A Comparison of Two New Technologies for Percutaneous Vertebral Augmentation: Confidence Vertebroplasty vs. Sky Kyphoplasty

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ABSTRACT: **Background:** Cement vertebroplasty has been performed for over a decade to treat painful osteoporotic vertebral compression fractures (OVCFs). Kyphoplasty is considered a further step in the evolution of vertebral augmentation.

Objectives: To evaluate the efficiency and safety of two systems to treat OVCF: Confidence Vertebroplasty (CV) compared to Sky Kyphoplasty (SK).

Methods: This prospective study included 45 patients with OVCF. Fourteen were treated with CV and 31 with SK. An imaging evaluation using a compression ratio (height of anterior vs. posterior wall) and local kyphotic deformity (Cobb angle) was performed prior to the procedure and 12 months later. Evaluation of pain was carried out using a visual analogue scale.

Results: The mean compression repair was 12% in the CV group compared to 25% in the SK group. Mean kyphotic deformity restoration achieved using CV was 41% compared to 67% using SK. In both groups the pain severity was equally reduced by a mean of 43%.

Conclusions: The SK system is technically superior in restoring the vertebral height and repairing the kyphotic deformity, an advantage that was not manifested in pain relief – the most important variable. Both systems have a high level of safety. The cost-benefit balance clearly favors the CV system.

IMAJ 2011; 13: 394–397

KEY WORDS: osteoporosis, vertebral fracture, cemental augmentation, vertebroplasty, kyphoplasty

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One-quarter of women over 65 seek medical treatment after osteoporotic vertebral compression fracture, which entails sudden onset of pain and muscle spasm following an injury, physical strain, or no apparent etiology. In one-third of all the patients with OVCF the pain becomes chronic and is accompanied by significant limitation in quotidian functioning [1]. In contrast to what is acceptable in osteoporotic fracture of the neck of femur, which is treated urgently with an internal fixation, limited success is noted in the clinical OVCF with an open fixation using an implant, since there is a real risk of mechanical failure of the anchored screw in the osteoporotic bone, causing high postoperative morbidity.

Vertebroplasty, a minimally invasive technique, was first demonstrated in 1984. This modality involves an augmentation of the OVCF using a percutaneous injection of cement directly into the vertebral body [2]. The preliminary clinical surveys reported a mechanical stabilization of the fracture and immediate and significant pain relief [3]. However, some reservations were raised, mainly the lack of efficiency of this technique to reconstruc the vertebral height and a real risk of neurological deficit following fluid cement leakage into the spinal canal [4].

In 1998, a kyphoplasty technique was described based on the percutaneous insertion of a balloon into the fractured vertebral body. Inflation of the balloon created a defined void with a wall of compressed bone into which the cement can be injected [5]. The first clinical surveys favored the kyphoplasty technique for reconstructing the collapse and for the fewer occurrences of cement leakage [5-7]. However, later reports moderated the importance of maximal reconstruction of the OVCF: although kyphoplasty carries the advantage of lower risk of cement leakage, its high cost as compared with vertebroplasty led a few researchers to the conclusion that the procedure is not cost beneficial [8,9].

The aim of this study was to demonstrate the Confidence Vertebroplasty system, which was designed to restore the clinical efficiency of the standard vertebroplasty, while minimizing the risks of cement leakage. This system was tested in comparison with the Sky Kyphoplasty system. Both were developed by an Israeli company (Disc-O-Tech Medical Technologies Ltd. Herzliya, Israel).

CV = Confidence Vertebroplasty
SK = Sky Kyphoplasty

PATIENTS AND METHODS

The study comprised 45 patients hospitalized in the Meir Medical Center, Kfar Saba, Israel, following OVCF. The study was limited to a single OVCF type A1.2 A1.3, according to the AO classification. The inclusion criteria for the study group were: collapse ≥ 15% of the vertebral height and substantial pain (VAS ≥ 5), which for 8 weeks had not responded to conservative treatment. The exclusion criteria in the study group were: general poor physical state, collapse ≥ 50% of the vertebral height, local kyphotic deformity ≥ 30 degrees, computed tomography demonstrating retropulsion of the posterior wall of the vertebral body and/or signs of root irritation or neurological deficit, and inability to communicate. All patients signed an informed consent.

The Confidence Vertebroplasty system was first introduced in Meir Medical Center in May 2006. The treatment is based on a routine technique of inserting a cannula into the vertebral body. The upgrade is expressed in the unique putty-like cement, mixed in a sealed container, and introduced into the vertebral body using a hydraulic delivery system. Its viscosity, higher than normal, is intended to reduce the risk of leakage.

The Sky Kyphoplasty system has been in use since February 2006. The treatment is based on a routine technique of inserting a balloon into the vertebral body and inflating it to create a defined void with a wall of compressed bone. The system was designed to improve the reconstruction of the vertebral body height and to reduce the cement leakage by use of a piston syringe, which is able to inject the cement in an assessable amount (according to the volume of the balloon) and enable pressure control.

In both groups of patients a clinical assessment was taken, emphasizing possible signs of root irritation/neurological deficit, and the quantification of pain by a visual analogue scale. At the same time, an imaging assessment was performed of the compression ratio (height of anterior wall vs. posterior) of the vertebral body and the kyphotic deformity (Cobb angle). A CT was performed routinely to establish that the posterior wall of the vertebral body is intact.

In both groups the percutaneous surgical approach was identical: the fracture was restored to the maximum by laying the patient in a prone, over-extended position. Under local anesthesia a metal pin was inserted into the vertebral body using real-time imaging in two planes. In general, an extra-pedicle approach was performed in the dorsal spine and trans-pedicle in the lumbar spine. At this stage, the cement was injected according to each system. All patients were discharged after 24 hours and were advised to avoid extreme physical strain for 2 months. Follow-up consultation was at 1, 6 and 12 months after the procedure. These follow-ups included clinical and X-ray assessments, as performed prior to surgery. During the follow-up, any patient who suffered from another compression fracture was excluded from the study group.

All statistical analyses were performed with the use of SPSS software, version 12 (SPSS Inc., Chicago, IL, USA). We used the Fisher exact test for categorical variables. Data at baseline and at follow-up were compared with the use of Wilcoxon signed-rank test for matched pairs. The Mann-Whitney unpaired test was used to find differences between groups. Results are presented as means ± standard deviations. $P < 0.05$ was considered to indicate statistical significance.

RESULTS [Table 1]

The study included 45 OVCFs, 20 in dorsal vertebrae (1=D7, 3=D8, 1=D9, 1=D10, 4=D11, 10=D12) and 25 in lumbar vertebrae (12=L1, 2=L2, 7=L3, 4=L4). Patients' mean age was 72.2 ± 11.9 (CV = 75.57 ± 7.3, SK = 70.74 ± 13.4). Two-thirds of the patients were women (CV = 64%, SK = 71%). 14 OVCFs were treated with CV and 31 with SK. All the fractures were treated within 8 weeks. Deviations within this time frame for both groups were negligible.

The mean compression ratio for both groups was 0.66 prior to treatment and 0.82 following treatment. The CV group's mean compression ratio of 0.71 was restored to 0.81 ($P = 0.029$), and in the SK group the 0.60 was restored to 0.80 ($P = 0.025$). The mean kyphotic deformity for both groups was 16.13 degrees prior to treatment, which was restored to 8.21 degrees. In the CV group, the 17.22 degrees changed to 10.00 degrees ($P = 0.003$), and in the SK group the 15.22 degrees changed to 5.00 degrees ($P = 0.022$).

On admission, the patients reported a mean pain intensity of 7.51 (on a scale of 1–10), and after follow-up the mean pain

Table 1. Comparison of data from both SK and CV series

	CV	SK	Total
No. of patients	14	31	45
Men/women	5/9	9/22	14/31
Age (yrs, mean)	7.4 ± 75.6	13.4 ± 70.74	72.2 ± 11.9
Compression ratio pretreatment	0.71	0.60	0.66
Compression ratio post-treatment	0.81	0.80	0.88
Compression repair (%)	12	25	25
Kyphotic deformity pretreatment (angle)	17.22 ± 5.3	7.2 ± 15.22	16.13 ± 6.3
Kyphotic deformity post- treatment (angle)	10.00 ± 5.2	5.00 ± 4.4	8.21 ± 5.4
Repair of kyphotic deformity (%)	41	67	49
Pain prior to treatment (VAS)	8.07 ± 1.07	7.26 ± 1.9	1.7 ± 7.51
Pain following treatment (VAS)	4.79 ± 2.5	4.03 ± 1.2	4.27 ± 2.2
Reduced pain (%)	41	45	43

VAS = visual analogue scale

intensity was 4.27. In the CV group the mean pain intensity was reduced from 8.07 to 4.79 ($P = 0.002$). In the SK group the mean pain intensity was reduced from 7.26 to 4.03 ($P = 0.0001$).

In both systems there was no report of mechanical procedural failure. No gross leakage out of the vertebral limits was observed using real-time imaging and X-rays at follow-up. No signs of root irritation or neurological deficit throughout or subsequent to the procedure were reported. No infection or signs of embolism were reported.

DISCUSSION

The majority of patients in the study group were women in their eighth decade of life who were suffering from OVCF in the dorso-lumbar junction, and these data correlate to the general profile of OVCF patients. The timing of the treatment is problematic. The time interval until treatment was limited to 2 months. Vertebral augmentation has been shown to have high efficiency in the deformity test so long as it was performed within this time interval [10]. In all probability, the time limitation could prevent the option of non-operative treatment. Recently, controlled trials have questioned the overall efficacy of vertebroplasty as compared with conservative treatment [11,12].

The mechanism of OVCF causes bending and compression that causes a maximal collapse of the vertebral frontal wall, creating a local kyphotic deformity. The objective of stabilization is maximal reconstructing of the vertebral height, restoring the kyphotic deformity, and more importantly, immediate pain relief. The impression was that SK had an advantage in reconstructing the collapse. The restoring mechanism of the collapse in the CV is laying the patient in a prone over-extended position [13-15]. The goal of injecting the cement is to preserve the restored state. The "jack" effect, achieved in SK, was found to have greater efficiency. The term kyphoplasty refers to reconstructing the deformity measured in degrees. The impression was that SK has a certain advantage with this variable as well, in concordance with literature reports that address parallel devices [16,17].

The most significant variable in the OVCF treatment is the relief of associated pain. Even though SK was superior in reconstructing the collapse and repairing the kyphotic deformity, this advantage was not manifested in pain reduction. Patients in both groups reported relief of intense pain, up to half the intensity following augmentation, which agrees with other reports [8,18]. Relief of pain is ascribed to the mechanical stabilization of the vertebrae and thermal elimination of the sensory neural system [19]. This is attained equally with both systems.

Cement leakage from the vertebrae was reported by others in approximately a quarter of the injection cases [20,21], and its prevalence is directly related to the pressure regulation capability of the injection and the low viscosity of the cement. In the CV system, safety is achieved by the designated compressor, which allows effective regulation of the pressure needed for injecting the viscose cement. In the SK system safety is achieved by creating a defined void with compressed bone walls, limiting the leakage of cement out of its boundaries. Indeed, a real-time control through imaging and X-ray at follow-up prevented crude cement leakage in each of the patients in both groups. No significant short-term complication occurred, such as neurological deficit, lung embolism, or deep infections, as were reported at a mean rate of 2.4% using parallel systems [22].

Secondary OVCFs, following stabilization of the primary OVCF, were not examined in this study. We believe neither of the systems offered an advantage in this context. The kyphoplasty systems are superior in repairing the angle of the local kyphosis; however, they do not change the general sagittal balance of the spine significantly [23]. Compromise of the latter was associated directly with occurrences of subsequent OVCFs [24]. The consensus is that additional/subsequent OVCFs are a consequence of basic pathology, which weakens all the vertebrae [25].

In summary, we have shown that the SK system is technically superior in reconstructing the collapse and repair of the local kyphotic deformity, but this advantage is not manifest in the main index of procedure success – namely, pain relief. Both systems have a high level of safety. In the cost-benefit balance, the CV system has a clear advantage.

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