

Silicon Matrix Calcium Phosphate as a Bone Substitute: Early Clinical and Radiological Results in a Prospective Study With 12-Month Follow-up

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ABSTRACT

Introduction

Autograft has been the “gold standard” for orthopedic bone grafting applications, but with some clinical challenges. Here we present the rationale and clinical outcomes supporting the use of a bone substitute material that consists of a mixture of two calcium phosphates (HA and β -TCP), which are integrated into a silicon xerogel matrix, promoting nanocrystalline apatite layers on the surface of the material following implantation into a physiological environment.

Methods

Twenty-four patients with a median age of 53.80 (36–81) years underwent lumbar spinal fusion for degenerative disease, selected by clinical presentation, X-rays, and MRI findings. Subjects were evaluated preoperatively and postoperatively at 1, 3, 6, and 12 months. The outcome assessment consisted of visual analog scale (VAS), Oswestry Disability Index (ODI), and radiological assessment analyzing the state of fusion on X-ray and CT evaluation by 3 independent radiologists.

Results

All patients completed 12-month follow-up. The mean VAS decreased from 9.3 (\pm 0.9) to 2.4 (\pm 1.6) and the mean ODI decreased from 55.0 (\pm 9.2) to 19.3 (\pm 11.4) at 12-month follow-up. Three months after surgery, 10 patients (41.67%)

had solid fusion based on analysis of CT scans and dynamic radiographs. At 6 months postoperatively, the fusion rate had increased to 75% (18 patients). Twelve months after surgery, 95.83% of patients had solid fusion (23 patients).

Conclusions

The clinical results from this study of silicon matrix calcium phosphate are consistent with previous in vitro studies indicating that this material stimulates formation of a bioactive layer and provides an effective bone graft material for lumbar fusion applications. In comparison with previous studies involving rhBMP-2, silicon matrix calcium phosphate provided a lower fusion rate at 3- and 6-month follow-up points, but after 12 months, the fusion rate was similar, with no statistical differences and lower overall costs. No clinically relevant adverse events were associated with either the cage or graft material. With increasing evidence of high rates of enhanced fusion development in this spinal application, additional research is encouraged, including longer periods of follow-up, to further confirm the efficacy of silicon matrix calcium phosphate as a safe and effective bone graft substitute.

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