Bioactive Glass for Lumbar and Cervical Spine Fusion:

A Retrospective Case Series

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Introduction

Lumbar and cervical fusion remain the gold standard to treat various spinal disorders, such as degenerative disc disease and spinal stenosis. Traditional bone grafts have shown good clinical success but have limitations. Bioactive glass is a unique class of biomaterials with osteoconductive properties that make it a compelling alternative to traditional bone grafts and/or biologics. Here, we review a large retrospective case series of patients treated with **NovaBone Collagen Bioglass Bone Graft (NovaBone)** in both cervical and lumbar fusion surgery.

Methods

This study is a retrospective review of medical records for patients that received spinal fusion surgery between 2014 and 2021 with the use of NovaBone. A waiver of consent was received from the IRB for the data collection.

The procedures were performed by one orthopedic spine surgeon and included anterior cervical discectomy and fusion (ACDF), anterior lumbar interbody fusion (ALIF), and lateral lumbar interbody fusion (LLIF). A variety of cages were used for the procedures and the treatment ranged between 1-4 levels for cervical and 1-3 levels for lumbar.

Patient data was collected from the electronic medical record at the following timepoints (when available); pre-operative, surgery, and post-operative through longest follow up. Eligible patients must have presented for a visit at 6 months or later. Data collected included patient demographics, relevant medical history, surgical details, imaging, patient reported outcomes, and complications. Patient reported outcomes included the Visual Analogue Pain Scale (VAS), Oswestry Disability Index (ODI), and Neck Disability Index (NDI).

Patient medical history and demographics were collected and reviewed for comorbidities that could impact bone fusion and/or healing. Comorbidities analyzed include treated levels, diabetes, tobacco use, BMI≥40, and age ≥60. Available images were assessed by the surgeon for determination of bone fusion.

Results

There were **130 cervical** and **121 lumbar patients** that met eligibility for inclusion in the analysis. As a retrospective study, the inclusion criteria were patients that received NovaBone during a spinal fusion with a minimum of 6-month follow-up post-surgery.

Follow-up rates were as expected for a retrospective data collection study, but some patients did present 3 years following surgery. **(Figure 1)**.

Demographics for the cervical and lumbar patient cohorts are included as **Table 1**.

FIGURE 1. FOLLOW-UP RATES

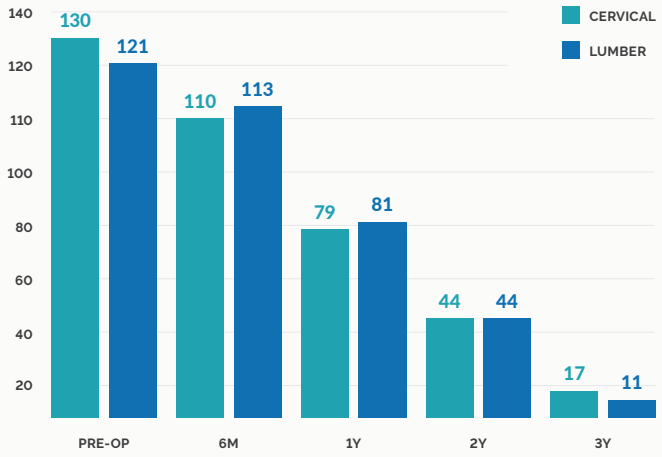


TABLE 1. PATIENT DEMOGRAPHICS

CERVICAL	ONE-LEVEL	TWO-LEVELS	THREE-LEVELS	FOUR-LEVELS
N	64	45	18	3
AGE MEAN ±	50.0 ± 10.8	54.3 ± 9.0	58.9 ± 7.8	66.7 ± 7.5
BMI MEAN ±	31.4 ± 6.2	30.2 ± 4.5	29.8 ± 4.5	28.3 ± 0.9
MALE (%)	40 (62.5)	27 (60.0)	9 (50.0)	1 (33.3)
FEMALE (%)	24 (37.5)	18 (40.0)	9 (50.0)	2 (66.7)
LUMBAR	**ONE-LEVEL**	**TWO-LEVELS**	**THREE-LEVELS**	**FOUR-LEVELS**
N	88	25	8	N/A
AGE MEAN ±	54.4 ± 13.5	58.7 ± 11.6	53.9 ± 9.9	N/A
BMI MEAN ±	30.8 ± 6.5	32.7 ± 6.6	36.2 ± 5.3	N/A
MALE (%)	42 (47.7)	15 (60.0)	3 (37.5)	N/A
FEMALE (%)	46 (52.3)	10 (40.0)	5 (62.5)	N/A

The cervical procedures were all ACDF with a variety of cervical fusion cages. The distribution of cervical levels treated is included as **Table 2** and included a total of **220 cervical levels treated.**

The lumbar procedures were ALIF and LLIF procedures that ranged between 1 to 3 levels, with posterior fixation.

The surgical approach and fusion cage were at the discretion of the surgeon. The distribution of lumbar levels treated is included as **Table 3** and included a total of **162 lumbar levels treated**.

TABLE 2 AND 3. CERVICAL AND LUMBAR TREATED LEVELS

CERVICAL LEVELS TREATED	NO. PATIENTS
ONE-LEVEL	**64**
C3-C4	7
C4-C5	11
C5-C6	33
C6-C7	13
TWO-LEVELS	**45**
C3-C5	6
C4-C6	12
C5-C7	26
C6-T1	1
THREE-LEVELS	**18**
C3-C6	8
C4-C7	10
FOUR-LEVELS	**3**
C3-C7	3

LUMBAR LEVELS TREATED	NO. PATIENTS
ONE-LEVEL	**88**
L2-L3	1
L3-L4	7
L4-L5	37
L5-S1	43
TWO-LEVELS	**25**
L2-L4	3
L3-L5	10
L44-S1	12
THREE-LEVELS	**8**
L2-L5	2
L3-S1	6

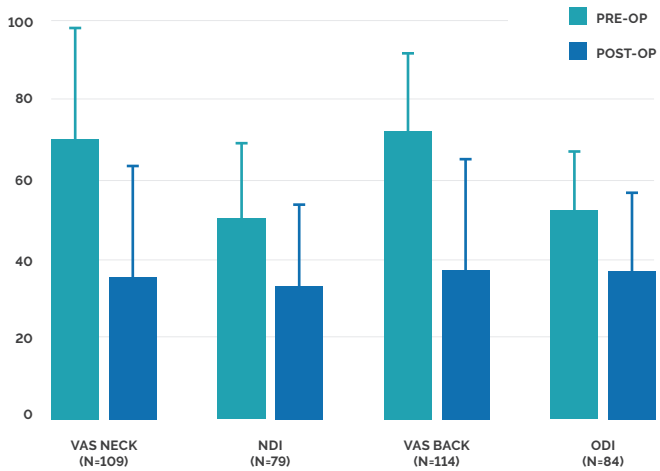
As a real-world patient cohort, there were numerous comorbidities in this population that could impact outcomes. These comorbidities included age ≥ 60, smoking, diabetes, and body mass index ≥ 40; they have been stratified and included as **Table 4**. Multiple levels of surgical treatment with fusion have also been shown to impact outcomes; treated levels were stratified previously in **Tables 2 and 3.**

TABLE 4. PRE-OPERATIVE PATIENT COMORBIDITIES

COMORBILITY	CERVICAL (N=130)	LUMBAR (N=121)
AGE ≥ 60 (%)	35 (26.9)	51 (42.1)
DIABETES (%)	26 (20.0)	23 (19.0)
SMOKING (%)	26 (20.0)	29 (24.0)
BMI ≥ 40 (%)	7 (5.4)	11 (9.1)

Patient reported outcomes were analyzed pre-operative and a minimum of 6-months post-operatively. The last available time point available post-operatively was utilized for analysis. For inclusion in this analysis, the patient must have reported both a pre-operative and post-operative score for evaluation. Patient reported outcomes available for cervical and lumbar patients are included as **Figure 2**. On average, patients treated with NovaBone during cervical spine surgery reported 36.7 points of improvement in VAS neck pain score and 17.0 points of improvement in NDI score.

FIGURE 2. VAS, NDI, AND ODI SCORES PRE AND POST OPERATIVE



Lumbar patients experienced similar improvements in VAS back pain and ODI with 35.5 and 15.1 points of average improvement, respectively.

Fusion was assessed by the surgeon and was confirmed on 77/79 (97.5%) cervical patients and 72/77(93.5%) lumbar patients. Patient follow-up and image compliance were noted as issues when assessing fusion.

Complications were reviewed at surgery and all post-operative visits. There were no complications or adverse events deemed related to the use of the NovaBone product.

In the cervical cohort there was one patient that required a revision surgery that involved the treated level. The initial treated level of C5-C6 was extended to a C4-T1 fusion.

In the lumbar cohort there were two revision surgeries. One patient required the removal of posterior hardware at L5-S1 that became painful following a motor vehicle accident. The second revision was following a 3 level ALIF procedure (L2-L5); the cage at the L4-L5 level had shifted. Ten weeks post-operatively, the revision surgery was performed to relocate the cage posteriorly with no further complications.

Conclusion

The use of NovaBone as the bone graft in these lumbar and cervical spine fusion cases resulted in high rates of bone fusion. Although a retrospective study, there were 251 patients with 220 cervical and 162 lumbar levels treated with NovaBone, with no reported complications associated with the product.

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