

CLINICAL EVALUATION OF SILICATE-SUBSTITUTED CALCIUM PHOSPHATE CERAMIC IN POSTEROLATERAL LUMBAR SPINAL FUSION AT ONE AND TWO YEARS

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Introduction

The “gold standard” autogenous cancellous bone graft from iliac crest harvest has been used to enhance the bone healing process in spinal fusion. There are disadvantages, however, to the procedure including added time to the procedure, blood loss, risk of infection, and nerve injury. Patients may also experience significant pain at the donor site of graft harvest, which frequently slows or delays their mobilization and increases their hospital length of stay and rehabilitation

Study Purpose

In recent years, natural and synthetic forms of calcium phosphate ceramics have been developed as alternative materials to autograft for bone repair and augmentation. This group of materials closely resembles the mineral composition, properties and microarchitecture of human cancellous bone and has a high affinity for binding proteins. Silicate substitution (0.8%) of phosphate (Si-CP) ceramics has been shown to have beneficial effects on osteoblast proliferation and bone formation. **The goal of this study is to evaluate Si-CP (Actifuse™ Synthetic Bone Graft, Apatech, Elstree, UK) as a bone graft substitute (BGS) in instrumented posterolateral lumbar fusion (PLF).**

Methods

Forty-two patients (average age 67.8+/-8.2; range 48-80; 29 females/13 males) were evaluated in a prospective nonrandomized series. 27 single level and 15 two level surgeries were performed (57 total levels). IRB approval was obtained for data review. Surgical indications included one or two-level lumbar degenerative disc disease and / or spondylolisthesis with spinal stenosis.

Si-CP (10 cc/ level) was combined in a 50:50 mixture with 10cc of iliac crest bone marrow aspirate and implanted as a graft substitute (**no local or harvested iliac crest graft was added to the composite**).

Results

Thirty six (36) patients have completed 12 month and 29 patients completed 24 months follow up. No infections, nerve injuries, morbidity related to iliac crest aspiration or reaction to Si-CP were noted. Fusion rate (for all levels) was 30.9% at 6 months, 77.7% at 12 months, and 75.9% at 24 months. Ten radiographic nonunion were noted at one year but none required revision surgery. Clinical outcomes revealed reduction in both back and leg pain by 64% and 79%, respectively.

Discussion

Silicate has been identified at trace levels in immature bone and it has been suggested to play a significant metabolic role in new bone formation. In its soluble form, silicate has been demonstrated to up-regulate collagen synthesis when maintained within physiological levels and to up-regulate osteoblast metabolism and differentiation *in vitro*.

Conclusions

The results suggest that clinical outcomes of a silicate-substituted ceramic BGS including pain relief and functional improvement are well-within established results for these procedures. Radiographic outcomes based on CT interpretation of posterolateral fusion are comparable to the published literature and an acceptable arthrodesis rate is achieved. The findings from this investigation confirm that Si-CP is an acceptable means of establishing posterolateral lumbar fusion when combined with BMA and avoiding iliac crest harvest.

