



Hybrid stabilization of unstable osteoporotic thoracolumbar vertebral body fractures: clinical and radiological outcome after a mean of 4 years

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Abstract

Purpose The aim of this study was to evaluate midterm results after hybrid stabilization of unstable osteoporotic fractures of the thoracolumbar junction.

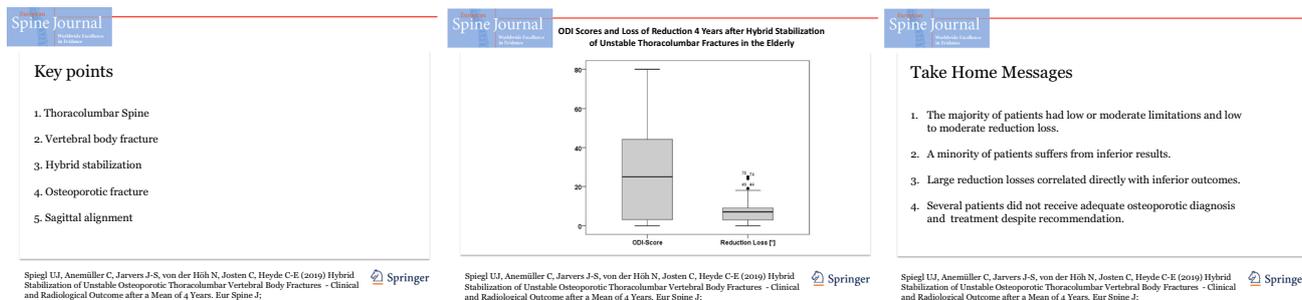
Methods This retrospective study was performed at a level I trauma center. A total of 113 patients aged 61 and older were stabilized using hybrid stabilization consisting of short-segmental posterior instrumentation and augmentation of the fractured vertebral body after suffering an unstable osteoporotic vertebral body fracture at the thoracolumbar spine. All patients were treated by hybrid stabilization. The primary outcome parameters were the ODI score and loss of reduction. Secondary radiological outcome parameters were the sagittal alignment parameters.

Results Seventy-two women and 41 men (74.6 ± 6.8 years) were included. Sixty-nine patients (61%) were re-evaluated after a mean of 48 months. Seventeen patients have died during the follow-up period (15%). A total of five in-patient complications were documented (4.4%). Additionally, 12 patients (17.4%) suffered from further osteoporotic vertebral body fractures affecting vertebral bodies of different levels. The average ODI score at the final follow-up was $29.9 (\pm 22.0)$. Thereby, 66.6% of all patients had low to moderate limitations. The average regional sagittal loss of reduction was $7.4\% (\pm 5.6\%)$. Loss of reduction was below 10° in 78% of the patients. There were statistically significant correlations between the loss of reduction and the ODI score, pelvic incidence and latest Cobb angle, and between the ODI scores and the lumbar lordosis.

Conclusions The majority of patients had low or moderate limitations and low to moderate reduction loss. Thereby, high loss of reduction correlated directly with inferior outcomes.

Graphical abstract

These slides can be retrieved under Electronic Supplementary Material.



Electronic supplementary material The online version of this article (<https://doi.org/10.1007/s00586-019-05957-8>) contains supplementary material, which is available to authorized users.

Extended author information available on the last page of the article

Keywords Thoracolumbar spine · Vertebral body fracture · Hybrid stabilization · Sagittal alignment · Osteoporotic fracture

Introduction

A trend of an increasing number of osteoporotic vertebral body fractures has been reported [10]. Thereby, operative reduction and stabilization is indicated in unstable vertebral body fractures of the thoracolumbar spine. Cement-augmented procedures are especially indicated in osteoporotic vertebral fractures [8]. Many authors recommend kyphoplasty or vertebroplasty for fracture treatment [1, 21, 27]. However, there is a risk of fracture progression after cement augmentation [13, 14]. Additionally, relevant reduction loss and a high number of adjacent vertebral fractures after both kyphoplasty and vertebroplasty have been reported [3]. Therefore, several authors perform hybrid stabilization consisting of posterior cement-augmented stabilization in combination with kyphoplasty of the fractured vertebral body in those patients with higher fracture instability [19]. Thereby, higher construct stability can be achieved what might improve radiological outcome. Thus, pathologic spinopelvic alignment might be avoided. However, on the best knowledge of the authors, there exists no evidence evaluating midterm results after hybrid stabilization of osteoporotic thoracolumbar fractures under consideration of the spinopelvic alignment.

The aim of this study was to evaluate the clinical and radiographic midterm results of hybrid stabilization for the treatment of unstable burst fractures of the thoracolumbar spine in patients aged 60 years or higher under consideration of the spinopelvic alignment. The first hypothesis was that hybrid stabilization leads to mainly good clinical and radiographic outcome. The second hypothesis was that the spinopelvic alignment correlated with the clinical outcome.

Methods

This retrospective study was performed at a single level I spine center [certificated by the German Spine Association (DWG)] between December 2009 and May 2014. The study was approved by the regional ethic committee. All patients admitted with spinal injury were examined clinically and received conventional radiographs.

A magnetic resonance imaging (MRI) of the whole spine was performed in those patients without MRI contraindications. Additionally, computer tomography (CT) was carried out in those patients with moderate- and high-energy traumas and those with contraindication for MRI.

Spinal stability was assessed using the new AO spine classification [24] and the OF-classification [18] (Table 1). All patients underwent a thorough neurologic examination in

accordance with the ASIA protocol. Patients with any neurologic deficit were excluded. Stable fractures were treated conservatively by adequate analgesia based on WHO and physiotherapeutic mobilization without corset or brace. Conventional radiographs were performed before mobilization as well as after mobilization and after one week in standing position. Instability was assumed in all patients with fracture-type OF 3 or higher (A3 fractures with more than one-fifth of the posterior cortex affected + A4 fractures + B-/C-type fractures) as well as those with high pain levels (VAS > 4) despite analgesia, relevant reduction loss after mobilization (> 5°), and regional bisegmental kyphosis (superior end plate of the vertebral body above and inferior end plate of the vertebral body below the fractured vertebral body) of more than 20° or regional bisegmental scoliosis of more than 5° (analogue to the Cobb angle). All inclusion and exclusion criteria are listed in Table 2.

Surgical techniques

Hybrid stabilization was done minimally invasive by posterior cement-augmented short-segmental (one level above and one level below the fractured vertebral body) stabilization without fusion (Matrix, Fa. DepuySynthes; Viper, Fa. DepuySynthes, West Chester, PA, USA; Longitude, Fa. Medtronic, Minneapolis, MN, USA) and bilateral transpedicular kyphoplasty (Vertecem, Fa. DepuySynthes) of the fractured vertebral body. All pedicle screws were cement augmented.

The patients were placed in prone position. Preparation for kyphoplasty was performed first. Incision was performed under fluoroscopic control just lateral of the lateral borders of both pedicles of the fractured vertebral body under anterior–posterior view. Next, Yamshidi needles were placed through the pedicles in the posterior part of the fractured vertebral body under fluoroscopic control. Afterward, the

Table 1 OF-classification

Type	Description
OF 1	No deformity (Bone bruise)
OF 2	Compression fracture without or only minor posterior cortex defect (< 1/5)
OF 3	Incomplete burst fracture with a relevant posterior cortex defect (> 1/5)
OF 4	Complete burst fracture
OF 5	Type B/type C fractures

Table 2 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Age: > 60 years	Prior or subsequent fractures of the vertebral spine caused by another trauma
Unstable fracture or failed conservative treatment	Inability or unwillingness to join the study
Location: Th10–L4	Neurologic impairment
Acute fracture situation	Pathologic vertebral body fractures (tumor/infection)

Th 10 thoracic vertebral body 10, *L 4* lumbar vertebral body 4

balloons were inserted in the central part of the vertebral body and extended under fluoroscopic control in order to reduce the fractured endplate. Next, incisions of about 2–3 cm of length at the lateral border of both pedicles of the vertebral body above and below of the fractured vertebral body were performed. Yamshidi needles were inserted through all four pedicles under fluoroscopic control parallel to the superior end plates. Pedicles screws were inserted after evaluation of the diameter and screw length which were chosen as large/long as possible. Afterward, cement augmentation of all pedicle screws was performed. This was performed slowly under fluoroscopic control until 1 ml of cement was inserted or signs of cement leakage were visible. After removing the kyphoplasty balloons, cement augmentation of the fractured vertebral body was performed. Next, the rods were shuffled below the fascia using the above-mentioned incisions and attached to the screws as instructed by the manufacturer.

Postoperative management

Postoperatively, all patients received conventional radiographs while standing. An additional CT scan was taken in cases of uncertainty of correct screw placement or anatomic reduction or in symptomatic patients. No brace or corset was used. Physiotherapy was initiated on the day after surgery to improve mobility and muscle strength. Clinical and conventional radiological assessment was performed at 2 weeks, 6 weeks, 3 months, and 12 months postoperatively. DEXA measurement and sufficient anti-osteoporotic therapy were recommended to all patients.

Follow-up

All patients were followed up for a minimum of 24 months after initial surgery. Initially, the patients were contacted by phone and asked if they were willing to participate. Scores were mailed to those patients who were willing to participate, but did not wish further radiographs or were not able to attend the follow-up examination. Those patients filled out the clinical scores. The others were evaluated clinically, radiologically, and filled out the clinical scores. An

anterior–posterior X-ray centered on the injured vertebral body and lateral 36-inch views while standing was performed (Fig. 1). Patients who were not able to attend the follow-up examination and were willing to perform actual radiographs were asked to send these for evaluation. All patients included in the study were asked about their actual bone mineral density (BMD) score and their current anti-osteoporotic therapy.

Outcome parameters

The primary parameter of interest was the Oswestry Disability Index (ODI) after the latest follow-up as well as the reduction loss defined as the increase in bisegmental kyphosis (angle between superior endplate of the level above versus inferior end plate of the level below the fractured one) after surgery compared to the latest follow-up. Further outcome measures were analysis of the complications and surgical revisions, level of pain (VAS 0–10 scale; 0: no pain, 10: maximal pain), level of satisfaction (VAS 0–10 scale; 0: lowest satisfaction, 10: highest), and SF-36 score (physical summary component and mental summary component). In addition, radiological parameters were measured, including the postoperative and latest bisegmental kyphosis, loss of reduction, pelvic tilt, pelvic incidence, sacral slope, lumbar lordosis, thoracic kyphosis, C7 plump line, and any signs of hardware loosening or instability. All measurements were performed by C.A. who was not involved in any surgical procedures.

Statistics

Statistical analysis was performed using standardized SPSS software 17.0 (SPSS®, Inc. Chicago, USA). Statistical analysis was made using descriptive statistics. Fisher's exact test was used to evaluate any associations between clinical outcome parameters and radiological outcome parameters as well as between regional radiological outcome parameters and alignment parameters. A significance level of 0.05 was used.



Fig. 1 Seventy-three-year female–male patient who suffered an incomplete burst fracture of the first lumbar vertebral body after stumbling and falling on her back (a, b). An incomplete burst fracture was seen at the CT examination (c). The MRI showed an acute fracture situation (d). An hybrid stabilization was performed 4 days after

the accident (e, f). At the latest follow-up after 26 months, the patient was happy with only mild temporary pain (VAS: 3), mild limitations (ODI: 9), and mild reduction loss as well as compensated sagittal balance (g)

Results

A total of 113 patients met all inclusion criteria. The average age was 74.6 years (range 61 to 98 years), and the majority of patients were females (74%). Most fractures were located at L 1 ($n=47$) and Th 12 ($n=25$), less commonly at L 2 ($n=17$), L3 ($n=12$), Th 11 ($n=7$), L 4 ($n=3$), and Th 10 ($n=2$). Most fractures were incomplete burst fractures. Seventy-one of those fractures had a relevant posterior cortex affection of more than 20% and were classified as OF 3 fractures, and 29 had minor or no posterior cortex affections and were classified as OF 2 fractures [18]. Thirteen patients suffered from complete burst fractures (A 4; OF 4). All patients with OF 2 fracture

had persistent pain and gained relevant loss of reduction after mobilization.

A total of 69 patients (61.1%) were followed over an average of 48 months (range: 24–78 months). Seventeen of the patients who have been lost to follow-up have died during the follow-up period (15.0%). The other 27 patients could not be reached or did not agree to participate (23.9%) (Table 3). There was no age difference between those that could be contacted and those who died or could not be reached. However, the percentage of males that died was significantly higher than those who were followed ($p=0.029$).

A total of five in-patient complications were seen (4.4%). One patient suffered from an incomplete conus cauda syndrome after surgery. An MRI on the same day of surgery diagnosed severe spinal canal stenosis at the fracture level without cement leakage or screw displacement. Emergency revision surgery with decompression of the affected segment was performed. The neurologic deficit recurred completely afterward. Three patients showed impaired wound healing postoperatively. All three received revision surgery after an average of 6 days (range: 4–8). The further course was uneventful. One patient suffered from pneumonia and received antibiotics intravenously.

Table 3 Follow-up patients compared to loss of follow-up patients

Parameter	Follow-up	Died	Could not be reached
Number (n)	69	17	27
Age	73.9±6.4	75.7±6.3	75.7±7.9
Gender	66.7% female	35.7% female	74.1% female

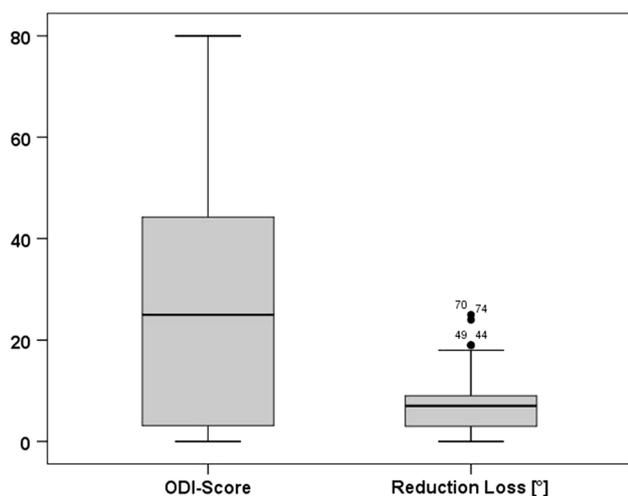


Fig. 2 Box plot showing the ODI scores (left) and the reduction loss in degrees (right) of all patients at the final follow-up examination after a mean of 4 years. Thereby, patient numbers 44, 49, 70, and 74 were negative outlier suffering from high loss of reduction ($> 19^\circ$)

At the latest follow-up, 12 patients suffered from further adjacent or different level vertebral body fractures (17.4%) and two patients from further osteoporotic fractures (proximal humerus, femoral neck fracture). The mean time period between surgery and further vertebral body fracture was 6.9 months (range: 2–24). Five of these patients had more than one further vertebral body fracture (mean: 4.2; range 2–6). Revision surgery was done in 12 patients with additional osteoporotic fractures.

Primary outcome

The ODI scores and reduction loss are presented in Fig. 2. The mean ODI score was 29.9 representing a moderate limitation. However, the scores ranged from 0 to 80. In detail, the majority of patients had low limitations (36.8%) or moderate limitations (29.8%). However, 24.6% had severe limitations with ODI scores between 40 and 60, whereas five patients (8.8%) were negative outliers with scores of above 60. Those five patients are enrolled in Table 4. Similarly, the mean loss

of reduction varied widely ranging from 0° to 25° . Again, the majority of patients had minor loss of reduction of less than 5° (44.1%) or moderate loss of reduction (more than 5° but less than 10° ; 33.9%). All clinical outcome parameters are summed up in Table 5.

Secondary outcomes

Table 6 displays the results of the spinopelvic alignment parameters. Altogether, there were significant correlations between the regional loss of reduction (Cobb angle) and ODI scores ($r=0.337$; $p=0.033$), the lumbar lordosis and the ODI scores ($r=-0.426$; $p=0.027$), as well as the pelvic incidence and the latest Cobb angle ($r=0.371$; $p=0.043$).

Anti-osteoporotic diagnostic and therapy

No bone mineral density measurement was performed in one-third of all patients who were seen during follow-up. Twenty-nine percent of the others had a T score of less than -2.5 , and 14% could not remember their scores. All others suffered from osteopenia.

Generally, 33% of these patients received an anti-osteoporotic therapy (vitamin D and/or specific treatment such as bisphosphonate therapy).

Discussion

The main finding of this study was that there was a wide range of clinical and radiological results after an average of 4 years after hybrid stabilization of unstable vertebral body fractures in elderly patients. The majority of patients had low limitations, low pain levels, and only minor reduction losses. However, some patients suffered from major limitations and high pain levels. Interestingly, there was a statistically significant correlation between clinical outcome parameters as well as regional and global alignment parameters. The numbers of complications particularly further osteoporotic vertebral body fractures were high. Unfortunately, the rate

Table 4 Negative outliers

Patient	Age	ODI score	VAS score	Further Ost. fractures	Other relevant diagnosis
1	75	80	10	Th 11, L 3/4/5	None
2	81	78	7	Th 10, L 1	None
3	72	66	5	Th 5/6/7 + FNF	Depression
4	83	70	5	None	Depression + chron pain syndrome
5	78	73	3	Prox. humerus	Mb Parkinson

Ost. osteoporotic, *Th* thoracic vertebral body, *L* lumbar vertebral body, *FNF* femoral neck fracture, *prox.* proximal, *chron* chronic, *Mb* morbus

Table 5 Clinical outcome scores

Parameter	Mean	Std	Range
ODI score	29.9	22.2	0–80
VAS score	3.5	2.5	0–10
Patient satisfaction	6.6	3.1	0–10
SF 36—physical summary component	37.1	11.9	17.8–59.1
SF 36—mental summary component	47.5	9.9	27.6–72.2

ODI Oswestry disability index, VAS visual analogue score, Std standard deviation

Table 6 Radiological results

Parameter	Mean (°)	Std (°)	Range (°)
Reduction loss	7.4	5.6	0–25
Sacral slope	39.1	13.6	21–68
Pelvic tilt	21.1	8.1	7–38
Pelvic incidence	31.3	16.4	34–96
Lumbar lordosis	40.8	12.2	10–67
Thoracic kyphosis	53.9	13.0	32–75

Std standard deviation

of correct osteoporotic diagnosis and anti-osteoporotic treatment was low.

Hybrid stabilization for the treatment of unstable thoracolumbar vertebral body fractures has been reported in several studies [7, 11, 16, 25]. Some authors used this strategy in osteoporotic vertebral body fractures only [6, 20], whereas others performed this technique in patients with good bone stock, too [11, 25]. Most of the studies reported of mainly good clinical and radiological results. However, inferior outcome after osteoporotic fractures has been observed in many studies [9, 22]. Thereby, osteoporotic vertebral body fractures seem to be correlated with the worst results [22]. Therefore, it might be no surprise that some of the elderly patients with osteoporotic vertebral body fractures experienced inferior results [9]. This was particularly the case in those patients with high risk factors of inferior results. Those are appearance of further osteoporotic fractures, chronic pain syndrome, or limited mobilization based on comorbidities such as Mb Parkinson.

Generally, the mean loss of reduction seen in our patient collective was in the lower range in comparison to the literature. The loss of reduction in geriatric patients ranged between 4.6° and 23° [20, 23, 26]. Thereby, no cement augmentation of the pedicle screws was performed in some of those studies what might increase the risk of screw cut out and impaired regional alignment [19].

In accordance with the literature, surgery was performed minimally invasive [19]. One drawback of this technique is a small additional risk of clinically relevant cement

embolism caused by cement augmentation of the fractured vertebral body and the pedicle screws [17]. However, no clinical symptomatic cement embolism has been seen in our patient collective. The number of in-patient complication was higher than that reported in the literature [11]; however, this might be partly related to the higher patient age and the correlated comorbidities. Fortunately, all complications could be treated without long-term effects, what was particularly important in the patient suffering from the postoperative incomplete conus cauda syndrome. Additional decompression surgery was not performed during initial surgery based on the absence of a history of claudicatio spinalis and no abnormalities during physical examination. Nowadays, the authors changed their therapy concept and perform additional segmental decompression in patients with MR-tomographical signs of relevant spinal canal stenosis at the fracture level more aggressively.

Interestingly, a high number of our patients did not receive a sufficient osteoporotic diagnosis and/or treatment despite a clear recommendation at the end of the hospital stay. Similarly, Aubry-Rozier et al. [2] reported a percentage of patients having dual X-ray absorptiometry to diagnose osteoporosis was only 26% in patients treated by general practitioner. Additionally, Che et al. [5] found a 31.5% rate of anti-osteoporotic treatment in patients suffering from a vertebral fracture cascade, defined as three osteoporotic vertebral body fractures during 1 year. In contrast, this percentage was 72% if a fracture liaison service was used. Therefore, a simple recommendation for a further diagnostic work-up in the discharge report seems to be insufficient. In contrast, the diagnostic work-up should be initiated during the hospital stay, or a liaison service needs to be started to optimize the osteoporotic therapy.

Most notably, there is a significant correlation between the final ODI scores and the lumbar lordosis on the one side and the reduction loss on the other side despite the wide range of radiological and clinical results. Besides, Li et al. [12] could find a positive correlation between lumbar lordosis and fatty infiltration of the low back muscles that could explain worse clinical outcome. Thus, a stable recreation of an anatomic alignment might have positive impact on the outcome and the further course of degeneration. Thereby, it seems to be important to adapt anatomic reduction to the individual patient's age and his or her age-related alignment. Thus, pre- and postoperative 36-inch radiographs for defining and controlling the operative strategy are important and should be included in the working process.

Generally, the indication for surgery has to be discussed critically in all patients [4]. Some of the patients might have comparable clinical outcomes without surgery or with augmentation procedures of the fractured vertebral body alone. Generally, we have seen the indication for an operative stabilization very strictly. Surgery was indicated in patients with

unstable vertebral fracture and relevant destruction of the anterior column defined by OF scores of three and higher or failed conservative therapy [18]. Additionally, all patients were instructed about a non-operative therapy summing all advantages and disadvantages. Thereby, non-operative treatment with semirigid or rigid orthoses is associated with a relatively high complication rate and low patient comfort [15].

Altogether, this study offers several limitations. First of all, the retrospective study design has to be discussed critically. Additionally, follow-up rate is rather low. However, the loss of follow-up is often higher in elderly patient collectives. With an average age of 79 years at the time of the final examination after an average follow-up of 4 years, a mortality rate of 15% might not be very surprising. However, the rather high number of patients included and the long follow-up period are definitely strengths of this study. Based on these results, the authors changed their therapy strategy by starting with anti-osteoporotic medications during the hospital stay and starting to include all patients prospectively to increase the evidence in order to optimize treatment outcome.

Conclusion

Clinical and radiological results varied widely 4 years after hybrid stabilization of unstable osteoporotic thoracolumbar fractures. The majority of patients had low or moderate limitations, low pain levels, and low to moderate reduction loss. However, a minority of patients suffered from inferior results, particularly those with further osteoporotic fractures. Thereby, large reduction losses correlated directly with inferior outcomes. Several patients did not receive adequate osteoporotic diagnosis and treatment. Thus, anti-osteoporotic therapy has to be performed more consequently, and further studies are necessary to identify potential risk factors for inferior outcome.

Compliance with ethical standards

Conflict of interest This work was not supported by any external sources of funding. Two of the authors are in advisory boards of companies, C-EH for Fa Medacta, CJ for Fa Zimmer, Fa. Ziehm and Fa. Silony. Additionally J-SJ received honorary for speaking from Fa. Ziehm. Two authors (UJS and C-EH) received material supply for biomechanical testing by Fa. Medacta.

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