

**TREATMENT OF TRAUMATIC SPINAL PATHOLOGY  
UTILIZING SILICATED CALCIUM - PHOSPHATE GRAFT  
IN POSTEROLATERAL FUSION.  
A PRELIMINARY REPORT.**

---

**Authors:**

Eskander MS, Hays P, Eskander JP, Brooks DD, Franklin P, Connolly PJ

## Abstract

Acute spinal injuries are among the most common causes of morbidity and mortality in trauma. The early identification and treatment of spinal instability may prevent neurological compromise. While this can be achieved through immediate fixation with instrumentation, long-term stability is dependent on obtaining a solid, mature bony fusion.

This retrospective study reviews 15 patients who underwent posterolateral fusions with a phase-pure silicated calcium phosphate graft (Actifuse™ Synthetic Bone Graft, ApaTech Ltd., Elstree UK) following spinal trauma, to identify early trends in healing, symptoms, and complications. Ionic silicate has an important role in up-regulating osteoblast proliferation and differentiation, promoting osteoinductive gene expression, and increasing Type I collagen synthesis. Surgery was performed at two or more levels in 80% cases, with 13% of patients requiring both an anterior and posterior approach. Results showed a marked improvement in back pain, with disability decreasing from 91% to 34%, at 9 months. Radiographic imaging by plain radiographs revealed 62% bridging bone at 3 months increasing to 93% at 9 months and confirmed the clinical outcome, with no signs of implant loosening. The use of silicated calcium phosphate granules provides a good alternative to autologous graft.

## Introduction

Acute spinal injuries are among the most common causes of morbidity and mortality in trauma, with about 50,000 bony injuries each year in the United States<sup>1</sup>. There have been a number of significant advances in the understanding and treatment of these injuries. In particular, treatment of spinal instability may prevent neurological compromise under normal physiologic loads. Treatments have been targeted toward limiting such abnormal motion by providing fixation at selected levels with the expectation that, after fixation, the spinal cord and nerve root will be protected from further injury. While this can be achieved through immediate fixation with instrumentation, long-term stability is dependent on mature bony fusion.

Several factors influence fusion rates, and it is important to identify these since non-unions frequently lead to unsatisfactory clinical results<sup>2</sup>. Instability during the postoperative course is one such factor. In general, successful outcome is dependent on obtaining a solid fusion, as well as recreating the normal vertebral height<sup>3</sup>. Single level Anterior Lumbar Interbody Fusion (ALIF) procedures have fusion rates ranging from approximately 70 to 80%,<sup>4,5,6</sup> but these rates become significantly worse with the addition of a second level, possibly due to decreased stability.

There is heightened interest in the spine community regarding novel technologies that can increase the rate of spinal fusion. Fusion of the anterior column of the spine can be addressed with femoral ring allografts, interbody cages, or other types of structure containing bone graft, while the posterior spine can be instrumented with translaminar facet screws or pedicle screws attached to plates or rods<sup>7,8</sup>. The posterolateral fusion mass can be derived from a variety of sources including autograft, allograft, and synthetic bone graft substitute materials<sup>4,5,9</sup>. Autograft is the ideal choice in terms of osteoinductive and osteoconductive properties, but it presents some issues surrounding its use, especially with iliac crest bone graft, which is associated with increased donor site morbidity<sup>10</sup>, limited supply, and extra time spent under anesthesia. Allograft presents one alternative, but this has highly variable osteoconductive properties, has been shown to work poorly in posterolateral fusions, and carries a small, though finite, risk of disease transmission.

Bone graft substitutes form a large and growing alternative category. These include bone morphogenetic protein (BMP), allograft demineralized bone matrix (DBM)<sup>11</sup>, and synthetic bone substitutes. BMP is strictly osteoinductive; it has been shown to be excellent at growing bone but there are some reservations over cost and safety, and results are highly dependent upon the operative site and the carrier used to deliver the BMP. DBM is considered to be osteoinductive, but this is highly variable due to differences in the manufacturing processes between suppliers. Other newer fiber-based DBM fabrications also exhibit some osteoconductive properties, but currently DBM is most often employed as a bone graft expander. The last class of bone graft substitutes is synthetic bone substitutes. Several different products

n=15		
Avg. Age	38	
Male	11	73%
Female	4	27%
<b>Work Status</b>		
Full Time	8	53%
Student	1	7%
Unknown	3	20%
Other	3	20%
<b>Primary Diagnosis</b>		
Fracture	5	33%
Burst	9	60%
Subluxation	1	7%
<b>Vertebral Levels</b>		
C2-3	1	6%
C4-5	1	6%
C5-6	2	13%
C6-7	1	2%
C7-T1	1	6%
T4-5	1	6%
T7-8	2	13%
T11-12	2	13%
T12-L1	2	13%
L1-2	1	6%
L3-4	2	13%
L4-5	1	6%
<b>Past Medical History</b>		
Autoimmune Disease	2	13%
Psychiatric	4	27%
Other	4	27%
<b>Nicotine Use</b>		
Never	9	60%
<1 pk/day	6	40%

Table 1. Demographics

exist, with varying compositions and claims made for them. Most synthetics are used in conjunction with bone marrow aspirate to combine a passive scaffold that works with the patient's own BMP's and bone forming cells.

The purpose of this retrospective study was to review patients who underwent posterolateral fusions with a

phase-pure silicated calcium phosphate graft (Actifuse™ Synthetic Bone Graft, ApaTech Ltd., Elstree UK) following spinal trauma, to identify early trends in healing, symptoms, and complications. This particular synthetic bone graft was specifically developed to exploit the osteo-stimulatory effects of silicon, since earlier studies had shown that silicon has a metabolic role in bone formation<sup>12</sup> and increases bioactivity<sup>13</sup>. The silicated calcium phosphate graft used in this clinical series is similar to the structure of bone mineral but has site-specific substitution of phosphate (PO<sub>4</sub><sup>3-</sup>) ions with silicate (SiO<sub>4</sub><sup>4-</sup>) ions. Ionic silicate, particularly with calcium ions, has a role in up-regulating osteoblast proliferation and differentiation<sup>14</sup>, promoting osteoinductive gene expression<sup>15</sup>, and increasing Type I collagen synthesis<sup>16</sup>. The ultimate hope is that this may improve healing rates sufficiently to preclude the need for autograft.

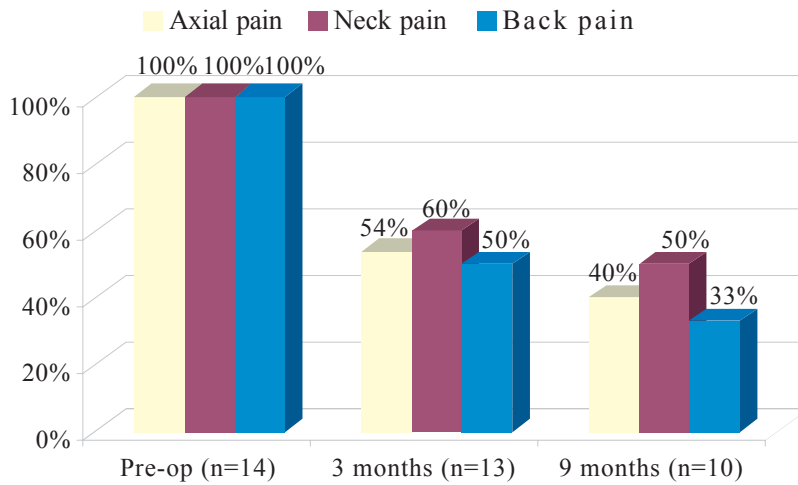
## Methods

### *Surgical Methods*

All spine trauma patients since April 2005 with indications for a posterolateral spinal fusion procedure were seen by one of our authors (DDB). The surgeon performed the appropriate decompressive surgery for bony fragments, disc herniations, or foreign bodies as the clinical pathology dictated. All surgeries used a combination of instrumentation with silicated calcium phosphate granules mixed in a 1:1 volume ratio with

Single Level	3	20%
2 Level	8	53%
6 Level	1	7%
7 Level	1	7%
8 Level	2	13%
Cervical Level	7	15%
Thoracic Level	26	54%
Lumbar Level	15	31%
Anterior & Posterior	2	13%
Posterior	13	87%
Hardware used	100%	
Average Actifuse	36ml	
Average EBL.	437ml	

Table 2. Operative Information



Graph 1. Pain Following Posterolateral Spine Fusion in Trauma Patients

autologous bone marrow aspirate harvested from the posterior vertebral structures for the posterolateral fusion. Subsequent stabilization surgery was also performed with appropriate instrumentation.

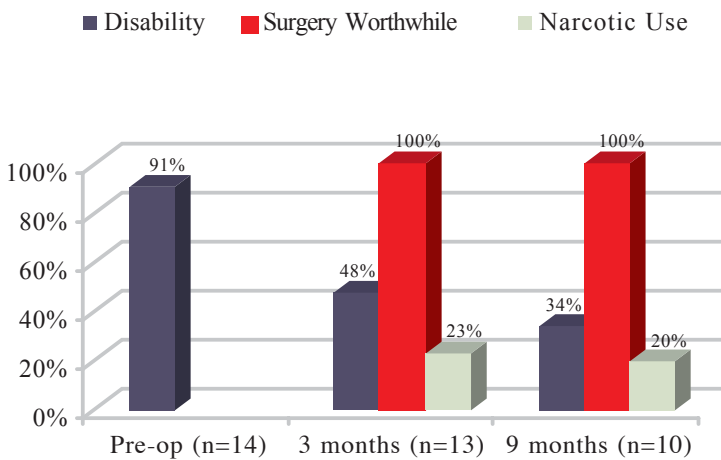
and post-operatively. Recorded operative data included location of graft, amount used, and intraoperative complications. Post-operative imaging was evaluated for evidence of bony fusion.

*Research Methods*

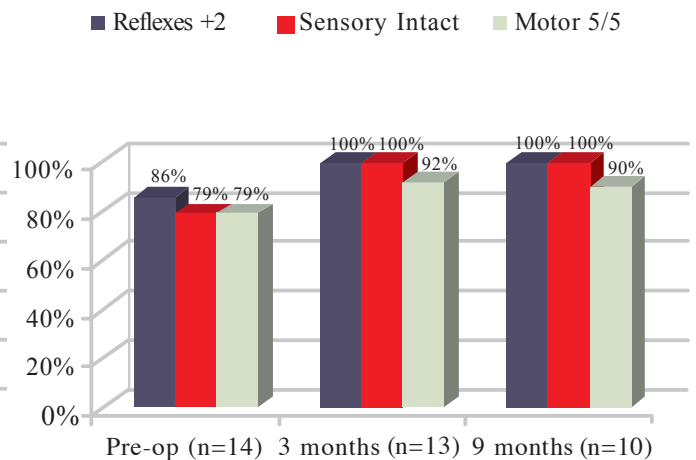
Medical records for all patients treated with Actifuse were confirmed with operating room records. Data collected included demographic information and documented co-morbidities. Pain information and neurological status was documented preoperatively

**Results**

The group demographics are outlined in Table 1. There were 15 patients with an average age of 38, of whom 11 (73%) were male and 4 (27%) worked full time. The cohort had a mixture of spinal injuries with 5, 7 and 4 fractures in the cervical, thoracic, and lumbar

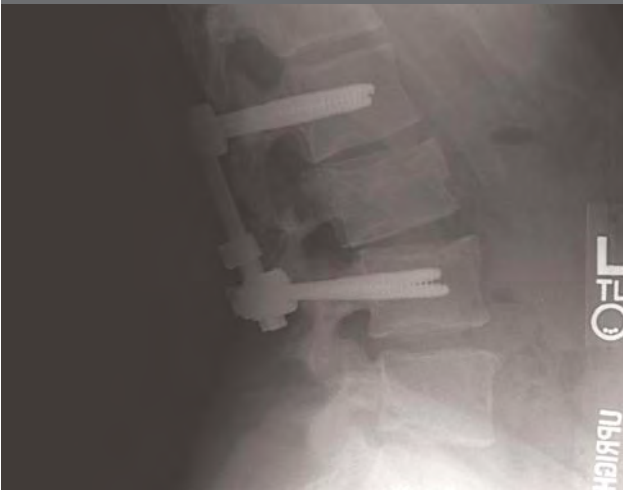


Graph 2. Physical Exam

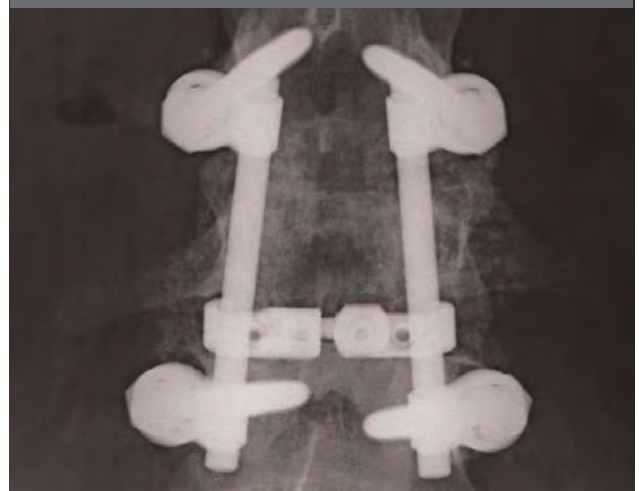


Graph 3. Function

Lateral X-ray at 3 months Post-op.



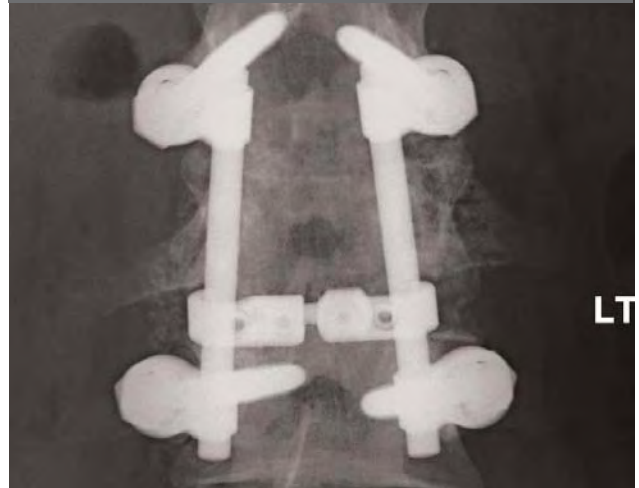
AP X-ray at 3 months Post-op



Lateral X-ray at 6 months Post-op



AP X-ray at 6 months Post-op



Lateral X-ray at 9 months Post-op.



AP X-ray at 9 months Post-op

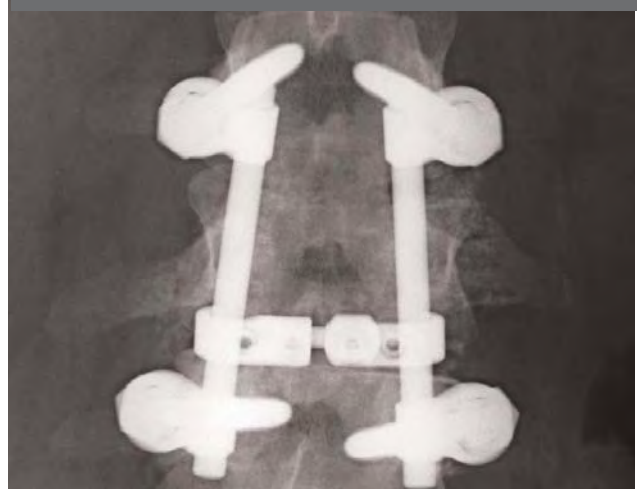


Figure 1. Lateral X-ray at 3, 6 and 9 months post-op.

Figure 2. AP X-ray at 3, 6 and 9 months post-op.

spine respectively. Nine patients (60%) presented with a burst fracture. There were relatively few comorbidities, 9 patients (60%) were nicotine free while the rest smoked less than 1 pack/day, and no patient was taking prior pain medication.

Surgery was at a single vertebral level in 20% of cases, at two levels in 53% of the cases, and at six to eight levels in the remaining 27% of operated cases, with 13% of patients requiring both an anterior and posterior approach (Table 2). All cases had implants, with some component of posterior fusion. An average of 36 ml of silicated calcium phosphate granules were implanted per patient. Intra-operative blood loss averaged 437 ml and there were no surgery-related complications.

The preoperative assessment revealed 100% had back pain and 100% had neck pain, (Graph 1) Pre-operative data was unavailable for 1 patient. Their disability status was quite high as a group, with 91% disabled or bedridden using a 5-stage scale (Graph 2). Neurological status was well preserved with 86% having normal reflexes and 79% being intact from a motor and sensory standpoint (Graph 3). There was no treatment prior to surgery for this group as these are not elective cases.

Thirteen patients (87%) returned for postoperative follow-up at an average of 3 months (Graphs 1-4). Fifty percent continued to have some degree of back pain and 60% had some element of neck pain. Forty-

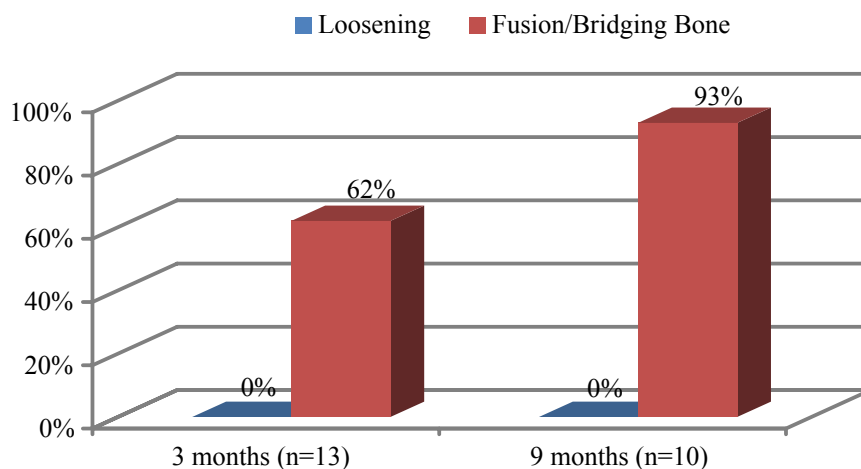
eight percent had some level of residual disability. All patients had normal reflexes, there were no motor deficits demonstrated and all patients believed the surgery was worthwhile. Twenty three percent of the patients required narcotics for analgesia.

At 9 months (n=10), the number of patients with some degree of back or neck pain had reduced to 33% and 50% respectively. Thirty four percent had some level of residual disability, a considerable reduction from the pre-operative level of 91%. All patients believed the surgery was worthwhile with only 20% still requiring narcotics for analgesia.

The imaging assessment by plain radiographs revealed 62% fusion/bridging bone at 3 months, increasing to 93% fusion/bridging bone at 9 months with no evidence of implant loosening (Graph 4). Figures 1 and 2 are representative plain radiographs showing postoperative progression of the fusion mass from 3 to 9 months.

### Discussion

It is unusual to present a consecutive series of spine trauma patients, all treated by the same surgeon using a single synthetic bone graft product. While much of this information is early due to the relative short-term follow-up of patients, there are some encouraging results. This cohort represents a wide range of significant injuries throughout the spine, many of



Graph 4. Fusion Rates

which required surgical intervention at multiple spinal levels. This is an interesting group to evaluate since fusion rates, with correspondingly poor outcomes, tend to worsen with additional levels fused. In addition, approximately 40% of the cohort were smokers, which is known to impede bone healing and subsequent fusion. Fortunately, there was a relative low incidence of neurological complications with the bony injury to the spine.

The preliminary nature of this report means we do not have long-term follow up in all patients. The early data show excellent return of neurological function and a minimal amount of residual pain. The results show a marked improvement in back pain with decreased disability and excellent fusion/bridging bone by 9 months. Radiographic imaging confirms no signs of implant loosening which would be evidence of a poor fusion mass.

The actual surgical procedures were not altered from a standpoint of approach and fixation method. The only new factor is the use of silicated calcium phosphate granules which, as previously discussed, provides a suitable alternative to autologous graft and is potentially superior to other types of allograft or synthetics.

## Conclusion

This study demonstrates good results with respect to pain, neurological status, function and work status in treating traumatic spine disorders. Radiographic imaging supports the clinical picture of solid fusion. The use of silicated calcium phosphate granules provided a good alternative to autologous graft and did not require any change to surgical technique in either approach or fixation method. For the future, we need to further characterize the fusion mass with other imaging modalities, and additional patients in this series will get flexion/extension radiographs and CT scans at their one-year follow up visits.

## References

- 1) Spivak, JM, Connolly PJ, Initial Evaluation and Management of Spinal Trauma: Orthopedic Knowledge Update. *Spine*. 2006 ; 3: 179-187.
- 2) Ferlic DC, Clayton ML, Leidholt JD, et al. Surgical treatment of the symptomatic unstable cervical spine in rheumatoid arthritis. *J Bone Joint Surg Am*. 1975; 57: 349-54.
- 3) Tiusanen H, Hurri H, Seitsalo S, Osterman K, Harju R. Functional and clinical results after anterior interbody lumbar fusion. *Eur Spine J*. 1996; 5(5): 288-92.
- 4) Boden SD. Overview of the biology of lumbar spine fusion and principles for selecting a bone graft substitute. *Spine*. 2002; 27: S26-31.
- 5) Sandhu HS. Anterior lumbar interbody fusion with osteoinductive growth factors. *Clin Orthopaedics & Related Res*. 2000; (371): 56-60.
- 6) Steinmann JC, Herkowitz HN. Pseudoarthrosis of the spine. *Clin Orthop*. 1992; 284: 80-90.
- 7) Eskander MS, Brooks DD, Ordway N, Dale E, Connolly PJ. Analysis of Pedicle and Translaminar Facet Fixation in a Multi-Segment Interbody Fusion Model. *Spine*. 2006; manuscript in press.
- 8) France JC, Yaszemski MJ, Laueran WC, et al. A randomized prospective study of posterolateral lumbar fusion: Outcomes with and without pedicle screw instrumentation. *Spine*. 1999; 24: 553-60.
- 9) Lane JM, Tomin E, Bostrom MP. Biosynthetic bone grafting. *Clin Orthopaedics & Related Res*. 1999; (367 Suppl): S107-17.
- 10) Kahn B. Superior gluteal artery laceration, a complication of iliac bone graft surgery. *Clin Orthop*. 1979; 140: 204-7.
- 11) Peterson B, Whang P, Iglesias R, Wang J, Lieberman J. Osteoinductivity of commercially available demineralized bone matrix: Preparations in a spine fusion model. *J Bone & Joint Surgery - American Volume*. 2004; 86-A(10): 2243-2250.
- 12) Carlisle EM. Silicon: a possible factor in bone calcification. *Science*. 1970; 167: 179-280
- 13) Gibson IR, Huang J et al. Enhanced in vitro cell activity and surface apatite layer formation on novel silicon-substituted hydroxyapatites. *Bioceramics* 1999; 12:191-194
- 14) Guth K, Buckland T, Hing KA. Silicon dissolution from microporous si-substituted HA and it's effect on osteoblast behaviour. *Bioceramics*. Kyoto 2005.
- 15) Xynos ID, Edgar AJ, Buttery LDK, Hench LL, Polak JM. Gene expression profiling of human osteoblasts following treatment with the ionic products of Bioglass 45S5 dissolution. *J Biomed Mater Res* 2001; 55(2): 151-7
- 16) Reffitt DM, Ogston, N, Jugdaohsingh, R, Cheung HF, Evans BA, Thompson RP, Powell JJ, Hampson, GN. Orthosilicic acid stimulates collagen type 1 synthesis and osteoblastic differentiation in human osteoblast-like cells in vitro. *Bone* 2003; 32(2): 127-35