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CLINICAL INVESTIGATION

Vertebral Augmentation with Nitinol Endoprosthesis: Clinical Experience in 40 Patients with 1-Year Follow-up

Giovanni Carlo Anselmetti · Antonio Manca · Stefano Marcia · Gabriele Chiara · Stefano Marini · Gamal Baroud · Daniele Regge · Filippo Montemurro

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Abstract
Purpose This study was designed to assess the clinical outcomes of patients treated by vertebral augmentation with nitinol endoprosthesis (VNE) to treat painful vertebral compression fractures.
Methods Forty patients with one or more painful osteoporotic VCF, confirmed by MRI and accompanied by back-pain unresponsive to a minimum 2 months of conservative medical treatment, underwent VNE at 42 levels. Preoperative and postoperative pain measured with Visual Analog Scale (VAS), disability measured by Oswestry Disability Index (ODI), and vertebral height restoration (measured with 2-dimensional reconstruction CT) were compared at last follow-up (average follow-up 15 months). Cement extravasation, subsequent fractures, and implant migration were recorded.
Results Long-term follow-up was obtained in 38 of 40 patients. Both VAS and ODI significantly improved from a median of 8.0 (range 5–10) and 66 % (range 44–88 %) to 0.5 (range 0–8) and 6 % (range 6–66 %), respectively, at 1 year ($p < 0.0001$). Vertebral height measurements comparing time points increased in a statistically significant manner (ANOVA, $p < 0.001$). Overall cement extravasation rate was 9.5 %. Discal and venous leakage rates were 7.1 and 0 % respectively. No symptomatic extravasations occurred. Five of 38 (13.1 %) patients experienced new spontaneous, osteoporotic fractures. No device change or migration was observed.
Conclusions VNE is a safe and effective procedure that is able to provide long-lasting pain relief and durable vertebral height gain with a low rate of new fractures and cement leakages.

G. C. Anselmetti (✉)
Interventional Radiology Unit, Villa Maria Hospital, Strada Comunale di Mongreno 180, Turin 10132, Italy
e-mail: gc.anselmetti@fastwebnet.it

G. C. Anselmetti · G. Baroud
Departement de Genie Mecanique, University of Sherbrooke, 2500, boul. de l'Université, Sherbrooke, QC, Canada
e-mail: gamalbaroud@gmail.com

A. Manca · G. Chiara
Interventional Radiology Unit, Institute for Cancer Research and Treatment (IRCC), Strada Provinciale no 142 Km.3,95, 10060 Candiolo, Turin, Italy
e-mail: anto.manca@gmail.com

G. Chiara
e-mail: gabriele.chiara@ircc.it

S. Marcia · S. Marini
Institute of Radiology, University of Cagliari, Via Raffa Garzia 13, 09126 Cagliari, Italy
e-mail: stemarcia@gmail.com

S. Marini
e-mail: stemarini@gmail.com

D. Regge
Radiology Unit, Institute for Cancer Research and Treatment (IRCC), Strada Provinciale n° 142 Km.3,95, 10060 Candiolo, Turin, Italy
e-mail: daniele.regge@ircc.it

F. Montemurro
Internal Medicine Unit, Institute for Cancer Research and Treatment (IRCC), Strada Provinciale no 142 Km.3,95, 10060 Turin, Italy
e-mail: filippo.montemurro@ircc.it

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Introduction

Osteoporotic vertebral compression fractures (VCF) are associated with postmenopausal bone loss. Sixteen percent of women after menopause and 20 % of all adults older than age 70 years suffer from vertebral compression fractures [1].The main complication of VCF is acute pain, reported in up to 84 % of patients with radiographic evidence of a compression fracture [2]. Vertebroplasty and kyphoplasty vertebral augmentation procedures have been shown to be more effective than conservative treatment when treating painful vertebral compression fractures [3, 4].

Vertebral body collapse associated with VCF can lead to hyperkyphosis. The degree of hyperkyphosis depends upon the number and severity of vertebral body fractures (especially wedge-type VCF). Hyperkyphosis can produce a reduction of pulmonary function and may lead to increased risk for subsequent fracture(s) [5, 6]. In 1998, the kyphoplasty procedure was developed to lift vertebral endplates using inflatable, intervertebral balloon bone tamps, with the goal of securing height restoration, kyphosis reduction, and pain relief [7, 8]. Bone cement polymethylmethacrylate (PMMA) injection follows removal of the balloon for stabilization. Clinical experience has demonstrated a potential limitation of kyphoplasty with loss of restored height after balloon deflation due to vertebral elastic recoil. A nitinol vertebral endoprosthesis has been designed to treat VCF, providing an intervertebral scaffold that maintains height restored during the procedure before cement injection. Less vertebral height loss compared with kyphoplasty has been demonstrated [9, 10].

The VerteLift™ System (SpineAlign Medical, Pleasanton, CA) consists of nitinol implants designed to exert a force from endplate to endplate, restoring lost height. This device allows the preservation of cancellous bone and promotes cement interdigitation and perfusion, which ultimately result in height restoration and a potential for reduced fracture due to a reduction in the stiffness of the treated vertebrae. For these reasons and because of the possibility to reduce the volume of the cement used, nitinol implants may offer several advantages compared with kyphoplasty [9].

On these premises, we sought to assess the safety, effectiveness, and vertebral height restoration of nitinol endoprosthesis-assisted vertebroplasty and to analyze maintenance of vertebral height, occurrence of new vertebral fractures, complications, and impact on perceived pain and quality of life during long-term follow-up.

Materials and Methods

Population and Study Design

From December 2008 to September 2009, 40 patients (36 females; mean age 73.6 ± 8 years) were treated with percutaneous vertebral augmentation performed by placement of 84 nitinol endoprostheses (two devices in each vertebra; two patients were treated for two vertebral fractures) at a single institution. Patients were informed of potential treatment-related complications and each provided signed, informed consent in accordance with the Declaration of Helsinki. Outcome assessments were preplanned as part of the routine care of patients at our institution. The internal review board approved this retrospective analysis.

Inclusion Criteria

- Age ≥55 years
- Osteoporotic vertebral fracture A1.1, A1.2 or A1.3 (Magerl's classification)
- Bone marrow edema within the fracture assessed with MRI
- Significant back pain (Visual Analogue Scale score ≥5)
- Tenderness to palpation over the spinous process of the fractured vertebra
- Persistence of back pain after a minimum of 8 weeks and no more than 12 weeks of conservative medical treatment consisting of bisphosphonates or other bone antiresorption agents and pain medications (nonsteroidal anti-inflammatory drugs and/or oral or parenteral opiates)

Exclusion Criteria

- Fracture A2, A3, B, and C (Magerl's classification)
- Tumoral vertebral collapse
- Systemic infection or any suspicious infective spondylodiskitis
- Uncorrectable coagulation disorders
- Nerve root pain or neurological deficit due to the fracture

Technique

Procedures were performed in an angiography room equipped with flat-panel digital fluoroscopy with rotational acquisition and computed tomography (CT)-like multiplanar reconstructions (MPR) (Allura Xper CT; Philips, the Netherlands). Patient's heart rate, pulse oximetry, and blood pressure were monitored continuously throughout

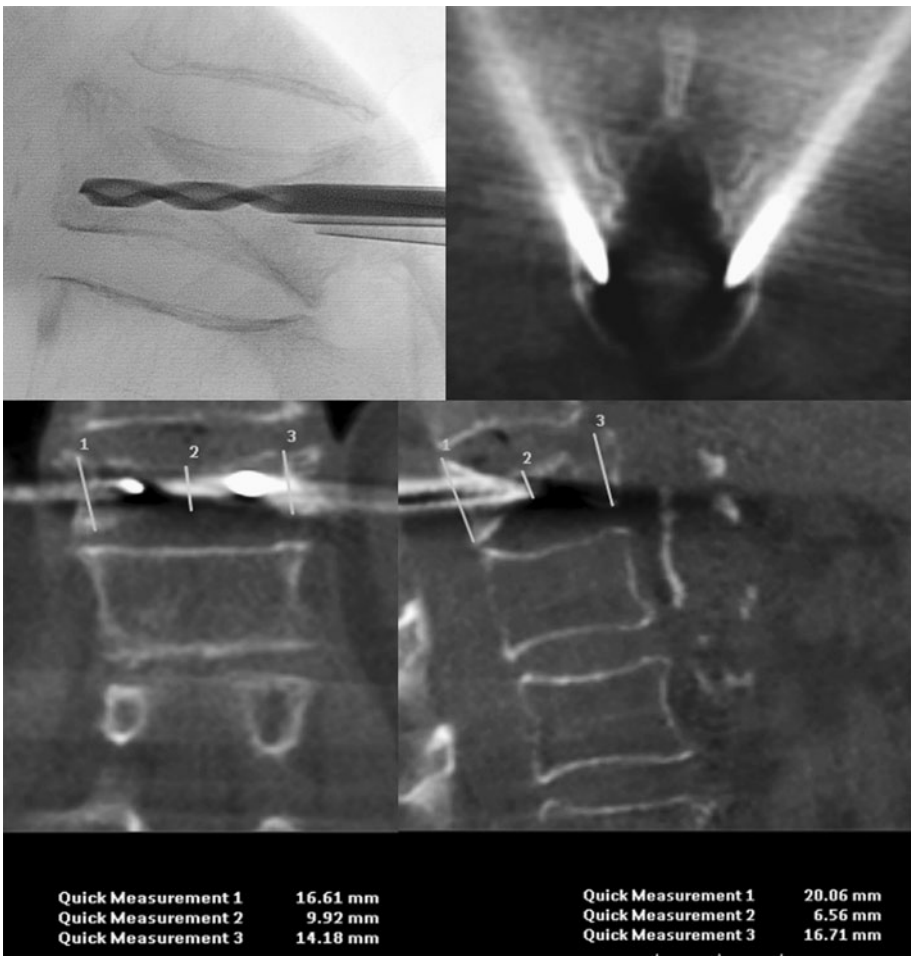

Fig. 1 Fluoroscopic lateral view during manual drilling to create the channels for the implant; CT-like axial multiplanar reconstruction to assess needle correct pathway and to measure vertebral height before implant expansion

the procedure. All procedures were performed with local anesthesia by injection of 2 mL or less of 2 % lidocaine hydrochloride using a 22-gauge Quincke needle, administered percutaneously over the pedicle periosteum. Access cannulae were inserted using the oblique projection and then advanced in the anteroposterior (AP) projection to the medial aspect of the pedicle. CT scan was performed to assess the correct cannula positioning and to measure preprocedural vertebral height. The delivery pathway for the implant was created using trocars and a coaxial manual drill through transpedicular cannulae (Fig. 1). Bone tissue removed during drilling was gathered for histological examination.

The implants were delivered through the access cannulae (diameter 8 gauges), and the implants were positioned and deployed using a multifunctional handle (actuates the collapse and opening of the implant) attached to the delivery system. The nitinol implants were positioned and adjusted under fluoroscopy approximating an "XX" image in the AP projection (Fig. 2). This "XX" intervertebral orientation allows the device struts to deliver height restoration force to the endplates. When the implants were properly positioned and expanded, the delivery system was detached.

Injection cannulae were prefilled with polymethylmethacrylate (KyphX HV-R®; Elmdown LTD. London, England). When the cement reached a viscosity similar to "toothpaste consistency," the prefilled cannulae were coaxially advanced through the working cannulae to the distal end of the implant. Cement injection was performed manually under continuous fluoroscopic monitoring (Fig. 3). An average of 5 mL of PMMA was injected per level. Cement injection was stopped when satisfactory intervertebral interdigitation and cement distribution was observed. When cement injection was complete, the cannulae were withdrawn. CT scan was performed to record postprocedural vertebral height measurements, to assess complications, and to record any extravasation (Fig. 3).

Device

The VerteLift endovertebral prosthesis used in this study is a nitinol (nickel/titanium alloy) cage CE Marked for treatment of vertebral body fractures resulting from

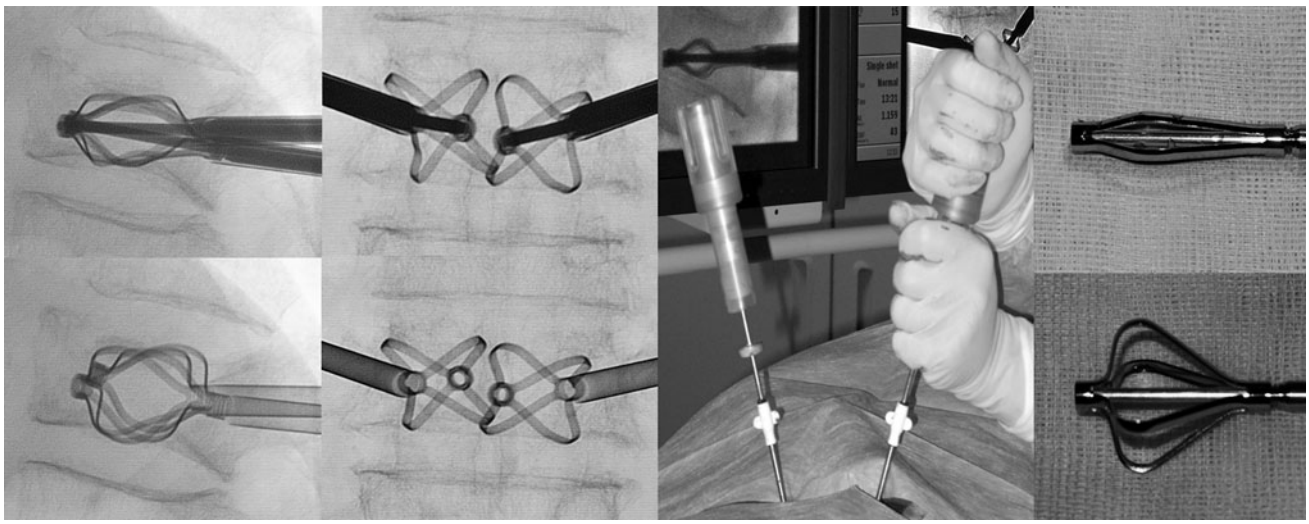

Fig. 2 Nitinol implants in the open fashion in lateral view and in the anteroposterior view (XX fashion) before and after detachment from delivery system using handles ("amber" prototype) under fluoroscopic guidance. On the right, the implant in the closed and in the open fashion (asymmetric)

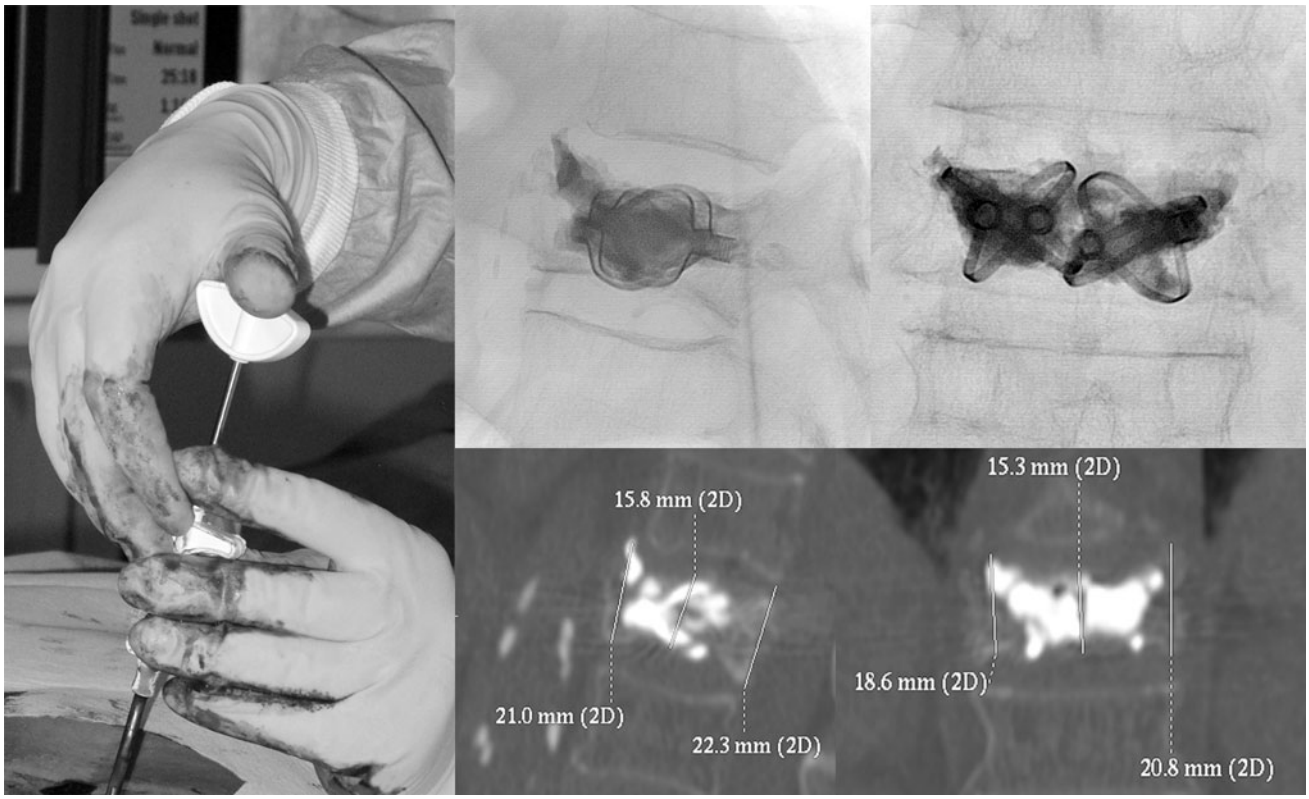

Fig. 3 PMMA injection. Prefilled cannulae with blunt-tip pusher and the nitinol implants encased in bone cement. CT multiplanar reconstruction was performed for height measurements after implant expansion and PMMA injection

osteoporosis, tumor, or trauma. The implants are available in four heights (14, 16, 18, and 20 mm), and each height is available in symmetric and asymmetric configurations suitable for concave/biconcave and wedge-type vertebral compression fractures, respectively. The nitinol implant is designed to be collapsed and expanded multiple times allowing proper positioning of each implant and can be withdrawn through the cannula when completely expanded (if necessary), before PMMA injection; this characteristic is unique compared to other endovertebral stents, allowing

a more precise and safer positioning. The transpedicular channel is created with a manual drill. The nitinol implant and delivery device is inserted into a handle, which allows expansion, positioning, and collapsing of the implant with manual rotation and actuation of directional switches. The implant is collapsed for insertion through transpedicular working cannulae. A transpedicular access kit is available comprised of two 8 gauges (4.8 mm) diameter working cannulae, two pedicle trocars (11 gauges), a manual drill (11 gauges), and six cement injection cannulae.

Radiological Assessment and Vertebral Height Measurements

Vertebral height was measured immediately before and after vertebral augmentation with CT-like multi-planar reconstruction (MPR) obtained by angiographic imaging equipment. Six measurements were taken for each treated level: left, central, and right in the midcoronal reconstruction and anterior, central, and posterior in the midsagittal reconstruction. A CT scan (LightSpeed16; General Electric, Milwaukee, WI) was performed on each patient 1 year postprocedure to check implant position and to repeat measurements. On the same day, a standing plain radiograph of the spine was taken to assess spine alignment, fracture stability, and occurrence of new fractures. Two independent radiologists, blinded to clinical outcomes, performed CT measurements and plain film evaluations.

Pain and Quality of Life Assessment

Patients were asked to rate their perceived pain using a visual analog scale (VAS) of 0–10 where 0 is no pain and 10 is the worst pain imaginable. VAS scores were collected preprocedure (baseline), 24 h postprocedure, and 1 year postprocedure. A reduction of $\geq$2 points on the VAS scale was considered clinically significant [11].

Quality of life (QoL) was assessed using the Oswestry Disability Index (ODI) by administering a questionnaire at the time of clinical interview (baseline), 2 weeks (postprocedure), and 1 year after the procedure. A postprocedural reduction of $\geq$15 points was considered clinically significant [12]. In addition to the evaluations at the planned time points, all patients received standard clinical follow-up.

Statistical Methods

CT measurements of vertebral height followed a normal distribution and therefore means and standard deviations were used as summary statistics for this variable. Baseline, postprocedural and 1-year vertebral height measurements were compared by analysis of variance (ANOVA) with repeated measures. Pairwise comparisons of vertebral height at different time points were performed by the paired Student's t test.

Because VAS and ODI scores did not follow a normal distribution, medians and their ranges were used as summary statistics and comparisons were performed by nonparametric tests. Baseline, postprocedural and 1-year VAS and ODI scores were compared by the Friedman test. Pairwise comparisons of VAS and ODI scores at different time points were performed by the Wilcoxon test. Statistical analyses were performed by the SPSS version 17 statistical package (IBM; Chicago, IL), and significance was set at $p < 0.05$. For multiple comparisons, the Bonferroni correction was applied, so that statistical significance was set at $p < 0.017$ (0.05/3).

Study Limitations

Our Study has Some Limitations:

- Retrospective cohort study, although eligibility and assessments were preplanned.
- Nonrandomized design
- Small number of patients
- No measurements of the Kyphosis angle
- The procedure may be technically complex and time-consuming.

Results

All implants were successfully delivered, positioned, and secured in all study patients. No major complications or perioperative deaths occurred. No venous PMMA leakages were detected during the procedure or with postprocedural CT. Mild asymptomatic cement leakages were detected in 4 of 42 treated levels: one para-pedicular and three inside the vertebral disc. The overall leakage rate was 9.5 % and discal rate was 7.1 %. During follow-up, no device change or migration was observed by blinded radiologists.

Vertebral height measurement, VAS, and ODI scores were available at the baseline and after the procedure (within 24 h and at 2 weeks for VAS and ODI, respectively) for all 40 patients and at 1-year follow-up for 38 patients (median follow-up 15 months; range 11–21 months). Two patients did not complete the 1-year follow-up: patient #30 experienced incomplete pain relief requiring surgical fixation for an underlying mild listhesis, and patient #22 died 6 months postprocedure due to a coronary event unrelated to the procedure.

Table 1 changes in vertebral height are summarized in Table 2. Vertebral height measurements were statistically

Table 1 Patients demographics

Pt. #	Sex	Age (yr)	Disease	Treated Vt	Magerl's class	N° tot	VAS pre	VAS post (early)	VAS diff (early)	VAS 1-year	VAS diff 1-year	Pain relief	New fracture (time and level)	Analg before	Analg after	Brace before	Brace after
1	F	76	Osteoporosis	L3	A1.3	1	10	0	10	3	7	Yes	No	3	0	1	0
2	F	62	Osteoporosis	L2	A1.1	1	6	0	6	0	6	Yes	Yes (15 days L3 trauma)	1	0	1	0
3	F	65	Osteoporosis	L2	A1.3	1	9	2	7	1	8	Yes	No	1	0	1	0
4	F	68	Osteoporosis	T12	A1.1	1	7	0	7	1	6	Yes	No	1	0	1	0
5	F	78	Osteoporosis	T12	A1.1	1	5	0	5	0	5	Yes	No	1	0	0	0
6	F	64	Osteoporosis	T11	A1.1	1	9	0	9	3	6	Yes	Yes (2 mo T11)	1	0	1	0
7	M	55	Trauma	L4	A1.3	1	5	0	5	0	5	Yes	No	1	0	1	0
8	F	78	Osteoporosis	L2	A1.1	1	6	0	6	0	6	Yes	No	1	0	1	0
9	F	77	Osteoporosis	L3 L4	A1.3 A1.3	2	8	2	6	0	8	Yes	No	1	0	0	0
10	F	72	Osteoporosis	T11	A1.1	1	7	1	6	2	5	Yes	No	1	0	0	0
11	M	55	Trauma	L1	A1.1	1	7	0	7	0	7	Yes	No	1	0	0	0
12	F	84	Osteoporosis	T12	A1.3	1	8	1	7	1	7	Yes	No	1	0	1	0
13	F	78	Osteoporosis	T12	A1.2	1	9	1	8	1	8	Yes	No	1	0	1	0
14	F	67	Osteoporosis	T12	A1.1	1	6	0	6	0	6	Yes	No	1	0	0	0
15	F	73	Osteoporosis	L1	A1.1	1	9	0	9	0	9	Yes	No	1	0	1	0
16	M	74	Osteoporosis	L3	A1.1	1	6	0	6	1	5	Yes	No	1	0	0	0
17	F	77	Osteoporosis	L1	A1.3	1	6	0	6	0	6	Yes	No	1	0	1	0
18	F	80	Osteoporosis	L4	A1.1	1	8	0	8	8	0	No	Yes (12 mo L5)	1	1	1	0
19	F	73	Myeloma	L1	A1.3	1	9	1	8	4	5	Yes	Yes (10 mo L2, L3 myeloma)	1	0	0	0
20	F	85	Osteoporosis	T12	A1.2	1	9	2	7	1	8	Yes	No	1	0	1	0
21	F	86	Osteoporosis	T12	A1.1	1	8	0	8	5	3	Yes	No	1	0	1	0
22	F	67	Osteoporosis	L2	A1.1	1	8	0	8	-	-	Yes	No (deceased after 2 mo)	1	0	1	0
23	F	63	Osteoporosis	T12	A1.2	1	9	1	8	1	8	Yes	No	1	0	0	0
24	F	67	Osteoporosis	T11	A1.2	1	5	0	5	0	5	Yes	No	1	0	1	0
25	F	78	Osteoporosis	L1	A1.1	1	10	1	9	1	9	Yes	No	3	0	1	0
26	F	81	Osteoporosis	T12	A1.2	1	9	1	8	3	6	Yes	Yes (2 mo T11)	1	0	1	0
27	F	70	Osteoporosis	L2	A1.1	1	8	0	8	0	8	Yes	No	1	0	1	0
28	F	72	Osteoporosis	L4	A1.3	1	10	2	8	1	9	Yes	No	3	0	1	0
29	F	65	Osteoporosis	T11	A1.2	1	10	0	10	1	9	Yes	Yes (1 mo T10)	1	0	1	0
30	F	66	Osteoporosis	L5	A1.3	1	10	8	2	-	-	No	Surgical fixation	1	1	1	1
31	F	85	Osteoporosis	T12	A1.2	1	10	0	10	0	10	Yes	No	3	0	1	0
32	F	85	Osteoporosis	L1	A1.2	1	10	1	9	1	9	Yes	No	3	0	1	0

Table 1 continued

Pt. #	Sex	Age (yr)	Disease	Treated Vt	Magerl's class	N° tot	VAS pre	VAS post (early)	VAS diff (early)	VAS 1-year	VAS diff 1-year	Pain relief	New fracture (time and level)	Analg before	Analg after	Brace before	Brace after
33	F	76	Osteoporosis	T12	A1.2	1	8	0	8	0	8	Yes	No	1	0	1	0
34	F	80	Osteoporosis	L3	A1.3	1	10	1	9	1	9	Yes	No	1	0	1	0
35	F	74	Osteoporosis	L3	A1.1	1	7	0	7	0	7	Yes	No	1	0	1	0
36	F	82	Osteoporosis	L1	A1.3	1	7	0	7	0	7	Yes	No	1	0	1	0
37	F	83	Osteoporosis	L1	A1.1	2	8	1	7	0	8	Yes	No	3	0	1	0
				L5	A1.3												
38	F	60	Osteoporosis	L2	A1.2	1	7	0	7	0	7	Yes	No	1	0	1	0
39	F	83	Osteoporosis	L1	A1.3	1	10	0	10	0	10	Yes	No	3	0	1	0
40	M	81	Osteoporosis	L4	A1.3	1	5	0	5	0	5	Yes	No	1	0	0	0

significant (ANOVA with repeated measures, $p < 0.001$). Compared with baseline values, vertebral height was significantly increased immediately after the procedure and at the 1-year time point. Conversely, no statistically significant difference between postprocedural and 1-year height measurements were observed, indicating that increases in height obtained with the procedure were stable and long-lasting (Fig. 4).

Median VAS scores at baseline (preprocedure), within 24 h, and at 1 year postprocedure were: 8.0 (range 5–10), 0 (range 0–8), and 0.5 (range 0–8), respectively ($p < 0.0001$). Although all patients achieved a VAS improvement of at least two points, patient #30 with baseline VAS score of ten still had significant pain after the procedure due to underlying listhesis. At 1 year postprocedure, 5 of 38 patients (13 %) had experienced pain increase (≥2 points VAS score increase) compared with initial postprocedural values (Fig. 5). Multiple comparisons showed that both postprocedural and 1-year VAS scores were significantly reduced compared with the baseline ($p < 0.001$ for both comparisons). Conversely, the difference between postprocedural and 1-year scores was not considered statistically significant ($p = 0.06$).

Median ODI scores at baseline (preprocedure), 14 days, and at 1 year postprocedure were: 66 % (range 44–88 %), 4 % (0–82 %), and 6 % (range 6–66 %), respectively ($p < 0.001$). At 1 year, the majority of patients maintained the ODI score achieved at the initial postprocedural time point (Fig. 6). Multiple comparisons showed initial postprocedural and 1-year scores were significantly reduced compared with the baseline ($p < 0.001$ for both comparisons). Conversely, the difference between day 14 and 1-year scores was not statistically significant ($p = 0.176$).

Seven patients experienced new vertebral fractures during follow-up, for an overall subsequent fracture rate of 18.4 %. Patient #2 experienced a high-energy trauma (fell down stairs) 2 weeks after vertebral augmentation. Patient #19 was diagnosed with multiple myeloma at biopsy. Five additional patients experienced new spontaneous, osteoporotic fractures, which equates to a new fracture rate of 13.1 %; all fractures were at adjacent levels. Three fractures were detected on the levels above the treated vertebra (all spontaneous) and four on the level below (including two spontaneous, one traumatic, and one in the patient with myeloma).

Discussion

Vertebral augmentation performed with the nitinol implant system was demonstrated to be safe in this series of patients. No major complications or unanticipated adverse events occurred during the intervention or at 1-year follow-

Table 2 Summary of vertebral height measurements at each time point

Measure	Baseline	Postprocedural	1-year	Diff. post-procedural versus baseline	*p*	Diff. 1 year versus baseline	*p*	Diff. 1 year versus postprocdural	*p*
Mid coronal									
Left	19.6 (4.7)	22.0 (4.4)	21.2 (4.6)	2.5 (2.4)	<0.001	1.7 (2.4)	<0.001	−0.7 (2.4)	0.07
Center	13.2 (4.4)	17.2 (3.5)	17.0 (3.4)	3.9 (2.9)	<0.001	3.8 (2.7)	<0.001	−0.14 (2.1)	0.684
Right	19.0 (4.5)	20.6 (4.5)	21.0 (4.0)	1.6 (1.9)	<0.001	2.0 (2.1)	<0.001	0.39 (1.7)	0.156
Mid sagittal									
Anterior	17.2 (5.6)	19.4 (5.0)	19.2 (5.3)	2.3 (2.3)	<0.001	2.1 (2.8)	<0.001	−0.20 (2.5)	0.611
Center	12.2 (4.5)	16.9 (2.9)	16.4 (2.9)	4.7 (3.6)	<0.001	4.2 (3.2)	<0.001	−0.5 (1.9)	0.096
Posterior	21.7 (3.9)	23.7 (2.9)	23.6 (3.6)	2.0 (2.2)	<0.001	1.5 (2.7)	0.001	−0.44 (2.2)	0.215

Cells report mean values in millimeters with standard deviations in parentheses

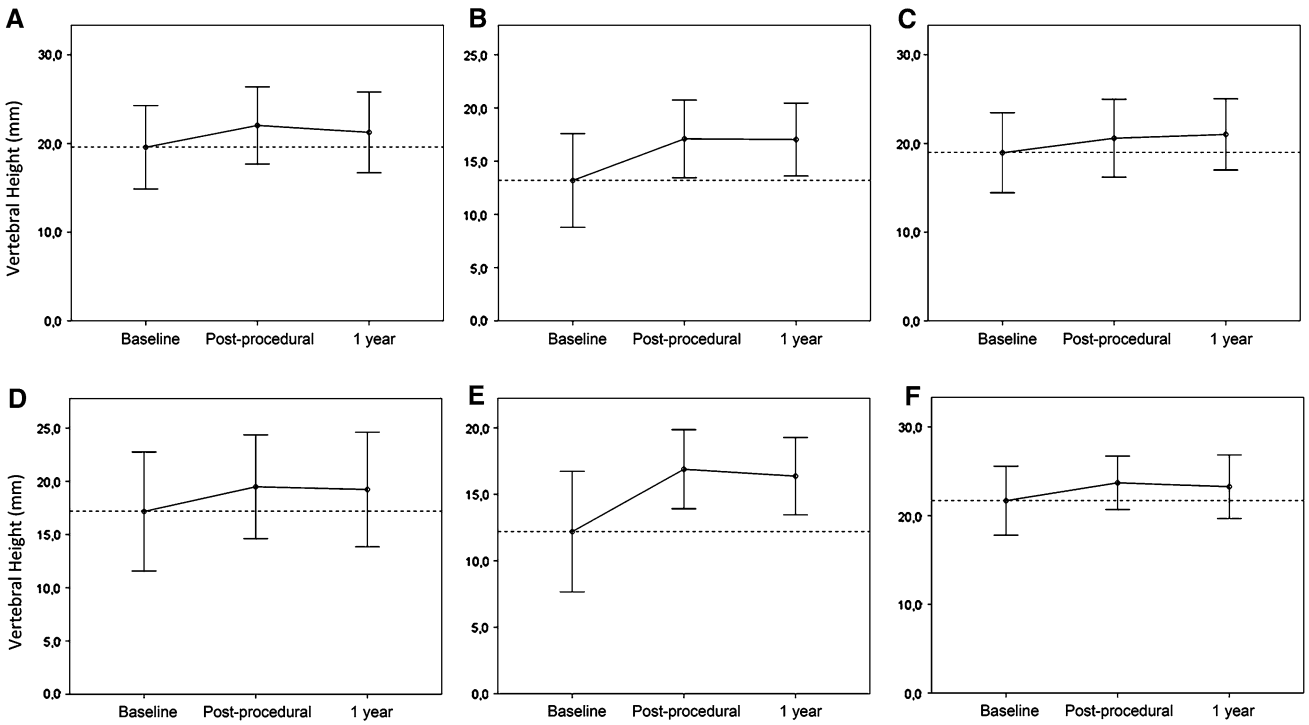

Fig. 4 Changes in vertebral height at different time points in midcoronal (**A** left; **B** center; **C** right) and in midsagittal (**D**, anterior; **E**, center; **F**, posterior) reconstructions. Circles represent mean values and bar represent standard deviations. The *dashed line* is drawn at the *baseline* value on the y axis

up. No venous cement leakages were observed, and the 84 implanted devices exhibited no positional change or observable migration through 1-year follow-up.

There is minimal data published on intervertebral implants for the treatment of vertebral compression fractures, but occurrence of implant migration is not likely to happen as the devices utilize PMMA to provide long-term stabilization and anchoring by surrounding the implant itself. One adverse event was reported in FDA MAUDE database for delayed migration of an implant approved for vertebral body replacement (StaXx ®XD Expandable Device; Spine Wave, Shelton, CT) 3 months after intervention, requiring surgical removal [13]. Because vertebral augmentation is routinely performed percutaneously, an important goal is to minimize complications requiring surgical revision as a result of malpositioning or migration of the implant.

The method of vertebral augmentation in this study was effective in terms of immediate pain relief and quality of life improvement. The improvements in VAS and ODI were durable, lasting through 1-year follow-up, which constituted the main endpoints of this study. The nitinol implant has the theoretical advantage to prevent loss of vertebral height intraoperatively and postoperatively by

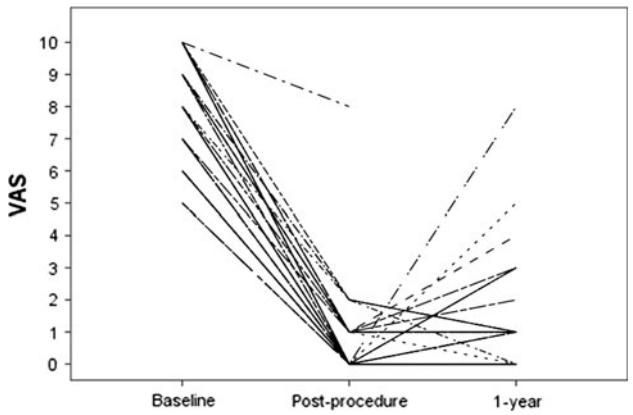

Fig. 5 Changes in VAS scores at different time points. Each line represents a patient

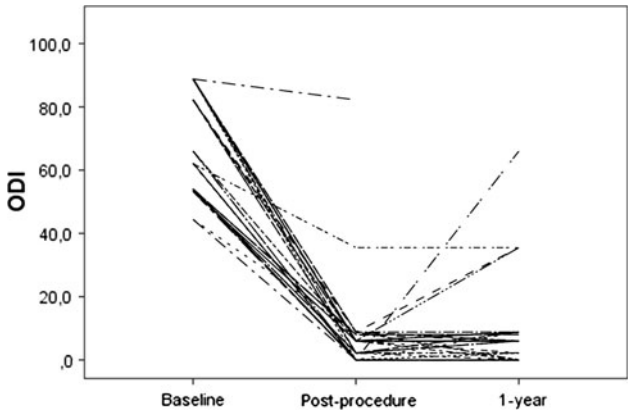

Fig. 6 Changes in ODI scores at different time points. Each line represents a patient

exerting an endplate to endplate lifting that is sustained until bone cement injection and is permanently maintained after polymerization of the PMMA. It has been observed during balloon kyphoplasty procedures that vertebral height restored during inflation of the bone tamp can be lost after balloon deflation due to elastic recoil of the vertebral body. This has been demonstrated in an in vitro study where anterior height loss was significantly higher in balloon kyphoplasty compared with vertebral body stenting (VBS): 12 versus 4 %, respectively ($p = 0.003$) [9]. Both kyphoplasty and VBS rely on balloon-assisted vertebral fracture reduction methods. The presence of an internal, permanent scaffold in the VBS prevents elastic recoil and loss of restored vertebral height. Current VBS technology compared with the nitinol implant used in this study is not easily retrievable or repositionable after expansion, because it is designed for single-stage, permanent deployment. VBS also creates greater bone compaction upon inflation of the expansion balloon. The VBS cavity creating procedure may create less chance for cement interdigitation. Furthermore, VBS cannot reach endplate to endplate, because the stents are smaller in diameter than vertebral body height.

VerteLift access cannulae diameter of 8 gauge is the same as balloon kyphoplasty and other endovertebral stent instrumentation but larger than percutaneous vertebroplasty needle (usually 13 gauges); this should be considered in terms of minimally invasive procedure. Moreover, this procedure requires bipedicular cannulation and is therefore more time consuming (average procedural time of 45 min) than a unipedicular approach, which is usually adequate for vertebroplasty.

In this series of 40 patients, vertebral height was measured in the central point of the endplates. Highest gains were found in the central measurement taken in midcoronal (3.9 mm $\pm$ 2.9) and in midsagittal reconstruction (4.7 mm $\pm$ 3.6). It is possible that height restoration at the point of maximum loss in some patients was greater than the mean values reported because the greatest height loss may have occurred outside the midcoronal or midsagittal plane. Vertebral height restoration was stabilized by the cemented nitinol implant. No statistically significant height loss was detected at 1-year follow-up, whereas height loss at 1-year follow-up for kyphoplasty [14] and vertebroplasty [15] has been reported in the literature.

A comparative trial involving balloon kyphoplasty and a titanium implant was performed in a biomechanical in vitro study [9]. Significantly greater vertebral height loss ($p < 0.025$) was detected after reconstruction with kyphoplasty repair compared with the titanium mesh implant. The biomechanical properties of the two repair techniques were not found to be statistically different, whereas the amount of bone cement required for the titanium implant was less than for kyphoplasty. Cancellous bone was more likely to be preserved with the mesh device, creating a smaller void.

The nitinol implant has been shown to provide endplate-to-endplate partial lifting capabilities in this series, with the additional value of nearly unlimited positioning, repositioning, and retrieval before PMMA injection to achieve optimal vertebral reconstruction. The placement and deployment of the nitinol implant provided predictable, intraoperative vertebral height restoration while preserving cancellous bone. It is likely that preserved cancellous bone provides for effective cement interdigitation and lower volumes of PMMA injection (average 5 mL) necessary for stabilization compared to kyphoplasty procedures. This may be an important observation as the amount and the distribution of bone cement has been associated with the incidence of a subsequent adjacent vertebral fracture [16]. In our experience, all new fractures were located at the adjacent levels, which usually occurs with osteoporotic patients, even if all of them were under medical therapy for osteoporosis before and after the procedure. However, the incidence of new spontaneous vertebral fractures was 13.1 %, which compares favorably with the lower value

ranges reported in other vertebral augmentation procedures.

Conclusions

Vertebral augmentation performed with the nitinol implant is an effective procedure, producing immediate and long-term pain relief, significant improvement in QoL, and durable height restoration with a good safety profile.

Conflict of interest All authors have no conflict of Interest

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