

# The use of a Calcium Phosphosilicate in lower lumbar spinal fusion

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## Abstract

During the course of the past 12 months in a busy orthopaedic private practice, 22 patients have received posterolateral spinal fusion in their lower lumbar spine. NovaBone, a calcium phosphosilicate bone graft substitute, was used in 22 of these patients. The results have been largely excellent with only one patient experiencing non-union at two levels. This paper analyzes the results and assesses the use of NovaBone in one and two-level lumbar surgery.

## Introduction

Lower back pain has many different pathologies and presentations. Patients with lower back pain can be some of the most difficult to treat due to the wide range of pathologies. Disease processes which include everything from degenerative disc disease to spinal stenosis lead to patient presentations of lower back pain and problems. A significant portion of the population will at some point in their lives experience lower back pain with a percentage of them leading to significant changes in lifestyle and some progressing to disability. Solutions for alleviating the symptoms of lower back problems are as diverse as the etiologies. Over the years many different approaches to relief have been tried; exercise, physical therapy/ stretching, pain medication, steroids, chiropractic manipulation and surgical. All have met with some success and mixed results for patients. A successful surgery for treatment of lower back and radicular pains has been to fuse the lumbar spine which decompresses the spinal canal and nerve roots, thus alleviating pain and radiculopathy (if present). There are a variety of surgical approaches to accomplish the decompression of the spine along with instrumentation that can stabilize and limit motion.

To create a stable fusion between lumbar discs, many different osteoinductive and osteoconductive materials have been used. Harvesting iliac crest bone from the patient during the surgical procedure has been considered the standard material for bone grafting. This has proven to have its own problems with morbidity at the surgical site for obvious reasons. Allograft (DBM) has been used successfully as a bone grafting material, but has a risk of infectious transmission from donor to recipient. Biologics (BMP) have been developed to improve the grafting

N=22 Average Age	59	
Male	8	36%
Female	14	64%
<b>Primary Diagnosis</b>		
Stenosis	20	91%
Spondylolisthesis	18	82%
DDD	3	14%
Failed Back	2	9%
<b>Vertebral Levels</b>		
L3-4	4	18%
L4-5	22	100%
L5-S1	4	18%
Total	30	
<b>Past Medical History</b>		
Leg Pain	21	95%
Back Pain	13	59%
<b>Nicotine Use</b>		
Smoker	7	32%
Non-smoker	15	68%
<b>Prior Treatment</b>		
Steroids	20	91%
Pain Medication	20	91%
Prior Surgery	2	9%

Table 1. Demographics

process and at the same time neutralize some of the risks of autograft and allograft bone, but at an expensive price. Calcium Phosphosilicated bone graft have been shown to increase the production and differentiation of osteoblasts which improves the growth of bone and fusion within spinal surgery<sup>1</sup>.

The retrospective study outlined here used a silicated biomaterial called NovaBone, (NovaBone Products LLC., Jacksonville, FL) on 22 patients who received the NovaBone bone graft with local bone or local bone and iliac crest bone graft (ICBG) as a composite. In previous studies silicon has been shown to improve and up-regulate osteoblasts for better bone growth and fusion<sup>2,3</sup>. NovaBone is the only bone graft product that has been approved by the FDA to make the claim that it is an osteostimulator. This refers to the silicate biomaterial produced by NovaBone having been shown in extensive research studies to activate the genetics of osteoblasts which signals the upregulation of the cells<sup>4</sup>. This has important implications for the patient in fusion rate as well as recovery time.

### **Material and Methods**

There were 14 female patients and 8 male patients whose age range was from 31 to 84 (mean 59.0 years). Seven of these (mainly female) were smokers and only one was receiving workers compensation. All of them suffered from low back pain or leg pain or both. The location of the fusion was L4-5 in 14 patients, L4-S1 in 3 patient, L3-5 in 4 patients and L5-S1 in 1 patients. The pre-operative diagnosis was spinal stenosis and spondylolisthesis in 18 patients with a variety of diagnoses in the others. Two patients had previous back surgery. NovaBone and local bone graft was used in all 22 patients and iliac crest bone graft in 15 patients. All of the patients received a posterolateral spine fusion with NovaBone and local bone or NovaBone, local bone, and iliac crest bone and nine patients also received an interbody fusion with a combination of the materials. Rods and pedicle screws were used in every patient. The blood loss was minor ranging from 100ccs to 450ccs (mean 290ccs). The only immediate postoperative complication was urinary retention in one elderly male patient which resolved rapidly.

All patients were evaluated and a posterolateral fusion (PLF) technique was used. There were 9 patients who had the additional technique of interbody arthrodesis along with PLF. All patients received decompression for indications of degenerative disc disease, spondylolisthesis, spinal stenosis or other degenerative processes with fixation and instrumentation as required. Calcium phosphosilicate (10cc) was mixed with local bone in all patients. Iliac crest bone graft was mixed with local bone and calcium phosphosilicate (10cc) in 15 patients. The mixture was distributed into the posterolateral gutters and interbody space when a cage was used.

### **Results**

Of the 29 levels fused, there were only 2 instances of non-union. The first patient had a complete non-union which was initially treated with a bone growth stimulator, but this did not work so a second fusion was scheduled. The other patient was fused at 2 levels, the upper level (L3/4) fused satisfactorily but the lower level (L4/5) failed to fuse and she now

has an asymptomatic non-union at this level. A third patient continued to have low back pain and in spite of the radiographs appearing normal with a stable fusion; she underwent an open inspection of the fusion which appeared to be stable. All but one of the patients assessed themselves as very satisfied with the operative results stating a reduction in pain and symptoms and a return to a normal lifestyle.

Procedure		
Single Level	15	68%
2 Level	7	32%
PLF	22	100%
Interbody Arthrodesis	9	41%
Hardware used	41%	
Avg. NovaBone	10cc	
Avg. EBL (cc)	286	
Complications	1	Urine retention

Table 2. Surgical Information

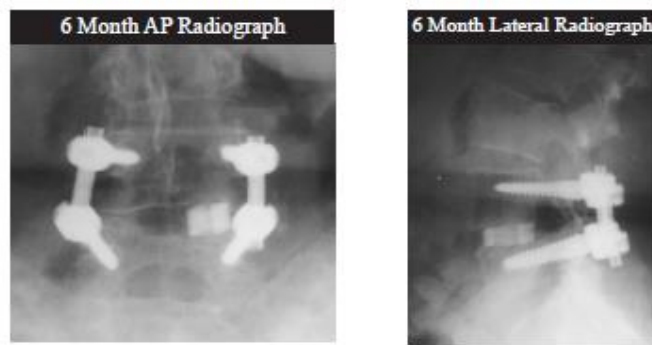


Figure 1 - Radiograph imaging of EJ

**Case Study I - EJ** is a 73 year old female with an acute history of bilateral lower extremity pain and weakness. Pre-operative evaluation confirmed stenosis of L4-L5 with spondylolisthesis. Based upon the progression of symptoms, surgery was recommended. In February of 2009, the patient

underwent a posterolateral fusion of L4-L5 with an anterior disc spacer. NovaBone (10cc) was combined with ICBG/local bone and 10cc was applied. Imaging at six months revealed solid bilateral fusion with remodeling (Fig. 1). Clinically, the patient's symptoms have resolved with improving lower extremity function.

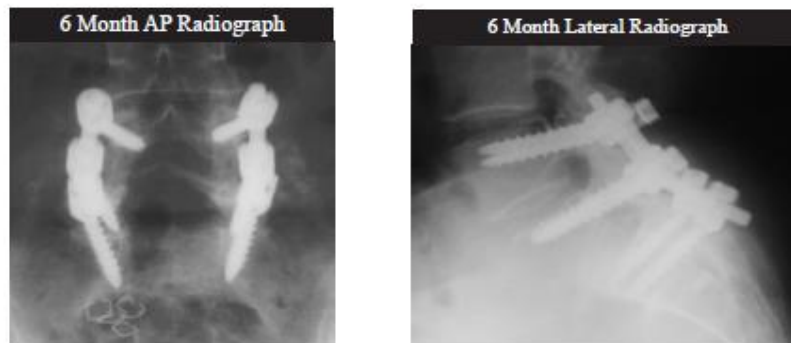


Figure 2 - Radiograph imaging of MD

**Case Study II - MD** is a 53 year old female with an acute history of LBP and bilateral lower extremity pain and weakness. Pre-operative evaluation confirmed stenosis of L4-S1 with spondylolisthesis. Patient was treated conservatively, without improvement. In February of 2009, the patient

underwent a posterior L4-S1 laminectomy with posterolateral fusion. NovaBone (10cc) was combined with ICBG/local bone and applied as a graft composite. Imaging at six months revealed significant bilateral fusion with remodeling (Fig. 2). Clinically, the patient is doing well with resolution of her symptoms.

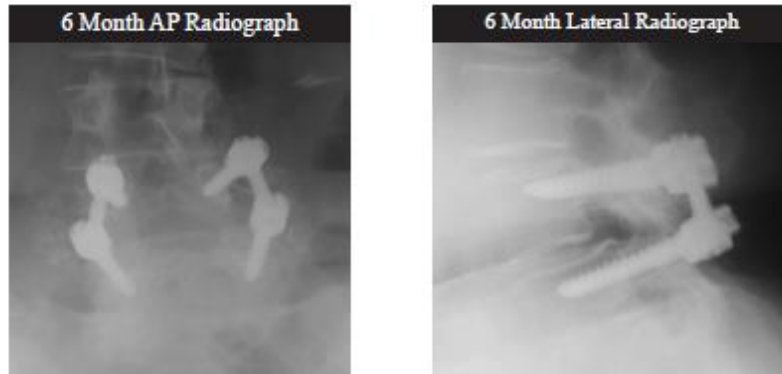


Figure 3 - Radiograph imaging of NB

**Case Study III** - NB is a 72 year old female with a chronic history of LBP and bilateral lower extremity pain and weakness. Pre-operative evaluation confirmed stenosis of L4-L5 with spondylolisthesis. The patient failed conservative management with steroid injections and pain medication. In December of 2008, the patient underwent a

posterior fusion of L4-L5. NovaBone (10cc) was combined with local bone and 10cc was applied. Imaging at six months revealed bilateral fusion with remodeling (Fig. 3). The patient continues to do well at follow-up with minimal LBP and marked improvement in lower extremity pain and weakness.

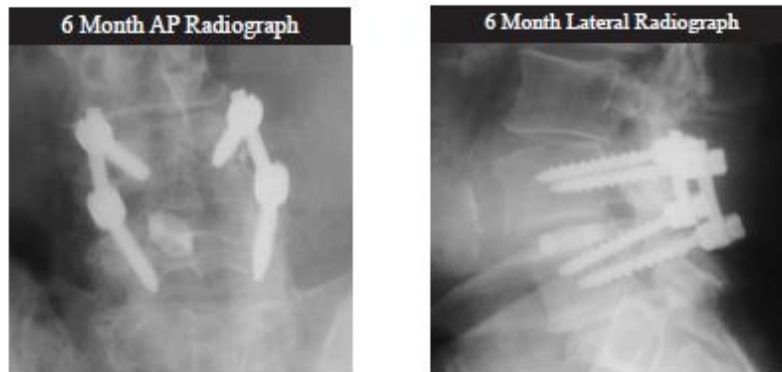


Figure 4 - Radiograph imaging of SI

**Case Study IV** - SI is a 60 year old male with an acute history of LBP and bilateral lower extremity pain and weakness. Radiographic evaluation confirmed stenosis of L4-L5 with spondylolisthesis. The patient was treated using pain medication and steroid injections with no relief. In April of 2009, the patient underwent a transforaminal

interbody fusion of L4-L5 with posterior fusion. NovaBone (10cc) was combined with ICBG/local bone and 10cc was applied. Follow-up imaging at six months revealed bilateral fusion and remodeling (Fig. 4). The patient continues to do well with minimal LBP and resolution of lower extremity pain.

## Discussion

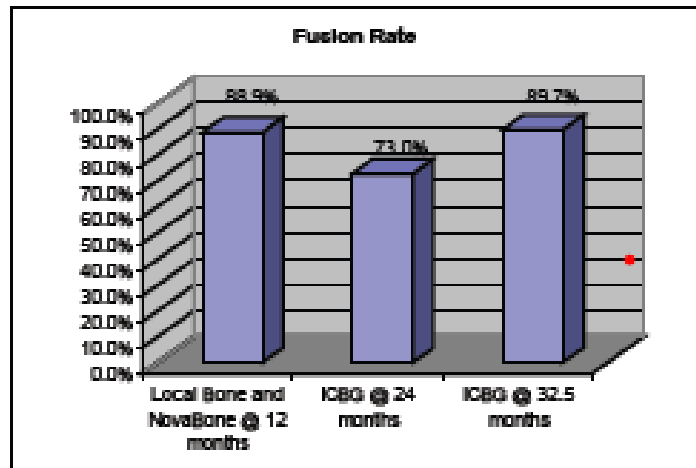
Many materials have been used to fuse the lower lumbar spine in patients with low back pain (and radiculopathy) including autograft bone from the iliac crest. A number of papers published in the last 6 years have analyzed the fusion rates using ICBG as the gold standard for comparison. Vaccaro, et al looked at fusions using ICBG in 10 patients and found a 40% fusion rate over 24 months. Dimar, et al also looked at ICBG fusion in 45 patients and found a 73% fusion rate over 24 months. Chen, et al used ICBG in 74 patients over a 32.5 month

period and found an 89.7% fusion rate.<sup>5,6,7</sup> In this study 7 patients received local bone with NovaBone for a total of 9 levels fused (2 patients received 2 level fusion) with only 1 asymptomatic non-union in a 2 level fusion. This would signify a 88.9% fusion rate of local bone and NovaBone at 12 months follow up compared to the gold standard of ICBG with a fusion rate of 89.7% after 30 months.

Over the past 10 years various synthetic materials

have been used including:

- Hydroxyapatite and beta tricalcium
- Nanocrystalline hydroxyapatite paste - OSTIM
- Biphasic calcium composite - BCC
- Calcium phosphate ceramics
- Crystalline semi hydrate form of calcium sulphate – STIMULAN



Most of these materials closely resemble the mineral composition, properties and architecture of human cancellous bone and have a high affinity for binding proteins. In particular, silicon substitution of phosphate ceramics has been shown to induce osteoblastic proliferation and bone formation. Silicon has been found as a trace mineral in immature human bone. In its soluble form it has been shown to regulate collagen synthesis. NovaBone is a calcium phosphosilicate bone graft substitute with elements naturally occurring in the body. NovaBone's formulation is engineered to react and release ions as soon as it is exposed to an osseous defect. When implanted, it delivers a controlled release of ions over time that enhance cell signaling. Within hours of implantation, calcium and phosphorus ions, along with soluble silica, are released forming a silica-gel and hydroxycarbonate apatite layer creating an ideal environment for cellular attachment and for protein and growth factor absorption. The formation of the reaction layers and the absorption of these organic molecules results in the signaling and recruitment of osteoprogenitor cells (mesenchymal stem cells) to the site and their early attachment and proliferation at the material surface. The continued calcium and silicon ion release modulates the differentiation of the cells, resulting in a population of osteoblasts and precursor cells that have the potential to become bone forming cells, ultimately upregulating the bone forming process. This bone formation continues on an accelerated path as multiple families of genes directly involved with the proliferation and differentiation of osteoblasts and precursor cells are regulated. This accelerated early healing response results in bone formation on NovaBone surfaces at rates equivalent to autograft, with particle absorption keeping pace with bone remodeling. The cumulative effect is an increase number of cells capable of dividing and forming new bone and healing tissue.

## Conclusion

This retrospective study of 22 patients has demonstrated how NovaBone is an excellent bone graft extender. As the data has shown, 15 out of 15 patients who had a single level fusion were successfully fused at 12 months, a 100% fusion rate. When adding the small cohort of patients who had a 2 level fusion to the data it is demonstrated that the fusion rate is 26 of 29 total levels fused, a fusion rate of 90%. It was also significant and worth noting that 7 patients who had local bone with NovaBone had an 88.9% fusion rating after 12 months which compares favorably to the gold standard of ICBG that has a fusion rating of 89.7% after 32.5 months. The fusion rate of NovaBone calculated from the data demonstrates how NovaBone has a higher fusion rate than using ICBG alone or autograft with DBM. With an increase in the fusion rate there is an increase in the positive outcome for these patients.

Authors	Publication	No. of Patients	Modality	Graft Material	Fusion Rate
Dimar, et al	Spine 31:2534-2539, 2006	45	Fine cut CT	Iliac crest autograft	73% at 24 months
Cammissa, et al	Spine 29:660-666, 2004	81	Plain radiographs	Iliac crest autograft(a)	54% at 24 months
Chen, et al	Spine 30:2293-2297, 2005	74	Plain radiographs	Iliac crest autograft(b)	89.7% at 32.5 months
Fernandez-Fairen, et al	Spine 32:395-401, 2007	42	CT	Iliac crest autograft(c)	90% at 36 months
Vaccaro, et al	Spine 30:2709-2716, 2005	10	Plain radiographs	Iliac crest autograft(d)	40% at 24 months

(a) Study involved combining Grafton DBM gel / autograft composite on one side and autograft only on the other side in the same patient. The results shown here are the autograft only side.

(b) Study involved combining Osteoset Calcium sulfate pellets / local autograft composite on one side and autograft only on the other side in the same patient. The results shown here are the autograft only side.

(c) Study involved combining autograft / bicalcium phosphate ceramic composite with unilateral or bilateral transpedicular fixation. The results shown here are for the bilateral fixation group.

(d) Study involved iliac crest graft as a control vs. OP-1. No fixation was utilized.

Table 3. Contemporary Literature Review of Reported Posterolateral Lumbar Spinal Fusion Rates

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