

Original Article

High lumbar noninstrumented fusion rates using lamina autograft and Nanoss/bone marrow aspirate

Nancy E. Epstein

Chief of Neurosurgical Spine/Education, NYU Winthrop Hospital, Mineola, New York, USA

E-mail: *Nancy E. Epstein - nancy.epsteinmd@gmail.com

*Corresponding author

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Abstract

Background: Patients with marked osteoporosis and/or obesity/morbid obesity and severe multilevel lumbar stenosis and other pathology often undergo multilevel laminectomies with non instrumented posterolateral fusions (PLF). The other pathology may include combinations of degenerative spondylolisthesis/lysis, foraminal/far lateral discs, and/or synovial cysts requiring more extensive facet resections. Presently, spine surgeons often use bone graft expanders to supplement the lamina autograft harvested in the course of laminectomy/decompressions for the PLF mass.

Methods: In 59 patients, we prospectively analyzed the fusion rates following multilevel laminectomies/noninstrumented fusions using lamina autograft and the bone graft expander Nanoss (RTI Surgical Alachua, FL, and USA) with autogenous bone marrow aspirate (BMA). Patients averaged 66.1 years of age; many exhibited marked osteoporosis (48 patients) and obesity (13 of 27 morbidly obese). Magnetic resonance (MR) and computed tomography (CT) studies documented stenosis/ossified yellow ligament (OYL) and degenerative spondylolisthesis (51 patients)/lysis (2 patients), synovial cysts (32 patients), and disc herniations (10 of 21 far lateral). Patients were followed remove up for an average of 3.12 years.

Results: Average 4.0 level laminectomies/1.2 level noninstrumented fusions utilized lamina autograft and Nanoss/BMA. Both X-ray/CT studies performed an average of 4.9 months postoperatively documented a 97% fusion rate (57 of 59 patients). Two patients with severe osteoporosis, morbid obesity, and smoking histories exhibited pseudarthroses; neither was sufficiently symptomatic to require secondary surgery.

Conclusions: Fifty-nine patients with multilevel lumbar stenosis/OYL and other pathology underwent multilevel lumbar laminectomies/noninstrumented fusions using lamina autograft and Nanoss/BMA. Both dynamic X-ray/CT studies confirmed

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a 97% fusion rate an average of 4.9 months postoperatively. Nanoss/BMA contributed to a high posterolateral lumbar non instrumented fusion rate without complications.

Key Words: Bone marrow aspirate, non instrumented fusions, nanoss

INTRODUCTION

Following the prospective performance of 59 multilevel lumbar laminectomies for stenosis/ossification of the yellow ligament, patients underwent partial non instrumented posterolateral lumbar fusions (PLF). Notably, many patients were osteoporotic and/or obese/morbidly obese. Many PLF required additional partial/full facetectomies to address combinations of degenerative

spondylolisthesis, spondylolysis, lateral/foraminal/far lateral discs, and synovial cysts and/or disc herniations [Figures 1-3]. Because the volume of lamina autograft harvested during the laminectomies/decompressions was not sufficient, we added the bone graft expander Nanoss (RTI Surgical Alachua, FL, USA) with autologous bone marrow aspirate (BMA). Over an average postoperative follow-up of 3.12 years, we utilized both dynamic X-rays and CT studies to evaluate the postoperative



Figure 1: T2-weighted sagittal midline MR showing transitional L5-S1 level with mild grade I degenerative spondylolisthesis at the L3-L4 and L4-L5 levels, and ossification of the yellow ligament. These contributed to dorsolateral compression at the L3-L4 and L4-L5 levels.

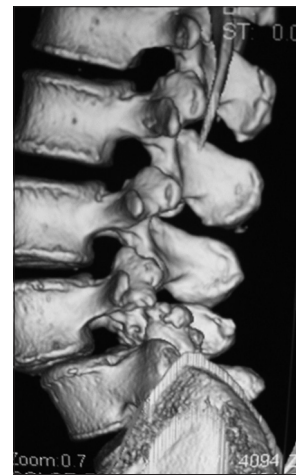


Figure 2: Lateral 3D-CT study showing grade I spondylolisthesis at the L4-L5 level with marked degenerative changes involving the L4-L5 facet joint and narrowing of the L4-L5 foramen

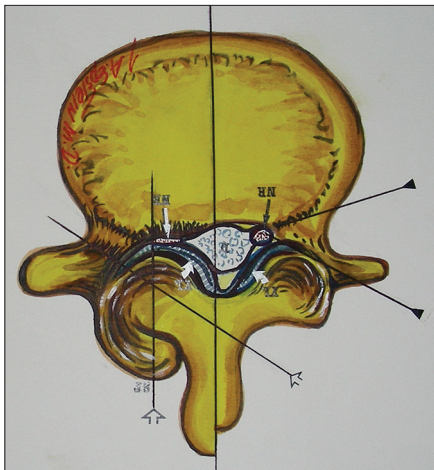


Figure 3: Axial illustration (Joseph A. Epstein M.D., copyright Nancy E. Epstein M.D.) of lumbar stenosis with right-sided lateral/foraminal compromise attributed to hypertrophy of the yellow ligament. Similar compression may also be due to synovial cysts. Additionally, note the marked hypertrophic changes of the right L4-L5 facet joint



Figure 4: This figure illustrates (Joseph A. Epstein M.D., copyright Nancy E. Epstein M.D.) on the patient's left side (dorsal view), a focal laminotomy at the L4-L5 level. On the right side you see a partial L3 hemilaminectomy, and full hemilaminectomies at the L4 and L5 levels with medial facetectomies/foraminotomies. The largest number of patients in this series underwent full L3-S1 laminectomies

fusion rate lamina autograft combined with Nanoss/BMA [Figures 4-8].

MATERIALS AND METHODS

Clinical data

Fifty-nine patients, averaging 66.1 years of age, prospectively underwent multilevel lumbar laminectomies with noninstrumented fusions. These procedures utilized lamina autograft (harvested during the decompression) and the bone graft expander Nanoss (RTI Surgical Alachua, FL, and USA) with autogenous BMA [Table 1] [Figures 4 and 5]. Noninstrumented fusions were specifically chosen in this population due to the high incidence of severe osteoporosis (48 patients) and/or obesity/morbid obesity (13 of 27 obese patients morbidly obese). Magnetic resonance (MR) and computed tomography (CT) studies uniformly

documented stenosis and OYL along with degenerative spondylolisthesis (51 patients), lysis defects (2 patients), synovial cysts (32 patients: 29 at the level of degenerative spondylolisthesis requiring partial facet resection), and disc herniation (21 total discs; 10 far lateral discs warranting full facetectomy) [Figures 1-3]. Postoperatively, both dynamic X-rays and CT studies were performed to document fusion. Patients were followed up for an average of 3.12 years (range 1–5.5 years) [Figures 6-8].

Surgery

Laminectomy

Lumbar laminectomies were routinely performed through a midline incision, and included medial facetectomy/foraminotomy except for more extensive facet resections warranted with spondylolisthesis/lysis (Gill procedure). More extensive foraminal decompressions

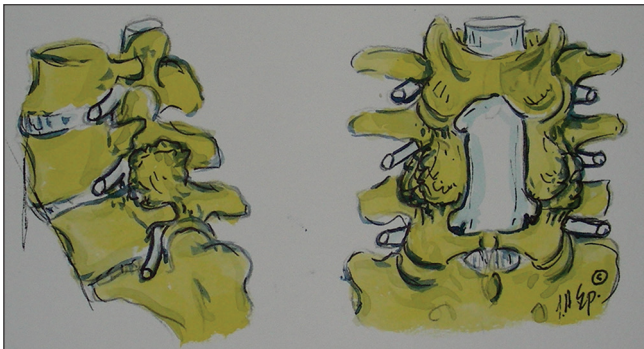


Figure 5: The illustration (Joseph A. Epstein M.D., copyright Nancy E. Epstein M.D.) on the left shows at L4–L5, marked degenerative spondylolisthesis, severe facet arthrosis, and superior foraminal L4 inferior L5 root compression. On the right, a laminectomy L3–L5 with medial facetectomy/foraminotomy is shown; undercutting preserved the L4–L5 facets

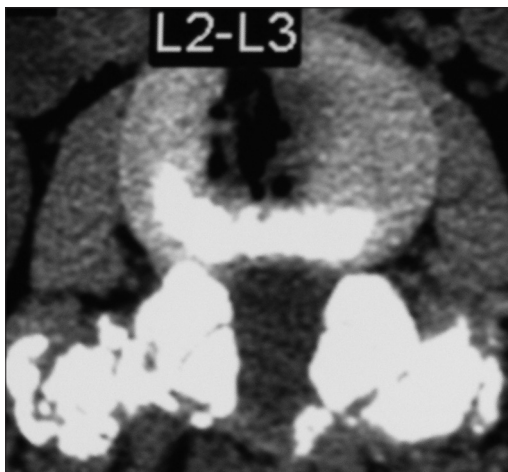


Figure 7: This axial L2-L3 soft tissue window CT demonstrated continuity/fusion of the posterolateral fusion mass and additional arthrodesis across the L2–L3 facet joints. The adequacy of fusion was also checked on the bone window axial CT as the soft tissue study may exaggerate the adequacy of fusion

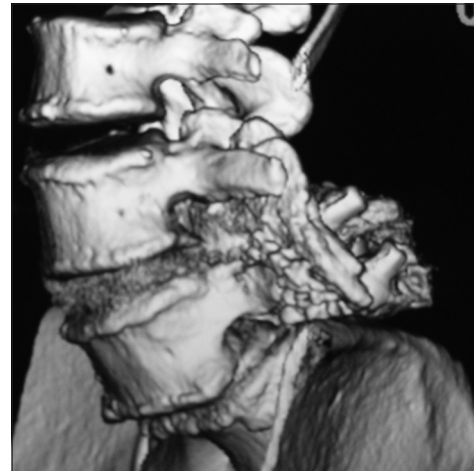


Figure 6: This parasagittal 3D-CT demonstrated a solid posterolateral noninstrumented fusion 6 months postoperatively. Note there is continuity of the bone fragments without intervening lucency of the lamina autograft/Nanoss/BMA fusion mass spanning the L4–L5 transverse processes in a patient with grade I degenerative spondylolisthesis



Figure 8: This coronal bone window 2D-CT at the L3–L5 levels documented pseudarthrosis/discontinuity of the of the posterolateral fusion mass

Table 1: Clinical data for lumbar laminectomy/noninstrumented fusion using lamina autograft and Nanoss with bone marrow aspirate

Variables	Nanoss (59 patients)
Average age	66.1
Range	45-83
Median	68
Sex	
Females	42
Males	17
Prior surgery	
Lumbar	4
Cervical	1
Comorbidities	
Obesity (BMI >30)	27
(Morbid obesity (BMI >35-40))	(13)
Hypertension	30
Diabetes	7
Osteoporosis	48
Foraminal synovial cysts MR/CT	32
One	14
Two	18
Foraminal synovial cysts: level of slip	29
Massive foraminal synovial cysts	15
Far lateral lumbar discs MR/CT	10
L2-L3	1
L3-L4	2
L4-L5	6
L5-S1	1
All lumbar discs (foraminal/far lateral) on MR/CT	21
L2-L3	2
L3-L4	3
L4-L5	18
L5-S1	1
Degenerative spondylolisthesis MR/CT	51
L2-L3	1
L3-L4	7
L4-L5	36
L3-L4/L4-L5	4
L5-S1	1
L4-L5/L5-S1	1
Lysis L5-S1	2
Duration of follow-up	
Average	3.12 years
Range	1-5.5 years

CT: Computed tomographic scan, MR: Magnetic resonance image; BMI: Body mass index, mos: Months

also addressed; foraminal/far lateral synovial cysts and foraminal/far lateral discs [Figures 4 and 5]. All operations were performed with somatosensory evoked potential monitoring (SEP) and electromyography (EMG).

Fusion mass: Lamina autograft and Nanoss/BMA

The fusion mass included all autogenous bone harvested during the laminectomy plus Nanoss/BMA. The Nanoss 10 cm × 2.5 cm strips were impregnated with 10 cc of BMA harvested with dry cottonoids from back-bleeding once the spinous processes were removed with a rib cutter. Prior to application, the strips were cut longitudinally into quarters. For a one-level noninstrumented PLF, two quarters were placed dorsal to the autograft [following prior decortication of the transverse processes (TP)] covering two TPs; for a two-level fusion, typically two strips were used, one on each side covering the three TPs.

Noninstrumented fusion

Noninstrumented PLF fusions required exposure of the TP. This requires adequate muscle/adipose/soft tissue removal over the TP to create a pocket to hold the fusion mass following TP decortication [Figures 6-8]. Once the TP are decorticated, the lamina autograft is applied (morcellated with a Rongeur not a bone mill as the bone dust will diffuse away from the site), followed by dorsal placement and packing of the Nanoss/BMA. Notably, Nanoss/BMA is more readily packed posterolaterally compared with other prior products and better helps hold the autogenous bone graft in place.

RESULTS

Average 4.0 level laminectomies and 1.2 level noninstrumented PLF fusions were performed requiring an average operative time of 4.1 hours [Table 2]. The most common levels decompressed included in descending order; L3-S1 (19 patients), L2-S1 (15 patients), L1-S1 (13 patients). Fusions mostly included the L4-L5 level (38 patients) followed by L3-L4 (8 patients), and L3-L4/L4-L5 combined (7 patients). Fusion was confirmed on both dynamic X-ray and CT studies in 57 (97%) of 59 patients an average of 4.9 months postoperatively [Figures 6 and 7]. The two patients with radiographic pseudarthrosis at 6 postoperative months were both severely osteoporotic, morbidly obese (BMI >40), and continued to smoke (e.g. >1 pack/day ×20 years) [Figure 8]. Fortunately, neither was sufficiently symptomatic to require secondary surgery.

Six cerebrospinal fluid leaks (three due to prior epidural injections) did not contribute to postoperative pseudarthroses

Six patients had intraoperative cerebrospinal fluid (CSF) fistulas; 3 were attributed to prior epidural steroid injections (e.g., Tuohy needle holes), 2 had calcified synovial cysts extending through the dura, and 1 had marked scar due to prior surgery. All 6 were primarily

Table 2: Surgical data for 59 lumbar laminectomies noninstrumented fusions with lamina autograft and Nanoss/bone marrow aspirate (BMA)

Variable	Nanoss 59 patients
Surgical duration	
Average	4.1 hours
Range	3-5
STDEV	0.64
Laminectomy levels	Average 4.0 (Range 3-) Levels
L2-L4	1
T12-S1	1
L1-L4	1
L1-L3	1
L1-S1	13
L2-S1	15
L3-L5	5
L3-S1	19
L4-S1	3
Noninstrumented fusions	Average 1.2 Levels (Range 1-2)
L2-L3	1
L3-L4	8
L3-L4/L4-L5	7
L4-L5	38
L4-L5/L5-S1	4
L5-S1	1
Estimated blood loss (EBL)	179.0 cc (STDEV 95.4)
Average EBL	50-500 cc
Range	150 cc
Median	100 cc
Mode	
Average time to fusion (Months)	4.9 mos.
Range (Months)	3.5-7.5
STDEV	0.87
Fusion rate	57 of 59 (97%)
Fused	57
Pseudarthrosis	2
Reoperations	0
CSF leaks	6
Prior surgery	1
Calcified synovial cysts/OYL	2
Epidural steroid injection/punctate	3
CTA PE protocol positive postop	3
Day 0	1
Day 1	2
Intraoperative transfusions	5 patients
EBL	1500 cc/5 patients (Average 300)
Range	200-500 cc
RBC	8 (2 Preop HCT Low transfused 1 UPC)

Table 2: Contd...

Variable	Nanoss 59 patients
Platelets	5
FFP	3
Postoperative transfusions due to drainage	3 patients
RBC	3 (1 per patient)

EBL: Estimated blood loss, FFP: Fresh frozen plasma, CTA: Computed tomographic angiogram, PE: Pulmonary embolism, CSF: Cerebrospinal fluid, OYL: Ossification yellow ligament, STDEV: Standard deviation, BMA: Bone marrow aspirate, Preop: Preoperative, HCT: Hematocrit

repaired in a watertight fashion using 7-0 Gore-Tex sutures (Gore Medical, Flagstaff, AZ, USA), muscle patch grafts for the latter 3, and Duragen in all cases (Integra Surgical, Hawthorne, NY, USA) [Table 2]. Of interest, none of the 6 patients developed recurrent postoperative CSF fistulas or pseudarthroses.

No postoperative infections with lamina autograft and Nanoss/BMA

None of the 59 patients undergoing multilevel lumbar laminectomies with noninstrumented PLF using lamina autograft and Nanoss/BMA developed a postoperative infection. The prevention of infection was largely attributed to the use of Hibiclens washes started 2 weeks preoperatively, the intraoperative use of antibiotic irrigation every 15 minutes, the routine use of postoperative prophylactic antibiotics, and employing Silverlon dressings for up to one postoperative month.

Postoperative pulmonary emboli requiring 6-week delayed full-dose Lovenox did not correlate with postoperative pseudarthroses

None of the 3 patients who developed pulmonary emboli (PE) documented on computed tomographic angiography (CTA)-PE protocols the night of surgery (1 patient) and on postoperative day 1 (2 patients) [Table 2] developed postoperative pseudarthrosis. Interestingly, documentation of immediate postoperative PE led to the future adoption of a routine preoperative regimen that included lower extremity Doppler surveillance. Note, it was likely that all three patients had deep venous thrombosis (DVT)/PE prior to admission. Following positive CTA/PE protocols for PE, all 3 patients immediately received inferior vena cava filters. However, subcutaneous full-dose Lovenox (Enoxaparin Sodium) was only started 6 weeks after the surgery, once MR studies confirmed no significant postoperative hematomas/seromas.

Postoperative pseudarthrosis did not correlate with intraoperative or postoperative transfusions

None of the 5 patients who required intraoperative or 3 patients who required postoperative transfusions later developed pseudarthroses [Table 2].

Contd...

DISCUSSION

Prior documentation of the efficacy of bone graft expander Vitoss/BMA for lumbar instrumented and noninstrumented posterolateral fusions

Previously, Epstein documented the efficacy of Vitoss/BMA as a bone graft expander for PLF. In 2006, Vitoss/BMA and lamina autograft (50:50 mix) were utilized to perform 40 laminectomies (average 3.7 levels), and one (27 patients) and two (13 patients) level posterolateral instrumented pedicle/screw/rod fusions.^[2] Six months postoperatively, dynamic X-rays/CT scans documented fusion for 26 of 27 single-level, and 11 of 13 two-level arthrodesis; only 1 of 2 patients with pseudarthrosis in the latter group required additional surgery. In 2008, the fusion rate for 60 mostly geriatric patients undergoing average 5.4-level laminectomies and one- to two-level noninstrumented PLF utilizing autograft and Vitoss/BMA was evaluated.^[4] At 6 postoperative months, dynamic X-rays/CT studies documented a 15% (9 patients) pseudarthrosis rate; nevertheless, only 1 patient required secondary surgery. In 2008, Epstein reviewed how different bone graft expanders [e.g., demineralized bone matrix (DBMs)/allografts, hydroxyapatite (HA), and Beta TriCalcium Phosphate (B-TCP: Vitoss)] resulted in similar fusion rates and outcomes for both noninstrumented and instrumented lumbar fusions.^[3]

Bone graft extender Nanoss/BMA

Nanoss was approved by the Food and Drug Administration (FDA) in 2008 as a bone void filler/extender for posterolateral spinal fusions (e.g., including lumbar fusions). It is a nanostructured hydroxyapatite (HA), with an engineered extracellular osteoconductive bioscaffold matrix that facilitates cell infiltration. When lamina autograft and BMA are added, it becomes not only osteoconductive, but also osteoinductive and osteogenic.

Comparable efficacy of Vitoss vs. Nanoss/BMA as a bone graft extender for noninstrumented lumbar PLF

In 2015, Epstein documented the comparable safety/efficacy of lamina autograft with Vitoss/BMA (213 patients) vs. Nanoss/BMA (45 patients) for posterolateral lumbar noninstrumented PLF.^[6] Following comparable multilevel lumbar laminectomies (average 4.6 vs. 4.5 levels, respectively) and noninstrumented PLF (average 1.3 vs. 1.2-levels, respectively), both groups demonstrated similar times to fusion (5.3 months vs. 4.8 months), fusion rates [210 (98.6%) vs. 45 (100%) patients], rates of pseudarthroses [3 (1.4%) vs. 0], incidence of postoperative seromas [2 (0.94%) vs. 0], and deep wound infections [2 (0.94%) vs. 0].

Safety/Efficacy of lamina autograft and Nanoss/BMA alone for noninstrumented lumbar PLF

In this series, patients underwent average 4.0-level lumbar laminectomies/average 1.2 level noninstrumented PLF fusions using lamina autograft and Nanoss/BMA. An average of 4.9 months postoperatively, both dynamic X-rays and CT studies documented a 97% (57 of 59) fusion rate. Two patients had radiographic pseudarthrosis; both were severely osteoporotic, morbidly obese, and were active smokers; neither required secondary surgery. No Nanoss-related complications such as infections, seromas, and or hematomas were observed. Note the higher fusion rates seen in the more recent studies with both Vitoss/BMA (older study 85%, newer study 98.6%) and Nanoss/BMA (100% and 97%) may have in part been attributed to better operative technique learned over time by the same surgeon.

Efficacy of demineralized bone matrix/inductive conductive matrix (DBM/ICM: Medtronic, Memphis, TN, USA) to supplement lamina autograft for multilevel laminectomy and noninstrumented posterolateral fusion

In 2008, Epstein evaluated fusion rates for 75 patients (average age 69) undergoing average 4.9-level lumbar laminectomies and average 2.0-level noninstrumented PLF utilizing lamina autograft with demineralized bone matrix/ICM (50:50 mix autograft: DBM/ICM).^[5] An average of 5.6 months postoperatively, dynamic X-rays and 2D-CT studies documented an 82.3% fusion rate with a 17.3% (13 patients) pseudarthrosis rate. Only 1 patient with pseudarthrosis was sufficiently symptomatic to require a secondary fusion. Note the higher pseudarthrosis rates noted in 2008 for DBM/ICM (17.3%) and in 2008 for Vitoss/BMA (15%) were comparable; because the same surgeon performed all operations, differences in the earlier PLF technique may have contributed to these higher nonfusion rates.^[3,5]

Other bone graft expanders

Bone morphogenetic protein (BMP: INFUSE, Medtronic, Memphis, TN, USA), other DBM, and ceramics

Other bone graft expanders, including bone morphogenetic protein (BMP: INFUSE, Medtronic, Memphis, USA), other demineralized bone matrix (DBM) products, and ceramics have been utilized alone or in combination with autograft to promote spinal fusion. Although BMP promoted fusion even when used alone as a bone graft substitute, increasingly, there were major concerns about its complications (e.g., heterotopic ossification, osteolysis, postoperative seromas, increased infection, and increased cancer rates).^[1,7,8] In 2013, Grabowski and Cornett acknowledged that BMP/INFUSE was increasingly being used, but noted “recent concern regarding their safety (BMP) has tempered enthusiasm regarding their use.”^[7] In 2015, Bauman *et al.*

evaluated the efficacy of stand-alone demineralized bone matrix (DBM) vs. autograft for performing 101 posterolateral thoracolumbar instrumented fusions (PLF) addressing traumatic vertebral fractures.^[1] Although the DBM/PLF numbers were small, similar fusion and complication rates were observed in both groups; 94% fusion with DBM/PLF (16 patients) and 100% fusion with autograft/PLF (46 patients), 1 deep infection with DBM/PLF, and 2 superficial wound infections in the autograft/PLF group. In 2016, Kadam *et al.* further identified 181 clinical studies that utilized BMP (62 studies), ceramics (40 studies), and allografts (39 studies) as bone graft expanders/substitutes for spinal fusions; although the best fusion rates were observed for BMP followed by allograft and DBM, there were again major concerns regarding BMP-related complications.^[8]

Actifuse (Baxter Corporation, Franklin Lakes, NJ, USA, Deerfield II, USA)

Actifuse was another bone graft extender used for posterolateral spinal fusions.^[9,10] Lerner and Liljenqvist in 2013 used Actifuse (Si-CaP) with BMA as the stand-alone fusion mass for adolescent idiopathic scoliosis surgery (AIS).^[9] Although they noted iliac autograft was the “gold standard,” their concern regarding the increased morbidity of donor site harvesting led them to use only Actifuse/BMA. With 20–40 ml of ACTIFUSE/BMA, 100% fusion was documented at 2 postoperative years based on X-ray studies alone (note no CT studies). In 2015, Licina *et al.* conducted a randomized controlled trial over a 2-year period (2015) utilizing Actifuse (SiCaP: 9 patients) vs. BMP (rhBMP-2; 10 patients) to perform posterolateral instrumented lumbar fusions (PLF); they found similar high fusion rates for both groups (e.g., Actifuse 9 of 9 patients; BMP 9 or 10 patients).^[10] Nevertheless, the very small number of patients in either group raises major concerns regarding the significance of the conclusions.

CONCLUSION

Multiple bone graft extenders/supplements/substitutes, including BMP/INFUSE, DMB/ICM, DBM, Actifuse, Vitoss, and now Nanoss/BMA have been utilized to perform instrumented and noninstrumented lumbar posterolateral fusions. Here, we prospectively performed 59 average 4.0-level laminectomies and average

1.2-level noninstrumented fusions in patients with severe osteoporosis and/or obesity (morbid obesity) utilizing lamina autograft and Nanoss/BMA. Pathology contributing to instability included degenerative spondylolisthesis (51 patients)/lysis (2 patients), and/or foraminal/far lateral synovial cysts (32 patients) and/or discs (21 patients) warranting partial/full facetectomies. Both dynamic X-ray and CT studies documented a 97% fusion (57 of 59 patients) rate an average of 4.9 months postoperatively; 2 pseudarthroses were attributed to severe osteoporosis, morbid obesity, and smoking. As no other Nanoss-related complications occurred, this study confirms the safety/efficacy of Nanoss/BMA as a bone graft extender for noninstrumented PLF.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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