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Silicate-Substituted Calcium Phosphate Ceramic Bone Graft Replacement for Spinal Fusion Procedures

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Study Design. Retrospective study.

Objective. To assess the clinical and radiographical outcomes in spinal fusion procedures using silicate-substituted calcium phosphate (Si-CaP).

Summary Of Background Data. Si-CaP is a newer-generation synthetic ceramic designed to maximize osteoinduction and osteoconduction.

Methods. This is a retrospective analysis of a prospectively collected patient database including 108 patients (204 individual spinal levels). Different surgical procedures performed included 25 anterior cervical discectomy and fusions, 17 posterior cervical fusions, 7 combined anterior and posterior cervical fusions, 10 thoracic fusion surgeries, 18 transforaminal lumbar interbody fusions with 12 axial lumbar interbody fusions, 11 transpsoas discectomy and fusions, and 8 combined thoracolumbar fusion procedures. Si-CaP was used as bone extender without any additional graft material, bone marrow aspirate, or bone morphogenetic protein. Clinical outcomes were assessed using the visual analogue scale (VAS), Oswestry Disability Index, and Neck Disability Index. Fusion was determined by the presence of bony bridging on 2 consecutive sections in at least 2 planes on computed tomographic imaging.

Results. At a follow-up of 12 (±4.7) months, 90% of all patients demonstrated radiographical fusion. Fusion rates were highest in the cervical spine (97%) followed by thoracic and lumbar spines (86% and 81%, respectively). There were significant improvements in all clinical outcome measures—Oswestry Disability Index, 11.1 (±10.2) and Neck Disability Index, 9.0 (±11.4); VAS-back, 3.1(±3.0); VAS-leg, 3.5 (±3.6); VAS-neck, 3.7 (±2.5); and VAS-arm 4.0 (±3.2). There was no radiographical loosening of instrumentation due to infection or nonunion in this series, and no subsequent revisions for nonunion were required.

Conclusion. Si-CaP is an alternative to autogenous bone graft in spinal arthrodesis procedures. At 12-month follow-up, we detected high levels of bony fusion using Si-CaP in combination with various surgical spinal techniques.

Key words: silicate-substituted calcium phosphate; bone graft substitute, ceramic, spine, spinal, fusion, surgery. **Spine 2012;37:E1264–E1272**

Spinal disorders such as degenerative scoliosis, degenerative spondylolisthesis, trauma, and oncological diseases will frequently be treated with operative interventions requiring instrumentation and fusion once nonoperative treatment has failed.

Autogenous bone, commonly obtained from the iliac crest, constitutes the ideal graft and currently represents the "gold standard" for spinal fusion procedures. The cortical component provides initial mechanical stability, and the cancellous component provides excellent osteoinductive and osteoconductive properties. However, the amount of iliac crest bone available is limited, and its harvesting is associated with increased operative times and with significant donor site morbidity.[1,2] Thus, there is a need for an alternative bone graft material, and several types are currently used: allograft, demineralized bone matrix, and various ceramics. Allograft circumvents the need for intraoperative bone harvest and exhibits good osteoconductive properties but is associated with poor osteoinductive qualities as well as the risk of disease transmission.[3–5]

These limitations have prompted the development of novel synthetic biomaterials. Ceramics have been considered in particular because of their biocompatibility and microscopic structure, which seems similar to normal bone.[6,7] Multiple configurations of ceramics have been investigated for spinal

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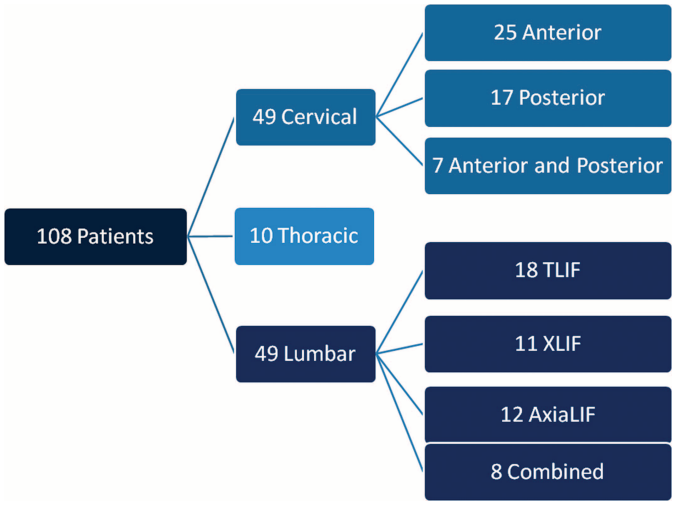

Figure 1. Surgical procedures by spinal level. TLIF, transforaminal lumbar interbody fusion; XLIF, extreme lateral interbody fusion; AxiaLIF, axial lumbar interbody fusion.

fusion. Ceramics that are currently in clinical use are primarily based on calcium phosphate salts. The reported fusion-promoting properties of these ceramics have been inconsistent and variable, reflecting their individual chemical and physical properties[8–12] and the variability in the previous study designs. A newer generation of ceramics has been formulated in which a partial substitution of phosphate by silicate has been performed in a controlled manner, typically 0.8% weight. The potential advantages with substituted silicate include a superior biocompatibility, nonimmunogenity, and osteoconductivity.[13–15] Silicate is a nonmetallic ion that has previously been shown *in vitro*[16–19] and *in vivo*[20–22] studies to have a role in bone metabolism. Silicate-Substituted Calcium Phosphate (Si-CaP) exhibits an increased *in vivo* reabsorption rate compared with traditional hydroxyapatite (HA) ceramics.[23,24] The development of the mineralized skeleton and the upregulation of osteoblastic cells are associated with the presence of silicon,[25] and its absence has been linked to an abnormal osteoid development.[26]

The aim of this study was to evaluate the fusion rate and clinical outcome in spinal fusion procedures using silicate-substituted calcium phosphate.

METHODS AND MATERIALS

Patient Population

We retrospectively analyzed our prospectively collected institutional database and identified all consecutive patients with spinal fusion procedures performed using Si-CaP (Actifuse, Baxter, Deerfield, IL). Cases were excluded when any other bone extenders were used in addition to Si-CaP. All spinal regions were represented in this series. Surgeries were performed at our hospital between August 2007 and March 2010. There were 108 patients comprising 51 men and 57 women, with a mean age of 59.9 (±16 SD) years. Patient demographics are detailed in Figure 1. The indications for surgery were degenerative disease (73%), trauma (16%), metastatic disease (4%), and other (6%). The number of patients and procedures are detailed in Table 1. Of the 17 posterior cervical cases, 1 was an occipitocervical fusion. Institutional research board approval was granted. All patients provided informed consent for data collection regarding their treatment and outcomes.

Patient Assessment

Demographic data included patient age, sex, preoperative diagnosis, number of involved levels, and smoking and medical comorbidities. Intraoperative data and postoperative complications were recorded. The patients were followed clinically on the basis of a previously defined protocol up to 1 year after surgery or longer if necessary. The Oswestry Disability Index, Neck Disability Index, and visual analogue scale (VAS) scores were collected preoperatively and postoperatively at 1, 6, 12 weeks, and 6 and 12 months.

TABLE 1. Number of Cases and Levels by Anatomical Region and Approach

	Cervical		Thoracic		Lumbar	
	Number	No. Fused (%)	Number	No. Fused (%)	Number	No. Fused (%)
Anterior						
Patients	25	24 (96)	…	…	2	2 (100)
Levels	49	47 (96)	…	…	4	4 (100)
Posterior						
Patients	17	16 (94)	…	…	…	…
Levels	42	41 (98)	…	…	…	…
Anterior and posterior						
Patients	7	7 (100)	10	8 (80)	47*	36* (76)
Levels	15	15 (100)	14	12 (86)	80*	64* (80)

**Includes lumbar with thoracic extension.*

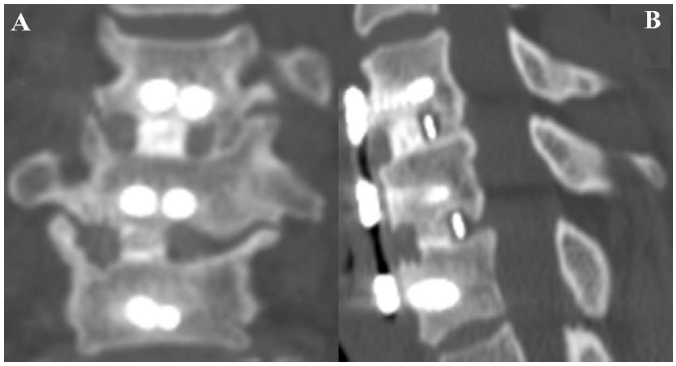

Figure 2. Example of anterior cervical discectomy and fusion. **(A** and **B)** Coronal and sagittal computed tomographic scans of a 51-year-old woman, 20 months after the procedure.

A board-certified neuroradiologist performed the fusion assessment using computed tomographic (CT) scans. On the basis of our protocol, this scan was scheduled for 1 year after surgery; however, the actual time varied from patient to patient. Plain radiographs were only obtained as clinically needed. Confirmation of fusion required the presence of bridging bone with consolidation on at least 2 contiguous sections in 2 or 3 planes (axial, sagittal, or coronal)[27] (Figure 2).

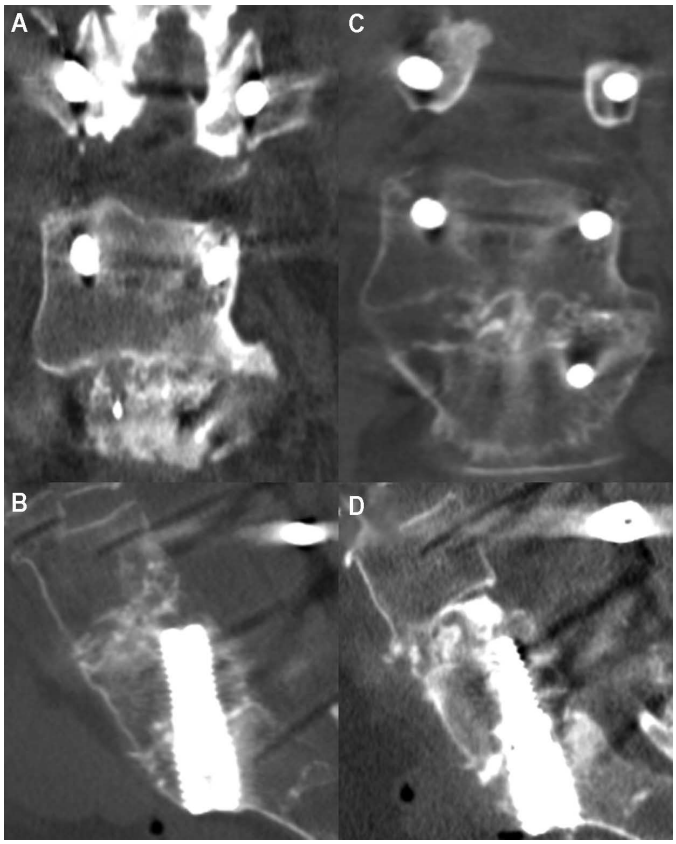

Figure 3. Example of transforaminal lumbar interbody fusion (at L4–L5 level). **(A** and **B)** Coronal and sagittal computed tomographic (CT) scans of a 71-year-old woman, immediate postoperation. **(C** and **D)** Coronal and sagittal CT scans of the same patient, 1 year after the procedure.

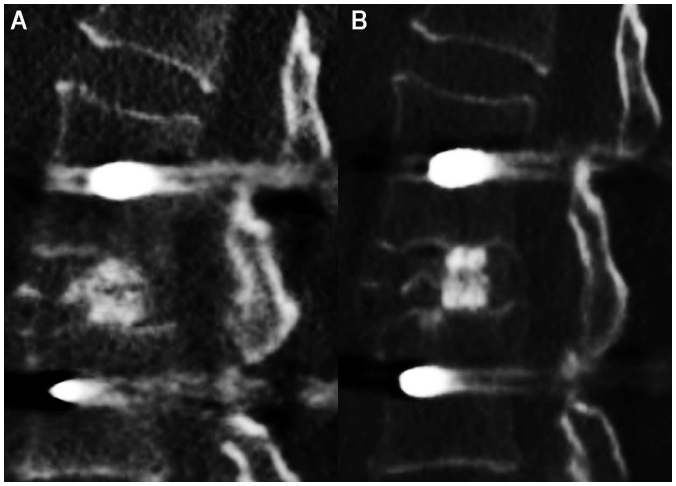

Figure 4. Example of extreme lateral interbody fusion. **(A)** Sagittal computed tomographic (CT) scan of a 52-year-old woman, immediate postoperation. **(B)** Sagittal CT scan of the same patient, 2 years after the procedure.

Surgical Technique

During interbody fusion, the endplates were carefully prepared before the placement of graft material. For a posterolateral fusion, the posterior bony elements were decorticated before the placement of the graft material, and implant insertion was performed using a standard technique. In all of these cases, Si-CaP was used alone as graft material without local bone or bone marrow aspirate (BMA).

Axial Lumbar Interbody Fusion

The standard paracoccygeal percutaneous approach to the presacral space was used. A drill was used to enter the sacrum and advanced into the L5 vertebra.[28] Discectomy was performed in the standard fashion using angled loops, and the disc space filled with up to 10 mL of Si-CaP prior to axial lumbar interbody fusion (AxiaLIF) screw insertion (Trans1, Wilmington, NC). Posterior fixation was added in all cases.

Transforaminal Lumbar Interbody Fusion

We performed a standard minimally invasive microsurgical approach with tubular retractors involving facetectomy, discectomy, and endplate preparation. A polyetheretherketone interbody spacer filled with graft material was inserted. The remaining disc space was filled with graft material, using the Actifuse MIS gun. Posterolateral fusion was performed in open cases (Figure 3).

Transpsoas Discectomy and Fusion

A lateral microsurgical transpsoas approach was performed as described by Ozgur *et al*,[29] using the MaXcess system (NuVasive Inc., San Diego, CA). Discectomy and subsequent endplate preparation were followed by implantation of a Si-CaP–filled polyetheretherketone cage. Most cases underwent supplementary stabilization with posterior instrumentation (Figure 4).

TABLE 2. Patient Demographics. Overall and by Fusion Outcome

Measure	Value	Fused	Nonfused
Age, mean ± SD (yr)	59.9 ±16.0	56.7 ± 16.3	58.5 ± 14.2
Male:female	51:57	93 (86%)	15 (14%)
Body mass index	28.1	28.3	26.4
Pathology			
Degenerative	79	69 (87%)	10 (13%)
Tumor	5	3 (60%)	2 (40%)
Trauma	17	15 (88%)	2 (12%)
Other	7	6 (86%)	1 (14%)
Smoker			
Yes	12 (11%)	9 (75%)	3 (25%)

Posterior Cervical Fusion

Posterior cervical exposure and laminectomy were performed in the standard fashion. A posterolateral fusion was performed using Si-CaP.

Anterior Cervical Discectomy and Fusion

A microsurgical right-sided Smith-Robinson approach to the appropriate level[30] with removal of the pathological intervertebral disc and endplates preparation in the usual fashion was followed by insertion of a Si-CaP–filled polyetheretherketone cage. Anterior instrumentation was used in all cases.

Statistical Analysis

Descriptive statistics was used for continuous variables such as patient demographics and continuous data. Preoperative and follow-up clinical outcomes were compared using the Wilcoxon signed-rank test. Clinical outcomes between nonfused and fused patients were analyzed using the Mann-Whitney *U* test. Significance was determined to be 0.05 or less. All statistical analyses were performed in SPSS (PASW) Version 18.0 (SPSS Inc., Chicago, IL).

RESULTS

This study included 108 patients (Table 2). The surgical levels, procedures, and fusion results are detailed in Table 3. All values are given in mean (±SD). The average radiological follow-up was 12 (±4.7) months (range, 8–28 mo) whereas the average clinical follow-up was 11.8 (±5.6) months (range, 7–26 mo).

Radiological Evaluation

Fusion rates were determined for both patients and independent levels, as detailed in Tables 1 and 3.

For cervical surgery, 96% of patients (47 of 49) and 97% of levels (103 of 106) fused. Cervical nonfusion occurred in a single-level posterior surgery and in an anterior 3-level approach. For thoracic procedures, 80% of patients (8 of

TABLE 3. Fusion Outcomes at a Mean Follow-up of 12 (±4.7) Months

Procedure	Patients	Levels Treated	Levels Fused (%)
Lumbar			
TLIF			
1-level	13	13	10 (77)
2-level	5	10	10 (100)
Total	18	23	20 (87)
TLIF combined procedures	6	6	6 (100)
Combined total	24	29	26 (89)
XLIF			
1-level standalone	1	1	1 (100)
3-level standalone	1	3	3 (100)
1-level	2	2	2 (100)
2-level	2	4	4 (100)
3-level	4	12	8 (67)
4-level	1	4	4 (100)
Total	11	26	22 (85)
XLIF combined procedures	4	5	4 (80)
Combined total	15	31	26 (84)
AxiaLIF			
1-level	9	9	7(78)
2-level	3	6	4 (67)
Total	12	15	11 (73)
AxiaLIF combined procedures	5	6	2 (33)
Combined total	17	21	13 (62)
Combined procedures			
TLIF and AxiaLIF 1-level	3	6	5 (83)
TLIF and AxiaLIF 2-level	1	2	1 (50)
TLIF and XLIF	2	4	4 (100)
XLIF and AxiaLIF	1	2	0 (0)
XLIF and thoracic PLF	1	5	5 (100)
Total	8	20	15 (75)
Thoracic			
1-level	9	9	7 (78)
5-level	1	5	5 (100)
Total	10	14	12 (86)
Cervical			

(*Continued*)

TABLE 3. (*Continued*)

Procedure	Patients	Levels Treated	Levels Fused (%)
Anterior only			
1-level	8	8	8 (100)
2-level	12	24	24 (100)
3-level	3	9	7 (78)
4-level	2	8	8 (100)
Total	25	49	47 (96)
Anterior and posterior			
1-level	3	3	3 (100)
2-level	1	2	2 (100)
3-level	2	6	6 (100)
4-level	1	4	4 (100)
Total	7	15	15 (100)
Posterior only			
1-level	8	8	7 (87)
2-level	1	2	2 (100)
3-level	3	9	9 (100)
4-level (1 patient to T2)	3	12	9 (75)
5-level	1	5	5 (100)
6-level	1	6	6 (100)
Total	17	42	41 (98)
All levels combined			
Total	108	204	183 (90)
Excluding AxiaLIF	91	178	166 (93)

TLIF indicates transforaminal lumbar interbody fusion; XLIF, extreme lateral interbody fusion; AxiaLIF, axial lumbar interbody fusion; PLF, posterior lumbar interbody fusion.

10) and 86% of levels (12 of 14) fused. Thoracic nonfusion occurred in 2 patients who each underwent a single-level posterior fusion surgery. In lumbar procedures, 77% of patients (38 of 49) and 81% of levels (68 of 84) fused. Lumbar nonfusions occurred in 3 single-level transforaminal lumbar interbody fusion (TLIF) surgeries, two 3-level transpsoas discectomy and fusion surgeries (each fused at 2 levels), 2 single-level AxiaLIF surgeries, a 2-level AxiaLIF case, a combined transpsoas discectomy and fusion and AxiaLIF (both single-level) surgery, a combined TLIF and AxiaLIF (both single-level) surgery, and in a combined single-level TLIF and 2-level AxiaLIF surgery.

The overall combined fusion rate was 86% of patients (93 of 108) and 90% of levels (183 of 204). When the data underwent secondary analysis excluding any surgeries involving AxiaLIF (Figure 5), the overall fusion rate was 92% of patients (84 of 91) and 93% of levels (166 of 178).

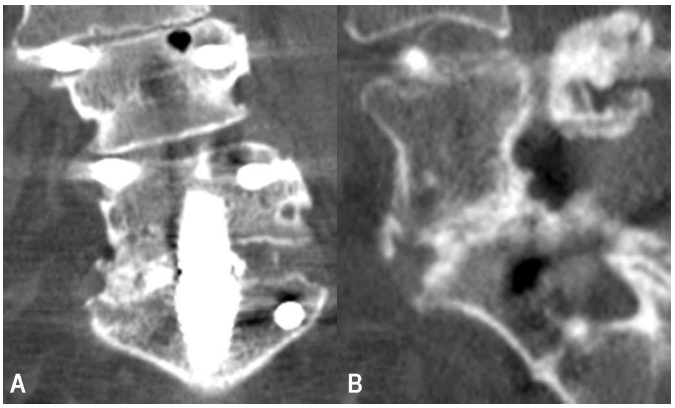

Figure 5. Example of axial lumbar interbody fusion. **(A** and **B)** Coronal and sagittal computed tomographic scans of a 72-year-old woman, 1 year after the procedure.

Clinical Evaluation

The clinical outcomes at a mean follow-up of 11.8 (±5.6) months are detailed in Table 4. Postoperatively, there was a significant improvement in Neck Disability Index and VAS scores for neck and arm pain with cervical surgery. Lumbar surgery was associated with a significant improvement in the Oswestry Disability Index and VAS back and leg scores. There were no statistically significant differences between the clinical outcomes of fused and nonfused patients, except in the Oswestry Disability Index for thoracic surgeries and the VAS arm score for cervical surgeries, both of which contained small numbers (Table 5).

COMPLICATIONS

There were 5 superficial surgical site infections—2 for TLIF procedures, 2 for AxiaLIF procedures, and 1 for a single combined case of anterior and posterior cervical surgery. All were successfully treated with antibiotics, and further surgery was not required. Two patients with an anterior cervical approach experienced persistent dysphagia at the mean follow-up of 12 months. In those 47 patients who had undergone lumbar surgery, 1 patient presented with deep vein thrombosis and 3 patients experienced pulmonary embolus. Four patients underwent further surgical procedures—1 revision laminectomy for a recurrent herniation, 1 revision laminectomy for a case of postlaminectomy syndrome, 1 patient who required revision and extension of posterior fixation for pedicle screw failure, and a pedicle screw revision for a misplaced screw without neurological deficit. There was no gross loosening of instrumentation due to infection or nonunion in this series, and no subsequent surgeries for nonunion were required.

DISCUSSION

Approximately 60% of the commercially available bone graft substitutes are ceramics,[31] primarily calcium sulfate, bioactive glass, or calcium phosphate. The use of ceramics based on calcium phosphates is driven in part by the fact that the primary inorganic component of bone is calcium HA, which is a subset of the calcium phosphate group. In addition, calcium

TABLE 4. Clinical Outcome Scores at a Mean Follow-up of 11.8 (±5.6) Months

	Preoperation	Postoperation	Improvement*	*P*
Cervical				
NDI	22.5	13.7	**8.8**	<0.001
VAS neck	7.3	3.0	**4.3**	<0.001
VAS arm	6.7	2.8	**3.9**	<0.001
Thoracic				
ODI	25.6	12.5	**13.1**	0.012
VAS back	6.5	3.4	**3.1**	0.097
Lumbar				
ODI	22.5	11.5	**11**	<0.001
VAS back	7	3.8	**3.1**	<0.001
VAS leg	6.3	2.8	**3.4**	<0.001

**Change in preoperative to postoperative scores. ODI and NDI (100 points), VAS (10 points).*

NDI indicates Neck Disability Index; VAS, visual analogue scale; ODI, Oswestry Disability Index.

phosphates are osteoconductive, osteointegrative, and, in some cases, osteoinductive.[31] In this study, we have focused on Si-CaP. The presence of silicate in the ceramic increases the negative surface charge, and it is hypothesized that this attracts more osteoblasts to the surface of the material,[32] rendering it osteoinductive.

Implantation of Si-CaP in the femoral intercondylar notch of a rabbit model demonstrated earlier promotion of bone growth than non–silicate–substituted HA.[33] Silicon level of 0.8% weight resulted in a significantly higher bone ingrowth at 3 and 6 weeks than silicon level of 0%, 0.2%, 0.4%, and 1.5% weight. Also, in an ovine model with a distal femoral epiphysial critical defect, Si-CaP implants with higher porosity resulted in earlier neovascularization and higher absolute volume of bone growth than implants with lower porosity.[34] *In vitro* studies suggested higher bone absorption and cell attachment in Si-CaP than HA; it was mostly mediated by specific biochemical features of the protein layer developed at the interface of the graft and the bone. These biochemical features are the negative surface charge, the nature of the ionic species at the interface, and the resultant hydrophilicity of the surface.[35,36] We use Si-CaP without any local bone or BMA, because this graft material has been shown to result in successful fusion in our experience. Recent *in vitro* studies suggested that Si-CaP is capable of differentiating stem/progenitor cells into functional osteoblasts without addition of known soluble osteogenic factors.[37] In addition, the use of Si-CaP alone eliminates the additional time required for local bone harvesting. Other articles have assessed silica-containing graft materials and have noted a similar cellular response and bone regenerative capabilities.[20,38]

TABLE 5. Comparison Data for Fused and Nonfused Patients

	Fusion	Nonunion	*P*
No. of patients	93	15	
Average age	56.7 ± 16.3	58.4 ± 14.2	0.842
Cervical			
No. of patients	47	2	
Change in NDI	8.3 ± 10.7	25 ± 19.7	0.186
Change in VAS neck	3.7 ± 2.6	4.0 ± 0.7	0.935
Change in VAS arm	4.1 ± 3.2	1.0 ± 1.4	0.103
Thoracic			
No. of patients	8	2	
Change in ODI	12.7 ± 13	4.5 ± 3.5	0.103
Change in VAS back	3.1 ± 5.2	1.0 ± 1.4	0.478
Lumbar			
No. of patients	38	110	
Change in ODI	11 ± 10.1	11.8 ± 14.6	0.820
Change in VAS back	3.4 ± 3.1	2.1 ± 3.1	0.277
Change in VAS leg	4.0 ± 3.4	2.6 ± 3.6	0.248

The values indicate mean ± SD.

NDI indicates Neck Disability Index; VAS, visual analogue scale; ODI, Oswestry Disability Index.

Determination and Definition of Fusion

Bony bridging on CT scans combined with a lack of significant motion between segments on lateral flexion-extension views is highly suggestive of a solid fusion.[39] However, some degree of motion between segments may be present even when the spine has fused, dependent on measurement technique.

There is no consensus on the amount of motion allowable to be indicative of fusion. The assessment of fusion with the presence of instrumentation has also not been adequately explored.[39]

The radiographical methodology used to determine the presence or absence of a fusion has changed with time and the improvements of imaging modalities. Previous studies showed that there is very little agreement (68%) when comparing a radiographical assessment of fusion and the surgical findings at exploration.[40,41] In 1989, a retrospective review of 20 patients who underwent CT scanning prior to surgical exploration found only an 80% correlation between the CT study–based diagnosis of fusion and the intraoperative diagnosis of fusion.[42] Since the publication of these earlier studies, CT imaging technology has advanced. The use of thin-section axial sequences, improved resolution, and multiplanar imaging capability has enhanced the ability of CT scanning to assess lumbar fusion. Using fine-cut CT scans to evaluate the status of the fusion is more reliable and accurate, with an 89% agreement with surgical assessment in a 2007 study.[27,43] Accurate assessment is of clinical importance because the lack of fusion between vertebrae may eventually lead to mechanical failure of the internal fixation. Currently, there is insufficient evidence in the literature regarding long-term outcomes to correlate nonunion or the presence of a pseudarthrosis with decreased clinical outcomes, which may be due to insufficient power or medium term-data in previous studies.

The variety of pathologies treated in this study reflects the spectrum of surgeries undertaken in a spinal practice, and in our opinion, it is the strength of this study. We use Si-CaP

TABLE 6. Fusion Rates From the Literature Using Ceramics as Bone Extenders

Author	Year	No. Patients	Indications for Surgery	Graft Material	Type of Surgery	Assessment of Fusion	Follow-up (mo)	Fusion Rate (%)
Cervical								
Cosar *et al*[46]	2008	17	Degenerative	Beta-TCP-coated hydroxyapatite	ACDF	X-ray-flexion and extension	20	94.1
Chou *et al*[47]	2008	9	Trauma, spondylosis, OPLL, and herniation	Biphasic calcium phosphate ceramic	ACDF	X-ray-flexion and extension	12	100
Chang *et al*[48]	2009	22	Degenerative	Hydroxyapatite graft	ACDF	X-ray-flexion and extension	12	98.2
Khoueir *et al*[49]	2007	66	Neural compression	Collagen-hydroxyapatite matrix with bone marrow aspirate	ACDF	X-ray-flexion and extension	18	97
Bruneau *et al*[50]	2001	54	Herniation and spondylosis	Hydroxyapatite graft	ACDF	X-ray-flexion and extension	25	99
Mastronardi *et al*[51]	2006	36	Degenerative	Coralline hydroxyapatite	ACDF	X-ray-flexion and extension	12	100
Tian *et al*[52]	2000	18	Spinal stenosis	Coralline hydroxyapatite	Posterior fusion	X-ray-flexion and extension	26	70.9
Thalgott *et al*[53]	1999	26	Stenosis and herniation	Coralline hydroxyapatite	ACDF	X-ray-flexion and extension	30	100
Lumbar								
Carter *et al*[45]	2008	20	Degenerative	Collagen-hydroxyapatite sponge with bone marrow aspirate	TLIF	CT scans and X-ray-flexion and extension	24	91
Jenis and Banco[44]	2010	42	Degenerative	Si-CaP + BMA	Postero-lateral	CT scans	24	76.5
This study								
Nagineni *et al*	2011	108	Degenerative, trauma, metastatic and other	Si-CaP		CT scans	12	90

TCP indicates tricalcium phosphate; ACDF, anterior cervical discectomy and fusion; OPLL, ossification of posterior longitudinal ligament; TLIF, transforaminal lumbar interbody fusion; CT, computed tomographic; Si-CaP, silicate-substituted calcium phosphate; BMA, bone marrow aspirate.

ceramic in its manufactured form and have found that it to be easy to use and versatile, allowing direct application (manually or *via* an MIS Actifuse system in TLIF cases). Overall fusion rates were 90%, and when secondary analysis excluded the AxiaLIF cases, the fusion rate increased to 93%. We have insufficient data to determine whether the lower fusion rate with AxiaLIF was related to the specific biomechanical characteristics of the device—the silicated-substituted calcium phosphate or a combination of factors in this subset of cases using this procedure. We have amended our surgical approach in such cases; we now include bone morphogenetic protein and undertake only single-level fixations in an effort to improve the radiographical outcomes.

The fusion rate in this study was compared with other ceramic bone grafting studies (Table 6). A literature search was performed using the PubMed Database on April 22, 2011. The search strategy used the MeSH terms "spine," "spinal fusion," and the text words "ceramic," "hydroxyapatite," and "calcium phosphate"; these were then limited to human studies and the abstracts were reviewed for suitability as comparison studies.

Our fusion rate is similar to previous studies (Table 6) when comparing cervical and lumbar fusion procedure. However, the assessment criteria for fusion used in our study are more stringent than the ones used by other authors. We looked for bridging bone on 3-dimensional reconstruction in biplanar CT scan, which is more difficult to achieve than lack of motion on radiographs. Considering lumbar fusion procedures, the 2 previous studies[44,45] which used CT assessment demonstrated a fusion rate of 76% and 91% at 2 years. In both of these studies, the ceramic bone graft substitute was used in combination with BMA. The only other study using Si-CaP did this in lumbar surgeries for instrumented posterolateral fusion and observed a fusion rate of approximately 76% at 1 and 2 years. This relatively low fusion rate may be related to the lack of interbody fusion in their patients. Clinically, however, they found good results. Their study cannot be compared with ours because we used Si-CaP without BMA and always performed an interbody fusion.

Limitations

This study has limitations in common with all retrospective analysis, despite prospective data collection and a fusion analysis by an independent assessor. The follow-up is limited to 1 year; however, even at this end point, we are able to describe a successful fusion rate by stringent criteria. The fusion rates that have previously been reported are comparable in general. The previous studies have often used less stringent criteria, which may reflect an improved comparable fusion rate with the use of Si-CaP.

CONCLUSION

Si-CaP is a successful bone graft substitute for spinal surgery throughout the cervical, thoracic, and lumbar spines and in various surgical approaches, with an overall fusion rate of 90% of levels at a mean follow-up of 12 months. We observed no specific graft-related complications. We think that the successful application of this material as a viable bone graft substitute has been demonstrated.

➢ Key Points

- ❑ Silicate-substituted calcium phosphate is a new generation ceramic bone graft substitute.
- ❑ This is a retrospective case series of spinal fusion surgeries.
- ❑ Good fusion rates of 90% were demonstrated at a mean 12-month follow-up.
- ❑ No revision surgeries for nonunion were required.

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