

TREATMENT OF DEGENERATIVE SPINAL
PATHOLOGY UTILIZING
SILICATED CALCIUM PHOSPHATE GRAFT IN
POSTEROLATERAL FUSION

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Abstract

Spinal fusion of abnormal segments is a valuable treatment option in the management of low back pain due to lumbar instability. We describe a retrospective review of 27 patients with a wide range of degenerative conditions of the lumbar spine who underwent spinal fusion utilizing a synthetic bone graft substitute (BGS) of silicated calcium phosphate (Actifuse™ Synthetic Bone Graft, ApaTech Ltd, Elstree, UK). Radiographic imaging demonstrated excellent fusion rates, of over 96%, with excellent bridging and no implant loosening. Additionally, 85% believed the surgery was worthwhile. Since multi-level fusions, plus the risk factors of smoking and obesity, are generally associated with poor fusion rates and outcomes, this study confirmed that synthetic BGS of silicated calcium phosphate is an excellent alternative to autologous graft and is potentially superior to allograft or other types of synthetics.

Introduction

Low back pain (LBP) is the second leading cause of office visits, after respiratory infections, and the third leading cause of disability between the ages of 45 and 65. Overall, 80% of the population experience one or more episodes of LBP at some point in their lives^{1,2}.

Low back pain is a complex medical condition with a wide spectrum of etiologies. Normal motion in the lumbar spine under physiologic forces should range from 15-20 degrees of flexion/extension, 2-5 degrees lateral bending and 3-6 degrees of rotation,³ but may become more pronounced by additional forces such as changing position from sitting to standing⁴. Degenerative disc disease may lead to abnormal rotary forces with facet subluxation, resulting in lumbar instability³. One treatment to address instability is to limit pathological motion by fusing the abnormal segments.

Successful outcome of fusion depends largely on obtaining a solid bridge of bone across the affected level while maintaining the normal intervertebral height^{1,5}. Because non-union frequently leads to unsatisfactory clinical results and postoperative instability,⁵ it is important to identify those factors that influence successful fusion rates. Single level anterior lumbar interbody fusion (ALIF) procedures have fusion rates ranging from approximately 70 to 80%^{1,2,6}. However, these rates become significantly worse with the addition of a second level, possibly through

decreased stability, and this has led to the development of novel technologies to improve the rate of spinal fusion. Fusion of the anterior column of the spine can be performed with femoral ring allograft or interbody devices containing bone graft, while the posterior spine can be fused with facet screws or pedicle screws attached to plates or rods^{7,8}. The posterolateral fusion mass can be derived from a variety of sources, including autograft, allograft, and synthetic bone graft substitute materials^{1,2,9}.

While autograft has an excellent profile in terms of osteoinductive and osteoconductive properties, it presents issues with donor site morbidity¹⁰, bone quality, limited supply, and extra time spent under anesthesia. Cancellous chip allograft is osteoconductive to varying degrees, but still carries a small but finite risk of disease transmission. The large and growing category of bone graft substitutes includes bone morphogenetic protein (BMP), allograft demineralized bone matrix (DBM)¹¹, and synthetic bone substitutes. BMP has demonstrated excellent bone growth in the interbody space, when used with a metal interbody fusion cage via an anterior approach, but there are some reservations over cost and safety. Also, it is strictly osteoinductive and results are highly dependent upon the dose used, the operative site and the carrier used to deliver it. DBM claims osteoinductive properties, but this can be highly variable due to differences in the manufacturing processes between suppliers. The newer fiber-based DBM products exhibit some osteoconductive properties, but these are currently most often employed as bone graft expanders.

This study presents a retrospective review of patients who underwent posterolateral fusions utilizing a synthetic bone graft substitute of silicated calcium phosphate (Actifuse™ Synthetic Bone Graft, ApaTech Ltd., Elstree, UK). Earlier studies by Carlisle and others have shown that silicon promotes bone bonding and induction in silicon-containing bioactive glasses and glass ceramics¹². The silicated calcium phosphate graft used in this clinical series has been developed to exploit the osteo-stimulatory effects of silicon. It is similar in structure to bone mineral, but has site-specific substitution of phosphate (PO_4^{3-}) ions with silicate (SiO_4^{4-}) ions. Ionic silicate, particularly with calcium ions, is known to have a role in up-regulating osteoblast proliferation and differentiation, promoting osteoinductive gene expression, and increasing Type I collagen synthesis¹³.

Methods

Surgical Methods

All patients since April 2005 with indications for a posterolateral spinal fusion procedure were seen by one senior author (PJC). Appropriate decompressive surgery was performed for degenerative disc disease, spondylolisthesis or other degenerative processes as the clinical pathology dictated, with subsequent fixation using instrumentation as appropriate. Silicated calcium phosphate granules were mixed in a 1:1 volume ratio with venous blood and added to local autograft harvested from the surgical site. The composite was used for the posterolateral fusion mass in each case.

Research Methods

Medical records were reviewed for all patients treated with silicated calcium phosphate and confirmed from operating room records. Demographics, comorbidities, and pre- and post-operative pain levels and neurological status were recorded. Recorded operative data included: location of graft, amount used, and intraoperative complications. Postoperative imaging data, including plain radiographs and computerized tomography (CT) scans, were also evaluated for evidence of fusion.

Results

Group demographics are presented in Table 1. Twenty seven patients were treated with an average age of 56 years and 52% were male. Nine patients worked full time and eight were disabled. Presentation included 44% with a diagnosis of degenerative disc disease (DDD) of the lumbar spine, and 52% with degenerative spondylolisthesis, with disease present at two or more levels in 74% of patients. The cohort included a high number of smokers (30%) and obese subjects (44%).

Preoperatively, 100% had back pain (BP), 70% had right leg pain (RLE) and 63% had left leg pain (LLE) (Figure 1).

Disability status was quite high at 70% (Figure 2). Neurological status, however, was fairly well preserved as 85% had normal reflexes and 89% were intact from a motor and sensory standpoint (Figure 3). A total of 26% (7/27) of patients had single level fusions performed, 44% (12/27) had fusion at two

N=27 Average age	56	
Male	14	52%
Female	13	48%
Work Status		
Full Time	9	33%
Part Time	1	4%
Retired	6	22%
Student	1	4%
Disabled	8	30%
Other	2	7%
<i>Total</i>	27	
Primary Diagnosis		
Subluxation	1	4%
Degenerative Spondylolisthesis	14	52%
DDD	12	44%
Isthmic Spondylolisthesis	3	11%
Failed back	1	4%
Vertebral Levels		
L1-2	1	2%
L2-3	2	4%
L3-4	9	19%
L4-5	22	47%
L5-S1	13	28%
<i>Total</i>	47	
Past Medical History		
DM (good control)	4	15%
Obese	12	44%
Neurologic disease	1	4%
Autoimmune disease	4	15%
Psychiatric	3	11%
Other	21	78%
Nicotine Use		
Never	19	70%
Less than 1pk/day	5	19%
More than 1 pk/day	3	11%
Prior Treatment		
NSAIDS	24	89%
Narcotics	12	44%
Injection	17	63%
Ice/Heat/Baths	23	85%
Rest	23	85%
Physiotherapy	26	96%
Prior Surgery	10	37%
Other	6	22%

Table 1. Demographics

levels, and 8/27 (29%) of cases had fusion at three or four levels (Table 2). Sixty-three percent of cases (17/27) required posterior approach alone, but 37% (10/27) required both anterior and posterior approaches.

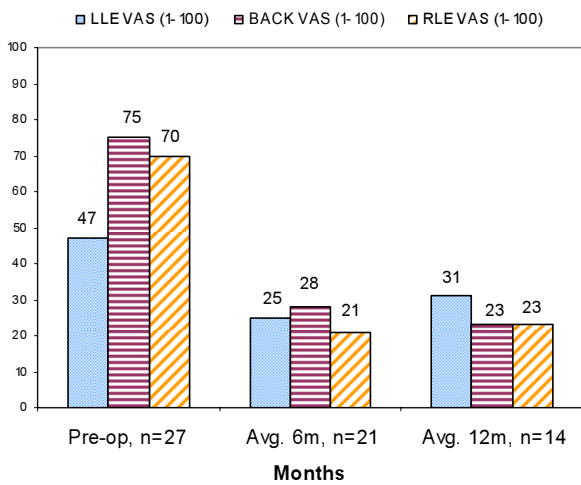


Figure 1a. VAS Pain Status

No implants were used in 36% of the cases. An average of 10.3cc of silicated calcium phosphate granules was used per level fused. There was one intraoperative complication (durectomy) in a patient who had had multiple previous surgeries with extensive adhesions.

Postoperative follow up was performed at an average of 6 months (21 patients) and 12 months (14 patients) (Figures 1-3 and Table 3). At 6 months, 81% of patients continued to have minimal amount of back pain while 57-60% had some degree of leg pain. A majority (95%) had no sensory or motor deficits and 85% believed the surgery was worthwhile. Approximately half (51%) of patients had some

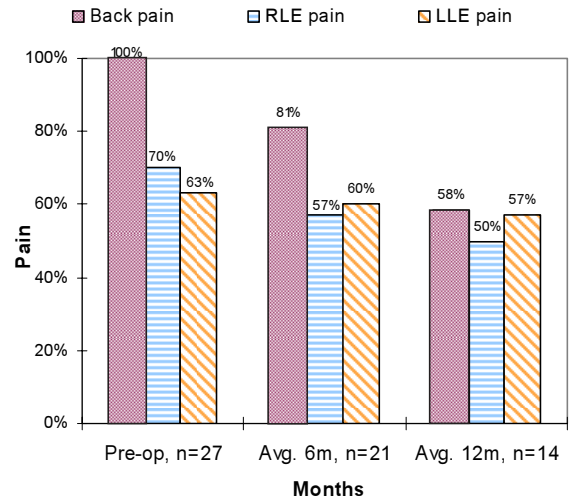


Figure 1b. Pain Status

residual level of disability. At 12 months, 58% continued to have minimal amount of back pain while 50-57% had some leg pain. None of these patients had sensory or motor deficits and 79% believed the surgery was worthwhile. Prior to surgery, 70% of patients had disability and 44% required narcotics for analgesia; at 6 months, these figures were 51% disability and 15% narcotic use, and at 12 months these were 52% disability and 29% narcotic use.

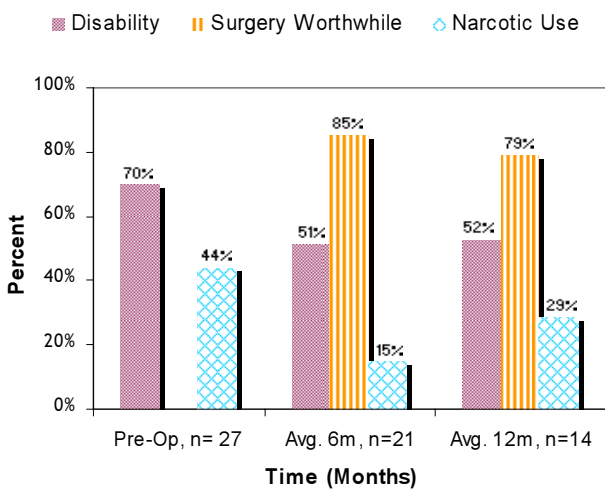


Figure 2. Function

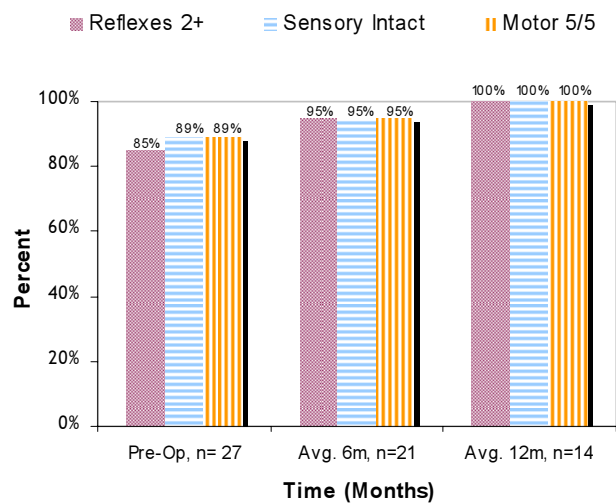


Figure 3. Physical Exam Vs Time Related to Surgery

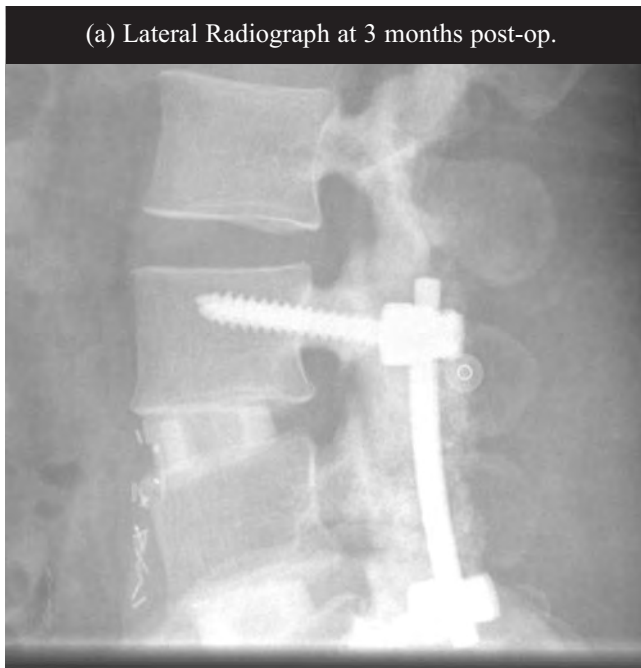


Figure 4. (a) and (b) Lateral Radiograph

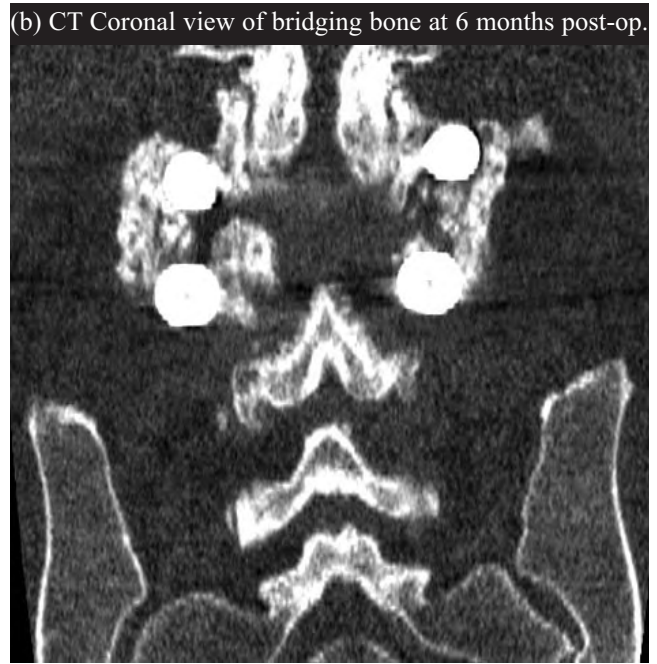


Figure 5. (a) and (b) CTs of bridging bone

Fusion was assessed utilizing plain film radiographs supplemented with CT scans when a definable fusion mass was questionable. For the purposes of this evaluation, the left and right sides of each operated level were assessed separately. This method revealed excellent fusion rates: at 6 months, 42 levels (84 sides) were evaluated and 2 sides (2%) did not exhibit bridging bone. At twelve months, 27 levels (54 sides) were evaluated and 2 sides (4%) did not exhibit

bridging bone. Only 1 patient was determined to exhibit a pseudoarthrosis at one year follow-up. There was also no evidence of implant loosening in any patient throughout the study (Figure 6). (See Figures 4 and 5 for plain radiograph progression of fusion mass from 3 to 12 months post op, and representative CTs)

Procedure		
Single Level	7	26%
2 Levels	12	44%
3 Levels	2	7%
4 Levels	6	22%
A & P	10	37%
Posterior	17	63%
Hardware used	64%	-
Avg. Actifuse	10.3cc	
Avg. EBL	520cc	
Complications	1	Durotomy

Table 2. Surgical Information

Work Status	Interval Change (6m)	Interval Change(12m)
Full time	-9.52%	2.38%
Part time	1.06%	3.44%
Retired	-12.70%	-22.22%
Student	-3.70%	-3.70%
Disabled	22.75%	13.23%
Unknown	0%	7.14%
Other	2.12%	-0.26%

Table 3. Work Status

Discussion

This cohort represents a wide range of degenerative conditions of the lumbar spine with significant pathology and, although there was a relative low incidence of neurological complications from bony injury to the spinal cord or nerve roots, 74% required multi-level fusions to treat their disability. Multi-level fusions, plus the risk factors of smoking and obesity that may impede bone healing and subsequent fusion, are generally associated with poor fusion rates and outcomes.

The early data at 6 months and 1 year follow-up showed good return of neurological function and a minimal amount of residual pain, with a decrease in disability rate from 70% pre-surgery to 52% at 12 months, although this was based on only 14 patients at the one-year follow-up. Radiographic and CT imaging provided objective confirmation for this good clinical outcome, with evidence of good fusion by bridging bone and no signs of implant loosening. Radiographic evidence of bridging bone, 98% at 6 months and 96% at 12 months, supports the clinical impression of a solid posterolateral fusion.

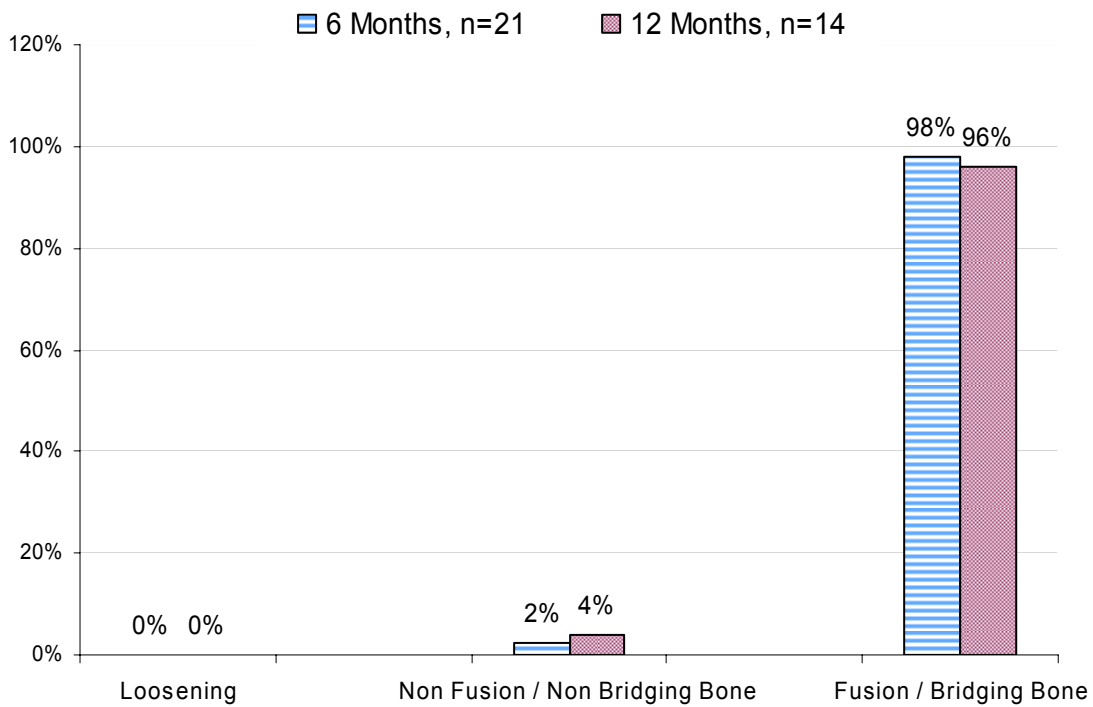


Figure 6. Imaging Assessment

Conclusion

This study confirmed that the use of synthetic bone graft substitute of silicated calcium phosphate mixed with local autograft is an excellent alternative to autologous graft and is potentially superior to allograft or other types of synthetics. No changes were required to our standard surgical techniques for either approach or fixation method, and the results at 6 and 12 months from this treatment of degenerative spine disorders with respect to pain, neurological status, function, and work status were highly encouraging. The imaging results supported the clinical picture of solid fusion, although we need to further characterize the fusion mass with other imaging modalities. It is planned that all future patients returning for their one year follow up visits will receive additional flexion/extension radiographs and CT scans.

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