

Treatment and Outcome of Osteoporotic Thoracolumbar Vertebral Body Fractures With Deformation of Both Endplates With or Without Posterior Wall Involvement (OF 4): Short-Term Results from the Prospective EOFTT Multicenter Study

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Ulrich J. A. Spiegl, Prof¹ , Philipp Schenk, Dr², Klaus John Schnake, MD^{3,4}, Bernhard W. Ullrich, MD^{5,6} , Georg Osterhoff, PhD¹ , Max J. Scheyerer, PhD⁷ , Gregor Schmeiser, MD⁸, Martin Bäumlein, MD⁹, Michael A. Scherer, MD¹⁰, Michael Müller, MD¹¹, Kai Sprengel, PhD^{12,13} , Katja Liepold, MD¹⁴, Simon Schramm, MD¹⁵, H.-Christopher Baron, MD¹⁶, Holger Siekmann, MD¹⁷, Falko Schwarz, MD¹⁸, Alex Franck, MD¹⁹, Volker Zimmermann, MD²⁰, Sebastian Katscher, MD²¹, and Working Group Osteoporotic Fractures of the Spine Section of the German Society of Orthopaedics and Trauma

¹ Department of Orthopaedics, Trauma and Plastic Surgery, University Hospital Leipzig, Leipzig, Germany

² Department of Science, Research and Education, BG Clinic Bergmannstrost Halle, Halle, Germany

³ Center for Spinal and Scoliosis Surgery, Malteser Waldkrankenhaus St. Marien, Erlangen, Germany

⁴ Department of Orthopedics and Traumatology, Paracelsus Private Medical University Nuremberg, Nuremberg, Germany

⁵ Department of Trauma, Hand and Reconstructive Surgery, University Hospital Jena, Jena, Germany

⁶ Department of Trauma and Reconstructive Surgery, BG Clinic Bergmannstrost Halle, Halle, German

⁷ Department of Orthopaedic and Traumatology, Faculty of Medicine and University Hospital Cologne, Cologne, Germany

⁸ Department of Spine Surgery, Schoen-Klinik Hamburg-Eilbek, Hamburg, Germany

⁹ Center for Orthopaedics and Trauma Surgery, University Hospital Giessen and Marburg GmbH, Marburg, Germany

¹⁰ Lehrkörper Medizinische Fakultät der, Technischen Universität München (Med. Fak. TUM), Munich, Germany

¹¹ Department of Orthopedic and Trauma Surgery, University Medical Center Schleswig-Holstein, Campus Kiel, Germany

¹² University of Lucerne, Hirslanden Clinic St. Anna, Lucerne, Switzerland

¹³ Department of Trauma, University Hospital Zurich (USZ), University of Zurich (UZH), Zurich, Switzerland

¹⁴ Department of Spine Surgery, Thuringia Clinic "Georgius Agricola" Saalfeld, Teaching Hospital of the University of Jena, Saalfeld, Germany

¹⁵ Department of Trauma Surgery, University Hospital Erlangen, Erlangen, Germany

¹⁶ Department for Paraplegia and Spine Surgery, BG Trauma Center, Tuebingen, Germany

¹⁷ Clinic of Trauma-, Hand- and Reconstruction Surgery, AMEOS-Clinic Halberstadt, Halberstadt, Germany

¹⁸ Department of Neurosurgery, - Friedrich Schiller University, Jena University Hospital, Jena, Germany

¹⁹ Department of Orthopaedics and Trauma Surgery, Regiomed Klinikum Coburg, Germany

²⁰ Department of Trauma and Orthopedic Surgery, Klinikum Traunstein, Traunstein, Germany

²¹ Interdisciplinary Center for Spine and Neurotrauma, Sana Klinikum Borna, Borna, Germany

Corresponding Author:

Ulrich J. A. Spiegl, Department of Orthopaedics, Trauma and Plastic Surgery, University Hospital Leipzig, Liebigstrasse 20, Leipzig 04103, Germany.

Email: uli.spiegl@gmx.de



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Abstract

Study Design: Multicenter prospective cohort study

Objective: To analyse therapeutical strategies applied to osteoporotic thoracolumbar OF 4 injuries, to assess related complications and clinical outcome.

Methods: A multicenter prospective cohort study (EOFTT) including 518 consecutive patients who were treated for an Osteoporotic vertebral compression fracture (OVCF). For the present study, only patients with OF 4 fractures were analysed. Outcome parameters were complications, Visual Analogue Scale, Oswestry Disability Questionnaire, Timed Up & Go test, EQ-5D 5L, and Barthel Index after a minimum follow-up of 6 weeks.

Results: A total of 152 (29%) patients presented with OF 4 fractures with a mean age of 76 years (range 41-97). The most common treatment was short-segment posterior stabilization (51%; hybrid stabilization in 36%). Mean follow up was 208 days (± 131 days), mean ODI was 30 ± 21 . Dorsoventral stabilized patients were younger compared to the other groups ($P < .001$) and had significant better TuG compared to hybrid stabilization ($P = .049$). The other clinical outcomes did not differ in the therapy strategies (VAS pain: $P = 1.000$, ODI: $P > .602$, Barthel: $P > .252$, EQ-5D 5L index value: $P > .610$, VAS-EQ-5D 5L: $P = 1.000$). The inpatient complication rate was 8% after conservative and 16% after surgical treatment. During follow-up period 14% of conservatively treated patients and 3% of surgical treated patients experienced neurological deficits.

Conclusions: Conservative therapy of OF 4 injuries seems to be viable option in patients with only moderate symptoms. Hybrid stabilization was the dominant treatment strategy leading to promising clinical short-term results. Stand-alone cement augmentation seems to be a valid alternative in selected cases.

Keywords

osteoporosis, spine, vertebral fracture, operative, OF classification

Introduction

Osteoporotic vertebral compression fractures (OVCF) of the thoracolumbar spine are frequent with an increasing prevalence.

Recently, a new classification system together with a score for therapeutic decision making have been developed by the working group "Osteoporotic Fractures" of the Spine Section of the German Society of Orthopaedics and Trauma.^{1,2} With regard to treatment, one of the most controversially discussed fracture type are OF 4 injuries with deformation of both endplates and with or without posterior wall involvement.³⁻⁵ Generally, the evidence for operative and non-operative treatment of OF 4 type fractures is very limited.^{6,7,8} The huge majority of studies did not specifically include OF 4 type fractures.^{5,6,8} Palmowski et al⁴ looked at the reduction potential of kyphoplasty and reported of reliable restoration of the vertebral bodies even in type OF 4 fractures. A recent cochrane database systematic review looked at the effect of exercise as component of non-operative treatment for improving outcomes after osteoporotic vertebral fracture.⁸ None of the included trials classified the fractures in detail. Thus, no associations can be made between fracture morphology and the outcome. However, from a biomechanical point, it can be expected that the fracture morphology has impact on the fracture stability which has an impact on the outcome depending on the treatment that has been applied.

To investigate the treatment of OVCF, a prospective German multicentric study (Evaluation of the Osteoporotic Fracture classification, Treatment score and Therapy recommendations - EOFTT) was concluded.

One aim of this study was to analyse the treatment choices, the incidence of new fractures, outcomes of patients suffering from OF 4 injuries and to assess related complications.

Materials and Methods

A multicenter prospective cohort study (EOFTT) was conducted at 17 spine centers in Germany and Switzerland. The study was approved by the local or regional institutional ethics committees of each participating center. Inclusion criteria were OVCF, either spontaneous or because of low energy trauma, in patients older than 18 years and proven osteoporosis following national and international recommendations.⁹ Patients received conventional AP and lateral radiographs, a CT scan and an MRI scan. Fractures were classified according to the OF classification.²

The OF score was applied including clinical information (pain, mobilization, neurology, health status) in addition to radiographic parameters. If the OF score is above 6 points surgical therapy is recommended. However, final treatment decision was at physician's discretion.¹

For clinical evaluation the type of treatment - conservative or surgical in general and detailed surgical intervention - and the following variables were obtained at time of treatment

decision (TD) and at follow-up (FU): Pain with visual analogue scale (VAS-P, 0-10), bone quality using either bone mineral density (DXA; t-score) or CT (Hounsfield units; HU),¹⁰ Oswestry Disability Index (ODI), Barthel index, Timed up and go test (TuG), EQ5D-5L index value and visual analogue scale of subjective health status from EQ5D (VAS-EQ5D). The TuG measures mobility impairment by measuring the patient's time needed for stand up on a chair with armrests, walk a distance of 3 meters, turn around and sitting down again. The EQ5D-5L index value was calculated using the data set for German index values. The higher the value, the better the health status up to a maximum of 1. The reported subjective health status in the EQ5D (VAS-EQ5D) was chosen with a VAS with the limits of 0 (zero) and 100, where 100 reflects the best and 0 the worst health status. The Barthel index is an assessment tool to define the autonomy of patients on tasks for daily living. Zero (0) represents complete independency whereas 100 reflects full autonomy.

For the present analysis, only patients with a fracture type OF 4 and a planned follow-up of at least 6 weeks were included. Generally, the last follow-up that was available was considered.

In addition to the clinical scores a further secondary outcome parameter was the occurrence of complications. Complications were divided in those related to the surgical intervention (implant failure, adjacent level fracture, neurological deficit and surgical site infections) and general complications (thromboembolic event, urinary tract infection, pneumonia, delirium). Surgical site infections were defined as any wound-related complication that required surgical revision.

Statistical Methods

All data was finally recorded in an Excel database (Microsoft Corp., Washington, DC, USA) and exported to SPSS 27.0 (SPSS Inc., Chicago, IL, USA) for statistical analysis. Data was summarized as mean with standard deviation (SD).

Differences in primary outcome parameters (depending variables) between conservative vs surgically treated in general and in addition differentiated between all therapy strategies (fixed factor) were analysed with separate multivariate, general linear models (GLM), respectively. Post hoc Bonferroni Test was performed for pairwise comparisons. The level of significance was defined as $P < .05$.

Results

In the EOFTT study, 518 consecutive patients were included between Sep 2017 and Jul 2020. Out of the entire group, 152 (29%) patients presented with OF 4 fractures. 76% were female and the mean age was 76 (range 41-97). Patient's characteristics are illustrated in Table 1.

The majority of fractures occurred at the thoracolumbar junction between T11 and L2 (68%).

34% of the patients suffered from insufficiency fractures and could not recall any trauma history.

In total 36 patients were treated conservatively (24%) and 116 of the patients (76%) received surgical therapy. The duration between the patients' admission and the treatment decision was 4 ± 4 days (range: 0-26, median 2 days) and did not differ depending on surgical or conservative therapy choice ($P = .376$). At the day of treatment decision the mean OF-score was 8.2 ± 1.7 (range 4-12) and differed between conservative (7.6 ± 1.8) and surgically treated patients (8.4 ± 1.7 , $P = .029$). Thereby a total of 15 patients were treated conservatively despite an OF score of more than 6 and 7 patients were treated surgically despite an OF score of less than 6. Additionally, the VAS-P differed significantly between the treatment choices (conservative: 4.3 ± 2.0 , surgical: 6.6 ± 2.2 , $P = .012$). No differences could be found for age ($P = .624$), ODI ($P = .587$), bone density (qCT $P = .537$, DXA $P = .323$, HU $P = .715$), Barthel Index ($P = .215$), TuG ($P = .383$), EQ5D-5L index value ($P = .685$) and VAS-EQ5D ($P = .736$) at the day of treatment decision. The most common surgical therapy strategy was short-segment stabilization with cement augmentation of the fractured vertebral body (Hybrid stabilization, Figure 1). Conservative treated patients showed shorter hospital stay (mean difference: 5d, $P = .002$).

At the follow up (208 ± 131 days, range 42-563 days), a complete data set of clinical outcome parameters was available for 101 patients (66%), consisting 21 patients treated conservatively with a mean follow up of (220 ± 124 days, range 42-453 days) and 80 patients treated operatively with a mean follow up of (165 ± 151 days, range 42-563 days, $P = .137$).

Functional outcomes at FU by different surgical interventions are outlined in Table 2. There were no statistically significant differences in all outcome parameters between patients treated in accordance with the OF-score recommendation (75%) and those who were not ($P > .320$). Additionally there were no significant differences between patients treated conservatively and those treated surgically ($P = .137$). Patients treated dorsoventrally were significantly younger (65 ± 7 years) than those treated with stand-alone cement augmentation (77 ± 8 years, $P = .010$), posterior stabilization with (77 ± 7 years, $P = .003$) or without (77 ± 7 years, $P = .012$) cement augmentation or long-segment stabilization (79 ± 5 years, $P = .005$). The dorsoventrally treated patients showed better TuG performance, compared to patients with hybrid stabilization ($P = .049$).

All complications are listed in Table 3. During the hospital stay the surgical related complication rate was 5% with a revision rate of 3%. The overall inpatient complication rate was 8% in the conservatively group and 16% in surgically treated group ($P = .418$). During follow-up period 14% of the conservatively treated patients experienced neurological deficits in contrast to 3% after surgically treatment ($P = .155$). During the follow up period, in each group new fractures occurred. Among surgically treated patients, the rate of new

Table 1. Baseline Characteristics.

Patients' Characteristics (n = 152)	Mean ± SD (min-Max)	Number of Patients (%)
Age	76 ± 9 (41-97)	
Gender (female)		116 (76)
OF score	8.2 ± 1.7 (4-12)	
Radiologic e/o osteoporosis		
qCT	58 ± 20 (14-115)	
T-score	-3.5 ± 1.1 (-6.0-4)	
HU	72 ± 31 (13-180)	
Etiology		
Trauma		97 (64)
No trauma reported		55 (36)
Location		
Midthoracic location (Th3-Th 10)		28 (18)
Thoracolumbar junction (Th11 – L2)		103 (68)
Lumbar spine (L3-L5)		21 (14)
Treatment		
Non-operative treatment		36 (24)
Operative treatment		116 (76)
Stand-alone cement augmentation (kyphoplasty eg)		20 (17)
Posterior short-segment stabilization only		29 (25)
Hybrid stabilization		42 (36)
Posterior long-segment stabilization		17 (15)
Dorsoventral stabilization		8 (7)
Pedicle screw augmentation*		82 (87)
Minimal invasive approach*		78 (67)
Outcomes		
Duration of hospital stay	12 ± 7 (0-43)	
VAS-P (FU)	4.2 ± 1.8 (0-8)	
ODI (FU)	.53 ± .17 (.10-.91)	
Barthel index (FU)	80 ± 20 (10-100)	
TuG (FU)	22 ± 16 (5-120)	
EQ5D-5L index value (IFU)	.62 ± .20 (-.05-1.00)	
VAS-EQ5D (FU)	52 ± 18 (5-90)	

SD: standard deviation; Min: minimum; Max: maximum; e/o: evaluation of; Hybrid Stabilization: posterior short-segment stabilization with cement-augmentation of the fractured vertebral body.

*in patients with posterior stabilization.

fractures was higher (26%), compared to the conservatively treated group (10%) ($P = .146$).

Discussion

Osteoporotic vertebral compression fracture show different morphological patterns. The recently proposed OF classification includes 5 subgroups.² OF 4 are defined as injuries with deformation of both endplates with or without posterior wall involvement. Thus, OF 4 injuries consist of complete burst fractures, pincer-type fractures, and fish-bone deformations. Due to the variety of fracture morphologies, it is no surprising finding that the therapeutic strategies varied considerably.

This study aimed to analyse the treatment concepts and outcomes of patients suffering from OF 4 injuries.

Scheyerer et al reported, that high degree of posterior wall affection is a risk factor for failure of conservative

treatment.¹¹ Blatter et al¹ recommended, surgical treatment with long-segment instrumentation or combined posterior short-segment fixation and anterior reconstruction for OF 4 injuries. In contrast, almost one quarter of our patients (24%) were conservatively treated. Generally, the majority of patients treated conservatively, had minor symptoms, lower complication rates favoring the conservative treatment. In contrast the mean VAS pain level at the time of treatment decision was more than 2 points higher in the surgically treated group. However, despite the favorable initial course of the patients treated conservatively this was associated with a high rate of neurological deficits at follow-up of 14%.

Just over 50% of the patients were treated with posterior short-segment stabilization most commonly a hybrid stabilization (augmented pedicle screws and cement augmentation of the fractured index-level vertebra).

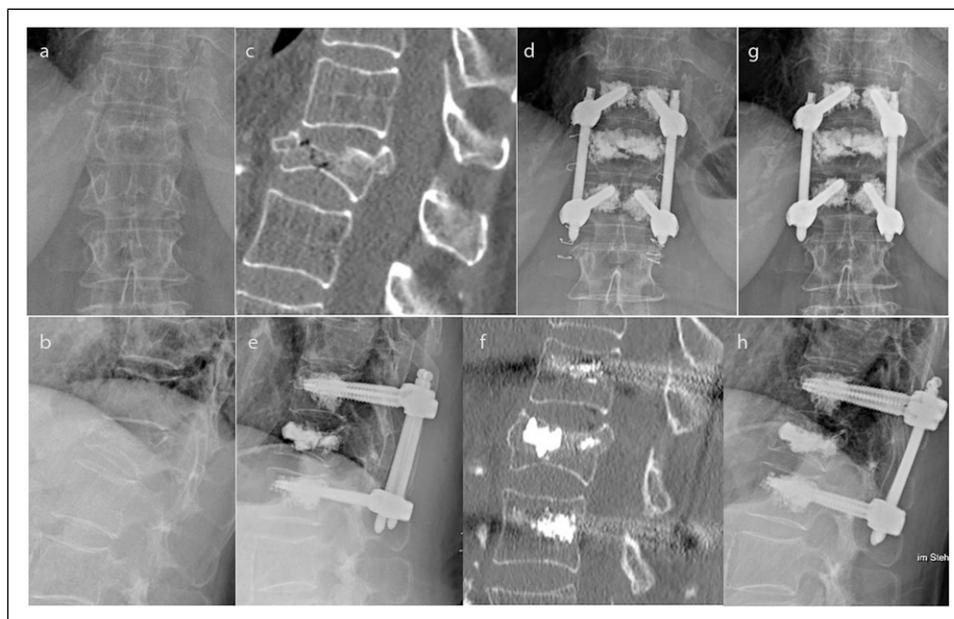


Figure 1. Legends: 74 years old woman with acute severe back pain after fall on buttock in garden. Xray and CT- scan demonstrate OF 4 type fracture of T12 and osteoporotic bone quality with HU 67 (a,b,c). OF score was 11 points and percutaneous stabilization with internal hybrid fixator was performed. X-ray in standing position after 3 days (d,e) and a CT (f) during the hospital stay showed correct implant positioning and an anatomic fracture reduction. Similarly, X-rays in standing position after 3 months (g,h) showed an unchanged situation. Pain without medication was moderate (3).

Table 2. Outcomes.

	Conservative (N = 21)	Operative (N = 80)	P-Value	Cement-augm. Only (N = 16)	Post. Short-Segmental ¹ (N = 16)	Hybrid Stabilization (N = 31)	Post. Long-Segmental (N = 10)	Dorso-ventral (N = 7)
Age	75 ± 10 (54-92)	76 ± 8 (55-90)	.040	77 ± 8 (59-90)	77 ± 7 (62-87)	77 ± 7 (55-88)	79 ± 5 (70-84)	65 ± 7 (57-77)
hospital stay [d]	7 ± 6 (2-25)	12 ± 7 (0-43)	.001	9 ± 4 (3-16)	13 ± 9 (3-36)	12 ± 6 (3-24)	18 ± 11 (9-43)	11 ± 8 (0-26)
VAS-P (TD)	4.5 ± 2.1 (2-8.5)	6.8 ± 2.2 (0-10)	<.001	7.4 ± 2.6 (0-10)	6.5 ± 2.2 (3-10)	6.9 ± 1.9 (1.5-10)	6 ± 2.3 (2.5-9)	7.3 ± 2.2 (3-10)
VAS-P (FU)	2.8 ± 2.1 (0-7.5)	2.7 ± 2.4 (0-8.5)	.465	3.2 ± 3.1 (0-8.5)	2 ± 1.6 (0-5)	3.1 ± 2.3 (0-8)	2.4 ± 2.2 (0-7)	1.7 ± 2.2 (0-6)
ODI (FU)	.32 ± .21 (0-.82)	.3 ± .22 (0-.90)	.313	.32 ± .24 (0-.69)	.24 ± .18 (0-.62)	.34 ± .22 (0-.66)	.34 ± .26 (.02-.90)	.15 ± .10 (.02-.30)
Barthel Index (FU)	94 ± 10 (70-100)	90 ± 15 (40-100)	.045	94 ± 8 (80-100)	95 ± 9 (70-100)	85 ± 18 (40-100)	85 ± 20 (40-100)	96 ± 11 (70-100)
TuG (FU)	15 ± 9 (5-31)	17 ± 12 (3-50)	.046	17 ± 11 (5-44)	15 ± 9 (5-32)	21 ± 13 (6-50)	15 ± 9 (5-36)	8 ± 3 (3-11)
EQ5D-5L index value (FU)	.79 ± .14 (.56-1.00)	0.78 ± .21 (-.21-1.00)	.367	.76 ± .19 (.36-1.00)	.82 ± .17 (.38-1.00)	.75 ± .18 (.28-1.00)	.74 ± .36 (-.21-1.00)	.92 ± .10 (.79-1.00)
VAS-EQ5D (FU)	66 ± 20 (30-96)	65 ± 20 (10-98)	.730	66 ± 24 (25-92)	67 ± 17 (30-90)	64 ± 19 (20-98)	59 ± 23 (10-85)	74 ± 21 (40-90)

1: posterior short-segmental stabilization without cement augmentation of the fractured vertebral body.

Stand-alone cement augmentation was performed in 17% of the patients. Finally, no significant differences in the outcome scores between the groups could be seen.

Taking the recent literature into account stand-alone cement augmentation seems to be justified. Palmowski et al^{4,12}

reported of favorable clinical and radiological results with reduction potential and low reduction loss in the short run. Similarly, Gu et al³ reported similar clinical results after both stand-alone kyphoplasty and hybrid stabilization. However, the authors found significant difference in the regional

Table 3. Complications.

	Conservative	Operative	Cement-augm. only	Post. Short- Segment	Hybrid Stabilization	Post. Long- Segment	Dorso- ventral
N/o patients	36	118	20	29	42	17	8
Primary							
Neurological deficit	1 (3%)	3 (3%)		2 (5%)	2 (5%)	—	
Radicular	—	—	—	—	—	—	—
Transversal							
Impl.associated	—	1 (1%)	—	—	—	—	1 (13%)
Wound healing disorders	—	2 (1%)	—	—	2 (5%)	—	—
Deep wound infection	—	1 (1%)	—	—	1 (2%)	—	—
Revision	—	4 (3%)	1 (5%)	—	2 (5%)	—	1 (13%)
Urinary tract infection	2 (6%)	10 (8%)	2 (10%)	4 (14%)	4 (10%)	—	—
Delir	—	5 (3%)	—	—	5 (12%)	—	—
Thrombosis	—	1 (1%)	—	—	1 (2%)	—	—
Pulomonray embolism	—	—	—	—	—	—	—
Pneumonia	—	—	—	—	—	—	—
Overall	3 (8%)	18 (16%)	3 (15%)	5 (17%)	9 (21%)	—	1 (13%)
Follow up	N = 21	N = 80	N = 16	N = 16	N = 31	N = 10	N = 7
Neurological	3 (14%)	4 (5%)	1 (6%)	1 (6%)	1 (3%)	—	1 (14%)
Radicular	2 (10%)	1 (1%)	—	1 (6%)	—	—	—
Transversal	—	—	—	—	—	—	—
Impl.associated	—	8 (10%)	1 (6%)	3 (19%)	2 (6%)	2 (20%)	—
Revision	—	7 (9%)	1 (6%)	2 (13%)	2 (6%)	2 (20%)	—
New fracture	2 (10%)	21 (26%)	3 (19%)	5 (31%)	8 (26%)	4 (40%)	1 (14%)
As adjacent fracture	—	12 (15%)	2 (13%)	4 (25%)	4 (13%)	2 (20%)	—
As multiple fractures	1 (5%)	6 (8%)	—	—	3 (10%)	2 (20%)	1 (14%)
Change therapy	2 (10%)	—	—	—	—	—	—
Overall	4 (19%)	28 (35%)	4 (25%)	7 (44%)	11 (35%)	5 (50%)	1 (14%)

Cement-augm.only: Stand-alone cement-augmentation such as kyphoplasty; Post.: posterior; Hybrid Stabilization: posterior short-segment stabilization with cement-augmentation of the fractured vertebral body; N/o: Number of; Impl.: Implant.

alignment with significant higher loss of reduction in the stand-alone cement augmentation group in the longer run, after 27 months.¹³ Thus, the loss of reduction seemed to be associated with higher numbers of adjacent fractures.¹³ However, more studies with longer follow-up periods are needed to analyse the status of stand-alone cement augmentation in OF 4 fractures correctly.

There were no differences in the clinical outcome of short-segment stabilization without cement augmentation compared to the hybrid stabilization. It can be hypothesized that the additional cement augmentation of the fractured vertebral body was performed mainly in severe fractures without sufficient reduction after patient positioning. Thus, a selection bias can be assumed.

Long-segment stabilization is recommended in the mid-thoracic spine.¹⁴ Additionally, the authors see the indication in patients with very unstable fractures, such as high local deformity and relevant differences in the bisegmental kyphosis

between standing radiographs and CT/MRI in supine position. The dorsoventral strategy was performed in a minority of 7% of the cases and only in patients < 70 years of age. Thereby patients treated dorsoventrally had significant better TUG test compared to the hybrid group. However, the differences in the TUG can be explained by the significantly younger patient age in that group. In contrast, no difference between midterm outcomes between hybrid stabilization and dorsoventral treatment was seen in the patient group between 60 and 70 years of age.¹⁵

In general, the clinical outcomes were in accordance with the literature.^{16,17} Considering the clinical outcome, conservative treatment, seem to be a suitable alternative therapy concept with similar results in patients with type 4 fractures. However, in highly unstable fractures conservative treatment may lead to neurological deficits during the further course. This was seen in 14% of our patients despite the high rate of compliance with the OF score.

Limitations

The study has several limitations. Based on the multi-centric approach of the study, the treatment strategy chosen was differently among participating centers. Additionally, the follow-up period of a minimum of 6 weeks is short. Bony consolidation may not be finally completed after 6 weeks. Thus, we did not present loss of lordosis or kyphotic malalignment as a complication to avoid any bias with respect of reduction loss and correlation to a specific treatment strategy. Generally, the mean follow-up was considerably longer consisted of more than 6 months. Moreover, further adjacent fractures might lead to inferior results in the further course. Besides, no radiologic outcome parameters were included. Regional kyphotic malalignment that might cause pain in the future could not be analyzed.

A strength of this study is its prospective, multicenter design with more than 500 patients with OVCF - including 152 patients with OF 4 injuries. However, the sample size of conservatively treated patients with type OF 4 fractures was rather small. Thus, a comparison of surgically treated patients with conservatively treated patients was limited.

Conclusions

Conservative therapy seems to be viable option in cases with only mild to moderate symptoms. Posterior percutaneous short-segment stabilization with or without augmentation of the pedicle screws and - if possible - the fractured vertebral body was the most commonly applied treatment strategy. Stand-alone cement augmentation seems to be a valid alternative in selected cases. Generally, surgical treatment leads to lower rates of neurologic deficits, but higher percentages of complications overall. However, further studies with longer follow-up are warranted.

Declaration of Conflicting Interests

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Authors' Contributions

Working group Osteoporotic Fractures of the Spine Section of the German Society for Orthopaedics and Trauma (DGOU): Conception and Study design. Ulrich J. Spiegl: Vice-chair of AG-OF, patients inclusions, data collection manuscript writing, literature research,

data management. Philipp Schenk: statistical analysis, editing manuscript. Klaus John Schnake: Chair of AG-OF, patients inclusions, data collection manuscript writing and editing, literature research. Bernhard W. Ullrich: Vice-chair of AG-OF, patients inclusions, data collection revision revision, Sebastian Katscher: Patients inclusions, data collection, manuscript writing and editing, literature research. Further coauthors: data collection, responsible for patient management of the respective spine centers

Ethics Approval and Consent to Participate

This study was approved by the research ethics committee of the medical Association of Saxony-Anhalt Germany (14. June 2017, file number 31/17) and was performed in accordance with the principles laid down in the current revision of the Declaration of Helsinki. The ethics committee determined that informed consent from each patient was not necessary due to the retrospective, anonymized nature of the research.

Consent for Publication

The authors give the consent for publication of all contents of this manuscript.

Availability of Data and Material

The datasets used and analyzed with this study are available on reasonable request from the corresponding author.

ORCID iDs

Ulrich J. A. Spiegl  <https://orcid.org/0000-0002-5179-4192>
 Bernhard W. Ullrich  <https://orcid.org/0000-0001-8748-1190>
 Georg Osterhoff  <https://orcid.org/0000-0001-5051-0998>
 Max J. Scheyerer  <https://orcid.org/0000-0003-1392-3990>
 Kai Sprengel  <https://orcid.org/0000-0001-5921-8272>

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