

Novel Graft Materials for Lumbar Spinal Fusion Procedures – 12-Months Outcomes

Daryll C. Dykes¹, Jill W. Ruppenkamp², Katherine A. Corso¹, Chantal E. Holy², Caroline E. Smith¹, Michelle Costa¹

¹: Johnson & Johnson, Raynham, MA, USA;
²: Johnson & Johnson, New Brunswick, NJ, USA

BACKGROUND

- Novel graft materials to enhance bone growth in spinal surgery are continuously developed.
- BMP utilization has increased over the last two decades, hence identified as the most relevant comparator due to its high use in lumbar spine surgery.
- Evaluating the effectiveness of fusion with grafts is challenging due to potential confounding by indication with novel and more expensive grafts used in more challenging patients.
- A 2012 literature review summarized fusion rates associated with bone grafts¹; however, more data are needed on real-world estimates of fusion and other outcomes associated with bone grafts.

OBJECTIVES

- Our study evaluated twelve-month outcomes in patients undergoing lumbar spinal fusion, based on graft material.

METHODS

Study Design: Retrospective, **non-comparative** cohort study of patients that had lumbar fusion with Bioglass bone graft or bone morphogenetic protein (BMP).

Data Source: Premier Healthcare database, October 1, 2015 to December 31, 2022.

Study Population:

- Inclusion:** Adult (18+ years) that had lumbar fusion (identified with ICD-10 codes) and presence of a chargemaster entry for Bioglass bone graft or BMP.
- Exclusion:** Patients having both grafts within the same hospital episode.

One-year outcomes:

- Pseudarthrosis
- Index hospital costs
- Six-month post-index hospital costs
- Twelve-month post-index hospital costs

Statistical Analysis:

- Costs were inflation adjusted to 2022.
- Poisson regression for adjusted rates of pseudarthrosis.
- Generalized linear models (GLM) with log link and gamma distribution and marginal analysis was used for costs.

References:

- Hsu WK, Nickoli MS, Wang JC, et al. Improving the clinical evidence of bone graft substitute technology in lumbar spine surgery. Global Spine J 2012;22:239-48. doi: 10.1055/s-0032-1315454.

RESULTS

- 1,197 patients with Bioglass graft and 72,614 with BMP were included in the analysis, with average age ~62 in both groups.
- In both groups, ~ 90% were elective and 94% were treated in the inpatient setting.
- Mean (SD) Elixhauser comorbidity score was 2.3 (1.8) and 2.1 (1.7), Bioglass and BMP, respectively.
- The anterior approach was used in roughly 29% and one level surgeries occurred in ~50% of patients in both groups.

Table 1. Baseline characteristics of the study cohort

Variable	Bioglass	BMP
n	1,197	72,617
Age (mean (SD))	62.8 (13.2)	61.4 (13.0)
Female n(%)	650 (54.3)	39164 (53.9)
Marital status n(%)		
Married	744 (62.2)	40728 (56.1)
Other	47 (3.9)	8154 (11.2)
Single	406 (33.9)	23735 (32.7)
Payer category n(%)		
Commercial	379 (31.7)	24404 (33.6)
Medicaid	86 (7.2)	4522 (6.2)
Medicare	657 (54.9)	36306 (50.0)
Other	75 (6.3)	7385 (10.2)
Elixhauser comorbidity Index Score (mean (SD))	2.3 (1.8)	2.1 (1.7)
Mortality n(%)	5 (0.4)	101 (0.1)
Discharge status n(%)		
Discharged to HHO	243 (20.3)	15125 (20.8)
Home	761 (63.6)	43801 (60.3)
SNF & Other	193 (16.1)	13691 (18.9)
APR Severity description n(%)		
Extreme	20 (1.7)	1340 (1.8)
Major	126 (10.5)	8140 (11.2)
Minor	517 (43.2)	32144 (44.3)
Moderate	451 (37.7)	27446 (37.8)
NA_Outpatient	83 (6.9)	3547 (4.9)
Spinal trauma at Index POA n(%)	49 (4.1)	2215 (3.1)
Stenosis at Index n(%)	830 (69.3)	44780 (61.7)
Spine infection Index POA n(%)	13 (1.1)	733 (1.0)
Degenerative disease at Index n(%)	484 (40.4)	31811 (43.5)
Spinal cancer Index n(%)	12 (1.0)	78 (0.1)
Deformity at Index n(%)	178 (14.9)	13206 (18.2)
AIS at Index n(%)	9 (0.8)	179 (0.2)
Smoking 12 months baseline+ Index n(%)	589 (49.2)	31042 (42.7)
Pseudarthrosis Index n(%)	51 (4.3)	6686 (9.2)
URBAN n(%)	1072 (89.6)	66822 (92.0)
Provider region n(%)		
MIDWEST	43 (3.6)	15021 (20.7)
NORTHEAST	287 (24.0)	17421 (24.0)
SOUTH	786 (65.7)	30227 (41.6)
WEST	81 (6.8)	9948 (13.7)
Beds n(%)		
000-999	200 (16.7)	2492 (3.4)
100-199	205 (17.1)	10989 (15.1)
200-299	216 (18.0)	8726 (12.0)
300-399	250 (20.9)	10105 (13.9)
400-499	87 (7.3)	9772 (13.5)
500+	239 (20.0)	30533 (42.0)
Teaching Status n(%)	350 (29.2)	42817 (59.0)
Annual Provider Volume (mean (SD))	428.5 (321.6)	484.2 (337.7)
Elective flag n(%)	1076 (89.9)	66593 (91.7)
Inpatient flag n(%)	114 (9.1)	68857 (94.8)
Discharge year n(%)		
2016	102 (8.5)	10180 (14.0)
2017	134 (11.2)	9688 (13.3)
2018	132 (11.0)	10137 (14.0)
2019	149 (12.4)	10960 (15.1)
2020	210 (17.5)	9988 (13.8)
2021	212 (17.7)	10513 (14.5)
2022	202 (16.9)	9427 (13.0)
2023	56 (4.7)	1724 (2.4)
Allograft use n(%)	168 (14.0)	21579 (29.7)
Autograft use n(%)	729 (60.9)	39183 (54.0)
Anterior approach n(%)	350 (29.2)	21323 (29.4)
Posterolateral approach n(%)	899 (75.1)	49165 (67.7)
Posterior Interbody approach n(%)	323 (27.0)	30758 (42.4)
Posterior Unspecified approach n(%)	77 (6.4)	2819 (3.9)
Interbody cage use n(%)	709 (59.2)	53900 (74.2)
Estimate of Total Number of Levels Fused n(%)		
1	571 (47.7)	35991 (49.6)
2	416 (34.8)	22397 (30.8)
3 or more	210 (17.5)	14,229 (19.6)

Abbreviations: SD = Standard Deviation; HHO = Home Health Organization; SNF = Skilled nursing facility; NA = Not available; APR = All Patient Refined; POA = present on admission; AIS = Adolescent Idiopathic Scoliosis.

- At twelve months post-index, the pseudarthrosis rate was 1.6% (95% confidence interval (CI): 1.0%-2.5%) in the Bioglass group and 1.5% (95%CI: 1.4%-1.6%) in the BMP group.
- Index procedural costs averaged \$44,801 (\$30,971) for Bioglass and \$47,282 (\$31,467) for BMP groups (Figure 2).
- Post-index six-month costs averaged \$11,014 (\$25,127) for Bioglass and \$11,349 (\$30,194) for BMP groups (Figure 2).
- Post-index twelve-month costs averaged \$13,558 (\$28,920) for Bioglass and \$15,094 (\$37,635) for BMP groups (Figure 2).

Figure 1. Two-year incidence (95% Confidence Interval) of pseudarthrosis (This study is non-comparative. No statistical adjustment for differences in cohorts conducted)

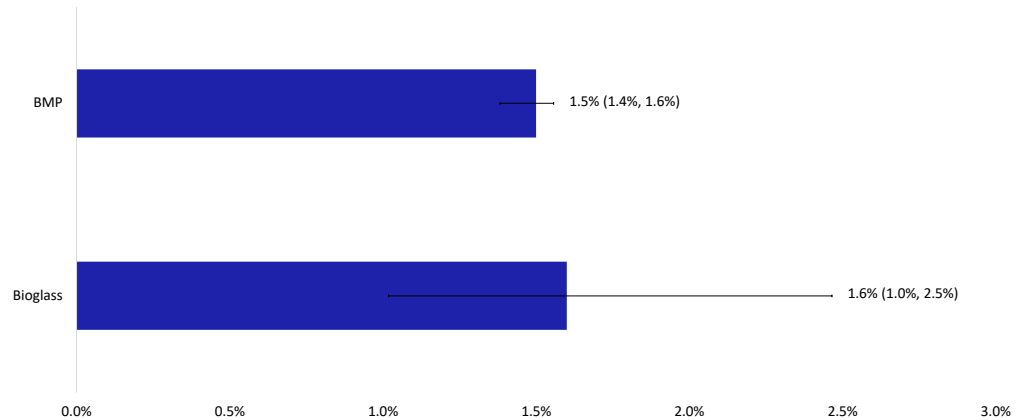
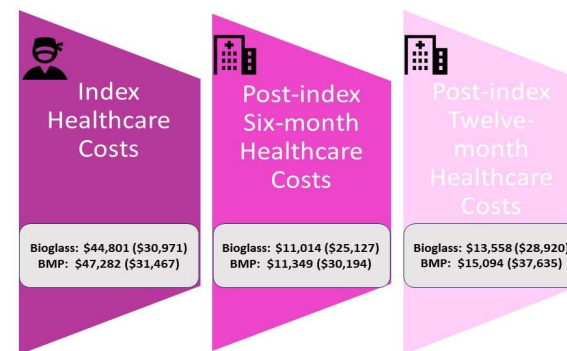


Figure 2. Mean (SD) Index and post-index six-month and twelve-month healthcare costs of Bioglass and BMP groups (This study is non-comparative. No statistical adjustment for differences in cohorts conducted.)



CONCLUSIONS

- This novel descriptive study provides fundamental baseline data on Bioglass and BMP bone grafts used for lumbar fusion surgery.
- When used for lumbar spinal fusion procedures, the Bioglass graft material resulted in twelve-month pseudarthrosis rates below 2%.