated risks of dysphagia, hematoma, seroma, swelling, and the potential need for intubation or tracheostomy in the cervical spine⁴⁸. Similarly, TE-CBA fusion rates in the lumbar spine were comparable to those reported for rh-BMP-2⁴⁹, without the associated complications including radiculitis, retrograde ejaculation, heterotopic ossification, graft subsidence, cage migration, and osteolysis⁵⁰. Additionally, Spine TE-CBA studies employed stringent fusion criteria, further validating the robustness of the reported outcomes. As with all grafting materials, patient-specific and procedural variables likely contribute to fusion success. Further investigation is needed to elucidate the biological mechanisms by which CBAs may mitigate the effects of risk factors on bone healing. Controlled, prospective studies comparing CBAs to traditional grafts will be essential to isolate their independent contribution and inform evidence-based graft selection in surgical practice.

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