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Spinal Orthoses in the Treatment of Osteoporotic Thoracolumbar Vertebral Fractures in the Elderly: A Systematic Review With Quantitative Quality Assessment

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Abstract

Study Design: Systematic review.

Objectives: Spinal orthoses are frequently used to non-operatively treat osteoporotic vertebral fractures (OVF), despite the available evidence is rare. Previously systematic reviews were carried out, presenting controversial recommendations. The present study aimed to systematic review the recent and current literature on available evidence for the use of orthoses in OVF.

Methods: A systematic review was conducted using PubMed, Medline, EMBASE and CENTRAL databases. Identified articles including previous systematic reviews were screened and selected by three authors. The results of retrieved articles were presented in a narrative form, quality assessment was performed by two authors using scores according to the study type.

Results: Thirteen studies (n = 5 randomized controlled trials, n = 3 non- randomized controlled trials and n = 5 prospective studies without control group) and eight systematic reviews were analyzed. Studies without comparison group reported improvements in pain, function and quality of life during the follow-up. Studies comparing different types of orthoses favor non-rigid orthoses. In comparison to patients not wearing an orthosis three studies were unable to detect beneficial effects and two studies reported about a significant improvement using an orthosis. In the obtained quality assessment, three studies yielded good to excellent results. Previous reviews detected the low evidence for spinal orthoses but recommended them.

Conclusion: Based on the study quality and the affection of included studies in previous systematic reviews a general recommendation for the use of a spinal orthosis when treating OVF is not possible. Currently, no superiority for spinal orthoses in OVF treatment was found.

Keywords

osteoporosis, vertebral fracture, spine fracture, orthosis, conservative treatment

Introduction

Spinal orthoses are traditionally applied treating thoracolumbar fractures, but their mechanism is currently not completely understood.[1,2] Nevertheless, over 60% of spine surgeons prescribe an orthosis for the treatment of fractures, degenerative diseases or use them after surgical treatment.[3] Most recently a systematic review found no evidence treating traumatic spinal

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fractures conservatively with an orthosis.[4] However, for osteoporotic vertebral fractures (OVF), spinal orthosis are recommended and previous systematic reviews highlight their benefits though the evidence of included studies is limited.[5-11] But methodical aspects of the included studies were not fully evaluated possibly resulting in controversial recommendations.[5-12] Additionally, several aspects like the type of diagnostics used, fracture region, number of fractures, orthosis treatment (daily treatment and duration) were sparsely reported. Although several reviews highlight the low quality of included studies, their recommendations are based on them. Besides a risk of bias (RoB) assessment, quality examinations are rare. We aimed to report on the evidence for spinal orthosis treating OVF and describe the treated population, fracture morphology and orthotic treatment. Secondarily, the investigated publications were graded using quantitative quality scores. Thirdly, previous systematic reviews were analyzed and qualitatively graded.

Materials and Methods

The present study was registered on the International Prospective Register of Systematic Reviews (PROSPERO) network (CRD42020177426) before starting the review process and performed accordingly to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

The first authors searched within PubMed, Medline, EMBASE and Cochrane Central Register of Controlled Trials (CENTRAL) without a limitation of the publication date but limited to English and German publications until April 2020 and updated the studies using PubMed messenger. According to the PI (CO) scheme the following question was formulated: Does spinal orthoses improve the outcome of patients suffering from thoracolumbar spinal fragility fractures and related deformities?

An example for the search strategy is outlined for PubMed:

(((((Orthotic devices [Mesh] OR Spinal orthos*) AND ((Spinal Fractures [Mesh] OR Spinal fracture) OR (Spinal Curvatures [Mesh] OR (Adult spinal deformity)) OR ((Fractures, Stress [Mesh] AND Spine) OR (Fracture, Spontaneous [Mesh] AND Spine)) OR (Osteoporosis [Mesh] AND Spine) OR (Osteoporotic Fractures [Mesh] AND Spine))) AND (“german" [Language] OR “english" [Language])) NOT (“case reports" [All Fields] OR “comment" [All Fields] OR “letter" [All Fields])) NOT cervical). Case reports, comments and narrative reviews were excluded. An exclusion based on the level of evidence or study type was not done. The remaining manuscripts were considered for inclusion. Retrieved titles of studies, abstracts and full texts were screened in triplicate by PP, UJS, CEH. At each step controversy was discussed until consensus was achieved. The screening process and extracted data included in tables and figures are presented in Figure 1. Data extraction and qualitative assessment were done by PP and UJS using a predefined Research electronic data capture (REDCap) form.[13] The Coleman Methodology Score (CMS) was assessed for all studies.[14] Higher scores indicate a less risk for bias and confounding factors. The CMS was graded as followed: excellent (85-100 points), good (70-84 points), fair (50-69 points), and poor (<50 points).[15] For non- randomized trials the Newcastle-Ottawa Scale (NOS) was assessed.[16] In addition, the total score was presented in percentage of the maximum available score, low risk of bias was considered if the score achieved ≥50% in the three categories.[17] Randomized controlled trials (RCT) were examined using the modified RoB tool.[18] Based on the 10 questions a score of 10 points is possible; a point is given for each question. A score >8 points indicate low risk of bias. In addition, the Detsky Score was used, a score ≥15 (75%) indicate high quality.[18,19]

Results extracted from analyzed studies were summarized in a narrative preformatted form after review of each author and approved by PP, UJS, CEH. The primary outcome were gait changes, radiological changes, pain, functional outcome, and quality of life (QoL). If two studies seemed to share data, these studies were summarized.

Studies were categorized as followed: report of only one orthosis without comparison, comparison of orthoses types, comparison of orthosis to no orthosis.

Previous systematic reviews were assessed regarding the following parameters: research question, similar articles included, reason for repetition of the review mentioned, recommendation of spinal orthosis, Oxman and Guyatt Index and PRISMA Score and Strength of Recommendation Taxonomy (SORT). The Oxman and Guyatt Index was categorized as followed: strong weakness 1-2 points, severe 3-4 points, moderate 5-6 points, minimal >7 points.[20,21]

The PRIMSA score was graded as followed: <19 low quality, 19-22.5 moderate quality, >22.5 high quality.[22,23]

A meta-analysis was not performed due to the heterogeneity of data.

Results

Thirteen studies and eight systematic reviews were analyzed. Seven studies were performed in Asia (four in Japan[24-27] and each one from China,[28] South Korea,[29] Taiwan[30]) and six from Europe (two from Germany[31,32] summarized to one due to an assumed shared patient cohort and one from Netherlands,[33] Denmark,[34] Greece,[35] and Italy[36] each; Supplemental Table 1). Seven studies defined a precise inclusion time frame.[24,26,27,29,33,34,36] All studies were unblinded. Three studies had a financial support,[29,31,32] two were funded by an orthosis manufacturer.[31,32]

The level of evidence was 4 in three studies,[24,33,34] 2 in eight studies[25,27,28,30-32,35,36] and 1 in two studies[26,29] (Table 1). Ten studies[24,27,29,33,34] were monocentric and three multicentric.[25,26,36] The mean age of the included patients was more than 65 years in all studies. Exclusively female patients were included in seven studies.[26,28,31-35] Symptom duration of patients ranged from days (four studies),[25,27-29] weeks

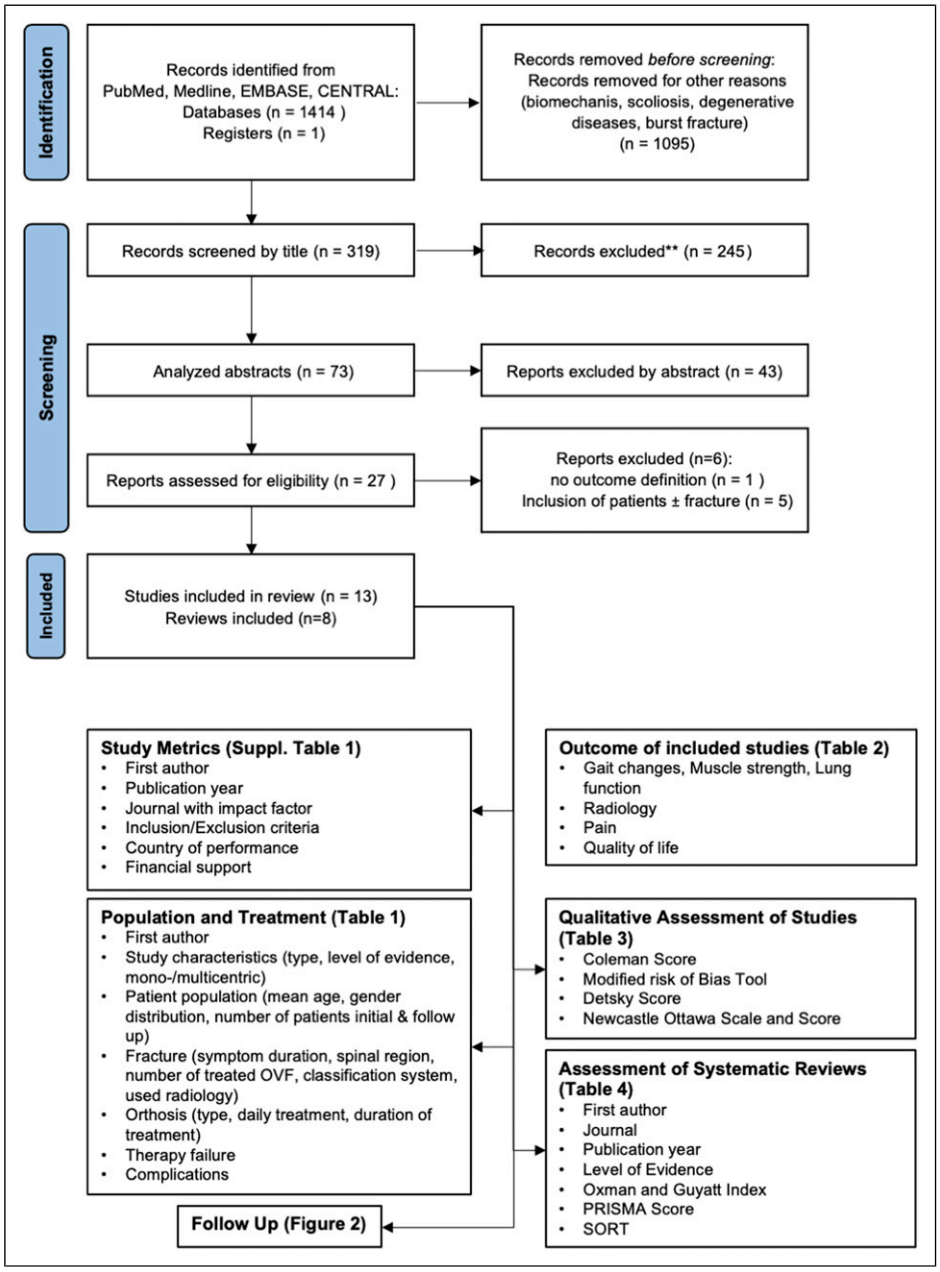

Figure 1. Scheme according to PRISMA criteria and retrieved data. ** Manuscripts were excluded due to wrong treatment indication or comparison to surgery (scoliosis, comparison of non-operative to operative treatment, missing relevant outcome). Retrieved studies were additionally excluded due to missing outcome definition (n = 1),[37] inclusion of patients ± fracture (n = 5).[38,41,55-57]

(two studies)[26,33] to months (two studies)[32,34] or were not defined (five studies).[24,30,31,35,36] The fracture was located in the thoracic and lumbar spine in seven studies,[24,25,27-29,35,36] thoracolumbar junction in two studies[26,33] and not defined in four studies.[30-32,34] The number of treated fractures ranged from 1 (six studies[24-27,29,36]), 2 (four studies[31-34]) to >3 in one study[28] and was not defined in two studies.[30,35] Three studies used a fracture classification system (AO, Genant, Sugita).[25,27,36]

Six studies used solely radiographs[28,30-32,34,35] and five studies radiographs and magnetic resonance imaging (MRI).[25-27,29,33] Each one study combined X-rays, CT scan and MRI[24] or X-rays and CT.[36]

Daily treatment ranged from 15 minutes/day (one study[34]) at the beginning, 2-3 hours/day (four studies[28,31,32,35]) to the whole day (four studies[26,27,29,33]) or only during sitting and standing.[36] Three studies did not define the daily duration.[24,25,30] The duration of treatment ranged from

Table 1. Population and Treatment. Study Characteristics, Investigated Patient Cohort and Fracture Related Parameters as Well Orthotic Treatment, Therapy Failure and Complications are Presented.

		Mei-Yun Liaw	Eva Jacobs	Tetsuya Abe	Kenji Murata	Gitte Hoff Valentin	Tsuyoshi Kato	Meng Li	Luigi Meccariello	Ho-Joong Kim	Yannis Dionyssiotis	Masatoshi Hoshino	Michael Pfeifer 2004	Michael Pfeifer 2011
	Type	PoS	PoS	PoS	PoS	PoS	RCT	RCT	Non-RCT	RCT	Non-RCT	Non-RCT	RCT	RCT
	Level of Evidence	2c	4	4	2c	4	1b	2b	2b	1b	2c	2c	2c	2c
Study Characteristics	Mo/Mult	mo	Mo	mo	mo	mo	mu	mo	mu	Mo	mo	mu	mo	mo
Patient population	Mean age	68.2	69	81.2	75.3	70.8	Soft brace 75.5 Hard brace: 76.0	Spinomed: 82 Soft lumbar orthosis: 81	3-PO: 81.9 Spinomed 82.8	No brace: 72.3 soft brace: 66.8 rigid 71.8	No orthosis: 61 Spinomed: 72.3; p=0.014	No brace: 77 Brace: 76.2	Control: 72.3 Spinomed: 72.8	Control: 69.7 Spinomed: 72.8 Spinomed active: 72.3
	Gender Distribution (f:m)	37:10	15:0	106:18	39:14	13:0	284:0	51:0	100:40	41:19	20:0	303:59	62:0	108:0
	Number of patients intial	47	15	124	55	13	284	51	140	60	20	362	62	108
	Follow-up	-	15	124	53	13	228	51	140	49	20	362	62	108
Fracture	Symptom duration	Nd	<3 we	Nd	<1 we	<3 we								
	Spinal Region	Nd	TLJ (TH11-L4)	TH+L (TH4-L5)	TH+L (TH1-L5)	nd	TLJ (TH12-L2)	TH+L (TH4-L5)	TH+L (TH6-L3)	TH+L (TH7-L3)	TH+L	TH+L (TH5-L5)	nd	<6 mo
	Number of treated OVF	Nd	1-2						1	1	nd	1	2	2
	Classification System Radiology	none	none	none	AO classification	none	none	none	Genant's classification		none	Sugita et al.	None	None
	X-ray	x	x	x	x	x	x	x	x	x	x	x	x	x
	CT	x	—	—	—	x	—	—	x	-	—	—	—	—
	MRI								—	x	—	x	—	—
Orthoses	Type	TLSO Knight-Taylor brace	TLSO Osteolind Plus	3-po Jewett brace	Plastic rigid TLSO	Spinomed III	Rigid TLSO (n=141)	1 we TLSO 2-3 we Spinomed+lumbar orthosis (n=27)	3-PO (n=72)	No brace (n = 20)	No orthosis (n = 10)	No orthosis (n=35)	No orthosis (n=31)	After 6 mon start with Spinomed (n=36)
							Soft TLSO (n = 143)	2-3 we soft lumbar orthosis (n = 24)	Spinomed (n = 68)	Rigid brace (n = 20)	Spinomed (n=10)	Tailor-made hard brace (n = 71)	Spinomed (n=31)	Spinomed for 12 months (n= 36)
										Soft brace (n = 20)		Tailor-made elastic braces (n = 190)		Spinomed active for 12 months (n=36)
												Ready-made elastic braces (n = 66)		
	Daily Treatment	Nd	24 h/d 6 we	nd	except for shower	15 min/d for 14 d increasing 2-4h/d in the next 10 we	24 h/d	24 h/d 3 h/d Spinomed soft lumbar orthosis rest	sitting and standing	24 h/d except during lying	2 h/d	n/d	2 h/d	2 h/d
	Duration of Treatment	nd	6 mon	3-6 mon	min. 2 mon	3 mon	3mon	3 we	2.5 mon	2mon	-	4.1 + 1.9 mon	6-12 mon	6-12 mon

(continued)

Table 1. (continued)

		Mei-Yun Liaw	Eva Jacobs	Tetsuya Abe	Kenji Murata	Gitte Hoff Valentin	Tsuyoshi Kato	Meng Li	Luigi Meccariello	Ho-Joong Kim	Yannis Dionyssiotis	Masatoshi Hoshino	Michael Pfeifer 2004	Michael Pfeifer 2011
	Type	PoS	PoS	PoS	PoS	PoS	RCT	RCT	Non-RCT	RCT	Non-RCT	Non-RCT	RCT	RCT
	Level of Evidence	2c	4	4	2c	4	1b	2b	2b	1b	2c	2c	2c	2c
Study Characteristics	Mo/Mult	mo	Mo	mo	mo	mo	mu	mo	mu	Mo	mo	mu	mo	mo
	Therapy failure	nr	nr	10 (surgical intervention)	non-union: n=6	nr	nr	nr	Non-union: 3-PO n = 5, Spinomed n = 4	nr	nr	nr	nr	nr
	Complications	nr	No complications	Urinary tract infection (n = 10) Pneumonia (n = 5) Ileus (n=1)	Decubitus (n = 3) Pneumonia (n = 1)	—	New OVF (n=16) Subjected to surgery (n=2)	nr	Gastric ulcer (each n = 6 3-PO, Spinomed) Decubitus (n = 8 3-PO) Inguinal hernia (n = 4 3-PO) Pulmonary disease (n = 4 3-PO) Re-fracture (n = 4 3-PO, n = 2 Spinomed)	—	nr	nr	nr	nr

PoS - Prospective observational study without comparison group; RCT – randomized controlled trial; Mo- monocentric; Mu- multicentric, national; 3-PO- 3-point orthosis; we- weeks; mon- months; d – days; nd – not defined; th- thoracic; TLJ- thorcolumbar junction; l- lumbar; TLSO- thoracolumbar orthosis; nr – not reported.

2.5 months to 1 year (Table 1). The different follow- up times are shown in Figure 2.

Spinal Orthosis Without Comparison (n=5)

By applying an orthosis an immediate and partial persistent improvements on gait stability resulting in an decrease of falls as well as an increase of back extensor muscle strength was observed.[30,33,34] Initially observed changes in alignment were not persistent during the follow-up though the wedge angle increased until 6 months.[33] Jacobs et al[33] observed a significant pain reduction Tables 1 and 2.[33]

Several aspects of QoL improved but Jacobs et al were not able to detect changes for general and mental health.[27,33] In contrast, Valentin et al. did not observed significant improvements in pain and QoL.[34] The effects were predominantly found during the first 6-12 weeks.[27,33] Using an orthosis resulted in a success rate of >80% analysing dynamic X-ray examination regarding persistent instability[24,27] but high intensity on T2-weightened MRI and vertebral instability >5° at 3-week follow were identified as risk factors for treatment failure.[24]

Comparison of Different Types of Spinal Orthoses (n = 3)

The Spinomed orthosis led to a significant higher forced expiratory volume in the first second compared to a 3-point orthosis (3-PO) Tables 1 and 2.[36]

The anterior vertebral body compression percentage (AVBCP) differed between soft and rigid brace after 12 weeks but not after 24 and 48 weeks. A higher decrease was found in the rigid brace group (MD 3 points) compared to the soft brace group (MD 1.6 points) during the follow-up.[26] Other radiological parameters like the Cobb´s angle did not differ comparing a Spinomed to a 3-PO.[36]

A significant improvement in pain, QoL for the Spinomed orthosis at 3- and 6 months follow-up but not after 1-week or 1-month was detected in comparison to a 3-PO.[36] Pain decreased significantly over time independent of the orthoses type.[28] In contrast to the study of Meccariello et al., QoL did not differ comparing orthoses types in two studies.[26,28] No association between QoL and AVBCP was determined.[26]

Spinal Orthosis to No Orthosis (n = 5)

Wearing an orthosis – independent of the type- did not lead to a significant improvement in QoL, pain, decelerated increase of radiological compression or minimized opioid use compared to patients who do not wear an orthosis.[29,35] Pain and QoL improved over time independent of the orthotic treatment.[25,29,35] In the study of Dionyssiotis et al,[35] the significantly younger control group refused to wear an orthosis. The two studies of Pfeifer et al[31,32] were summarized because the difference of cohorts could not be ensured (please see Table 1,[31] and Group A[32] regarding age and consecutive variables). In their planned crossover study, patients refused after 6 months to discard the orthosis. In contrast to the above-mentioned studies, Pfeifer er al.[31,32] observed a significant decrease for kyphosis angle using three-dimensional photomorphometry, improved body sway path length, body sway velocity, pain, QoL and abdominal and back extensor muscle strength. Noteworthy, Pfeifer et al[31,32] determined similar

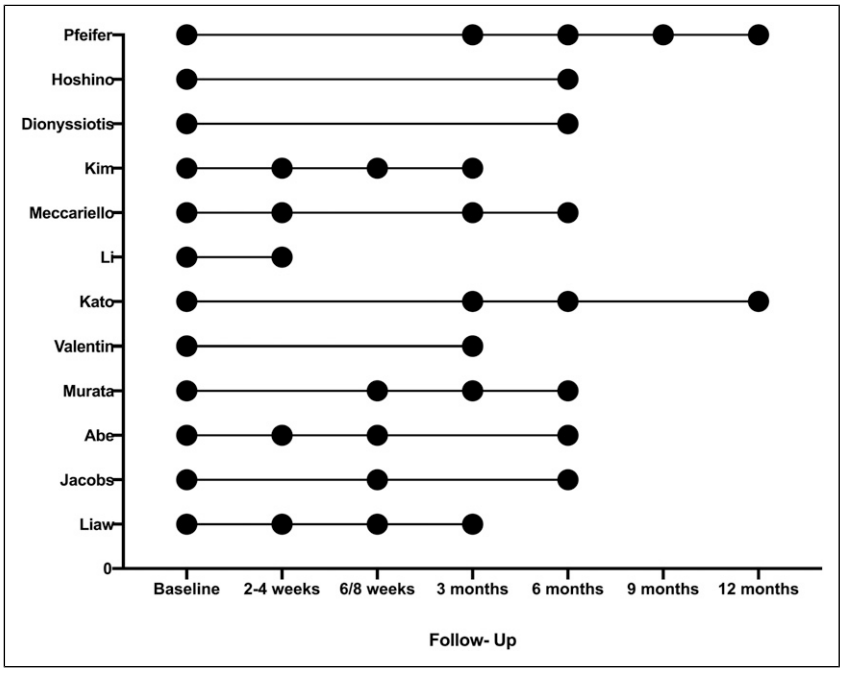

Figure 2. Presentation of the different follow-up visits of the included studies.

Table 2. Summarized Outcomes of Included Studies Separated According to the Paragraphs.

	First Author	Gait changes, Muscle strength, Lung function	Radiology	Pain	Quality of Life		
					Score	Domain	Different Time Points
Spinal orthosis without comparison	Mei-Yun Liaw	Greater average stability (MD 4.7%, $p < .001$) Frequency of falls closed eyes (MD 12, $p = .008$)	—	—	—		
	Eva Jacobs	Decreased trunk motion (decline 51%, $p = .006$) Increased walking speed (MD 0.21 m/s, $p < .001$) Increased stride length (0.05 m, $p = 0.007$) Decreased stride time (0.06 s, $p = .003$) Decreased cadence (5.62 steps/min, $p = .003$) Decreased step width (0.02, $p = .041$)	Wedge angle 6 weeks (MD 3.94, $p < .001$) Global sagittal alignment (MD 2.04, $p > .05$)	VAS (MD 3 po, $p < .001$)	QUALEFFO 41	+ pain, physical function and social function, $p < .001$ ± mental and general health	—
	Tetsuya Abe	—	Delayed union (n = 16, 14%)	—			
	Kenji Murata	—	Bony union (3 mon 79.2%; 6 mon 88.7%)	—	JOABPEQ	Low back pain (MD 36.5 po, $p < .05$) Lumbar function (MD 37.7 po, $p < .05$) Walking ability (MD 33.2 po, $p < .05$) Social life function (MD 26.2 po, $p < .05$) Mental health (MD 18.6 po, $p < .05$)	—
	Gitte Hoff Valentin	Increase of back extensor strength (MD 40N, $p < .01$)	—	VAS (MD 1 point, $p = .06$)	SF-36	PCS (MD 6.5 po, $p = .07$) MCS (MD 0.3 po, $p = .70$)	—

(continued)

Table 2. (continued)

	First Author	Gait changes, Muscle strength, Lung function	Radiology	Pain	Quality of Life			
					Score		Domain	Different Time Points
Comparison of different types of spinal orthoses	Tsuyoshi Kato	—	AVBCP (12 we MD 3.9; p = .04002; 24 we MD 3.9; p = .07; 48 we MD 2.5, p = .2)	VAS (12 we MD 0.2 points, p = .095; 48 we MD -1.9, p = .43)		EQ-5D-3L		12 we MD 0.02 po, p = .58
								48 we MD 0.01 po, p = .67
						JOABPEQ	Pain related disorder	12 we MD 3.6 po, p = .38
								48 we MD 3.3 po, p = .43
							Lumbar function	12 we MD 4.2 po, p = .29
								48 we MD -1.6 po, p = .91
							Walking ability	12 we MD 0.3 po, p = .92
								48 we MD 0.4 po, p = .82
							Social life function	12 we MD 2.7 po, p = .36
								48 we MD 5.7 po, p = .12
							Mental health	12 we MD 2.4 po, p = .14
								48 we MD -0.3 po, p = .96
	Meng Li	—	—	VAS (MD SP 2.7 po, MD SOL 1.8 po, p for time < .05)	FIM- motor score (MD SP 11.8 po, MD SOL 9.6 po, p for time < .05) Elderly Mobility Score (MD SP 5.1 po, MD SOL 5.2 po, p for time<0.05)		—	
	Luigi Meccariello	FEV1 (MD 3 mon 2.3%, MD 6 mon 11.5, p < .05)	DI (MD 6 mon 1.1°, p > .05)	VAS (MD 3 mon 1.3 po, MD 6 mon 1.7 po, p < .05)	OLBPDQ			3 mon MD 6.3 po, p < .05
			CA (MD 6 mon 0.2°, p > .05)					6 mon MD 13.7po, p < .05
			RKA (MD 3 mon 0.3°, 6 mon 0°, p > .05)					

(continued)

Table 2. (continued)

	First Author	Gait changes, Muscle strength, Lung function	Radiology	Pain	Quality of Life		
					Score	Domain	Different Time Points
Spinal orthosis to no orthosis	Ho-Joong Kim	—	BCR (p = .237)		VAS (p = .292)		
					Opioid use (MAXD 6.1%, p=0.912)		
	Yannis Dionyssiotis	Abdominal strength (MD 21.3N, p = .8)	—	VAS (MD 4 po, p = .67)	Baseline adjusted ODI (MD 1.88 to 2.49, p > .05)		—
					ODI (p = .26)	PCS (p = .716)	
		Back extensor strength (MD 28.3N, p = .6)			SF- 36	MCS (p = .889)	
	Masatoshi Hoshino	—	Vertebral collapse (MAXD 0.57)	Prolonged back pain (MAXD OR 0.51)	SF- 36	PCS ≤ 40 (MAXD OR 0.39)	
MCS ≤ 40 (MAXD OR 0.11)	—						
					Reduced ADL (MAXD OR 0.68)		
	Pfeifer	Abdominal strength (MD 71N, p < .01)	Kyphosis angle (MD 6.3°, p < .01)	Miltner's rating scale (MD 1.6po, p < .01)	Begerow well-being scale (MD 12.7po, p < .05)		—
		Back extensor strength (MD 182N, p < .01)			Leidig-Bruckner scale	PCS ≤ 40 (MAXD OR 0.39)	
		FEV1 (MD 6.7%, p < .01)				MCS ≤ 40 (MAXD OR 0.11)	

MD- mean difference, EQ-5D-3L- European Quality of Life-5 Dimensions, 3-Level questionnaire, SP- Spinomed, SOL- soft lumbar orthosis, po - points, FIM- Functional Independence Measure, OLBPDQ- Oswestry Low Back Pain Disability Questionnaire Score, FEV1- forced expiratory volume in the first second, DI- Delmas Index, CA- Cobb´s angle, RKA- regional kyphosis angle, VH- vertebral body height, BCR- Body compressions ratio, OR- Odd´s ratio, MAXD maximum difference, ADL- activities of daily living.

changes starting to wear the orthosis after 6 months Tables 1 and 2.

Quality Assessment

According to the CMS 4 studies were graded as poor[28,30,33,35] six studies as fair,[24,25,27,31,32,34] two studies as good[26,36] and one as excellent.[29] The overall NOS of non-randomized trials ranged from 22-78%, but only one study[36] achieved points in comparability and has therefore a low risk of bias. Of the RCTs, according to the RoB score two studies reached 8 points.[26,29] Thus, at all no study was considered with low risk of bias. Using the Detsky score two studies were graded as high quality Table 3.[26,29]

Comparison to Other Systematic Reviews (n = 8)

Two studies included a research question formulated according to the PICO scheme.[5,8] Ameis et al. solely analyzed previous systematic reviews and included the review of Rzewuska et al. who aimed to determine the efficacy of conservative treatment.[5,11] Both based their recommendations mainly on the studies of Pfeifer et al. Table 4.[31,32]

Three studies analyzed the effects of orthoses independent of their type on biomechanics, pain, QoL.[7-10] Besides of bracing Goodwin et al investigated the effects of taping and Hofler and Jones included studies with a crossover design and operatively treated patients.[6,12] Included articles in previous reviews, in the present review and excluded articles are summarized for each review in Table 4. The following articles were included in previous reviews and excluded here as follows: included in six[6-10,12] and excluded here due to no outcome definition,[37] included in two[9,10] and excluded due to language availability, included in three[7,9,10] and excluded due to missing fracture status (with/without/healed) (n = 5),[38–42] included in one[6] excluded because the intervention was taping,[43] included in one[11] and were excluded because primary intervention was medication,[44] included in one[12] and excluded here due to a crossover design to surgery,[45,46] comparison to kyphoplasty,[47] primary comparison regarding bed rest and inclusion of traumatic fractures,[48] orthosis not primary intervention and solely report of reduction over time,[49] orthosis not primary intervention.[50]

Despite five[5,7-10] reviews detected the low evidence for the use of orthoses in the treatment of OVF, their use was recommended. Two studies determined inconclusive evidence for orthotic use and therefore no recommendation was given.[6,11] Hofler and Jones neglected the standard use of orthosis.[12]

Five studies did not mention the reason for the repetition of the systematic review.[5,9-12] Three authors repeated the review because they detected missing clear recommendations, included further studies or performed statistical analyses.[6-8] Six previous reviews used RoB,[5-9,12] two the GRADE approach,[7,11] and two a meta-analysis[7,11] and one study did not perform a qualitative analysis.[9] Meta-analyses[7,11] based mainly on the Pfeifer studies.[31,32]

According to the Oxman and Guyatt index: three reviews had minimal,[6,9,11] three some[5,7,12] and one with severe weakness.[10] According to the PRISMA Score six reviews were graded low,[5,6,8-10,12] each one moderate[7] and high.[11] Except of one review[10] the remaining reviews had SORT grade B.

Discussion

Studies reporting on one orthosis described benefits over time and biomechanically immediately after application.

Liaw et al[30] and Jacob et al[33] showed benefits for gait parameters, decrease of falls and their persistence during follow-up but effects on function, pain and QoL remains unclear because no comparison groups are included. In addition, the orthosis showed a failure rate <25% in terms of bony union.[24,27] However, there is no mandatory relation of bony union to the function and QoL.[24,27] Most beneficial effects occurred in the first time after applying a spinal orthosis whereas effects after 3 months were rare[27] contradicting observations of other studies.[31,32]

In terms of the type of orthosis, the data favor soft orthosis or active orthosis like the Spinomed orthosis more than rigid braces based on a determined non-inferiority. Despite spinal orthosis led to a reproducible increase of trunk muscle strength,[34] previous reported improvements on pain and function were not reproducible.[31,32] The observed superiority of spinal orthosis was only reported in two studies of the same author.[31,32] The comparison of the here applied scores for pain, function and QoL are limited due to the missing use in the remaining studies.[31,32] In addition, the authors reported these beneficial effects after delayed treatment (6 months) after inclusion.[31,32] Considering the fracture union of >80% after 6 months[24,27] may lead to the assumption that spinal orthosis improved osteoporotic related pain but not mandatory fracture related pain.

Here, the used diagnostics in relation to fracture age and thereby fracture related pain of the different studies should be considered.[51] The MRI was only used in six studies and was shown as appropriate diagnostic for OVF.[51] All of them comparing orthosis to no orthosis (n = 2[25,29]) found no significant improvement by the orthosis. In addition, solely three studies[25,27,36] used fracture classification systems although they are required guiding therapy and may be used to for the outcome prognosis.[52] Apart from other classification systems, for example the OF classification seems to be an appropriate classification due to the inclusion of the MRI.[53] Considering the performed quality assessment and the thereby identified higher quality studies led to the following conclusions: Comparing orthosis types, a preference for soft or active orthosis compared to rigid braces was found. Nonetheless, the highest quality study[29] showed no inferiority of patients treated without an orthosis compared to patients treated with orthosis though the patient number is limited. A larger study,[25] though with limited quality, supported these findings. Thus, spinal orthoses seem to not significantly improve the outcome of patients suffering from thoracolumbar OVF. Despite previous systematic reviews underline the limited evidence for

Table 3. Qualitative Assessment of the Included Studies.

	PoS/non-RCT								RCT					
PoS/non-RCT	Tetsuya Abe	Yannis Dionyssiotis	Masatoshi Hoshino	Eva Jacobs	Mei-Yun Liaw	Luigi Meccariello	Kenji Murata	Gitte Hoff Valentin	Tsuyoshi Kato	Ho-Joong Kim	Meng Li	Michael Pfeifer	Michael Pfeifer	RCT
Coleman Score	61	33	51	44	39	72	69	51	84	89	46	67	64	Coleman Score
Newcastle Ottawa Scale									16	17	12	11	11	Detsky Score
Selection	**	***	****	**	*	**	***	**	8	8	2	3	3	Risk of Bias Tool
Comparability		—	—	—	—	**	—	—	low	low	high	unclear	unclear	randomization
Outcome	**	**	**	*	*	***	**	*	low	low	unclear	unclear	unclear	allocation concealment
Total (%)	46%	56%	67%	33%	22%	78%	56%	33%	high	unclear	unclear	unclear	unclear	surgeon or treatment provider blinding
									low	low	unclear	unclear	unclear	assessor blinding
									high	unclear	unclear	high	high	patient blinding
									low	low	unclear	low	low	patient follow-up
									low	low	unclear	high	high	selective outcome reporting
									low	low	low	high	high	objectivity of outcomes
									low	low	low	low	low	surgeon experience with treatment
									low	low	unclear	low	low	adequate sample size

Studies were categorized according to the study type and parameters.

Table 4. Assessment of the Included Systematic Reviews Including Quality Assessment and Strength of Recommendation Taxonomy (SORT).

First Author	Journal	Publication Year	Level Of Evidence	IS/ISH/ EX	Oxman & Guyatt Score	PRISMA Score	SORT
Arthur Ameis	European Spine Journal	2018	3a	6/1/5	5	11	B
Victora A Goodwin	BMJ Open	2016	3a	9/7/2	7	17	B
Ryan C. Hofler	WORLD NEUROSURGERY	2020	3a	16/10/6	5	16	B
Yuan Zhe Jin	Journal of Korean Medical Science	2016	3a	10/8/2	6	20	B
Barry Ting Sheen Kweh	Global Spine Journal	2020	3a	7/0/0	5	17	B
Meredith Newman	Archives of Physical Medicine and Rehabilitation	2016	2a	12/6/6	7	16	B
Michael Pfeifer	Zeitschrift für Rheumatologie	2017	2a	12/5/7	1	3	C
Magdalena Rzewuska	European Spine Journal	2015	1b	5/3/2	8	25	B

IS- included studies, ISH- included studies in the present review, EX- excluded studies in the present review but analyzed in the respective review.

the application of spinal orthosis and the high risk of bias of the included studies, at least weak recommendations for the application of spinal orthosis were given. At least three of them had only minimal weakness according to the Oxman and Guyatt Index. Thus, the contradicting recommendations given by us might be challenged. Compared to previous systematic reviews we performed a quality assessment and used the obtained results for our recommendations. In contrast, previously the recommendations and meta-analysis are based on two studies[31,32] which were here graded with low quality and a high risk of bias. Furthermore, it was not possible to detect if these studies[31,32] shared patients' cohorts as outlined above and a previous review assumed a potential conflict of interest.[11] Therefore, though the reviews were conducted with high quality, their recommendation and analyses were affected by the included studies and the overestimation of two studies caused by their initially planned study design.[54] Currently the evidence regarding the application of spinal orthosis is limited and based on small sample size and/or low-quality studies. Therefore, large multicenter studies considering appropriate diagnostics, the use of therapy guiding classification systems and with power should be carried out. Analyzing the inclusion and exclusion criteria highlight additionally the selective reporting because especially patients with cognitive impairment or neurodegenerative diseases as well as spinal degenerative diseases were excluded but in clinical practice a relevant patient cohort.

Conclusion

After the application of a spinal orthosis pain decreases and QoL improves over time. This is not different to the outcomes of patients treated without an orthosis. Thus, a clear recommendation for the application of spinal orthosis cannot be given. Indeed, this recommendation is predominately based on non-high-quality studies but is based on the grading of the different available studies and caused by the results of a meticulous quality assessment.

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Supplemental Material

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References

1. Agabegi SS, Asghar FA, Herkowitz HN. Spinal orthoses. *J Am Acad Orthop Surg*. 2010;18(11):657-667. doi:10.5435/00124635-201011000-00003.
2. Zarghooni K, Beyer F, Siewe J, Eysel P. The orthotic treatment of acute and chronic disease of the cervical and lumbar spine. *Dtsch Arztebl Int*. 2013;110(44):737-742. doi:10.3238/arztebl.2013.0737.
3. Spiegl UJ, Götz A, Grüninger S, et al. Stellenwert der orthetik für die wirbelsäule des erwachsenen – ergebnisse einer umfrage und diskussion der literatur. *Die Wirbelsäule*. 2020;4(3):174-181. doi:10.1055/a-0968-9210.
4. Spiegl UJ, Fischer K, Schmidt J, et al. The conservative treatment of traumatic thoracolumbar vertebral fractures. *Dtsch Arztebl Int*. 2018;115(42):697-704. doi:10.3238/arztebl.2018.0697.

5. Ameis A, Randhawa K, Yu H, et al. The global Spine care initiative: A review of reviews and recommendations for the non-invasive management of acute osteoporotic vertebral compression fracture pain in low- and middle-income communities. *Eur Spine J*. 2018;27(suppl 6):861-869. doi:10.1007/s00586-017-5273-6.
6. Goodwin VA, Hall AJ, Rogers E, Bethel A. Orthotics and taping in the management of vertebral fractures in people with osteoporosis: A systematic review. *BMJ Open*. 2016;6(5):e010657. doi:10.1136/bmjopen-2015-010657.
7. Jin YZ, Lee JH. Effect of brace to osteoporotic vertebral fracture: A meta-analysis. *J Kor Med Sci*. 2016;31(10):1641-1649. doi:10.3346/jkms.2016.31.10.1641.
8. Kweh BTS, Lee HQ, Tan T, et al. The role of spinal Orthoses in osteoporotic vertebral fractures of the elderly population (age 60 years or older): Systematic review. *Global Spine J*. 2021;11(6):975-987. doi:10.1177/2192568220948036.
9. Newman M, Minns Lowe C, Barker K. Spinal orthoses for vertebral osteoporosis and osteoporotic vertebral fracture: A systematic review. *Arch Phys Med Rehabil*. 2016;97(6):1013-1025. doi:10.1016/j.apmr.2015.10.108.
10. Pfeifer M, Gehlen M, Hinz C. Rückenorthesen in der behandlung von wirbelkörperfrakturen bei osteoporose: Eine systematische ubersichtsarbeit. *Z Rheumatol*. 2017;76(10):860-868. doi:10.1007/s00393-017-0404-3.
11. Rzewuska M, Ferreira M, McLachlan AJ, Machado GC, Maher CG. The efficacy of conservative treatment of osteoporotic compression fractures on acute pain relief: A systematic review with meta-analysis. *Eur Spine J*. 2015;24(4):702-714. doi:10.1007/s00586-015-3821-5.
12. Hofler RC, Jones GA. Bracing for acute and subacute osteoporotic compression fractures: A systematic review of the literature. *World Neurosurg*. 2020;141:e453-e460. doi:10.1016/j.wneu.2020.05.199.
13. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)–a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. 2009;42(2):377-381. doi:10.1016/j.jbi.2008.08.010.
14. Coleman BD, Khan KM, Maffulli N, Cook JL, Wark JD. Studies of surgical outcome after patellar tendinopathy: Clinical significance of methodological deficiencies and guidelines for future studies. Victorian institute of sport tendon study group. *Scand J Med Sci Sports*. 2000;10(1):2-11. doi:10.1034/j.1600-0838.2000.010001002.x.
15. Messner J, Papakostidis C, Giannoudis PV, Kanakaris NK. Duration of administration of antibiotic agents for open fractures: Meta-analysis of the existing evidence. *Surg Infect*. 2017;18(8):854-867. doi:10.1089/sur.2017.108.
16. Wells G, Shea B, O'Connell D, Peterson J, Welch V, Losos M, Tugwell P. *The newcastle-ottawa scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses*.
17. Ochtman AEA, Kruyt MC, Jacobs WCH, et al. Surgical restoration of sagittal alignment of the Spine: Correlation with improved patient-reported outcomes: A systematic review and meta-analysis. *JBJS Rev*. 2020;8(8):e1900100. doi:10.2106/JBJS.RVW.19.00100.
18. Smith CS, Mollon B, Vannabouathong C, et al. An assessment of randomized controlled trial quality in the journal of bone & joint surgery: Update from 2001 to 2013. *J Bone Joint Surg Am*. 2020;102(20):e116. doi:10.2106/JBJS.18.00653.
19. Detsky AS, Naylor CD, O'Rourke K, McGeer AJ, L'Abbé KA. Incorporating variations in the quality of individual randomized trials into meta-analysis. *J Clin Epidemiol*. 1992;45(3):255-265. doi:10.1016/0895-4356(92)90085-2.
20. Oxman AD, Guyatt GH. Validation of an index of the quality of review articles. *J Clin Epidemiol*. 1991;44(11):1271-1278. doi:10.1016/0895-4356(91)90160-b.
21. Dijkman BG, Abouali JAK, Kooistra BW, et al. Twenty years of meta-analyses in orthopaedic surgery: Has quality kept up with quantity? *J Bone Joint Surg Am*. 2010;92(1):48-57. doi:10.2106/JBJS.I.00251.
22. Tian J, Zhang J, Ge L, Yang K, Song F. The methodological and reporting quality of systematic reviews from China and the USA are similar. *J Clin Epidemiol*. 2017;85:50-58. doi:10.1016/j.jclinepi.2016.12.004.
23. Zhang J, Han L, Shields L, Tian J, Wang J. A PRISMA assessment of the reporting quality of systematic reviews of nursing published in the cochrane library and paper-based journals. *Medicine (Baltim)*. 2019;98(49):e18099. doi:10.1097/MD.0000000000018099.
24. Abe T, Shibao Y, Takeuchi Y, et al. Initial hospitalization with rigorous bed rest followed by bracing and rehabilitation as an option of conservative treatment for osteoporotic vertebral fractures in elderly patients: A pilot one arm safety and feasibility study. *Arch Osteoporos*. 2018;13(1):134. doi:10.1007/s11657-018-0547-0.
25. Hoshino M, Tsujio T, Terai H, et al. Impact of initial conservative treatment interventions on the outcomes of patients with osteoporotic vertebral fractures. *Spine Phila Pa*. 1976;38(11):E641-E648. doi:10.1097/BRS.0b013e31828ced9d.
26. Kato T, Inose H, Ichimura S, et al. Comparison of rigid and soft-brace treatments for acute osteoporotic vertebral compression fracture: A prospective, randomized, multicenter study. *J Clin Med*. 2019;8(2):198. doi:10.3390/jcm8020198.
27. Murata K, Watanabe G, Kawaguchi S, et al. Union rates and prognostic variables of osteoporotic vertebral fractures treated with a rigid external support. *J Neurosurg Spine*. 2012;17(5):469-475. doi:10.3171/2012.7.SPINE122.
28. Li M, Law S, Cheng J, Kee H, Wong MS. A comparison study on the efficacy of SpinoMed® and soft lumbar orthosis for osteoporotic vertebral fracture. *Prosthet Orthot Int*. 2015;39(4):270-276. doi:10.1177/0309364614528204.
29. Kim HJ, Yi JM, Cho HG, et al. Comparative study of the treatment outcomes of osteoporotic compression fractures without neurologic injury using a rigid brace, a soft brace, and no brace: A prospective randomized controlled non-inferiority trial. *J Bone Joint Surg Am*. 2014;96(23):1959-1966. doi:10.2106/JBJS.N.00187.
30. Liaw MY, Chen CL, Chen JF, Tang FT, Wong AMK, Ho HH. Effects of Knight-Taylor brace on balance performance in osteoporotic patients with vertebral compression fracture. *J Back Musculoskelet Rehabil*. 2009;22(2):75-81. doi:10.3233/BMR-2009-0218.
31. Pfeifer M, Begerow B, Minne HW. Effects of a new spinal orthosis on posture, trunk strength, and quality of life in women with postmenopausal osteoporosis: A randomized trial. *Am J*

Phys Med Rehabil. 2004;83(3):177-186. doi:10.1097/01.phm.0000113403.16617.93.

32. Pfeifer M, Kohlwey L, Begerow B, Minne HW. Effects of two newly developed spinal orthoses on trunk muscle strength, posture, and quality-of-life in women with postmenopausal osteoporosis: A randomized trial. *Am J Phys Med Rehabil*. 2011;90(10):805-815. doi:10.1097/PHM.0b013e31821f6df3.
33. Jacobs E, Senden R, McCrum C, van Rhijn LW, Meijer K, Willems PC. Effect of a semirigid thoracolumbar orthosis on gait and sagittal alignment in patients with an osteoporotic vertebral compression fracture. *Clin Interv Aging*. 2019;14:671-680. doi:10.2147/CIA.S199853.
34. Valentin GH, Pedersen LN, Maribo T. Wearing an active spinal orthosis improves back extensor strength in women with osteoporotic vertebral fractures. *Prosthet Orthot Int*. 2014;38(3):232-238. doi:10.1177/0309364613497393.
35. Dionyssiotis Y, Trovas G, Thoma S, Lyritis G, Papaioannou N. Prospective study of spinal orthoses in women. *Prosthet Orthot Int*. 2015;39(6):487-495. doi:10.1177/0309364614545416.
36. Meccariello L, Muzii VF, Falzarano G, et al. Dynamic corset versus three-point brace in the treatment of osteoporotic compression fractures of the thoracic and lumbar spine: A prospective, comparative study. *Aging Clin Exp Res*. 2017;29(3):443-449. doi:10.1007/s40520-016-0602-x.
37. Talic A, Kapetanovic J, Dizdar A. Effects of conservative treatment for osteoporotic thoracolumbal spine fractures. *Mater Sociomed*. 2012;24(1):16-20. doi:10.5455/msm.2012.24.16-20.
38. Hübscher M, Schmidt K, Fink M, Vogt L, Banzer W. Prospektive evaluation funktions- und lebensqualitätsbezogener effekte einer wirbelsäulenorthese bei frauen mit osteoporose. *Z Orthop Unfall*. 2010;148(4):443-447. doi:10.1055/s-0029-1240820.
39. Raeissadat SA, Sedighipour L, Pournajaf S, Vahab Kashani R, Sadeghi S. Effect of posture training with weighted kypho-orthosis (WKO) on improving balance in women with osteoporosis. *J Aging Res*. 2014;2014:427903. doi:10.1155/2014/427903.
40. Kaplan RS, Sinaki M, Hameister MD. Effect of back supports on back strength in patients with osteoporosis: A pilot study. *Mayo Clin Proc*. 1996;71(3):235-241. doi:10.4065/71.3.235.
41. Schmidt K, Hübscher M, Vogt L, et al. Einflüsse einer wirbelsäulenorthese auf gangparameter und alltagsfunktion bei postmenopausaler osteoporose. *Orthopä*. 2012;41(3):200-205. doi:10.1007/s00132-011-1867-6.
42. Sinaki M, Lynn SG. Reducing the risk of falls through proprioceptive dynamic posture training in osteoporotic women with kyphotic posturing: A randomized pilot study. *Am J Phys Med Rehabil*. 2002;81(4):241-246. doi:10.1097/00002060-200204000-00001.
43. Greig AM, Bennell KL, Briggs AM, Hodges PW. Postural taping decreases thoracic kyphosis but does not influence trunk muscle electromyographic activity or balance in women with osteoporosis. *Man Ther*. 2008;13(3):249-257. doi:10.1016/j.math.2007.01.011.
44. Vorsanger GJ, Farrell J, Xiang J, Chow W, Moskovitz BL, Rosenthal NR. Tapentadol, oxycodone or placebo for acute pain of vertebral compression fractures: A randomized Phase IIIb study. *Pain Manag*. 2013;3(2):109-118. doi:10.2217/pmt.13.5.
45. Bornemann R, Hanna M, Kabir K, Goost H, Wirtz DC, Pflugmacher R. Continuing conservative care versus crossover to radiofrequency kyphoplasty: A comparative effectiveness study on the treatment of vertebral body fractures. *Eur Spine J*. 2012;21(5):930-936. doi:10.1007/s00586-012-2148-8.
46. Lee HM, Park SY, Lee SH, Suh SW, Hong JY. Comparative analysis of clinical outcomes in patients with osteoporotic vertebral compression fractures (OVCFs): Conservative treatment versus balloon kyphoplasty. *Spine J*. 2012;12(11):998-1005. doi:10.1016/j.spinee.2012.08.024.
47. Colangelo D, Nasto LA, Genitiempo M, et al. Kyphoplasty vs conservative treatment: A case-control study in 110 post-menopausal women population. Is kyphoplasty better than conservative treatment? *Eur Rev Med Pharmacol Sci*. 2015;19(21):3998-4003.
48. Kishikawa Y. Initial non-weight-bearing therapy is important for preventing vertebral body collapse in elderly patients with clinical vertebral fractures. *Int J Gen Med*. 2012;5:373-380. doi:10.2147/IJGM.S25972.
49. Piazzolla A, Solarino G, Lamartina C, et al. Vertebral bone marrow edema (VBME) in conservatively treated acute vertebral compression fractures (VCFs): Evolution and clinical correlations. *Spine Phila Pa*. 2015;40(14):E842-E848. doi:10.1097/BRS.0000000000000973.
50. Shah S, Goregaonkar AB. Conservative management of osteoporotic vertebral fractures: A prospective study of thirty patients. *Cureus*. 2016;8(3):e542. doi:10.7759/cureus.542.
51. Spiegl U, Bork H, Grüninger S, et al. Osteoporotic fractures of the thoracic and lumbar vertebrae: Diagnosis and conservative treatment. *Dtsch Arztebl Int*. 2021;118(40):670-677. doi:10.3238/arztebl.m2021.0295.
52. Burstein AH. Fracture classification systems: Do they work and are they useful? *J Bone Joint Surg Am*. 1993;75(12):1743-1744.
53. Schnake KJ, Blattert TR, Hahn P, et al. Classification of osteoporotic thoracolumbar Spine fractures: Recommendations of the Spine section of the German society for orthopaedics and trauma (DGOU). *Global Spine J*. 2018;8(2 suppl l):46S-49S. doi:10.1177/2192568217717972.
54. Simunovic N, Sprague S, Bhandari M. Methodological issues in systematic reviews and meta-analyses of observational studies in orthopaedic research. *J Bone Joint Surg Am*. 2009;91(suppl 3):87-94. doi:10.2106/JBJS.H.01576.
55. Kaijser Alin C, Uzunel E, Grahn Kronhed AC, Alinaghizadeh H, Salminen H. Effect of treatment on back pain and back extensor strength with a spinal orthosis in older women with osteoporosis: A randomized controlled trial. *Arch Osteoporos*. 2019;14(1):5. doi:10.1007/s11657-018-0555-0.
56. Hosseinabadi M, Kamyab M, Azadinia F, Sarrafzadeh J. Effect of a spinomed orthosis on balance performance, spinal alignment, joint position sense and back muscle endurance in elderly people with hyperkyphotic posture: A randomized controlled trial. *Prosthet Orthot Int*. 2020;44(4):234-244. doi:10.1177/0309364620923816.
57. Vogt L, Hübscher M, Brettmann K, Banzer W, Fink M. Postural correction by osteoporosis orthosis (Osteo-med): A randomized, placebo-controlled trial. *Prosthet Orthot Int*. 2008;32(1):103-110. doi:10.1080/03093640701838265.