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*ORIGINAL STUDY*

# Vertebral body reconstruction with injectable hydroxyapatite cement for the management of unstable thoracolumbar burst fractures : A preliminary report

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**The aim of this prospective study was to evaluate the efficacy of an injectable hydroxyapatite cement in combination with long posterior transpedicular instrumentation, without fusion, for the treatment of unstable thoracolumbar burst fractures. Ten patients with this type of fracture were treated in the period 1999-2000 with bisegmental posterior transpedicular stabilisation above and below the fracture site, indirect reduction of the fracture, and transpedicular injection of hydroxyapatite cement into the fractured vertebral body. Postoperatively the mean Cobb kyphotic deformity angle (CKDA) and vertebral compression index (VCI) were statistically improved ($p < 0.001$). Both variables deteriorated slightly between surgery and follow-up after +/- 39 months ; this was statistically not significant for the CKDA ($p > 0.05$), but significant for the VCI ($p < 0.001$). These data suggest that hydroxyapatite cement can be a reliable way to reinforce the fractured vertebral body in the thoracolumbar region.**

**Keywords** : thoracolumbar spine ; burst fracture ; hydroxyapatite cement ; reconstruction.

## INTRODUCTION

Vertebral body reconstitution is a significant factor for the long-term efficacy of spinal fracture treatment. Thoracolumbar burst fractures entail loss of vertebral height, posterior wall displacement into the canal, and increase in interpedicular distance with, possibly, neural arch fracture. Instability of the thoracolumbar region includes kyphosis more than 20°, vertebral height loss over 50% and neurologic compromise (*1, 29, 38*).

Conservative treatment offers an option but should not be overrated (*28*). When surgical treatment is undertaken, distraction and lordotic curvature of the rods aim at restoring the vertebral height and reducing the retropulsed fragments of the posterior wall (*34, 42*). Failure of the surgical treatment is accepted when there is progressive kyphosis, pseudarthrosis, or infection accompanied with clinical symptoms. Hardware failure does not necessarily preclude patient satisfaction.

*Short segment* pedicle screw instrumentation (SSPI) has the advantage to fuse the minimum

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number of segments, saving motion segments above and below. Pedicular screw-rod systems can restore vertebral body height, but the problem is the maintenance of the initial reduction. Recent studies have shown a high rate of radiographic failure (*7, 24, 31*), even if clinical outcome may appear favourable (*39*). Even with intracorporeal reinforcement of the fractured vertebra, progressive kyphotic deformity has been observed (*1, 3*).

On the other hand, *long-rod* constructs without fusion have been used to stabilise the fractured vertebrae of young patients, but with unknown results (*9*). Bone grafts, acrylic bone cement or hydroxyapatite cement are used for vertebral body reinforcement. Previous biomechanical and clinical studies in distal radius, hip, tibial plateau and calcaneus fractures (*14, 18, 19, 32*), have shown that Norian Skeletal Repair System (Norian SRS, Cupertino, CA) (*8*), a novel hydroxyapatite cement, provides better resistance to axial loading than bone grafts, without the adverse effects from morbidity at the autograft donor site.

This is a preliminary report about the intravertebral use of hydroxyapatite cement for the treatment of unstable thoracolumbar burst fractures, in combination with long posterior instrumentation, without fusion. The Norian SRS cement was injected transpedicularly into the fractured body. The objective of this prospective study was to assess if the initial reduction was maintained over time, even without performing fusion.

## MATERIALS AND METHODS

### Study design

Ten patients, 23 to 46 years old (average : 35 years), with unstable thoracolumbar burst fractures between T10 and L3, were surgically treated in the period 1999-2000. According to the modified Magerl classification (*13*), these burst fractures were categorised in type A3. Indications for surgery were sagittal index exceeding 15°, angular deformity over 30°, anterior body height loss over 50%, more than 50% canal compromise and absence of neurologic deficit. Surgery took place between one and seven days after trauma. All 10 fractures were stabilised using long bisegmental instrumentation (two segments above and two below) and transpedicular hydroxyapatite cancellous bone cement (CBC) injection into the fractured vertebral body. Any segmental bony fusion was avoided. Titanium Moss-Miami rods and screws (De Puy, Indianapolis, USA) were used as posterior instrumentation. No thoracolumbar orthoses were used and all patients were progressively mobilised from the third postoperative day on.

The follow-up period ranged from 34 to 46 months (average : 39 months) and included both physical examination and radiographic follow-up assessment at 3, 6, 12, and 18 months postoperatively and after removal of instrumentation. Hardware removal took place on average after 15 months (range : 10 to 24).

### Hydroxyapatite cement

Norian is an almost non-exothermic cancellous bone cement (CBC), as it hardens *in situ* (Norian Skeletal Repair System (SRS), Norian Corporation, Cupertino, California, USA) (*7*). CBC hardens at physiological pH within 10 minutes after implantation. Its compressive strength after hardening is 20-55 MPa, greater than the compressive strength of autogenous cancellous bone (2-20 MPa), but smaller than that of autogenous cortical bone (50-200 MPa). On the other hand, allogeneic bone grafts resist a 4-13 MPa compressive force (*18*). The standard SRS kit contains a patented calcium source powder, solution, spatula and pestle. Under sterile conditions, the powder (triphosphoric calcium, phosphoric calcium, and carbonic calcium) and the solution (sodium phosphorus) are homogenised with an automatic mixer to form a paste. The working time of the paste, defined as the time between mixing and partial hardening, is 5 minutes at 20°C. In other words, after 5 minutes of viscous state, the paste begins to harden or “set”. No manoeuvres are allowed during this period. Hardening is accelerated by the body temperature and is complete after 10 minutes. The curing period lasts for twelve hours, but it already achieves 50% of its ultimate compressive strength after one hour, 85% at 4 hours and 100% at 12 hours.

### Radiological assessment

All the patients had anteroposterior and lateral radiographs of the involved spinal region and a CT-scan of the fractured vertebra preoperatively, postoperatively and at follow-up. Cobb’s kyphotic deformity angle (CKDA) (fig 1) and vertebral compression index (VCI) (fig 2) were calculated at all occasions (*11*). CKDA was measured as the angle between the superior and inferior

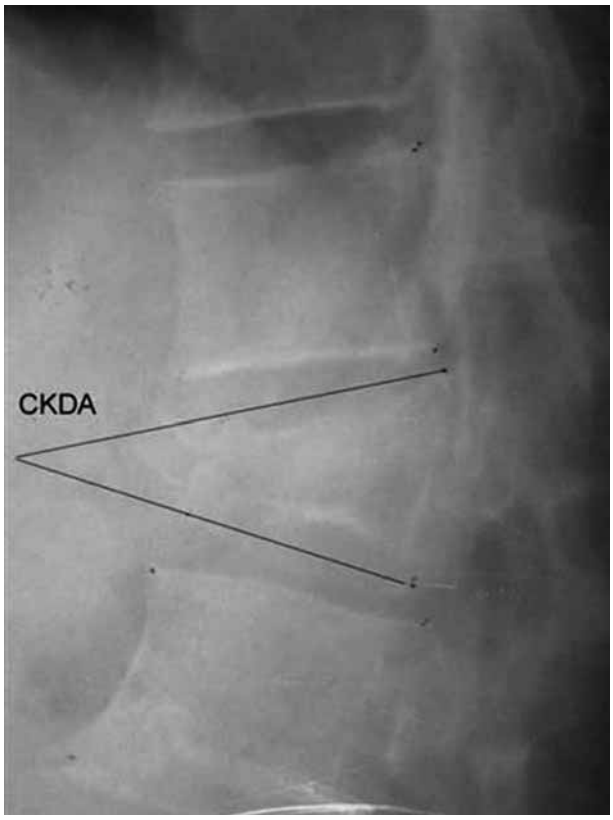


***Fig. 1.*** — Lateral view of an L1 burst fracture. Note the Cobb Kyphotic Deformity Angle (CKDA).

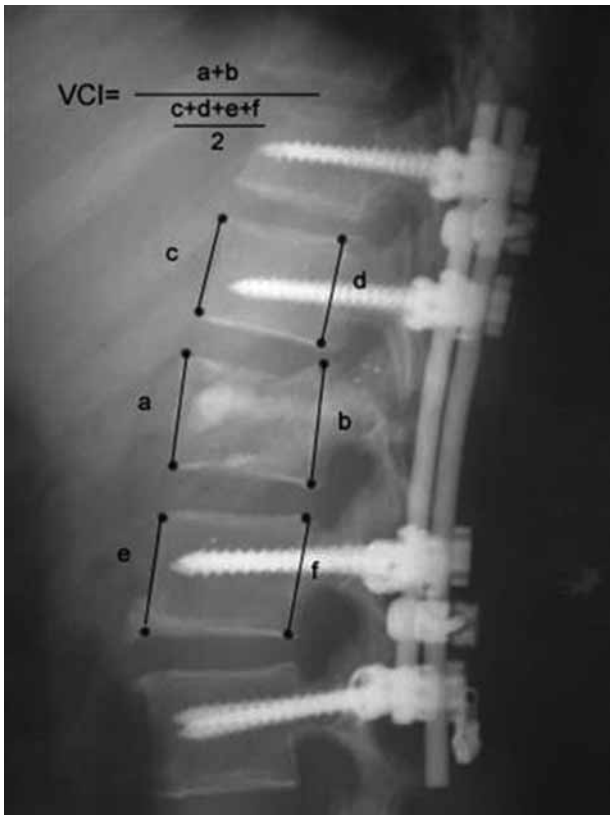


***Fig. 2.*** — Immediate postoperative lateral view. Note the Vertebral Compression Index (VCI).

endplate of the fractured vertebra. VCI estimated the loss of vertebral height and equalled the sum of anterior and posterior vertebral height of the fractured vertebra, divided by half the sum of these values obtained from the vertebrae above and below (VCI is equal to 1 in the normal spine).

All measurements were made independently by two orthopaedic surgeons. Increase of the kyphosis by more than 10° between postoperative and last radiograph was seen as a failure ; screw breakage was not.

**Statistical analysis**

The interobserver reliability of the measurements was assessed with a paired t-test. The data of the two observers were averaged. Differences between mean preoperative and postoperative, and between mean postoperative and follow-up data were evaluated with a paired t-test. A p-value $< 0.05$ was considered statistically significant.

**Surgical technique**

First, transpedicular titanium screws were inserted into the two vertebrae above and the two vertebrae below the fracture level. Then reduction was accomplished by distraction and ligamentotaxis. Laminectomy was avoided. Two cross-links were added to all constructs. An awl was used to make a hole in one of the pedicles of the fractured vertebra. Subsequently, a 6-mm curette was inserted into the vertebral body and used as a lever to elevate the upper vertebral endplate, under image amplifier control. Then the cavity created was irrigated with saline to be prepared for the injection of Norian. When the radiopaque SRS paste (5 ml) was ready, it was injected with a delivery gun through the pedicle with a 6mm-diameter cannula. Subsequently, the cannula was gradually withdrawn and the defect filled in a retrograde fashion.

The injection was performed slowly, carefully and under steady pressure. Image amplifier control avoided

Table I. — Patients' characteristics and radiographic measurements

| Patient | Age | Fracture level | Preop CKDA mean | Postop CKDA mean | Last follow-up CKDA mean | Preop VCI mean | Postop VCI mean | Last follow-up VCI mean | Screw breakage | Follow-up (months) |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 33 | L1 | 34° | 2° | 7° | 0.77 | 0.99 | 0.98 | + | 36 |
| 2 | 46 | L3 | 15.5° | 5.5° | 6° | 0.5 | 0.81 | 0.77 | – | 34 |
| 3 | 39 | L1 | 32.5° | 4° | 4° | 0.66 | 0.97 | 0.91 | – | 37 |
| 4 | 27 | L3 | 6.5° | 3.5° | 3.5° | 0.87 | 0.93 | 0.92 | + | 41 |
| 5 | 24 | L2 | 22° | 4° | 5.5° | 0.71 | 0.94 | 0.91 | + | 40 |
| 6 | 33 | L1 | 21° | 1.5° | 2.5° | 0.78 | 0.88 | 0.86 | – | 46 |
| 7 | 43 | L1 | 26° | 10° | 11° | 0.77 | 0.95 | 0.88 | – | 42 |
| 8 | 46 | T11 | 12.5° | 5° | 5.5° | 0.65 | 1.01 | 0.95 | – | 38 |
| 9 | 23 | T10 | 17.5° | 5.5° | 6.5° | 0.81 | 0.92 | 0.9 | – | 38 |
| 10 | 38 | L2 | 14.5° | 5° | 5° | 0.83 | 0.93 | 0.91 | – | 36 |
| Mean | 35 | | 20.2° ± 8.7° | | 5.6° ± 2.3° | | 0.93 ± 0.05 | | | 39 |
| | | | | 4.6° ± 2.3° | | 0.73 ± 0.10 | | 0.89 ± 0.57 | | |

spilling of the cement into the canal or into the disc spaces. The injection was stopped when an unacceptably high insertion pressure was needed, or when the cement was seen to approach the canal or the adjacent disc spaces, or when more than five minutes of injection had lapsed. The excess of cement flowing out of the needle was swept away before hardening and causing problems to the neighbouring tissues. Manipulation of the instrumentation was avoided during or after the setting time of the cement.

## RESULTS

The operative time averaged 103 minutes (range : 75 to 135). The estimated blood loss averaged 930 ml (range : 810 to 1050). The mean hospital stay was 12 days (range : 7 to 23). The interobserver reliability for the 210 individual radiographic measurements was 0.96 ($p < 0.001$). Clinically, all patients were almost pain free within three months after surgery and able for office work in the sixth postoperative month. No neurologic deterioration was observed.

The mean preoperative CKDA (table I) was 20.2° +/- 8.7° ; it improved to 4.6° +/- 2.3° directly postoperatively, and slightly worsened to 5.6° +/- 2.3° at the last follow-up. As to the VCI, the corresponding values were 0.73 +/- 0.10, 0.93 +/- 0.05 and 0.89 +/- 0.57. The improvement between the mean preoperative and postoperative values was statistically significant for both parameters ($p < 0.001$). On the other hand, the final deterioration was statistically not significant for the CKDA ($p > 0.05$), but significant for the VCI ($p < 0.001$). There was no more than 5° increase in CKDA between the first and the last postoperative radiographs, even in the cases with screw failure (3 in 3 patients).

Infection, venous thrombosis, neurologic deterioration or pulmonary embolism were not observed. Degeneration of the interapophyseal joints included in the instrumented segments was visualised on the last follow-up CT in 6 patients. The changes were more pronounced in the joints adjacent to the fractured vertebra. Three out of 80 screws broke ; this occurred in 3 patients at the far cranial or caudal instrumented level. These patients did not complain of pain or discomfort, but breakage was revealed at the final radiographic examination. Postoperative CT images showed adequate Norian osteointegration and remodeling (fig 3). Rod or screw bending, screw pull-out or loosening were not observed.

## DISCUSSION

The purpose of this study was to test the effectiveness of vertebral body augmentation with cancellous bone cement for the treatment of unstable

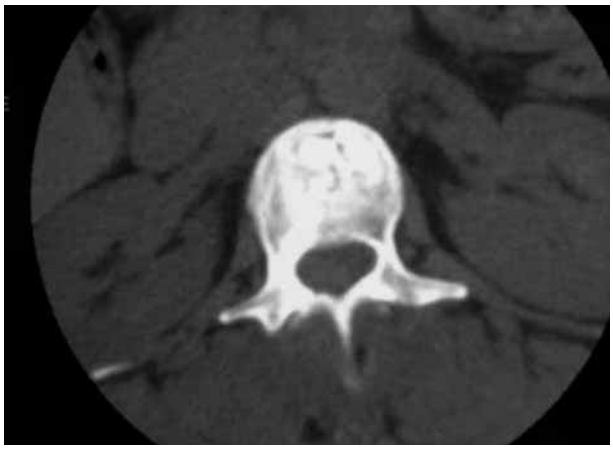

***Fig. 3.*** — CT scan after removal of hardware. Note the spread and integration of Norian SRS.

thoracolumbar burst fractures, in combination with long posterior instrumentation, without fusion.

It is known that spinal instrumentation provides a stable mechanical environment to enhance bony fusion (*17*). *Short segment* fixation has not prevented recurrent kyphosis or loss of reduction in thoracolumbar burst fractures (*22*), even though favourable clinical results have been obtained (*39*). Survivorship analysis of the short segment VSP system demonstrated that it was suitable for burst fractures only when anterior column augmentation was added (*10*). Furthermore, other studies reported that the high rate of failure after short segment instrumentation did not decrease even with additional intracorporeal grafting (*1, 3*). The first who tried *long* bisegmental (two levels above and two levels below the fracture level) transpedicular fixation for thoracolumbar fractures were Müller *et al* in 1999 (*27*). Yue *et al* (*41*) considered it as a safe and reliable method of posterior spinal stabilisation for unstable thoracic fractures. The postoperative correction of kyphosis and vertebral compression of unstable thoracolumbar burst fractures treated with posterior-only procedures, as described in the literature, are presented in table II.

Certainly, this is a preliminary report about a novel bone substitute in spine surgery. Its chemical composition and crystalline texture resemble those of the mineral phase of bone (*8, 12, 16*). Moreover, it lacks the complications caused by autograft harvesting or by the exothermic setting of acrylic

Table II. — Comparison of radiographic results of posterior-only surgical treatment for unstable thoracolumbar burst fractures

| | Cases | Follow-up (mo) | Type of vertebral anchorage | Levels with bony/ metallic fusion | Intra-corporeal augmentation of the fractured vertebra (patients) | Postop | | Latest follow-up | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | % correction of kyphosis | % correction of vertebr. compression | % correction of kyphosis | % correction of vertebr. compression |
| Speth, 1987 (*35*) | 12 | 77 | Pedicle screws | 3/3 | All | 47 | 11* | 43 | 11* |
| Müller, 1999 (*27*) | 20 | 77 | Pedicle screws | 2/3 | 6 | 70 | 29 | 50 | 21 |
| Yue, 2002 (*41*) | 32 | 13 | Pedicle screws | 5/5 | None | – | – | 33 | 23 |
| Korovessis, 2004 (*20*) | 20 | 52 | Hooks above ; screws below | 5/5 | None | 48 | 33** | 47 | 33** |
| Alvine, 2004 (*2*) | 11 | 24 | Pedicle screws | 3/3 | All | – | – | 94 | 29** |
| This study | 10 | 39 | Pedicle screws | 0/5 | All | 77 | 20 | 72 | 16 |

* only of the posterior height ** only of the anterior height.

cement (*4, 15, 30, 40*). Calcium phosphate cement also offers certain theoretical advantages over polymethylmethacrylate (PMMA). It is more biocompatible, has osteoconductive properties, is remodelled by bone, acquires half of its compressive strength in ten minutes and hardens at body temperature (*5, 25, 33*). There have been anecdotal reports of serious complications and even intraoperative deaths attributed to the use of Norian. Soft-tissue reaction to Norian after curettage of enchondromas has been reported (*37*), but we did not experience such toxic effects.

*In vitro* biomechanical studies about Norian SRS demonstrated the improved pullout strength and cyclic loading performance of hydroxyapatite cement augmented screws (*6, 23, 36*). Verlan *et al* (*36*) used a calcium phosphate mixture with similar properties as the one used in the present study, for balloon vertebroplasty, to reconstruct the fractured vertebral body in cadaveric thoracolumbar spine specimens. This technique proved to be efficient *in vitro*. The same method was used in a recent cadaveric study, showing that the new CaP cement could increase the strength of a fractured vertebra to at least its previous level (*21*).

In the present study, a long bisegmental instrumentation with cross-links was used for maximum biomechanical performance, without fusion. All fractured vertebrae were reinforced by calcium phosphate cement through a transpedicular route. Norian SRS constituted a feasible and lasting method of vertebral body augmentation. It significantly resisted kyphosis relapse between the immediate postoperative and last follow-up period, but did not significantly resist vertebral height loss in the same period. This might be attributed to inadequate distribution of Norian SRS.

Three out of 80 screws broke down, but this was not to be considered as a failure. All the screws broke at the site of entrance in the lamina ; this was to be attributed to the cantilever effect on the screw neck. The degenerative changes of the facet joints, adjacent to the fracture level, proved the 'arthritis effect' that instrumentation exerts on the mobile segments in the center of the construct but, apparently, this did not hinder the patients in the short term.

Although the effectiveness of Norian SRS is obvious, further randomised studies need to be undertaken in order to reevaluate these promising results.

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