

General

Is vertebral stenting kyphoplasty a good choice in the treatment of osteoporotic vertebral fracture? A series of 47 patients (v2)

Federico Fusini¹, Alessandro Rava², Fabio Zanchini³, Enrico Pola^{3 a}, Luigi Aurelio Nasto, MD, PhD³, Valerio Cipolloni⁴, Giosuè Gargiulo², Angela Coniglio², Alessandro Massè⁵, Girardo Massimo²

¹ Department of Orthopaedic and Traumatology, Regina Montis Regalis Hospital, ASL CN1, Strada S. Rocchetto 99, 12084, Mondovì (CN), Italy,

² Department of Orthopaedic and Traumatology, Spine Surgery Unit, Spine Surgery Unit, Orthopaedic and Trauma Centre, Città della Salute e della Scienza di Torino, via Zuretti 29, 10131 Turin, Italy, ³ Clinical Orthopaedics, University of Campania "Luigi Vanvitelli", via L. de Crecchio 4, 80138, Naples, Italy, ⁴ Spine Division, Department of Orthopaedics and Traumatology, A. Gemelli IRCCS University Hospital, Catholic University of Rome, Largo Francesco Vito 1, 00168, Rome, Italy, ⁵ Department of Orthopaedic and Traumatology, Orthopaedic and Trauma Centre, Città della Salute e della Scienza di Torino, University of Turin, via Zuretti 29, 10131 Turin, Italy

Keywords: percutaneous, poly-methyl-methacrylate, spine fracture, elderly, fragility fracture

<https://doi.org/10.52965/001c.56174>

Orthopedic Reviews

Vol. 14, Issue 4, 2022

Background

The incidence of vertebral fragility fracture is increasing over last three decades with an essential impact on quality of life. Some devices were proposed to improve conventional kyphoplasty in the last five years, known as vertebral stenting kyphoplasty (VSK).

Materials and Methods

All osteoporotic vertebral fractures (OVF) treated with VSK, single-level fracture without neurological impairment, and with more than 24 months of follow-up were included in the study. We recorded fracture types according to DGOU classification, fracture level, regional kyphosis angle (RKA), Oswestry disability index (ODI), and complications.

Results

Forty-seven consecutive patients were included. RKA significantly improved from pre to postoperative values ($p < 0.000001$) and to follow-up values ($p < 0.00001$). A significant difference was found between preoperative RKA of (OF2+OF3) and OF4 ($p < 0.00001$), confirmed immediately after surgery ($p = 0.005425$) and at last follow up ($p = 0.000947$). A significant difference was found in correction of RKA between (OF2+OF3) and OF4 at injury time and after treatment ($p < 0.00001$), and it was confirmed at the last follow-up ($p = 0.000026$). ODI showed a significant difference between (OF2+OF3) and OF4 type of fractures ($p = 0.038216$). We recorded five complications: 2 cases of leakage without neurological impairment, two progressions of kyphosis, and one implant migration.

Conclusions

VSK is an excellent and reliable option in the treatment of OVF, with good clinical results and preservation of obtained RKA at the time of treatment. However, in case of vertebral collapse with the involvement of both vertebral plates, surgeons must be aware of possible implant failure or migration.

Level of Evidence

4

^a Corresponding Author:

Enrico Pola PhD

email: enrico.pola@unicampania.it

phone: +390815665528

INTRODUCTION

The incidence of osteoporosis and fragility fractures is increasing incrementally in industrial countries, afflicting over 14 million people in 2020 in the United States alone.¹⁻³ Among the different types of fragility fractures, osteoporotic vertebral fractures (OVF) impact quality of life, pain, disability, and mortality.^{2,4-6} In this type of fracture, due to the comorbidities and reduced stress resilience of the most affected age group, the elderly, it is crucial to provide an effective and reliable solution to this problem.^{7,8} Typically, OVF can occur after low-energy trauma or with no relation to any specific injury. Treatment options may range from conservative to highly invasive treatments depending on several factors, including fracture shapes and level, the number of injured structures, spinal cord injury, patients' general health status, risk of segment kyphosis, and treatment-oriented scores.⁹

In the last five years, some devices were proposed to solve the increasing demand for fast recovery and pain relief in elderly patients, substituting and improving conventional vertebroplasty and kyphoplasty.¹ Vertebral stenting kyphoplasty (VSK) is a new procedure that allows the restoration of vertebral height and provides anterior support of the vertebral column to prevent any further vertebral collapse.

This study aims to clinically and radiologically evaluate the VSK of OVF of the thoracolumbar spine in elderly patients.

MATERIALS AND METHODS

Between 2017 and 2018, 86 consecutive patients (37 males and 49 females) affected by thoracolumbar OVF were treated by our institution. Patients aged over 65 were included in the study, and all patients had osteoporosis (T score < -2.5 in the DEXA exam within the last 6 months). We included: vertebral fractures according to DGOU classification for Osteoporotic Vertebral Fracture¹⁰ type OF 2, OF3, and OF4, which includes type A fractures of AOSpine Thoracolumbar Spine Injury Classification System.¹¹ Single-level fractures and the absence of neurological impairment were also inclusion criteria. We excluded from our analysis pathologic fractures, type OF 1 and 5, AOSpine type B or C fractures, ankylosing spondylitis, spondylodiscitis-related fractures, or multiple levels.

All patients underwent a posterior percutaneous assisted kyphoplasty with SpineJack (Stryker, USA) under fluoroscopic control.

Spine Jack is a titanium device for mechanical kyphoplasty of injured vertebra¹² intending to restore the height of the vertebral body. The system uses ligamentotaxis of the anterior longitudinal ligament to restore vertebral height. After the desired restoration is obtained under the force of progressive expansion of the device, polymethylmethacrylate augmentation (PMMA) is bilaterally injected to stabilize the system and prevent system malfunctioning.^{12,13}

Table 1. Main demographic characteristics of patients included in the study

	Patients (N=47)
Male	19
Female	28
Age	74,13 +/- 5,65
Follow up	30,68 +/- 8,26
Fracture level	T11 (6), T12 (9), L1 (10), L2 (7), L3 (6), L4 (6), L5 (3)
OF2	10
OF3	19
OF4	18

Table 2. Major findings of RKA before treatment, after treatment and at last follow up and ODI at last follow-up

	Main findings (Mean +/- SD)
Preoperative RKA	15,17° +/- 5,41°
Postoperative RKA	4,51° +/- 2,08°
Last follow up RKA	7,72° +/- 3,41°
ODI last follow up	11,66 +/- 13,44

X-ray examinations were conducted in the days after surgery and at the 1, 3, 6, and 12 months of follow-up and yearly. Radiological data were evaluated for the loss of correction in the sagittal plane with a regional kyphotic angle (RKA). Moreover, we recorded any system failure (progression of kyphosis, mobilization, or subsidence).

Clinical examination through Oswestry Disability Index (ODI)¹⁴ was performed every 6 months and recorded at the last follow-up.

Statistical analysis of RKA and Oswestry Disability Index was performed through Student's t-tests. Fisher exact test was used to assess differences between failure rates, defined as a progression of more than 10° of RKA at final follow-up, according to type lower impact OF fracture type (OF 2, OF3) or high impact OF fracture type (OF4). STATA 13 software was used to perform the statistical analysis. The level of significance was set at p<0.05.

RESULTS

According to inclusion and exclusion criteria, 47 patients (19 males and 28 females) were included in the study. The main demographic characteristics are reported in [table 1 \(tab.1\)](#).

Mean and SD of pre, postoperative and last follow-up RKA and ODI were reported in [table 2 \(tab. 2\)](#).

Statistical analysis showed the reduction of RKA from pre to postoperative values (p<0.00001) and from preoperative and last follow-up values (p<0.00001). The mean correction of RKA from pre to postoperative was 10.61° +/-

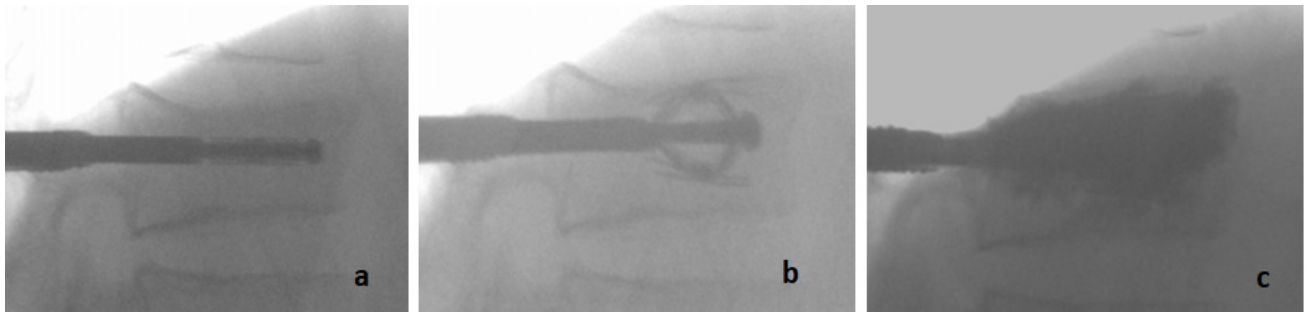


Figure 1. Percutaneous vertebral stenting kyphoplasty from (a) introduction of the device, (b) expansion, and (c) PMMA of the device



Figure 2. An example of implant failure: (a) postoperative VSK of the fractured vertebra and (b) 1 month after hospital discharge with the migration of the implanted device and PMMA to the discal space.

4.4°, while the correction from preoperative to the last follow-up was 7.45° +/- 4.63° (p=0.00099).

A significant difference in preoperative RKA of (OF2+OF3) and OF4 was found (p<0.00001), and the same difference was confirmed immediately after surgery (p=0.005425) and at the last follow-up (p=0.000947). A significant difference was found in RKA correction between (OF2+OF3) and OF4 at the time of injury and after treatment (p<0.00001), and it was confirmed before surgery and last follow-up (p=0.000026).

ODI showed a significant difference between OF2+OF3 and OF4 type of fractures (p=0.038216)

Fisher exact test showed a significant relationship between OF4 and an RKA at the last follow-up of more than 10° (p=0.0407), while the same was not observed for the fracture location (T11 (p=0.571); T12 (p=0.1672); L1 (p=0.0508); L2 (p=0.3287); L3 (p=0.571); L4 (p=1); L5 (p=1)).

We recorded 5 complications: 2 cases of leakage without neurological impairment, 2 progressions of kyphosis, and 1 implant migration. All mechanical complications occurred in patients with DGOU type OF 4 vertebral fractures.

DISCUSSION

In the last years, comprehensive literature supported the progressive shift towards less invasive techniques because mini-invasive approaches have provided similar outcomes to open surgery, with less morbidity.^{15,16}

More and less invasive approaches share the same goals: fracture stabilization to prevent further vertebral collapse and deformity and promote vertebral healing.^{17,18}

Severe kyphotic deformities are more likely to provoke pain; however, the exact degree of kyphosis at which pain is triggered is difficulty measurable.¹⁹ VSK improves conventional balloon kyphoplasty, where several stenting techniques provide reliable results.²⁰ The comparison of SJ with balloon kyphoplasty showed SJ supremacy for restoring vertebral height with less cement volume required.^{12,21}

In literature, an increasing number of studies focused on SJ-treated OVF.²²⁻²⁵

Noriega et al.²⁵ evaluated the clinical and radiological results of patients treated with conventional balloon kyphoplasty or with VSK. They found significantly better clinical outcomes and restoration of kyphotic angle for VSK. The authors found a mean reduction from 24.4° to 11.7°. Our study reached comparable results in kyphosis correction; however, our study showed a few worse out-

comes in ODI (11.66 +/- 13.44 of our study versus 6.0 +/- 3.7). However, it must be noted some differences between studies. The amount of patients treated with SJ is extremely different; we recruited more than 3 times the number of patients of Noriega. Moreover, the mean age of our patients was 74.13 +/- 5.65 (range 66-84) years old, while in the study of Noriega, they were 67.9 (range 61-74), which means the study population was elderly. These could be influencing factors explaining the slight differences between studies.

SJ is a device that provides anterior support to affected vertebral fractures and is especially suitable to prevent further collapse or lower stress on posterior instrumentation containing screws pull out. In literature, secondary loss of w of OVF treated with SJ is rarely reported and often very mild.^{26,27} In our series, we report some cases of implant migration and loss of correction; according to load sharing and traumatic fracture shape classification,^{28,29} more comminuted fractures can obtain a higher correction of kyphosis, but they are more unstable. Fusini et al. already demonstrate in their study that more fragmented and comminuted fractures are more likely to lose correction when treated conservatively. It also means that more severe fragmentation of the vertebral body is more susceptible to further collapse or implant migration.²⁴ As described in the literature, all three cases of mechanical complication occurred in DGOU type OF4 vertebral fracture.

A possible strategy to prevent mechanical complications is to protect the site of VSK with a short segment stabilization, as proposed by Caruso et al.³⁰ However, the inclusion of more vertebral levels in the thoracolumbar junction or lumbar spine instrumentation is essential to avoid loss in the range of motion.³¹

Regarding complications, the rate of cement leakage was comparable with the results of other studies. As for the major part of the literature, the cases of leakage did not require any corrective surgery and were symptomatic.^{22-25,32,33}

Some limitations to this study must be acknowledged: some are related to the retrospective nature of our research, some are intrinsic to the study design, and the low number of patients treated. Moreover, the lack of randomization and a comparative group are crucial biases affecting the results of our study.

CONCLUSIONS

VSK reliable option for the treatment of osteoporotic vertebral fractures, showing promising results. It allows satisfactory clinical results and preservation of obtained RKA at the time of treatment. However, in case of vertebral collapse with the involvement of both vertebral plates, the surgeons must be mindful of possible cement leakage, implant failure, or migration, occurring in approximately 10% of cases. Shall this be the case, short segment fixations of VSK should be taken into consideration.

COMPLIANCE WITH ETHICAL STANDARDS

The study was conducted according to the indications of the Declaration of Helsinki and further amendments. Written informed consent to be included in the study and publication was obtained from each patient.

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