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ORIGINAL ARTICLE

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Augmentation of (pedicle) screws with calcium apatite cement in patients with severe progressive osteoporotic spinal deformities: an innovative technique

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Abstract Screw augmentation with calcium apatite cement (CAC) was used in seven patients with a progressive osteoporotic spinal deformity. Thirty-nine spinal segments (64 screws) were augmented: 15 anteriorly (three patients) and 24 posteriorly (five patients). Dorsally, hemilaminectomy was performed at the level of all augmented screws to rule out CAC leakage. Autogenous bone graft was applied in all patients to induce fusion. Screw augmentation failure occurred in only one patient: 1 of the 16 ventral augmented screws (5.5%) was still loose after the augmentation procedure. In three other patients, 4 out of 48 augmented dorsal screws (5.5%) showed CAC leakage at the pedicle corpus vertebra level. Pedicle wall damage was present at two levels, while at two other levels no wall damage was found during visualization. No CAC-related complications were observed perioperatively. No implant migration was observed, and fusion was observed in all cases at follow-up examination performed at a mean of 32 months after surgery.

Key words Osteoporosis · Fusion · Pedicle screw augmentation · Spine · Calcium apatite cement

Introduction

Instrumentation using screw fixation (transpedicular, ventral screws through the vertebral body) is now widely used in spinal surgery to attain rigid stabilization after surgical intervention in conditions leading to a progressive spinal deformity and loss of mechanical stability to the spine. The advantage of using screws as part of a construct is that they provide a rigid bony fixation upon which internal fixation devices can be mounted. Consequently, a rigid stabilization can be achieved before solid bony union is established.

Rapid graft incorporation and successful spinal fusion have been shown to be more likely with rigid internal fixation [1, 11, 19]. Rigid internal fixation reflects the strength of screw attachment to the spine, which in turn is directly related to the quality of bone into which the (pedicle) screw is placed [4, 6, 11]. Consequently, dense good-quality trabecular bone enhances solid fixation while osteoporotic and poor-quality bone, as in osteogenesis imperfecta, carries an increased risk of screw loosening and pullout peri- and postoperatively [4, 5, 6, 8, 11, 13]. In extreme cases of poor bone quality, the use of screw fixation may even be precluded [4, 5, 6, 13, 23]. Experimental studies using human cadaveric vertebrae have demonstrated the suitability of in-situ setting calcium apatite cement (CAC) in augmenting initial fixation of pedicle screws in senile (osteoporotic) trabecular bone [15, 16].

We report operative strategies and outcome using CAC (Skeletal Repair System – SRS – Norian Corp., Cupertino, Calif.) for the augmentation of 64 (pedicle) screws in seven patients with severe progressive osteoporotic spinal deformities.

Materials and methods

Between 1994 and 1996, seven patients with a symptomatic progressive spinal deformity associated with severe osteoporosis were surgically treated by correction and/or stabilization of the deformity. In addition, bone grafting was performed to induce (multi)segmental fusion. The reported patients were the only patients treated in this fashion. Relevant clinical data are summarized in Table 1. There were five female patients and two male, with an average age of 36.1 years (range 11–62 years). All patients presented with clinical symptoms caused by a severe osteoporotic spinal deformity. In all patients, routine radiographic and additional computed tomography (CT) and/or magnetic resonance imaging (MRI) studies were performed to visualize the spinal deformity. Patients presenting with neurologic compression symptoms (cases 1, 3, 4, 5) were evaluated neurologically; they showed pathologic electromyographic (EMG) studies corresponding with specific nerve root irritation. In addition, internal evaluation including DEXA scans was performed in five patients (cases 1, 2, 3, 5, 6). All patients showed decreased bone mineral density measurements, twice the standard deviation below the expected mean value. Due to the severity of the osteoporosis, two patients (cases 3, 5) received multidrug substitution over a period of 3–4 months before surgical intervention, and all received multidrug treatment after surgery.

A total of 39 spinal segments were fixed using Steffee pedicle screws and Isola rods posteriorly (Acromed Corp., Cleveland, Ohio) and Kaneda screws and rods ventrally (Acromed Corp.,Cleveland, Ohio). In addition, the screws were augmented with in-situ setting CAC, an osteoconductive, completely biocompatible material (SRS; Norian Corp., Cupertino, Calif.). CAC is a crystalline material, similar in structure to the mineral phase of bone, allowing ingrowth of adjoining blood vessels and subsequently development of bone into the artificial scaffold provided [2,3].

Table 1 Clinical data of patients treated with augmentation of screws (*CAC* calcium apatite cement)

Case no.	Age (yrs)	Sex (M/F)	Presentation	Diagnosis	Augmentation	Complication	Follow-up/Result
1	42	F	Back pain + bilateral L4 root compression; stenosis L4-L5; fractures L3-L5; kyphosis of 10° (L1-S1)	Osteogenesis imperfecta; osteoporosis	Dorsal L3-S1 bilateral pedicles	CAC leakage L3 left	30 months, no symptoms; partial correction of kyphosis to 5° (L1-S1); fusion L3-S1; no analgesics
2	38	F	Back pain; fractures L1-L5; scoliosis of 45°	Osteoporosis, unknown aetiology	Dorsal L1-S1 bilateral pedicles	CAC leakage L4 right; lung infection	32 months, no improvement in back pain; no correction of deformity; fusion L1-S1; frequent analgesics
3	31	M	Back pain; left S1 root compression; height loss of 27 cm; kyphosis of 100° (T1-T12)	Osteoporosis, unknown aetiology	Dorsal T10-S1 bilateral pedicles	Pedicle wall damage + CAC leakage L1 left, L4 right; thrombosis; pulmonary embolism	52 months, occasional back pain; normal thoracic kyphosis; fusion C6-S1; occasional analgesics
4	62	F	Back pain + bilateral L4 root compression after breakout of L4 screws after attempted dorsal fusion L4-S1	Osteoporosis; spondylolisthesis grade 1 L4-L5	Dorsal L3-L4 bilateral pedicles		24 months, mild back pain; no correction performed; fusion L3-S1; no analgesics
5	49	F	Back pain + bilateral L4, L5 root compression; scoliosis of 40° (L1-L5)	Osteogenesis imperfecta; osteoporosis	Ventral T12-L4 (single rod); dorsal L3-S1 bilateral pedicles	Loosening of ventral L4 screw	44 months, Occasional chest pain; in situ spondylodesis; fusion T12-S1; occasional analgesics
6	19	F	Back pain; instability + scoliosis of 35° degrees (T12-L4)	Osteogenesis imperfecta; osteoporosis	Ventral T12-L4 (double T12 and L4 for double rod)	Temporary genitofemoral nerve palsy	28 months, occasional back pain; complete correction; fusion T12-L4; occasional analgesics
7	11	M	Back pain; thoracolumbar scoliosis of 80° (T6-L4)	Osteogenesis imperfecta; osteoporosis	Ventral T12-L3 (single rod)		22 months, No symptoms; correction to 25°; fusion T2-S1; no analgesics

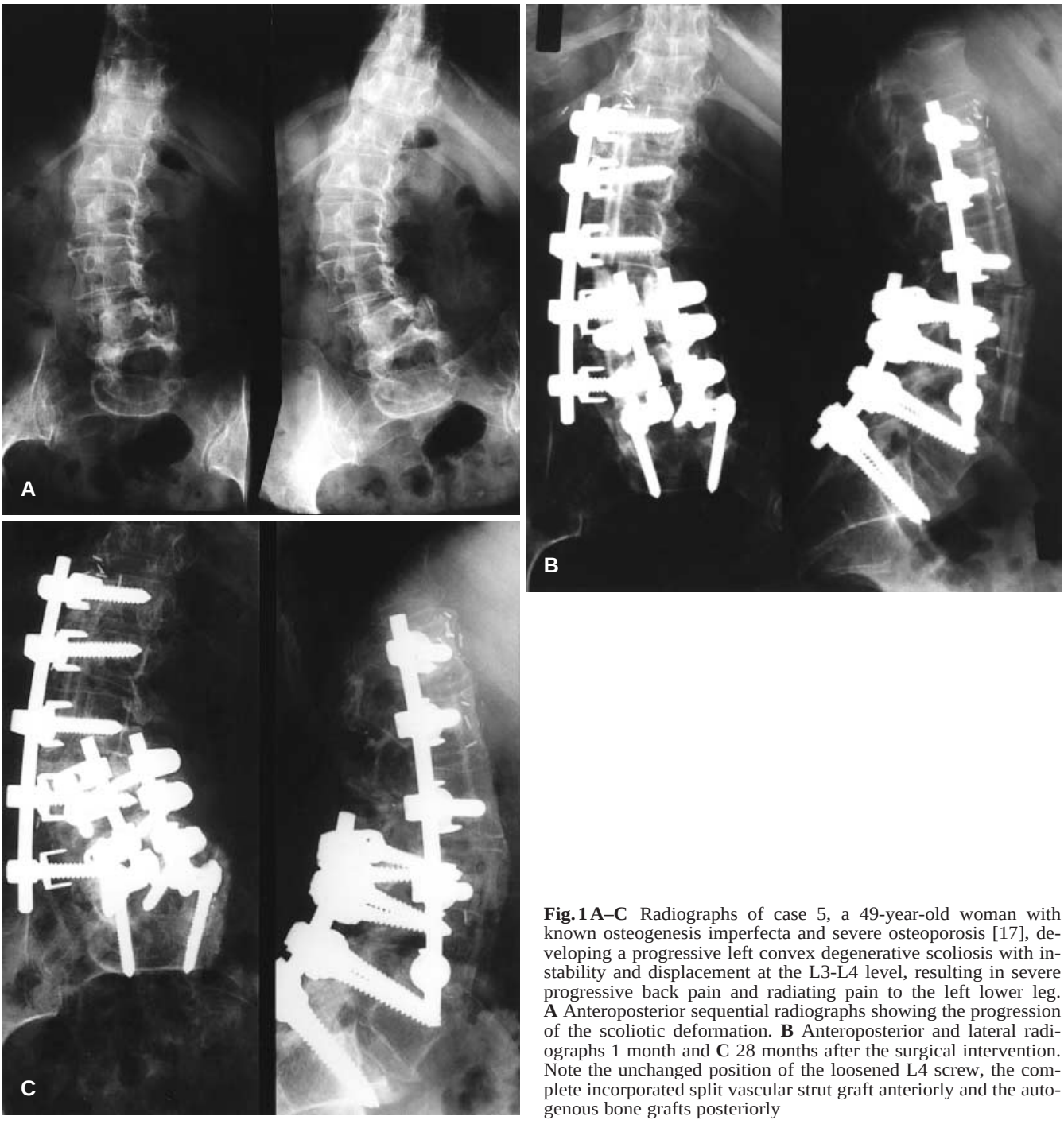

Fig. 1 A–C Radiographs of case 5, a 49-year-old woman with known osteogenesis imperfecta and severe osteoporosis [17], developing a progressive left convex degenerative scoliosis with instability and displacement at the L3-L4 level, resulting in severe progressive back pain and radiating pain to the left lower leg. **A** Anteroposterior sequential radiographs showing the progression of the scoliotic deformation. **B** Anteroposterior and lateral radiographs 1 month and **C** 28 months after the surgical intervention. Note the unchanged position of the loosened L4 screw, the complete incorporated split vascular strut graft anteriorly and the autogenous bone grafts posteriorly

Anterior approach

A staged anteroposterior intervention was planned in cases 5 (fusion T12–L4), 6 (fusion T12–L5) and 7 (fusion T12–L3), and was eventually performed in cases 5 (Fig. 1) and 7 (Table 1). In case 6, the posterior intervention was not performed because the patient did not give consent. To avoid screw (and rod) loosening and breakout, with subsequent loss of correction, after the anterior intervention, primary ventral screw augmentation was chosen as a part of the surgical reconstruction. The spine was exposed by means of an anterolateral thoraco-abdominal (retroperitoneal) approach. Once the vertebral levels were exposed, the segmental intervertebral discs were reamed and the ventral screw holes prepared using an awl, after which a self-tapping screw was inserted. The opposing cortical wall of the vertebral body was not perforated, to avoid leakage of the CAC. Subsequently, all screws were removed, followed by the preparation of CAC and its subsequent injection into the screw hole. The injection was performed in a non-pressurized, retrograde fashion using a 10-ml syringe and a 12-G needle. Between 2.0 and 3.0 cc of CAC was injected per

screw hole. The screws were then reinserted in pairs and held in place until the cement hardened (about 10–15 min). After hardening, bone grafting was performed and a single or double Kaneda rod system mounted, followed by correction and/or stabilization.

Posterior approach

In five cases (cases 1–5) bilateral posterior augmented screw fixation was performed. The patients were positioned on a radiolucent Wilson frame and a posterior midline approach was used. After a hemilaminectomy, the pedicle was prepared using an awl, followed by a probe to ensure that the cortex had not been breached. Under fluoroscopic control, the pedicle screw was inserted. The screws were then removed, followed by a second (direct) control of the canal. The CAC was now prepared and injected (about 2.0–3.0 cc per screw hole) into the screw hole, in a non-pressurized and retrograde fashion, followed by reinsertion of the screw under direct view and image intensification. Throughout the process of screw hole preparation, augmentation, and screw insertion, the dura and the nerve root were deviated medially for protection and also to enable direct visualization of cortical defect or cement leakage. Whenever leakage occurred, the cement was immediately removed. After cement hardening, all screws were tested manually and confirmed rigid. The connecting rods (or plates) were then mounted and, finally, stabilization and/or correction of the spinal deformity was performed. The procedure was finished with posterolateral bone grafting.

Results

The average duration of surgery was 6 h and 13 min (range 5.25–12 h). After augmentation, definitive screw reinsertion and cement hardening, repeated manual testing revealed all dorsally and ventrally placed screws to be clinically rigid, with the exception of 1 of the 16 ventral screws (5.5%) (L4 screw in case 5; Fig. 1). During cement injection and screw reinsertion, cement leakage was observed out of the entrance of the screw hole in a retrograde fashion. In addition, only observed upon pedicle screw placement and only during screw placement after screw hole augmentation, cement leakage occurred out of the bone at the base of the pedicle corpus vertebrae in a retrograde fashion in 4 out of 48 augmented screws (8.3%). In two patients (cases 1, 2) no pedicle wall perforation was observed under direct visualization, while in another patient (case 3), pedicle wall damage with CAC leakage was observed at two different levels. The cement was promptly removed before touching the medially deviated dura or nerve root and before hardening. No pedicle screw was removed and all four screws were well fixed after hardening of the CAC. No CAC leakage was observed in case 4, where bilateral screw breakout at the L4 level had happened after a previous dorsal intervention. With the technique described, two to three ventral screws and four pedicle screws (two spinal segments) were augmented in one step using 2.0–3.0 ml of CAC per screw hole. Other complications, such as lung infection (case 2), deep vein thrombosis with pulmonary embolism (case 3), and temporary genitofemoral nerve palsy (case 6), were successfully treated conservatively.

Postoperatively, all patients presenting with neurologic symptoms had complete relief of their nerve compression symptoms. In one patient (case 2), severe back pain persisted, while in all other patients occasional, periodic mild pain was mentioned at the latest follow-up (mean 33 months, range 22–52 months). In all patients except one (case 2), continuous analgesic intake had been stopped. In three patients (cases 3, 4, 7) a permanent, excellent correction and in another patient (case 1) a partial correction of the deformity was achieved. Only in one patient (case 5, Fig. 1) no correction of the deformity was performed, but she experienced a complete relief of her neurologic symptoms. In addition, multilevel laminectomy, foraminectomy and in-situ spondylodesis was successfully performed in two other patients (cases 2, 4). Bony fusion of the spine was achieved in all patients and no patients developed osteoporosis-related deformities adjacent to the fused spinal levels. Radiographic evaluation of the CAC over time was difficult to assess, however, due to overprojection of spinal hardware and the variable quality of the successive radiographs. For the same reasons, DEXA scans of the spine were not repeated.

Discussion

Surgical intervention may be considered in severely osteoporotic patients with vertebral fracture(s) and spinal compromise or worsening of a pre-existing deformity (degenerative scoliosis) and neurologic deficit [18]. Attainment of a rigid internal fixation can be extremely difficult in these cases, and sometimes may be precluded [4, 5, 8, 13, 22]. Reconstruction of these deformities poses technical challenges: the benefit of improvement in the quality of life by a surgical intervention should outweigh the potential technical and medical risks. Spinal interventions in elderly patients have resulted in improved function and pain relief after surgery [7,25]; however, using pedicle screw devices in (elderly) osteoporotic patients bears the risk of disruption of the screw-bone interface with subsequent loosening or pull-out of the fixation system intra- and/or postoperatively [4, 13, 25, 26]. These findings are supported by laboratory experiments demonstrating that osteopenia compromises pedicle screw fixation [4, 5, 20, 26]. Augmentation of screws with polymethyl methacrylate (PMMA) or CAC, as demonstrated in cadaveric specimens, is therefore a logical step aimed at facilitating a rigid screw fixation [13, 15, 16, 24, 26].

CAC is a composite of monocalcium phosphate monohydrate [$Ca(H_2PO_4)_2 \cdot H_2O$], α-tricalcium phosphate [$Ca_3(PO_4)_2$] and calcium carbonate [$CaCO_3$], dry mixed, and to which a sodium phosphate solution is subsequently added, converting it into a paste. Within 10 min of delivery the paste hardens at physiological pH levels, due to

the crystallization of dahllite (carbonated hydroxyapatite) [2,3]. It attains 50% of its maximum strength at 1 h after its implantation, 90% at 4 h and maximum strength at 24 h. Compared to PMMA, it has the advantage of being non-exothermic during solidification, and the potential for being resorbed and replaced in time with normal bone [2,3]. Encouraging clinical experiences have been gathered in the application of CAC in upper and lower limb fractures [9, 10, 14,21]. However, no reports of the clinical use of CAC as a screw augmentation technique in spinal surgery are available. Experimentally, CAC compares favourably with PMMA in the enhancement of initial fixation of pedicle screws [16]. Although the postaugmentation pull-out strengths seen with PMMA and CAC augmentation are similar, the failure modes of the two types of augmentation are quite different. CAC-augmented screws tend to pull out without causing any bony fracture, stripping the cement at the restored bone screw interface [16]. In contrast, the pedicle often fractures at or near its junction with the vertebral body during pull-out of PMMA-augmented screws, with the cement remaining intact while the bone around it fails [16].

The presented CAC augmentation technique was time-consuming, limiting the number of injections to 2–3 (ventral) and to 4 (posterior) prepared screw holes. A part of this problem may be explained by lack of experience with the procedure, the technique employed to prepare the CAC, and the injection technique. In addition, to perform the CAC injection safely posteriorly, a hemilaminectomy was required to exclude leakage of the CAC and to remove the CAC if leakage happened. Improving the CAC preparation and injection technique has solved some of these disadvantages, and using computer-assisted preparation and insertion of pedicle screws, reducing the number of misplaced screws, has also helped [12]. Another drawback in our series is the difficulty in detecting the cement margins on radiographs. It was almost impossible to clearly define the cement-screw and the cement-bone interfaces. Therefore, the cement fill along the length of the screw was difficult to assess. Equally, cement dislodgement and cement fracture could not be clearly defined on radiographs.

This study has all the shortcomings of a non-prospective, non-randomized study with only seven patients. The procedure described, however, appeared safe, showed no serious complications, and helped establish firm fixation of the (pedicle) screws. The presented data support both the theoretical benefits of and the satisfactory results of in vitro CAC screw augmentation. However, optimal screw hole preparation, cement characteristics (e.g. viscosity, composition, porosity), injection technique (non-pressurized/pressurized, seal use), screw types and sizes still need further study.

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