Osseofix® System for Percutaneous Stabilization of Osteoporotic and Tumorous Vertebral Compression Fractures – Clinical and Radiological Results After 12 Months

Minimalinvasive perkutane Stabilisierung osteoporotischer und tumoröser Wirbelkörperfrakturen mit dem Osseofix®-System – klinische und radiologische Ergebnisse nach 12 Monaten

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Abstract

Purpose: Determining whether implantation of an expandable titanium mesh cage (Osseofix® system) is a successful and safe minimally invasive therapy for osteoporotic and tumorous vertebral compression fractures (VCFs).

Materials and Methods: 32 patients (25 women, 7 men, mean age 71) with 46 osteoporotic or tumorous VCFs (T6 to L4) from June 2010 to January 2012 were included. All of them were stabilized with the Osseofix® system. Preinterventionally we performed X-ray, MRI, and bone density measurements (DXA). The clinical and radiological results were evaluated preop, postop and 12 months postop based on the visual analog scale (VAS) and the Oswestry Disability Index (ODI), X-ray (Beck Index, Cobb angle) and CT.

Results: There was a significant improvement in pain intensity (VAS) (7.8 to 1.6) as well as a significant reduction in the mean ODI (71.36 % to 30.4 %) after 12 months. The mean kyphotic angle according to Cobb showed significant improvements (12.3° to 10.8°) after 12 months. Postinterventional imaging showed one case of loss of height in a stabilized lumbar vertebral body (2.2 %) in osteoporosis and one case with adjacent fracture (2.2 %) in osteoporosis. We saw no changes in the posterior vertebral wall. Except for one pronounced postoperative hematoma, we saw no surgical complications including no cement leakage.

Conclusion: The clinical mid-term results are good at a low complication rate. The stabilization of symptomatic osteoporotic and tumorous VCFs with the Osseofix® system is a safe and effective procedure, even in fractures with posterior wall involvement. The Osseofix® system is an interesting alternative to the established procedures of cement augmentation.

Key Points:
- The Osseofix® system is well suited for stabilizing osteoporotic and tumorous VCFs.
- It is a safe and effective procedure without cement leakage and with a low complication rate.
- The procedure is an interesting alternative to established cement augmentation procedures.

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Zusammenfassung

Ziel: Ermittlung, ob das expandierbare Titannetz (Osseofix®-System) ein geeignetes und sicheres minimalinvasives Verfahren zur Versorgung osteoporotischer und tumoröser Wirbelkörperkompressionsfrakturen (WKKF) darstellt.

Material und Methoden: 32 Patienten (25 Frauen, 7 Männer, mittleres Alter 71) mit 46 osteoporotischen bzw. tumorösen WKKF (BWK6-LWK4) wurden im Rahmen einer prospektiven Studie zwischen Juni 2010 und Januar 2012 mit dem Osseofix®-System stabilisiert. Präinterventionell erfolgte eine Nativ-Röntgen- und eine MRT-Bildgebung sowie eine Knochendichtemessung (DXA). Evaluierung der klinischen und radiologischen Ergebnisse prä-, postoperativ und 12 Monate postoperativ anhand der Visuellen Analogskala (VAS), des Oswestry Disability Index (ODI), Nativ-Röntgen-Diagnostik (Beck-Index, Cobb-Winkel) und CT.

Ergebnisse: Es konnte eine signifikante Reduktion der Schmerzintensität (VAS) von präoperativ 7,8 auf 1,6 nach 12 Monaten und eine signifikante Verbesserung des Aktivitätsniveaus (ODI) von präoperativ 71,36 auf 30,4 % nach 12 Monaten erreicht werden. Der mittlere Kyphosewinkel nach Cobb zeigte eine signifikante Verbesserung von präoperativ 12,3° auf 10,8° nach 12 Monaten. Die bildgebende Verlaufsdiagnostik zeigte jeweils in einem Fall (2,2 %) nach stabilisierter lumbaler osteoporotischer Fraktur eine Wirbelkörpernachsinterung und eine Anschlussfraktur. Eine Veränderung der Hinterkantensituation sahen wir in keinem Fall. Operationsbedingte Komplikationen, inklusive Zementleckagen, sahen wir, bis auf ein nicht revisionspflichtiges ausgeprägtes postoperatives Hämatom, nicht.

Schlussfolgerung: Die klinischen Ergebnisse im mittelfristigen Verlauf sind gut bei niedriger Komplikationsrate. Die Stabilisierung osteoporotischer und tumoröser WKKF mit dem Osseofix®-System ist ein sicheres und effektives Verfahren, auch bei Beteiligung der Wirbelkörperhinterkante. Es stellt eine interessante Alternative zu etablierten zementaugmentierenden Verfahren dar.

Introduction

More than 400 000 vertebral fractures are diagnosed each year in Europe [1] with 80 % being osteoporotic and 20 % being tumorous or traumatic [2]. Osteoporosis as a very common systemic skeletal disease affects 4 – 6 million people in Germany alone [3] and results in vertebral compression fractures (VCFs) in 16 % of postmenopausal women and in 25 % of patients over the age of 70 [4]. Due to a change in demographics, the rate of vertebral fractures is expected to double by the year 2050 [5].

The key symptom of a vertebral fracture is back pain with limited functional mobility [6]. Vertebral fracture can cause kyphotic deformity of the spinal column and the limited mobility results in an increased risk of deep vein thrombosis, pulmonary embolism, and pneumonia [6].

In the case of a stable new symptomatic osteoporotic or tumorous vertebral fracture without symptoms of neurological deficit and if a conservative treatment approach, there being a clear recommendation for the treatment of such osteoporotic vertebral fractures in the current osteoporosis guidelines of the Umbrella Organization for Osteology [7], does not yield a sufficient reduction of symptoms, vertebroplasty and kyphoplasty are available as established minimally invasive methods for stabilizing vertebral bodies [7 – 10].

Special complications of both procedures are mainly caused by uncontrolled leakage of bone cement [8, 9]. Therefore, a suitable alternative was sought. Since 2009, the expandable titanium mesh cage (Osseofix® system) has provided a further option for the minimally invasive percutaneous stabilization of osteoporotic and tumorous thoracolumbar compression fractures [11].

The goal of our study was to clarify whether the Osseofix® system is a suitable minimally invasive procedure for stabilizing ***osteoporotic and tumorous vertebral compression fractures.*** Our study describes the method of the Osseofix® system with presentation of our clinical and radiological results after 12 months in 32 patients with 46 vertebral compression fractures.

Materials and Methods

Patients

In a prospective study, stabilization with an expandable titanium mesh cage (Osseofix® system) (Alphatec Spine Inc., Carlsbad, California, USA) was performed between June 2010 and January 2012 in 32 consecutive patients (25 women, 7 men, average age 71, min. 55, max. 89) with 46 symptomatic osteoporotic or tumorous vertebral compression fractures (AO-type A1.1-A1.3 and A3.1).

The average duration of symptoms was 8.9 weeks (min. 3, max. 15). A conservative treatment approach prior to surgery had not provided a sufficient reduction of symptoms. In 11 cases (osteoporotic fractures), MRI showed posterior edge involvement (AO type A3.1).

Table 1 provides an overview of the stabilized vertebral bodies in relation to location and cause of the vertebral fracture.

One vertebral fracture in 22 patients, two in 8 patients, three in one patient, and five in one patient were treated during surgery. A T12 fracture and an L1 fracture were stabilized simultaneously in two patients. Lumbar and thoracic bipedicular implantation was performed from T12 through 9. From T8, lateral extrapedicular stabilization was performed with an Osseofix® implant.

A vertebral body between two new vertebral fractures was not also stabilized in any case.

Inclusion criteria were a symptomatic new lumbar or thoracic osteoporotic or tumorous vertebral fracture and unsuccessful conservative therapy.

Exclusion criteria were symptoms of neurological deficit, involvement of the posterior edge with relevant constriction of the spinal canal and a known allergy to the ingredients of the Osseofix® system or the bone cement.

Clinical examination and recording of the anamnesis, evaluation of the pain intensity (visual analog scale (VAS)) and the activity level (Oswestry Disability Index (ODI)) [12], X-ray of the region in a standing position on 2 planes, MRI (T1w and T2w sequences including fat-suppressed sequences) to verify the new fracture, and a bone density measurement (DEXA) in the region of the lumbar spine (L1 – 4) and at the proximal femur (Lunar Prodigy Advance, General Electric) were performed preoperatively. Clinical and radiological follow-up evaluation was performed 3 days postoperatively and after 12 months (12 – 15 months).

Clinical evaluation was performed on the basis of the VAS and ODI.

Radiological evaluation was performed via X-ray of the region in a standing position on 2 planes and postoperative CT.

For the quantitative evaluation of vertebral deformation, the Beck Index [13], the vertebral kyphotic angle (α-angle), and the regional Cobb angle (γ-angle) [14] were determined (**Fig. 1a, b**). The kyphotic angle has a positive sign in the case of kyphosis and a negative sign in the case of lordosis. If non-adjacent vertebral bodies were stabilized in patients, the kyphotic angle was determined separately for each vertebral body height. If adjacent vertebral fractures were treated, the kyphotic angle was determined using the treated vertebral body [15].

The radiological follow-up evaluation included an assessment in relation to a loss of height and a change of the pos-

Table 1 Overview oft the stabilized vertebral bodies (n = 46) in relation to location and cause of vertebral fracture.

number	vertebral height	cause of fracture
1.	T6	osteoporosis
2.	T8	osteoporosis
3.	T8	osteoporosis
4.	T8	osteoporosis
5.	T8	plasmacytoma
6.	T9	osteoporosis
7.	T9	osteoporosis
8.	T9	breast cancer
9.	T9	unknown
10.	T10	osteoporosis
11.	T10	breast cancer
12.	T11	osteoporosis
13.	T11	osteoporosis
14.	T11	osteoporosis
15.	T11	breast cancer
16.	T12	osteoporosis
17.	T12	osteoporosis
18.	T12	osteoporosis
19.	T12	osteoporosis
20.	T12	osteoporosis
21.	T12	breast cancer
22.	L1	osteoporosis
23.	L1	osteoporosis
24.	L1	osteoporosis
25.	L1	osteoporosis
26.	L1	osteoporosis
27.	L1	osteoporosis
28.	L1	osteoporosis
29.	L1	osteoporosis
30.	L1	breast cancer
31.	L2	osteoporosis
32.	L2	osteoporosis
33.	L2	osteoporosis
34.	L2	osteoporosis
35.	L2	osteoporosis
36.	L2	osteoporosis
37.	L3	osteoporosis
38.	L3	osteoporosis
39.	L3	osteoporosis
40.	L3	osteoporosis
41.	L3	osteoporosis
42.	L3	osteoporosis
43.	L4	osteoporosis
44.	L4	osteoporosis
45.	L4	osteoporosis
46.	L4	prostate cancer

terior edge of the stabilized vertebral body, cement leakage, and adjacent fractures.

It was also determined whether there is a connection between the T-score and the postoperative pain intensity (VAS) and between the change in the sagittal spine alignment and the activity level (ODI).

Technique/application of the Osseofix® system

The Osseofix® system (Alphatec Spine Inc., Carlsbad, California, USA) was used in all cases. The system can currently only be used with bone cement.

Three implant sizes with an unexpanded diameter of 4.5 mm, 5.5 mm, and 7.0 mm are available (**Fig. 2**). The Osseofix® implants are for use in the T1-L5 region. They are made of a combination of a titanium alloy (Ti-6Al-4V, ASTM F 136) and pure titanium (Ti-CP2, ASTM F67).

Preoperative evaluation of plain radiographs of the spine for determining the suitable implant size as well as axial sectional images with respect to the pedicle convergence have proved to be successful.

The average operation time per vertebral body was 52 min. (SD ± 8.2, min. 35, max. 81) and a fluoroscopy time of 1.21 minutes (SD ± 0.29, min. 0.39, max. 2.89) with a cumulative radiation dose of 17.4 milligray (SD ± 2.1, min. 7.1, max. 35.2) was required.

Osseofix® implants with an original (not expanded) size of 4.5 mm (T6-L4) were used in 38 vertebral bodies and the size 5.5 mm (L1 – 4) was used in 8 vertebral bodies. The same size was always used for bipedicular implantation. An average of 0.65 ml of bone cement (SD ± 0.12, min. 0.5, max. 0.9) was applied per implant with more cement being used for the larger implants.

The operation was performed in every case under intubation anesthesia and the patients received a perioperative i. v. single-shot antibiosis (1.5 g Cefuroxime or in case of allergy 600 mg clindamycin). A uniplanar fluoroscopy unit (Veradius, Philips) with a double monitor was used intraoperatively.

Postoperative patient mobilization was performed in a pain-adapted manner starting on the first postoperative day with standing up of the patient under physiotherapeutic instruction and with physical therapy in the further course of recovery to strengthen the spine-stabilizing musculature. Postoperative thromboembolism prophylaxis with a low-molecular heparine derivative was performed in all patients. Previously prescribed pain medication was continued postoperatively and reduced over time. In the case of an osteoporotic vertebral fracture, a special osteo-

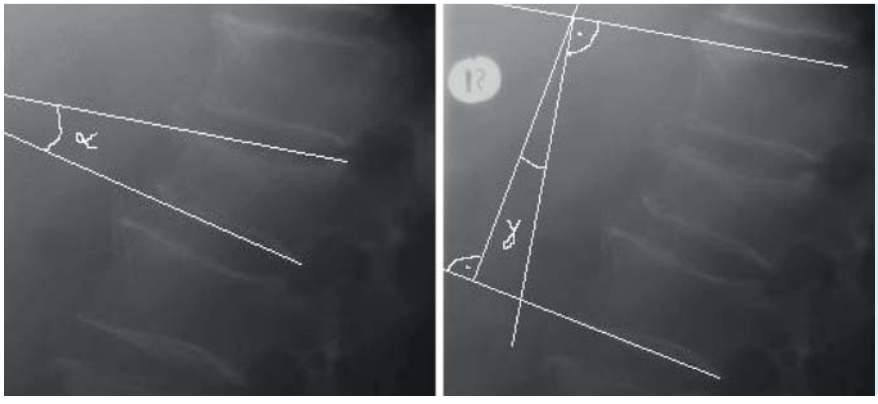


Fig. 1 **a** Determination of α-kyphosis angle. **b** Determination of y-kyphosis angle.

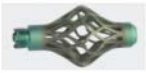
Non-expanded implants	Expanded implants	Original diameter (mm)	Original length (mm)	Maximum expanded diameter (mm)	Final length (mm)
 21290-45 S		4,5	26,4	11,4	22,8
 21290-55 S		5,5	30,0	13,0	26,4
 21290-70 S		7,0	35,2	14,8	31,7

Fig. 2 Osseofix® implants with technical specifications [Alphatec Spine Inc., Carlsbad, California, USA].

porosis medication was continued if available (29 % of the patients) or an oral medication with a bisphosphonate was started (71 % of the patients). In the case of a tumorous vertebral fracture, a previously prescribed bisphosphonate medication was continued (50 % of the patients) or in the case of oncological recommendation bisphosphonate medication was started (25 % of the patients). In addition, in the case of a tumorous fracture, the patient was postoperatively referred to a radiation therapy specialist for determining an indication for radiation or for undergoing radiation.

Interventional procedure of the Osseofix® system

Patient in prone position; determination of the height of the vertebral body to be stabilized via X-ray control on two planes; exact a. p. positioning of the vertebral body and subsequent transverse stab incision slightly lateral to the pedicle plane; positioning of an 11G Jamshidi needle with fully inserted trocar under X-ray control in the region of the upper outer pedicle quadrant and transpedicular advancement of the needle under X-ray control (a. p. and lateral beam path) until the posterior edge of the vertebral body is reached; no exceeding of the medial pedicle boundary in the a. p. beam path until the posterior edge of the vertebral body is reached; replacement of the trocar from the Jamshidi core needle with a guide wire and insertion of the guide wire into the vertebral body (middle third) under X-ray control, while ensuring that the wire does not cross the middle line on the a. p. plane; removal of the Jamshidi core needle while leaving the guide wire in place and introducing a drill sleeve to the pedicle base to protect soft tissues from the drill; insertion of the drill (drill diameter corresponds to the diameter of the non-expanded implant) via the guide wire into the drill sleeve; clockwise screwing in of the drill under X-ray control to the anterior third of the vertebral body; positioning of the drill in the anterior vertebral body so that it is several millimeters posterior to the anterior cortical bone of the vertebral body; removal of the drill; replacing of the drill sleeve with a working cannula of the insertion apparatus; insertion of the non-expanded Osseofix® implant screwed onto the distal tip of the insertion apparatus via the guide wire; positioning of the implant in the vertebral body under X-ray control with special attention being paid to ensuring an anterior position to the greatest extent possible since the implant is shortened in the front region when expanded; removal of the guide wire and subsequent expanding of the Osseofix® implant under lateral X-ray control; the system has a stop mechanism to prevent excessive expansion of the implant; removal of the insertion apparatus while leaving the working cannula in place; insertion of the Osseofix® bone cement (PMMA) into the implant via the cement cannula once the cement has reached the working consistency under a. p. and lateral X-ray control; application of approx. 0.6 – 0.9 ml of bone cement depending on the size of the implant until the cement minimally exceeds the implant boundaries; sealing of the posterior region of the implant with a plug until the cement hardens to prevent cement reflux; removal of the cement cannula and the working cannula after hardening of the cement and performing of a final X-ray control in a. p. and lateral projection; bipedicular approach to vertebral body stabilization if possible.

Statistical evaluation was performed with **SAS®** version **9.1** using the Wilcoxon rank sum test for continuous variables (α- and γ-kyphotic angle) and the sign test for changing variables (ODI and VAS). Evaluation with respect to a connection between the postoperative Cobb angle and the ODI and the T-score and the postoperative pain intensity (VAS) was performed with the Fisher's exact test. The results were calculated as averages and standard deviations (SD). A probability of $p < 0.05$ was required to reject the null hypothesis and to determine a statistically significant difference.

Results

Clinical evaluation

32 patients (46 treated vertebral fractures) were able to be evaluated preoperatively, postoperatively and after a follow-up period of 12 months.

A significant improvement ($p < 0.001$) of the average VAS and the ODI was seen after 12 months for all fractures (n = 46) as well as separately for the osteoporotic and the tumorous fractures. The average preoperative VAS was 7.8 points (n = 46, SD ± 1.6; min.: 5; max.: 10), the postoperative VAS was 2.1 (n = 46, SD ± 1.2; min.: 0; max.: 5) and after 12 months it was 1.6 points (n = 46, SD ± 0.95; min.: 0; max.: 3). The average preoperative ODI was 71.36 % (n = 46, SD ± 4.3; min.: 62; max.: 78), the postoperative ODI was 31.6 % (n = 46, SD ± 5.3; min.: 24; max.: 48) and after 12 months it was 30.4 % (n = 46, SD ± 3.6; min.: 24; max.: 42) (**Fig. 3a, b**).

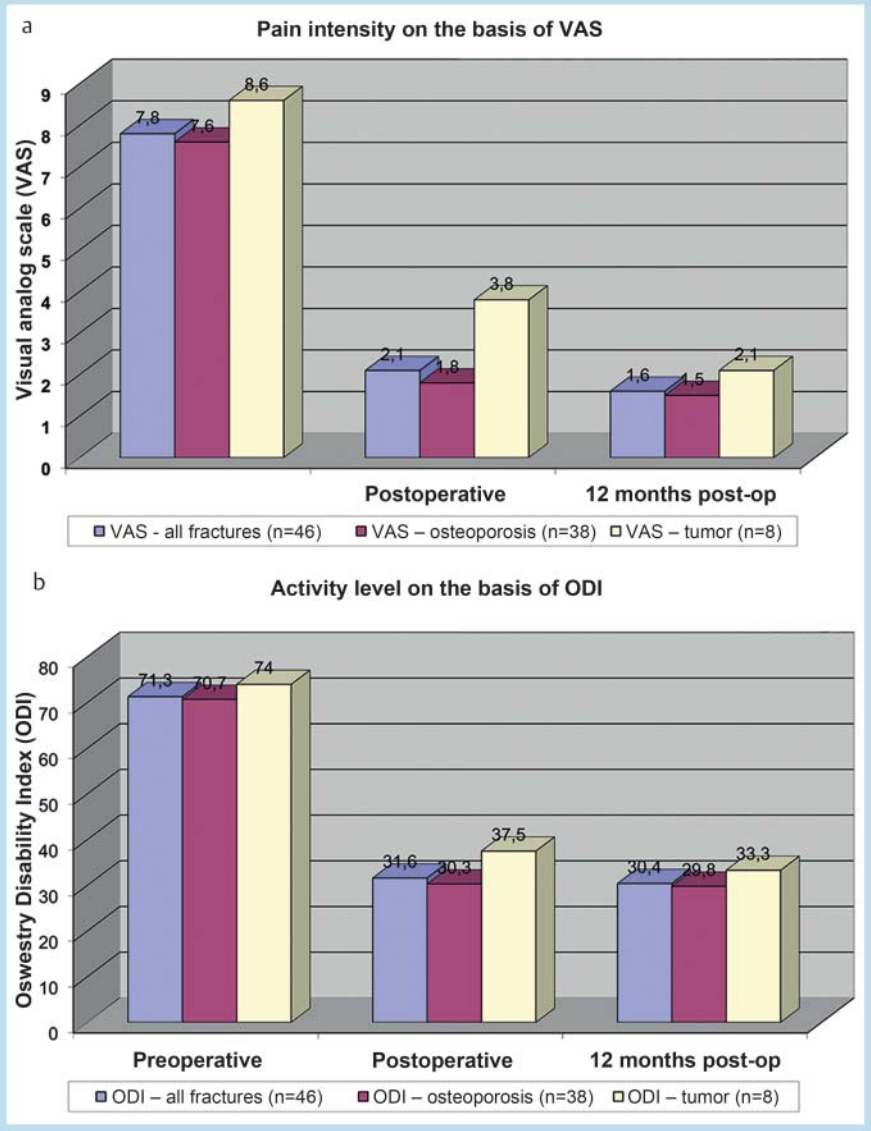


Fig. 3 **a** Change in VAS (46 vertebral fractures in 32 patients) – preoperative, 3 days postoperative and at 12-month follow-up; common reprensentation for all fractures (n = 46) and separately for osteoporotic (n = 38) and tumorous (n = 8) fractures. **b** Change in ODI (46 vertebral fractures in 32 patients) – preoperative, 3 days postoperative and at 12-month follow-up; common reprensentation for all fractures (n = 46) and separately for osteoporotic (n = 38) and tumorous (n = 8) fractures.

Table 2 Change in sagittal spine alignment (46 vertebral fractures in 32 patients) – preoperative, 3 days postoperative and after 12-month follow-up

sagittal spine alignment	average value preop	average value 3 days postop	average value 12 months postop	p-value preop.–12 months
vertebral kyphotic angle (α-angle)	9.0° (SD ± 5.8; min.: –2.8; max.: 21.9)	8.3° (SD ± 5.6; min.: –2.8; max.: 20.2)	8.3° (SD ± 5.5; min.: –2.8; max.: 20.1)	$p < 0.05$
Cobb angle (γ-angle)	12.3° (SD ± 16.4; min.: –38.0; max.: 34.0)	10.8° (SD ± 16.4; min.: –44.0; max.: 33.0)	10.8° (SD ± 16.3; min.: –44.0; max.: 33.0)	$p < 0.05$

Radiological evaluation

The average Beck Index changed from a preoperative value of 0.75 (n = 46, SD ± 0.14; min.: 0.42; max.: 1.1) to a postoperative value of 0.77 (SD ± 0.15; min.: 0.5; max.: 1.1) and to 0.77 (SD ± 0.14; min.: 0.5; max.: 1.1) in the follow-up evaluation. The changes of the average vertebral kyphotic angle (α-angle) and the average Cobb angle (γ-angle) are summarized in **Table 2**.

We did not see a change in the situation of the posterior edge or cement leaks.

Fig. 4, 5 shows radiological diagnostics in the course of time of two patients. The preoperative bone density measurement (DEXA) yielded an average BMD of 0.7959 g/cm^2 (SD sixsp;± 0.09, min. 0.92, max. 052), an average T-value of –3.3 (SD ± 0.74, min. –2.3, max. –5.4) and an average Z-value of –1.9 (SD ± 0.72, min. –0.8, max. –3.9).

General complications

We did not see any perioperative complications. A pronounced postoperative hematoma not requiring revision occurred in one patient with an intraoperative hypertonic crisis with systolic blood pressure values > 200 mmHg. Additional postoperative (up to 3 months after intervention) complications, such as neurological complications, bleeding, wound healing disturbance, infections, phlebothromboses and pulmonary embolisms, did not occur.

Special complications

A symptomatic L2 adjacent fracture occurred in one patient after stabilization of an osteoporotic L3 fracture during the stationary postoperative period. This was also stabilized with the Osseofix® system.

Minor loss of height of the stabilized L2 vertebral body in an osteoporotic fracture was seen in one case. The Beck Index changed postoperatively from 1.0 to 0.96 and the Cobb angle (γ) changed from 11 degrees to 13 degrees. The VAS value (2) remained unchanged.

Discussion

Kyphoplasty and vertebroplasty are established minimally invasive methods of stabilizing osteoporotic and tumorous thoracolumbar vertebral compression fractures [6, 16, 17].

Both procedures have yielded good medium-term (12 months) clinical results (VAS and ODI) for the stabilization of osteoporotic and tumorous vertebral compression fractures and significant postoperative pain reduction was also confirmed in the medium term [6, 8, 9, 16 – 18].

Vertebroplasty with its strong interlocking of bone cement and spongiosa provides low or no correction of the sagittal spine alignment, while kyphoplasty as a further development of vertebroplasty provides partial restoration of the original sagittal spine alignment by increasing the vertebral height [19]. However, the increased height of the vertebral body does not significantly improve clinical symptoms [20]. A connection between an increased risk for adjacent fractures and the degree to which the vertebral height was increased was found [21, 22].

Special complications of both procedures are the leakage of bone cement via the venous plexus with possible consecutive pulmonary embolism as well as leakage of cement into the epidural space with complications ranging from possible spinal canal constriction and resulting neurological deficits to symptoms of paraplegia [8, 9]. Due to the risk of epidural cement leakage, vertebral fractures with involvement of the posterior edge can only be treated by these two methods with restrictions [23]. The incidence of cement leakage is lower for balloon kyphoplasty [8] and can be explained by the cement application with low pressure in a previously created intraosseous cavity [23]. Cement leakage rates of 19 – 70 % (3 % symptomatic) for vertebroplasty in osteoporotic vertebral compression fractures and 4 – 13 % (1 % symptomatic) for balloon kyphoplasty [19, 24, 25] or 6 % for radiofrequency kyphoplasty [26] have been reported. Cement leakage rates of 15 – 79 % for vertebroplasty and 6 – 12 % for kyphoplasty have been reported for the stabilization of tumorous vertebral fractures [6, 17].

Since 2009, the Osseofix® system (expandable titanium mesh cage) has provided an interesting alternative for the percutaneous minimally invasive stabilization of the abovementioned vertebral compression fractures [11].

In our study the Osseofix® system showed clinical results comparable to those of vertebroplasty and kyphoplasty in the medium term. We saw a significant improvement in the pain intensity (VAS) and the activity level (ODI) after 12 months for osteoporotic and tumorous vertebral compression fractures.

We could not establish a relationship between the preoperative T-score and the clinical follow-up result (VAS) ($p = 1.0$). A bisphosphonate medication prescribed by us was still being taken after 12 months by 56 % of the patients with osteoporotic vertebral fracture and 100 % of the patients with tumorous vertebral fracture. Baum and Peters [28] reported a continuation rate of bisphosphonate medication of 62 % 12 months after the completion of intensive osteoporosis training.

We saw one case of adjacent vertebral fracture (2.2 %) during the follow-up examination after 12 months. This is a good result compared to the adjacent fracture rates of 0 – 8 % for vertebroplasty and 25 – 26 % for kyphoplasty (follow-up period of 3 – 12 months) for stabilized osteoporotic vertebral compression fractures [10, 27] and 0 – 18 % [6, 28] for vertebroplasty and 2.9 – 18 % for kyphoplasty (follow-up period of 9 – 12 months) for stabilized tumorous vertebral fractures [6, 17, 28]. This may indicate a change in the biomechanics of a vertebral body stabilized with the Osseofix® system compared to one stabilized exclusively with bone cement [11]. In addition to the abovementioned degree to which the vertebral body height is increased, the intradiscal cement leakage was shown to result in a method-based increased risk for adjacent fractures after vertebroplasty and kyphoplasty [21, 22].

We saw a minor loss of the height of the cover plate of a stabilized lumbar vertebral body (L2) in one case. The literature provides only sparse information about a secondary loss of height resulting in a certain recurrence of kyphosis [29]. Rates of 0 % to 63 % [30, 31] for vertebroplasty and 14 – 50 % for kyphoplasty are described [32, 33] (follow-up period of 6 – 27 months). Our rate of a secondary loss of height of 3.1 % is low. It must be taken into consideration here that the increase in vertebral body height by the Osseofix® system is minor compared to that of kyphoplasty. Lin et al. [30] found a significantly higher risk for vertebral refractures after vertebroplasty as a function of the increase in vertebral body height.

The average Cobb angle (γ-angle) improved significantly from a preoperative angle of 12.3° to 10.8° after 12 months. Comparable values for vertebroplasty have been reported [18]. However, significantly better values for kyphoplasty with an average improvement of the Cobb angle of 8° have been found in some cases [18, 25]. We did not find a relationship between improvement or lack of improvement of the Cobb angle and the clinical result (ODI) ($p = 1.0$).

In the Osseofix® system only small quantities of bone cement are applied to an existing cavity (expanded titanium mesh cage) (0.65 ml on average per titanium mesh cage). Cement leakage was not seen when using the Osseofix® system (cement leakage rate 0 %). In this regard, the use of the

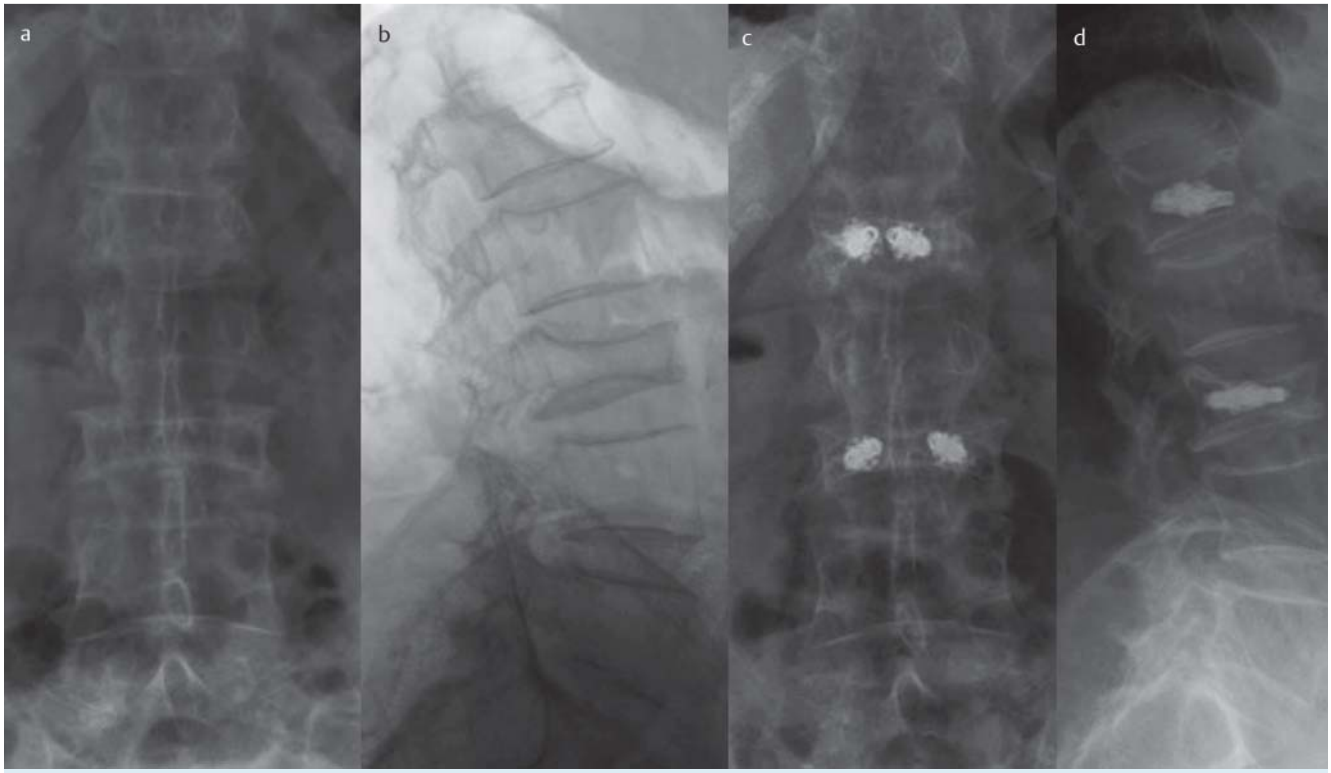


Fig. 4 **a–d** preoperative **a, b** and at 12-month follow-up **c, d** radiographs of L1 and L3 compression fracture and stabilization with Osseofix® system – (VAS 7 to 2 and ODI 68 to 24 from preop to 12 months).

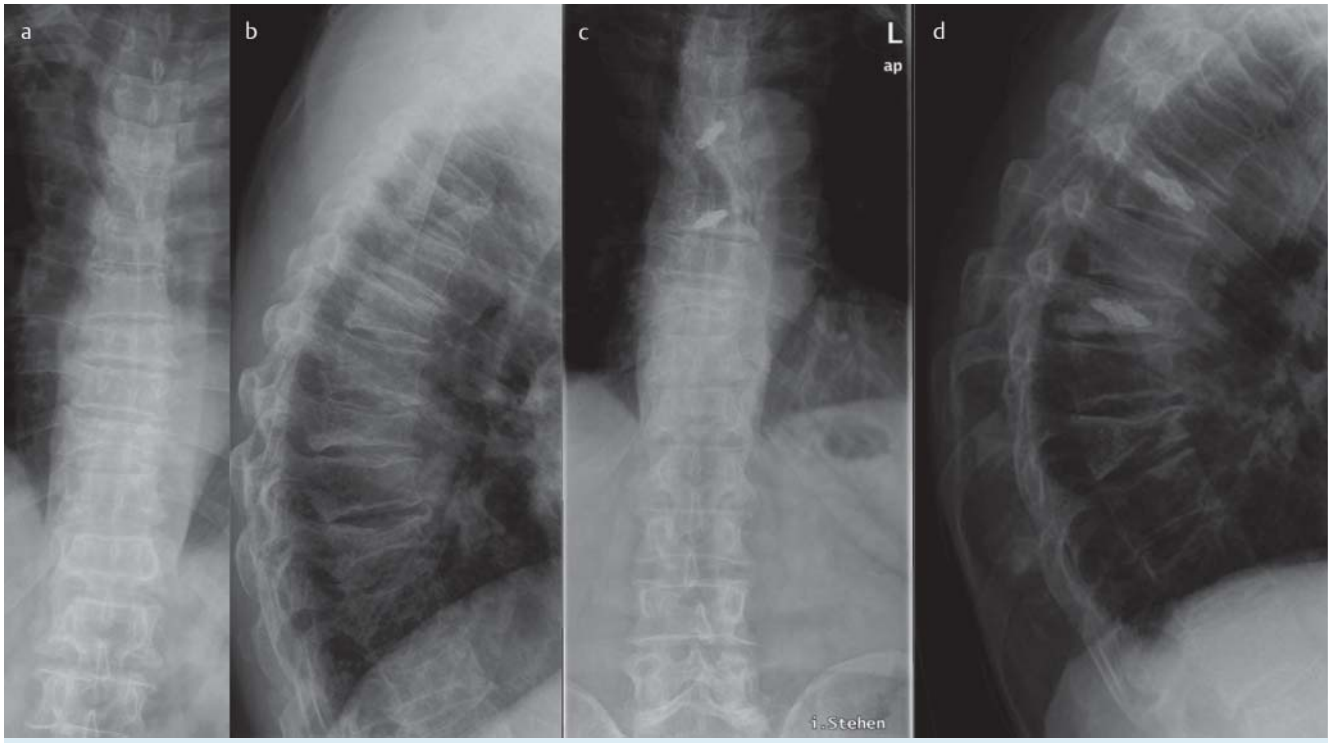


Fig. 5 **a–d** preoperative a, b and at 12-month follow-up c, d radiographs of T6 and T8 compression fracture and stabilization with Osseofix® system – (VAS 10 to 1 and ODI 68 to 28 from preop to 12 months).

Osseofix® system for vertebral compression fractures with involvement of the posterior edge seems more generous possible. This is additionally noteworthy in light of the proven relationship between intradiscal cement leakage and the increased occurrence of adjacent fractures [21, 22].

Summary

The stabilization of symptomatic **osteoporotic and tumorous vertebral compression fractures with the** Osseofix® system is a safe and effective method with a good reduction in pain and a low complication rate in the medium term (0 % cement leakage rate, 2.2 % adjacent fracture rate and loss of height rate). Like kyphoplasty, the method is easy to use and can also be effectively used in the case of involvement of the posterior edge of the vertebral body. Compared to kyphoplasty, the Osseofix® system provides a significantly lower increase in the height of the vertebral body and a smaller correction of the average Cobb angle without affecting the clinical result. The Osseofix® system represents a very interesting alternative to established cement-augmenting methods.

Clinical relevance of the study

The use of the Osseofix® system in ***osteoporotic and tumorous vertebral compression fractures*** provides a significant improvement in pain intensity and activity level and has clinical results comparable to those of established cement-augmenting methods (kyphoplasty, vertebroplasty).
It is a safe and effective method with a low complication rate (0 % cement leakage rate, 2.2 % adjacent fracture and loss of height rate) compared to established cement-augmenting methods and represents an interesting alternative.

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