

ONE YEAR RESULTS OF A PROSPECTIVE STUDY  
ASSESSING EFFICACY AND FUSION RATES OF A SILICATE  
SUBSTITUTED CALCIUM PHOSPHATE FOR ANTERIOR  
CERVICAL FUSION

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## Introduction

Autograft has been the standard for anterior cervical fusion but is associated with significant morbidity. Allograft can be complicated by issues such as cost, availability, and disease transmission. To overcome these obstacles, we assessed the use of a bone graft alternative, a silicate substituted calcium phosphate (Actifuse™, ApaTech Ltd., Elstree, UK) for patients undergoing one- and two-level anterior cervical fusions (ACF) for myelopathy and/or radiculopathy.

## Methods

A prospective, observational case-control study at one academic medical center was composed of 34 patients (10 smokers; 14 males, 20 females) who underwent standard ACF with Actifuse™, PEEK spacers, and anterior fixation. 15 patients had two-level fusion. 27 patients have had six month follow-up and 18 have had one-year follow-up. Patients were evaluated for pain, neurologic outcome, and fusion at baseline, 3-, 6-, 12-, and 24-month follow-up.

## Results

At six months post-op, 25 of 27 patients had significant improvement in upper extremity radiculopathy; two patients did not improve. All 27 (16 one-level, 11 two-level) had CT evidence of fusion at six months, with no movement on flexion-extension films. There were no surgical complications, and no patient was worse neurologically after surgery.

## Conclusions

Silicate-substituted calcium phosphate is a safe, efficacious alternative to allograft or autograft in selected patients undergoing one- or two-level ACF. Because further data is required to assess long-term outcomes in this population, these patients will continue to be followed post-operatively for 2 years.

## Case Histories

### Patient #1

#### Introduction

A 49 year old male non-smoker presented with neck and arm pain unresponsive to conservative treatment. The patient was unable to work. Clinical examination revealed neuropathy secondary to degenerative disc disease and disc herniation at C5-C7. Symptom evaluation revealed the Neck Disability Index (NDI) score was 24, the neck pain VAS score was 5 (scale of 1 to 10), and the arm pain VAS score was 6.5.

#### Surgical Treatment and Outcome

Anterior cervical discectomy and fusion was performed at C5-C7 using PEEK interbody cages packed with 5 cc of Actifuse silicate substituted synthetic bone graft granules. The construct was secured with a cervical plate and screws.

The patient's symptoms were significantly improved post-operatively and he returned to work 8 weeks after surgery. Fusion occurred by 3 months as demonstrated by lateral and flexion-extension x-rays.

#### 1 Year follow-up

Fusion was confirmed at 12 months by lateral and flexion-extension x-rays (Figure 1) and multiplanar CT. At 12 months follow-up the NDI Score decreased to 11, neck pain VAS to 1, and arm pain VAS to 0.

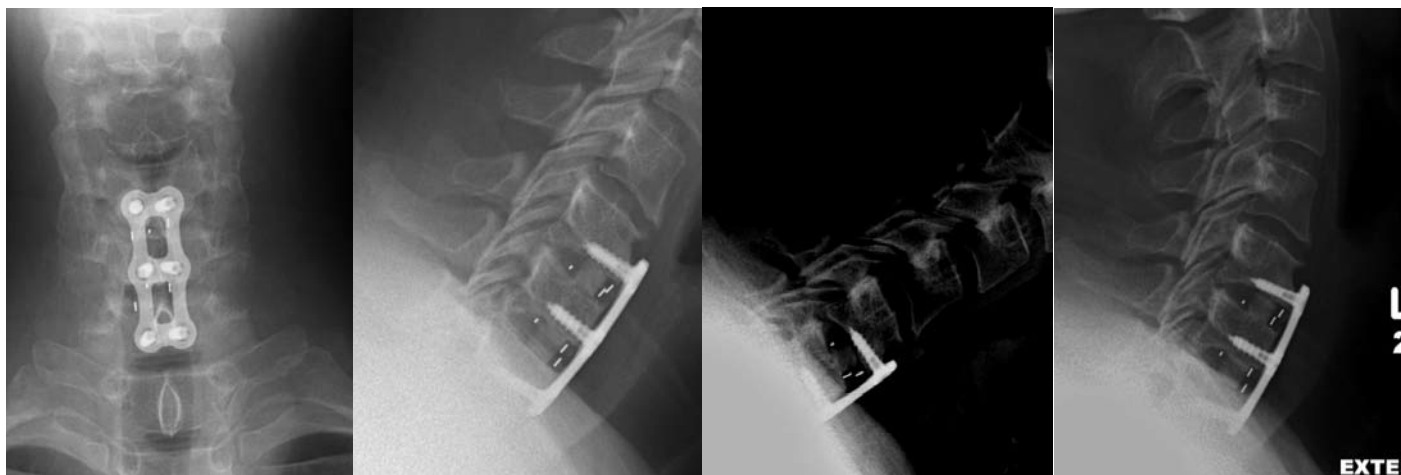


Figure 1. AP, Lateral, and Flexion-Extension x-rays at 12 month follow-up

## Patient #2

### Introduction

A 50 year-old male non-smoker presented with neck and arm pain unresponsive to conservative treatment. The patient was unable to work. Clinical examination revealed neuropathy secondary to degenerative disc disease and disc herniation at C5-C7. Symptom evaluation revealed the Neck Disability Index (NDI) score was 25, the neck pain VAS score was 5 (scale of 1 to 10), and the arm pain VAS score was 5.

### Surgical Treatment and Outcome

Anterior cervical discectomy and fusion was performed at C5-C7 using PEEK interbody cages packed with 5 cc of Actifuse silicate substituted synthetic bone graft granules.

The construct was secured with a cervical plate and screws. The patient's symptoms were significantly improved post-operatively and he returned to work 4 weeks after surgery. Fusion occurred by 6 months as demonstrated by lateral and flexion-extension x-rays.

### 1 Year follow-up

Fusion was confirmed at 12 months by lateral and flexion-extension x-rays (Figure 2) and multiplanar CT. At 12 months follow-up the NDI Score decreased to 10, neck pain VAS to 0, and arm pain VAS to 0.



Figure 2. AP, Lateral, and Flexion-Extension x-rays at 12 month follow-up

## Patient #3

### Introduction

A 37 year-old overweight (BMI 32) female one pack-a day smoker presented with severe neck and arm pain unresponsive to conservative treatment. The patient was retired. Clinical examination revealed neuropathy secondary to degenerative disc disease and disc herniation at C5-C6. Symptom evaluation revealed the Neck Disability Index (NDI) score was 29, the neck pain VAS score was 5 (scale of 1 to 10), and the arm pain VAS score was 4.

### Surgical Treatment and Outcome

Anterior cervical discectomy and fusion was performed at C5-C6 using a PEEK interbody cage packed with 5 cc of Actifuse silicate substituted synthetic bone graft granules. The construct was secured with a cervical plate and screws. The patient's symptoms were improved significantly post-operatively. Fusion occurred by 6 months as demonstrated by lateral and flexion-extension x-rays.

### 1 Year follow-up

Fusion was confirmed at 12 months by lateral and flexion-extension x-rays (Figure 3) and multiplanar CT. At 12 months follow-up the NDI Score decreased to 20, neck pain VAS to 0, and arm pain VAS to 0.



Figure 3. AP, Lateral, and Flexion-Extension x-rays at 12 month follow-up

