Review Article

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Effect of spinal orthoses on osteoporotic elderly patients kyphosis, back muscles strength, balance and osteoporotic vertebral fractures: (A systematic review and meta-analysis)

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Abstract

In this review and meta-analysis, we aimed to investigate the effect of spine orthotics in osteoporotic patients. The relationship between osteoporosis, osteoporotic vertebral fractures (OVFs), and age-related hyperkyphosis has made this effect unclear. We believe that taking participants' conditions into consideration may help to alleviate this controversy. The electronic database includes Web of Science, PubMed, Cochrane Library, Medline, and ClinicalTrials.gov. For English language literature was searched up to March 2023, and 34 articles were included in the review and 15 article had sufficient quality for meta-analysis based on the methodology quality index. There was no significant effect found from using either rigid or soft orthoses alone during the acute phase of one level (OVFs). Both semi-rigid and weighted orthoses have shown a positive significant effect on thoracic kyphosis angle and back extensor muscle strength in osteoporotic or older hyperkyphotic patients. The results of this review indicate that using a soft or rigid orthosis alone does not have a superior effect in the acute phase of one-level (OVFs) compared to not using an orthosis. However, using a semi-rigid or weighted orthosis in osteoporotic or hyperkyphotic older adults with or without (OVFs) can benefit thoracic kyphosis angle, back muscle strength, and balance.

Keywords

Orthosis, spinal orthotics, orthotic intervention, age-related hyperkyphosis, osteoporotic vertebral fractures

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Introduction

Changes in spine biomechanics[1] related to aging, osteoporosis, osteopenia, and postmenopausal hormonal changes in the older population, especially in women[2] Causes Asymmetrical load transmission of the intervertebral disc.[3] The spine-bent postures will provoke age-related hyperkyphosis or osteoporotic vertebral fractures.[4] While Hyperkyphotic older adults, 1.7 times more than older adults without hyperkyphosis face with future OVFs[5]; The exact cause-and-effect relationship between age-related hyperkyphosis and OVF is not clear.

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The prevalence of hyperkyphosis in the elderly population is 20% to 40%, varying between men and women,[6] and for osteoporotic vertebral fractures, 20% to 24%, varying between races.[7] Hyperkyphotic posture negatively impacts the quality of life, pulmonary and physical function, increasing the risk of falls, fractures, and mortality.[8] Osteoporotic vertebral compression fractures, reported as risk factors for age-related hyperkyphosis.[8]

Approximately 67% to 75% of OVFs are without clinical symptoms,[9,10] and only 10% of OVFs need hospitalization,[11] so conservative interventions are a priority for patients. Surgical and non-surgical interventions[12] like Percutaneous vertebroplasty, kyphoplasty, orthotic interventions, and analgesic drugs are prescribed for painful OVFs. Also, an equal effect on pain in 1-year follow-ups was reported for both.[13] Invasive and non-invasive methods seem to have advantages and disadvantages.[14–16]

Back extensor muscle strength (BES) and proprioception deficits as the functional and structural modifiable factors[8] and OVF as a preventable factor[17] were targeted by conservative interventions like orthotics, physiotherapy, exercises, and tapping[18–20] in age-related hyperkyphosis condition. Orthotic interventions have been used for decades to decrease age-related hyperkyphosis or improve flexed posture in kyphotic patients and protect the spine of people with OVF during the healing period, and meta-analyses evaluated different interventions.[19,21,22] Orthoses are conservative interventions that, in some designs, showed a remarkable effect on trunk muscle strength and kyphosis angle.[23–25]

However, controversy about using orthotic intervention in the osteoporotic population exists. Most of the studies in this field, inattentive to the relationship between age-related hyperkyphosis and OVF, omitted data about previous OVFs or thoracic kyphosis angles to include patients in a study about age-related hyperkyphosis or OVFs in the acute phase solely. Indeed one-third of hyperkyphotic older adults have at least one OVF, and subdividing these patients by inclusion criteria, which happened in previous reviews, cannot help us distinguish the effect of orthosis in osteoporotic patients.[26–28] Although some Meta-analyses results showed no impact of orthotic use in age-related hyperkyphosis[19] in comparison with other interventions, articles report significant improvements.[23,25] Otherwise, some meta-analyses showed controversy about orthosis benefits in pain, functional ability, and union duration in the acute and sub-acute phases of OVF[21,29,30] and neglected the structure, function, and design of an orthosis. Explaining the design, function, and target population of spinal orthotics in osteoporotic patients may change our expectations of an orthosis and define the proper manner of use of a spinal orthosis in osteoporotic patients.

The point is that orthotics in this field have different designs, goals, and roles. Therefore, defining the types, function, manner of use, wearing time, and describing the best choice based on patient characteristics may alleviate inconsistency about orthotic interventions in the osteoporotic elderly population. So, this systematic meta-analysis review aims to investigate the effect of orthotic interventions in osteoporotic patients based on the syndrome.

Methods

This systematic review and meta-analysis were designed and presented based on the instructions for preferred reporting in the systematic review and meta-analysis guidelines (PRISMA).

Eligibility criteria

In this review, studies that inspect the effect of orthotic interventions on pain (as a visual analog scale or part of a questionnaire), quality of life (any questionnaire about the physical and mental situation of patients), spinal function (any questionnaire or radiographical evaluation that explore physical function of the spine), OVFs anterior body compression ratio, intervention duration (includes bed rest duration or length of hospitalization), re-fracture (new OVFs that happened during follow up), Kyphosis angle (regional or global), Trunk flexor and extensor muscle strength, physical functioning (clinical tests like timed up and go or forward reach test), balance (through the center of pressure or sensory organization tests), gait spatiotemporal parameters, and plantar pressure were included from English language journals. The inclusion criteria were: (1) osteoporotic or age-related hyperkyphotic human participants with or without OVFs; (2) randomized or non-randomized prospective clinical trials with or without a control group; (3) specifying the type of orthosis used. Studies were excluded if they had healthy subjects or didn't report any quantitative results. Additionally, non-English-language articles were excluded.

Search strategy

Electronic databases containing Pub Med, Web of Science, Cochran Library, Medline, and clinicaltrial.gov were searched from the outset until March 2023. Keywords derived from the medical subject heading (MESH) and special terms that express the question of the review were used (Table 1). Then all included studies hand searched for articles that met inclusion criteria.

Study selection

All articles obtained by the search were imported to EndNote X9 (Thomson, Reuters, Carlsbad, CA), and one reviewer (FK) extracted duplicate or cross-references. Then the abstract of each article was evaluated independently by two reviewers (FK and MA). Disagreements between two investigators referred to consensual choice. A tertiary investigator (AB) is involved if there isn't consent.

Table 1. Search strategy table.

	Search terms
1	Osteoporosis.mp. OR osteoporo*.mp. OR exp osteoporosis/
2	Osteoporotic vertebral fracture.mp. OR OVF*.mp.
3	Kyphosis.mp. OR exp kyphosis/
4	Flexed posture.mp. OR hunch Back.mp.
5	OR/3-4
6	Exp muscle/OR muscle.mp.
7	Muscle strength.mp. OR exp muscle function*/
8	Trunk muscle*.mp. OR exp trunk muscle*/
9	Spinal muscle*.mp. OR exp spinal muscle*/
10	Back muscle*.mp. OR exp back muscle*/OR back extensor muscle.mp.
11	OR/6-11
12	Older adults.mp. OR exp older adults/Or elderly.mp. OR exp elderly/OR senior.mp.
13	Orthotic*.mp. OR Orthos*.mp. OR Brace*.mp. OR exp orthotic device/
14	Spinal orthos*.mp. OR exp spinal orthos*/
15	Thoracic orthos*.mp. OR exp thoracic orthos*
16	Thoracolumbo* orthos*.mp.
17	Body jacket.mp.
18	OR/14-17
19	gait.mp. OR exp gait/
20	Spatiotemporal. mp. OR temporospatial. mp.
21	Balance.mp. OR exp balance/
22	Center of pressure.mp. OR exp center of pressure/
23	Center of mass.mp. OR exp center of mass/
24	Exp COP/OR COP.mp
25	Exp COM/OR COM.mp
26	OR/22-25
27	12 AND 5 AND 11 AND 18 AND 26 AND 21 AND 20
28	1 AND 2 AND 11 AND 18 AND 26 AND 21 AND 20

Data extraction

Reviewers (FK and MA) extracted details from the included article about the author, publication year, characteristics of participants, including mean age, sex, number in each group, type of syndrome, concomitant disorders and drugs, bone mineral density level, and features of the study such as design, aim, type of interventions (Orthosis and other interventions that were used in comparison with orthosis), all outcome measures with numerical reports, including variables describing the level of fracture improvement and duration of improvement, variables representing hyperkyphosis improvement, and variables describe Balance and gait parameters. Means and standard deviation for Anterior vertebral body compression fracture (AVBCP), Oswestry disability index (ODI), Thoracic Kyphosis angle, Back extensor muscle strength, sensory organization test (SOT), and gait speed for calculation of effect size extracted. The effect size was reported as the standardized mean difference (SMD) with a 95% confidence interval. These data were used for a meta-analysis of outcomes reported with different units and to compare the effect of orthotic types on variables and syndromes. If the reported data wasn't based on the mean or Standard deviation, the study was excluded from the meta-analysis but still in review.

Methodological quality assessment

The Modified Downs and Blacks quality index (QI) tool is used for assessing the quality of methodology of all admitted studies by inclusion criteria. The QI tool is a checklist with 27 questions. This tool can evaluate Randomized controlled trials (RCTs) and non-randomized trials in four domains, including reporting via the first 10 questions, external validity via the following three questions, internal validity via questions 14 to 26, and power via the last question. The test-retest reliability ($r = 0.88$), inter-rater reliability ($r = 0.75$), internal consistency (KR-20 = 0.89), and criterion reliability ($r \geq 0.85$) of the QI were reported.[31] None of the QI items were changed, and the total score of this tool was 28 due to one of the items that scored up to two points. Reviewers (FK and MA) assessed each article independently using the QI tool, and any discrepancy was resolved in the consensus meeting, and disagreements were referred to the third investigator (AB). Differences and a 95% confidence interval were determined.

Data analyses

The means ± SD were extracted and imported into comprehensive meta-analysis V2 (CMA) software to investigate the statistical significance of orthoses effects on intended variables based on osteoporosis syndrome. Outcomes in some studies had different units, so standardized mean 15 scores in the QI tool were entered into the meta-analysis (Table 2). The meta-analysis was conducted for variables reported in more than two studies with enough data to analyze. The random effect model was used in the analysis as the articles had different sources of participants. A test of heterogeneity was conducted, and if the chi-squared p value was less than .05, or I squared (variation in SMD attributable to heterogeneity) was more than 50%, or the Tau squared (estimate of between-study variance) more than .05, the test of sensitivity was used to find the reason for heterogeneity, and subgroup analysis was conducted.

Results

Study selection

The document's title and abstract were evaluated according to inclusion criteria, and a context investigation for the final selection was conducted based on the review strategy. Discords were solved by consensus. A number of 4293 titles and abstracts were imported into EndNote X9, and after removing duplications and irrelevant items, 50 studies were

Table 2. Quality of included studies to meta-analysis.

	1. Reporting (percent of total score)	2. External validity (percent of total score)	3. Internal validity-bias (percent of total score)	4. Internal validity confounding-selection bias (percent of total score)	5. Power (percent of total score)
Kaplan et al., 1996[1]	80	34	43	67	100
Pfeifer et al 2004[2]	90	67	71	84	100
Sinaki et al., 2005[3]	100	34	43	50	0
Liaw et al., 2009[4]	90	67	57	67	0
Pfeifer et al., 2011[5]	100	67	57	100	100
Lee et al., 2012[6]	80	67	57	84	100
Azadinia et al., 2013[7]	80	67	71	67	100
Kim et al 2014[8]	70	67	71	100	100
Namdar et al., 2017[9]	90	67	57	67	100
Jacobs et al., 2019[10]	100	0	71	50	0
Kato et al., 2019[11]	100	34	71	67	100
Alin et al., 2019[12]	90	34	57	50	100
Hosseinabadi et al, 2020[13]	80	67	71	67	100
Rahimi et al., 2021[14]	80	67	57	50	0
Keshavarzi et al., 2022[15]	80	34	86	67	100

evaluated in full text. Eight items due to insufficient data about orthotic intervention,[16,32–38] two objects due to having different languages,[39,40] two objects for including healthy subjects,[41,42] one item with the qualitative design,[43] one entity with the case series design,[44] and two items for unclear results[45,46] were excluded, and 34 studies remained into this systematic review (Figure 1), that fifteen of them included to the meta-analysis (Table 3).

Study characteristics

Eight prospective non-randomized clinical trials, four future randomized clinical trials, and one case-control study with OVF patients in the acute phase (OVFs that happened in the last month), Two prospective randomized controlled trials, one prospective crossover study, and two trials with patients in the non-acute phase of OVFs (that happened in the last 6 month), six prospective randomized control trials, and four non-randomized clinical trials are included in this review. Besides, five trials assessed changes immediately after using an orthosis and compared them with the same patients without an orthosis, which were named "immediate effect" studies in this review. Orthoses designs were TLSO (Thoracolumbosacral orthosis), TLO (thoracolumbar orthosis), plaster jackets, three-point pressure, soft, Semi-rigid, and weighted with different names like PTS (posture training support),[47] WKO (weighted kypho orthosis),[48] DHB (Dynamic Hyperextension Brace),[49] or rucksack type orthosis.[46]

Quality assessment of included studies

The QI tool scores for each included study are reported for studies with Randomized clinical trials in (Table 4), for studies that evaluated the immediate effect of orthoses in (Table 5), and for studies with various prospective designs in (Table 6). Seven studies got equal to or less than 15 points and were excluded from the meta-analysis. 17 studies got equal or more than 20 points, with the highest score being 22. Blinding participants from orthotic intervention is impossible. The variance of the syndrome in the source of samples wasn't reported in any of the articles, and orthosis was not the in-use intervention in the source population in most of the studies. Some studies were multi-central.

Effects of orthoses in osteoporotic patients (with or without hyperkyphosis or OVFs)

Orthotic interventions type. Traditional classification of orthotics may cause ignorance of dynamic or static effect of

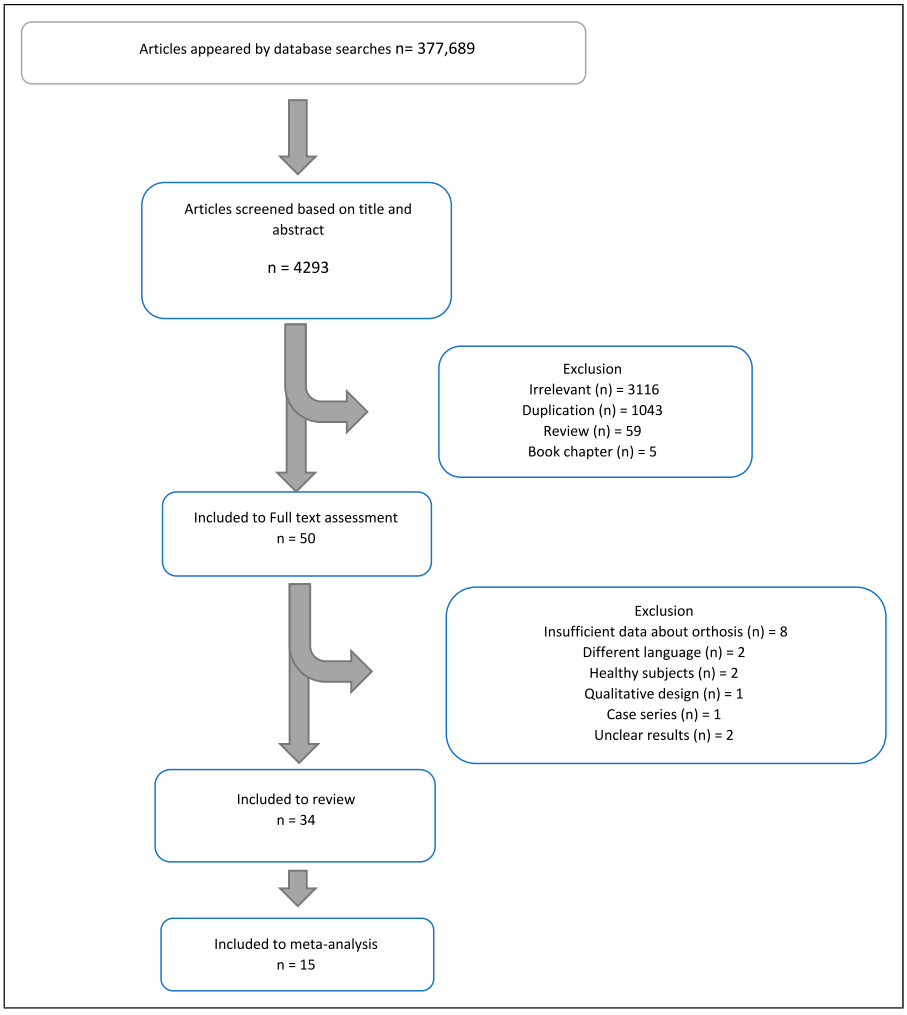

Figure 1. Flowchart depicting studies for the systematic review and meta-analysis.

orthosis on spine. Considering the details of each orthosis in this review, we categorize them into four groups: movement restrictor designs, soft designs, semi-rigid designs, and weighted designs. Explanation of details, goals, and the manner of use for each orthosis design mentioned in the discussion (part 4.5).

Orthoses used in the acute phase of OVFs. Orthosis types used in this part illustrated in Table 7. In seven out of 13 articles in group (OVFs acute phase), orthosis was a part of the conservative treatment that mostly started with weeks of bed rest and continued with exercise or physiotherapy and analgetic drugs. Six of 13 articles reported full-time wearing of the orthosis,[50–55] one study while walking only,[14] one study in walking, standing and sitting only,[56] and others didn't mention. The duration of orthosis use was different between 3 weeks and 16 weeks. Details about the orthosis type used in each study are reported in (Table 8).

The typical outcome measures in this part were the collapse rate of the anterior and posterior portions of the vertebral body, bone union rate or status, pain, number of refractures, and ODI scores. Additional outcome measures are detailed in (Table 8). As mentioned, we could enter three of the 13 articles in the meta-analysis with more than one group and report enough data after the intervention.[13,52,53] Due to high heterogeneity (p = .000, I2 = 92.638, and Tau2 = 0.579), samples were sub-grouped based on groups in the study. Meta-analysis showed a significant difference between rigid TLSO and no orthosis (SDM = −2.401, p = .000, and CI = 95%) and inflexible TLSO and soft back orthosis (SDM = −2.640, p = .000, and CI = 95%) for ODI score (Figure 2) (Kim/Kato/Lee). Meta-analysis showed no significant difference between the effect of rigid or soft orthosis and no orthosis group for anterior body compression ratio (Figure 3). The VAS after the intervention was only reported in three articles; two of them used orthotics as a part of conservative intervention after approximately 1-month of bed

Table 3. Type of orthosis used in acute phase of OVFs.

Orthosis name used in each study	Plaster jacket	Rigid TLSO	Rigid back orthosis	Three-point pressure	TLO	Taylor made hard	Osteolined	Taylor made elastic	Ready-made elastic	Ready-made soft back	Soft orthosis	Soft lumbar	Spinomed
Number of articles that used this type of orthosis	1	4	1	3	1	1	1	1	1	1	1	1	1
Categorization in this review	Movement restrictor designs							Soft designs					Semi-rigid designs

Table 4. Downs and black scale scores for included randomized controlled trials to systematic review.

	1. Aim	2. Main outcome	3. Patient characteristic	4. Intervention	5. Confounders distribution	6. Main finding	7. Random variability of main finding	8. Adverse event	9. Lost patients characteristic	10. Actual probability	11. Invitees represent entire population	12. Sample represent entire population	13. Intervention was usual treatment	14. Blinded subjects	15. Blinded examiners	16. Data dredging	17. Equal follow up length	18. Statistical tests	19. Reliable compliance	20. Reliable and valid outcome measures	21. Sampling of same population	22. Sampling in same period	23. Randomized intervention	24. Blinded randomization	25. Analysis of confounders	26. Take into account losses	27. Sufficient power	Total score
Lee et al., 2012[6]	1	1	1	0	1	1	1	0	1	1	1	0	1	0	0	0	1	1	1	1	1	1	0	0	1	1	1	19
Kim et al., 2014[8]	1	1	1	1	1	0	1	0	0	1	1	1	0	0	1	1	1	1	0	1	1	1	1	1	1	1	1	21
Kato et al., 2019[11]	1	1	1	1	1	1	1	1	1	1	0	1	0	0	1	1	1	1	0	1	0	1	1	0	1	1	1	21
Pfeifer et al., 2004[2]	1	1	1	1	1	1	1	0	1	1	1	0	1	0	0	1	1	1	1	1	1	1	1	0	1	1	1	22
Pfeifer et al., 2011[5]	1	1	1	1	1	1	1	1	1	1	1	0	1	0	0	1	1	1	0	1	1	1	1	0	1	1	1	22
Alin et al., 2019[12]	1	1	1	1	1	0	1	1	1	1	1	0	0	0	0	1	1	1	0	1	0	0	1	0	1	1	1	18
Hosseinabadi et al., 2020[13]	1	1	1	1	0	1	1	0	1	1	1	0	1	0	1	1	1	1	0	1	0	1	1	0	1	1	1	20
Rahimi et al., 2021[14]	1	1	1	1	0	0	1	1	1	1	1	0	1	0	0	0	1	1	1	1	0	1	1	0	0	1	0	17
Keshavarzi et al., 2022[15]	1	1	1	1	0	1	1	0	1	1	1	0	0	0	1	1	1	1	1	1	0	1	1	0	1	1	1	20
Kaplan et al., 1996[1]	1	1	1	1	0	0	1	1	1	1	1	0	0	0	1	1	1	0	0	0	1	0	1	1	0	1	1	17
Raeisssadat et al., 2014[16]	1	1	1	1	0	1	1	0	1	1	1	0	1	0	1	1	1	1	1	1	1	1	0	0	0	1	0	19
Shariatzadeh et al., 2017[17]	1	1	1	1	0	1	1	1	1	1	1	0	0	0	0	0	1	1	1	1	0	0	1	1	1	0	0	17

Table 5. Downs and black scale scores for included studies to review that evaluated immediate effect - red numbers choose based on consensus.

	1. Aim	2. Main outcome	3. Patient characteristic	4. Intervention	5. Confounders distribution	6. Main finding	7. Random variability of main finding	8. Adverse event	9. Lost patients characteristic	10. Actual probability	11. Invitees represent entire population	12. Sample represent entire population	13. Intervention was usual treatment	14. Blinded subjects	15. Blinded examiners	16. Data dredging	17. Equal follow up length	18. Statistical tests	19. Reliable compliance	20. Reliable and valid outcome measures	21. Sampling of same population	22. Sampling in same period	23. Randomized intervention	24. Blinded randomization	25. Analysis of confounders	26. Take into account losses	27. Sufficient power	Total score
Vogt et al., 2008[18]	1	0	1	0	1	0	1	0	1	0	0	0	0	1	0	1	1	1	1	1	0	1	0	0	0	0	0	12
Liaw et al., 2009[4]	1	1	1	1	0	1	1	1	1	1	1	0	1	0	0	1	0	1	1	1	1	1	0	0	0	1	0	18
Azadinia et al., 2013[7]	1	1	1	1	0	1	1	0	1	1	1	0	1	0	0	1	1	1	1	1	0	1	1	1	0	1	1	20
Namdar et al., 2017[9]	1	1	1	1	1	1	1	0	1	1	1	0	1	0	0	1	0	1	1	1	0	0	1	1	1	1	1	20
Karimian et al., 2021[19]	1	1	1	1	0	1	1	1	0	1	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	10

Table 6. Downs and black scale scores for included prospective randomized or nonrandomized clinical trials without control group to review - red numbers choose based on consensus.

	1. Aim	2. Main outcome	3. Patient characteristic	4. Intervention	5. Confounders distribution	6. Main finding	7. Random variability of main finding	8. Adverse event	9. Lost patients characteristic	10. Actual probability	11. Invitees represent entire population	12. Sample represent entire population	13. Intervention was usual treatment	14. Blinded subjects	15. Blinded examiners	16. Data dredging	17. Equal follow up length	18. Statistical tests	19. Reliable compliance	20. Reliable and valid outcome measures	21. Sampling of same population	22. Sampling in same period	23. Randomized intervention	24. Blinded randomization	25. Analysis of confounders	26. Take into account losses	27. Sufficient power	Total score
Fink et al., 2007[20]	1	1	1	1	1	0	1	1	1	1	0	0	0	0	0	1	1	1	1	0	1	1	0	0	1	1	0	17
Kishikava et al., 2012[21]	1	1	1	0	1	1	0	0	1	0	1	0	1	0	0	1	1	1	1	1	1	1	0	0	0	0	0	14
Talic et al., 2012[22]	1	1	1	1	0	1	1	1	1	1	1	0	1	0	0	1	1	0	0	1	1	1	0	0	0	1	0	17
Murata et al., 2012[23]	1	1	1	1	2	1	1	1	1	1	0	0	0	0	0	1	1	1	0	1	0	1	0	0	0	1	0	17
Borneman et al., 2012[24]	1	1	1	1	1	0	1	1	1	0	0	0	0	0	0	1	1	1	1	1	1	1	0	0	1	1	0	17
Hoshino et al., 2013[25]	1	1	0	0	0	0	1	0	1	0	1	0	0	0	0	1	1	1	0	1	0	1	0	0	1	0	0	11
Li et al., 2014[26]	0	1	1	1	1	0	1	0	1	0	1	0	0	0	0	1	1	1	1	1	1	1	1	0	1	1	0	17
Valentin et al., 2014[27]	1	1	1	1	1	1	1	1	1	1	1	0	0	0	0	1	1	1	0	1	1	1	0	0	1	1	0	20
Dionyssiotis et al., 2014[28]	1	1	1	1	0	0	0	0	1	1	0	0	1	0	0	1	1	0	0	1	0	1	0	0	0	0	0	11
Colangelo et al., 2015[29]	0	0	1	1	1	0	1	1	1	0	1	0	1	0	0	1	1	1	0	1	1	1	0	0	1	0	0	15
Piazzolla et al., 2015[30]	1	0	1	1	1	1	1	1	1	1	1	0	0	0	0	1	1	1	1	1	1	1	0	0	1	1	0	19
Meccariello et al., 2016[31]	1	1	1	1	0	1	1	1	1	0	0	0	0	0	0	1	1	1	0	1	0	1	0	0	0	1	0	14
Abe et al., 2018[32]	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0	1	1	1	0	1	1	1	0	0	1	1	0	20
Jacobs et al., 2019[10]	1	1	1	1	1	1	1	1	1	1	0	0	0	0	0	1	1	1	1	1	1	1	0	0	0	1	0	18
Kaplan et al., 1993[33]	1	0	0	1	1	1	0	0	1	0	1	0	0	0	0	1	1	0	1	0	1	0	0	0	0	0	1	0	11
Sinaki et al., 2002[34]	1	1	1	1	1	1	0	0	1	0	1	0	0	0	0	1	1	1	1	1	1	0	1	0	1	1	0	17
Sinaki et al., 2005[3]	1	1	1	1	1	1	1	1	1	1	1	0	0	0	0	0	1	0	1	1	1	0	0	0	0	1	0	16

Table 7. Demographic data of included studies to meta-analysis.

	Design	Number of participants	Mean age	Duration of intervention	Analyzed variable in meta-analysis
Kaplan et al., 1996[1]	Prospective randomized controlled study	45	71	3 months	Isometric back extensor muscle strength
Pfeifer et al., 2004[2]	Prospective randomized controlled study	62	72.55	6 months	Isometric back extensor muscle strength, thoracic kyphosis angle
Sinaki et al., 2005[3]	Clinical trial	12	71	Immediate	Balance (SOT)
Liaw et al., 2009[4]	Clinical trial	47	68.2	Immediate	Balance (SOT)
Pfeifer et al., 2011[5]	Prospective randomized controlled study	108	71.6	6 months	Isometric back extensor muscle strength, thoracic kyphosis angle
Lee et al., 2012[6]	Prospective clinical trial	259	71.5	3 weeks	Lumbar physical function
Azadinia et al., 2013[7]	Single blinded clinical trial	18	66.72	Immediate	Balance (SOT)
Kim et al., 2014[8]	Prospective randomized controlled study	60	70.25	12 weeks	Anterior vertebral body compression, lumbar physical function
Namdar et al., 2017[9]	Single blinded clinical trial	34	73.25	Immediate	Gait speed
Jacobs et al., 2019[10]	Observational single center study	15	69	Immediate	Gait speed
Kato et al., 2019[11]	Prospective randomized multi-center study	284	75.75	12 weeks	Anterior vertebral body compression, lumbar physical function
Alin et al., 2019[12]	Prospective randomized controlled study	113	76.1	6 months	Isometric back extensor muscle strength
Hosseinabadi et al., 2020[13]	Prospective randomized controlled study	44	67.7		Thoracic kyphosis angle
Rahimi et al., 2021[14]	Prospective randomized controlled study	40	67.39		Thoracic kyphosis angle
Keshavarzi et al., 2022[15]	Prospective randomized controlled study	48	65.6	12 weeks	Isometric back extensor muscle strength, thoracic kyphosis angle

rest with no control group,[13,52,57] so the results weren't solely the effect of orthotics. In 1961 patients, through 13 articles, 44 refractures happened in follow-ups in conservative groups, and 25 related to articles that exclusively used orthosis without rest or other interventions.[50–54,58,59] Also, refracture in 10 cases and cement leakage in 24 patients were related to other interventions reported.[13,50] Adverse events reported for the sole use of orthoses without rest were soreness, hernia, and pulmonary disease.[56,59] 4 of 13 studies had single-level OVF inclusion criteria,[14,52,53,56] and one reported a fusion of vertebral bodies adjacent to OVFs.[54]

Orthosis in OVFs happened in the recent 6 months. Only Five articles were chosen for this population (Table 9), and all of them used Spinomed or Spinomed active orthosis, a kind of semi-rigid orthosis.[15,60–63] Spinomed wore solely in Four articles[60–63] two to 4 h daily for 12 weeks or more, up to 4 years. One study used Spinomed for 12 weeks as a part of conservative treatment and the exact wearing time didn't mention.[15]

Three articles reported after intervention outcomes that one of them was excluded due to low methodological quality[60] and the remaining articles were related to each other[64] and had high quality with incontrovertible improvements in patients' conditions.[61,63] In these two articles, the mean pain of participants and their ability to extend and flex their trunk for muscle strength evaluation tests show that most of the participants weren't in the acute phase of OVFs, so these two articles were included in the meta-analysis with the following articles that measured comparable variables.

Orthosis in hyperkyphotic patients with or without OVFs. The included studies in this part are mentioned in Table 10.

Thoracic kyphosis angle. The orthosis type used in the age-related Hyperkyphosis group was (Spinomed) in five articles, (semi-rigid TLO) in one article, (Elderly spinal orthosis) in 1 article and (DHB) in 1 article. Six articles mentioned orthosis manner of use. Five out of six used a semi-rigid orthosis 2 h daily for 12 weeks and one used a weighted orthosis named DHB. The DHB orthosis wore 12 h daily for 1 year.

Table 8. Orthoses were used in acute phase of OVFs.

Study name (study design)	Orthosis type	Orthosis structures	Orthotic treatment duration	Daily wearing time	Wearing circumstances	Orthosis goals and participants condition	Outcome measures	Adverse effects or new OVFs
Kishikava et al., 2012[21] (conventional observational study)	Soft orthosis	Not mentioned	12 weeks	Not mentioned	2-weeks rest	Treatment of acute OVFs with severe pain, instability, neurological deficits, spinal malalignments, spinal canal stenosis	Collapse rate of anterior and posterior portion of vertebral body	Constipation (45%), dizziness (25%), nausea or vomiting (6%), cystitis (2%), and intercostal neuralgia (2%).
Talic et al., 2012[22] (prospective study)	1) Plaster corset 2) 3-point pressure	1) Cast, fulcrum on manubrium, sternum, and symphysis 2) Pressure points under clavicle, rigid frame, and an adjustable belt. The orthosis had four sizes.	3 months	Not mentioned	Not mentioned	1) Stationary of the thoracolumbar spine in neurologically intact acute OVFs. 2) Control of sagittal, frontal, and transvers plan, for acute OVFs of lower thoracic and lumbar spinal.	Treatment duration	Plaster corset in four patients removed after 4 weeks due to skin pressure sores. Nine patients in orthosis group and four patients in plaster corset group had wedge deformity more than 50% of vertebral body height.
Murata et al., 2012[23] (prospective study)	Plastic TLSO	Not mentioned	At least 2 months up to 6 months	24 h daily except for bath time	No bed rest	Treatment of OVFs for back pain happened in last week.	Mean vertebral dynamic mobility, local kyphosis, JOABPEQ	A decubitus ulcer in 3 patients and pneumonia in 1 patient. During 6 months, six patients' fractures remained unstable, and nine patients had new osteoporotic fractures.

(continued)

Table 8. (continued)

Study name (study design)	Orthosis type	Orthosis structures	Orthotic treatment duration	Daily wearing time	Wearing circumstances	Orthosis goals and participants condition	Outcome measures	Adverse effects or new OVFs
Lee et al., 2012[6] (prospective study+case report forms)	Rigid back orthosis	Not mentioned	3 weeks	Not mentioned	Orthosis was part of conservative treatments include bed rest, walking aid, analgesics	Treatment of severe back pain in one or two level of acute OVFs under T8.	VAS, ODI	Eight consequent OVF in the conservative groups.
Hoshino et al., 2013[25] (prospective multi-center study)	1) Taylor made hard orthosis 2) Taylor made elastic orthosis 3) Ready-made elastic orthosis	Not mentioned	6 months (mean = 4.1±1.9)	Not mentioned	Not mentioned	Treatment of patients with OVFs that a 75.1% of OVF were in the thoracolumbar junction region. Besides, 30.4% of patients had middle column vertebral body injuries and all had less than 50% anterior vertebral collapse.	Mini mental state examination (MMSE), VAS, short form SF-36	No

(continued)

Table 8. (continued)

Study name (study design)	Orthosis type	Orthosis structures	Orthotic treatment duration	Daily wearing time	Wearing circumstances	Orthosis goals and participants condition	Outcome measures	Adverse effects or new OVFs
Li et al., 2014[26] (prospective randomized trial-pilot trial)	1) Custom molded rigid TLSO (body jacket) 2) Soft lumbar orthosis 3) Spinomed	1) A three-point pressure orthosis include anterior and posterior portion, shaped on body and fastened with six straps. 2) A lumbosacral orthosis includes canvas and elastic layers, and tow moldable posterior metal uprights. Fitted by anterior hook and loops. 3) An orthosis with the moldable aluminum back support, stomach pad, elastic middle belt, pelvic belt, and shoulder straps.	3 weeks	1) 24 h a day 2) 24 h daily 3) 3 h daily	Both groups wore TLSO full time in first week then both groups wore soft lumbar orthosis full time unless intervention group wore spinomed 3 h daily during rehabilitation training and soft lumbar for rest of the day.	1) Pain remedy by forward flexion restriction in the thoracolumbar spine. 2) Pain remedy by lumbar spine movement control and boost abdominal pressure. 3) Strengthening trunk muscles through posture improvement.	Pain, functional independence measure-motor scores (fim-motor score), elderly mobility scale (EMS), modified functional ambulation category (MFAC).	No

(continued)

Table 8. (continued)

Study name (study design)	Orthosis type	Orthosis structures	Orthotic treatment duration	Daily wearing time	Wearing circumstances	Orthosis goals and participants condition	Outcome measures	Adverse effects or new OVFs
Kim et al., 2014[8] (prospective randomized trial)	1) Ready-made soft back orthosis (how Medical) 2) Rigid thoracolumbosacral (how medicare)	Not mentioned	10 weeks	1) Full time unless lye time 2) Full time unless lye time	All groups restrict spine motion, heavy lifting and caring and if needed used analgesics, after first 8 weeks, 2 weeks was weaning period.	Pain cure and disability improvement in one level thoracolumbar OVFs that only include anterior column and happened in the last 3 days.	VAS, ODI, anterior body compression ratio, general health status (SF-36).	No
Colangelo et al., 2015[29] (case control study-cohort)	TLO	Not mentioned	4 months	24 h daily	Not mentioned	As a standard conservative treatment for immobilization to prevent deformity in symptomatic OVFs happened in 2 last weeks.	EQ5D, SF-12, VAS, segmental kyphosis	No
Piazzolla et al., 2015[30] (prospective observational study)	C35-hyperextension orthosis	Not mentioned	3 months	Not mentioned	Bed rest for first 25 days and then wearing orthosis for next 90 days	As a conservative treatment for pain OVFs in the thoracic or lumbar region, happened in the last 10 days.	ODI, VAS, vertebral bone marrow edema.	Not mentioned
Meccariello et al., 2016[31] (prospective comparative non-randomized study)	1) Spinomed (SDO) 2) Standard 3-point corset	Not mentioned	2.5 months	During a day in standing and siting position	Weaning of both orthoses were started with abdominal, paravertebral and gluteal training	As an alternative for rigid thoracolumbar orthosis in osteoporosis in new OVFs in the thoracolumbar region (T6-L3) that only involved the anterior column of the spine.	Union rate, VAS, delmas index, local kyphosis angle, forced expiratory volume index, OLBPDQ.	22 patients in standard 3-point corset and 6 in spinomed groups faced ulcers, hernia, and pulmonary disease and 8 in standard 3-point corset and 2 in spinomed groups faced with refractures.

(continued)

Table 8. (continued)

Study name (study design)	Orthosis type	Orthosis structures	Orthotic treatment duration	Daily wearing time	Wearing circumstances	Orthosis goals and participants condition	Outcome measures	Adverse effects or new OVFs
Abe et al., 2018[32] (prospective single center cohort study)	Ready-to-use jewett orthosis (kobayashi medical, Shiman, Japan)	Not mentioned	12 to 24 weeks until the end of pain and vertebral instability	Not mentioned.	First 2 weeks of hospitalization with side lie down on bed rigorously. After more than 50% of pain relief, walking, lower limb muscle training, and orthosis started.	Control of lumbar flexion for acute single level OVFs in T4–L5, with back or low back pain started in two last weeks.	Hospitalization time, vertebral instability.	2 patients in this study lost their ability of walking and 10 urinary tract infection, 5 pneumonia, 1 ileus happened.
Jacobs et al., 2019[10] (observational single center study)	Semi rigid TLO orthosis osteolind plus (werkmeister, wanfried, Germany)	A semirigid orthosis composed of a moldable metal frame with padding and straps.	6 months	Full time in first 6 weeks then at least 6 h a day for 3 months and at least 3 h a day for rest of the study.	The orthoses were adjusted for each patient by an orthopedic technician. In the end of study orthosis wearing time was varied between 1 and 12 h.	Cure of symptomatic one or two level OVFs in thoracolumbar spine of ambulatory postmenopausal osteoporotic patients happened in last 3 weeks.	Radiographic sagittal alignment with surgi-map, spatiotemporal gait parameters, VAS, QUALEFFO41.	No
Kato et al., 2019[11]	1) Ready-made orthosis 2) Custom made rigid thoracolumbar sacral orthosis 3) Custom made soft thoracolumbar sacral orthosis	1) Not mentioned 2) An anterior opening one-piece mounded plastic fastened by four velcro straps. 3) An anterior opening corset made of elastic cotton or nylon material with steel uprights. Fastened by hook and loops.	12 weeks	Full time	Participants wore ready-made orthosis until put on a thoracolumbar sacral rigid orthosis or soft orthosis.	Cure of painful one level OVFs between T10 and L2. Happened in last 4 weeks.	Anterior vertebral body compression percentage, VAS, JOABPEQ, EQ-5D.	Seven rigid orthosis and nine soft orthosis patients faced new OVF.

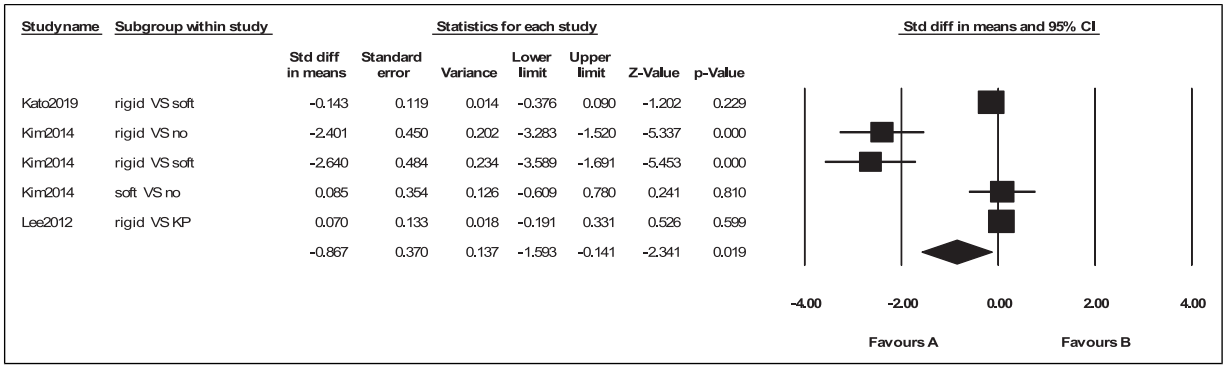

Figure 2. Effect of orthosis on oswestry disability index in OVF patients.

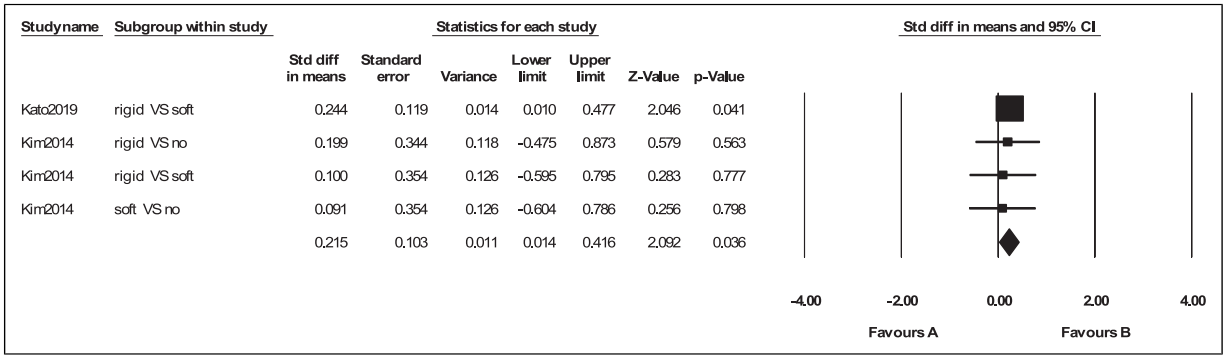

Figure 3. Effect of orthosis on anterior body compression ratio.

Four of the 11 articles[23,25,65,66] and two articles in part (3.5.2)[61,63] assessed the thoracic kyphosis angle, but only five of these studies were included in the meta-analysis due to enough data for analysis.[23,25,61,63,66] Another study had enough data on thoracic kyphosis angle, but this study's orthosis type differed from TLSO-type orthosis.[49] The heterogeneity was (p = .000/I2 = 92.322/Tau2 = 1.253). So, the data is sub-grouped based on groups in articles. Meta-analysis showed significant differences between corrective exercise (accommodated every 2 weeks based on each patient's condition) compared with ESO orthosis + exercise (SDM = −2.022, p = .000, and CI = 95%) and significant differences between corrective exercise (accommodated every 2 weeks based on each patient's condition) compared with spinomed + exercise (SDM = −1.629, p = .000, and CI = 95%) and significant differences between semi-rigid TLO orthosis in 3 months compared with no orthosis as a control group (SDM = −1.316, p = .000, and CI = 95%) (Figure 4). One study in this group excluded the thoracic kyphosis angle meta-analysis graph due to heterogeneity.[23] Two studies had patients with OVFs,[61,63] and three had pains between three and 6 VAS points.[61,63,66] In four studies,[23,25,61,63] orthoses were compared with no intervention. Other outcome measures related to balance, functional ability, back muscle endurance, and proprioception showed a significant relationship with kyphosis angle improvement, which wasn't entered in the meta-analysis due to variety and the inability to compare.

Back extensor muscle strength. Three of the nine articles in this part (Table 10) and two articles in part (3.5.2) measured back extensor muscle strength and had more than one group entered the meta-analysis.[24,25,61,63,65] Due to heterogeneity (p = .000, I2 = 92.784, and Tau2 = 1.216), data subgroups depend on reported groups. There were significant differences between PTS versus no orthosis (SDM = 1.645, p = .000, and CI = 95%), PTS versus conventional TLSO (SDM = 6.532, p = .000, and CI = 95%), conventional TLSO versus no orthosis (SDM = −2.633, p = .000, and CI = 95%), spinomed versus no orthosis (SDM = 1.566, p = .000, and CI = 95%), spinomed active versus no orthosis (SDM = 1.802, p = .000, and CI = 95%), and semi-rigid TLO versus no orthosis (SDM = 2.571, p = .000, and CI = 95%) (Figure 5). One study compared equipped exercise with spinomed, and no orthosis showed no significant differences.[65] The intervention duration in three studies was 6 months,[61,63,65] in one study was 4 months,[24] and in one study was 3 months.[25] Three studies had hyperkyphosis

Table 9. Orthoses were used in OVFs happened in recent 6 months.

Study name	Orthosis type	Orthosis structures	Orthotic treatment duration	Daily wearing time	Wearing circumstances	Orthosis goals and participants condition	Affected outcome measures	Adverse effects or new OVFs
Pfeifer et al., 2004[2] (prospective randomized controlled study)	The TLO orthosis spinomed (medi-bayreuth, bayreuth, Germany)	An orthosis composed of a moldable back pad, and belts. Adjustable with orthotist.	6 months	2 h daily	Not mentioned	Help for back pain caused by osteoporosis and one OVFs in active older adults, with more than 20% collapse and thoracic kyphosis angle more than 60°.	Back extensor and abdominal flexors isometric strength, kyphosis angle, body sway, vital capacity, average pain, well-being scale, disability scale.	No
Pfeifer et al., 2011[5] (prospective randomized controlled study)	1) Spinomed 2) Spinomed active	1) An orthosis composed of a moldable back pad, and belts. 2) A body suit, involved back rod and belts based on textile traction on pelvis and shoulders for fitting. -Both adjustable with orthotists.	6 months	2 h daily	Not mentioned	Help for back pain caused by osteoporosis and one OVFs in active older adults, with more than 20% collapse and thoracic kyphosis angle more than 60°.	Back extensors and abdominal flexors isometric strength, kyphosis angle, body sway, vital capacity, average pain, well-being scale, disability scale.	Three persons in the spinomed group due to continued pain and two persons in the spinomed active group due to low comfort stopped use of orthosis.
Borneman et al., 2012[24] (prospective cross over)	Spinomed III (semi-rigid)	Not mentioned	12 weeks	Not mentioned	Orthosis was part of conservative treatment include 2 times per week physiotherapy (massage, heat pack), pain relief medication.	Supportive of OVF with pain more than five based on VAS and symptoms onset in the last 2 months.	VAS, ODI.	During the initial 6 weeks of conservative care, most vertebrae lost anterior and central height and had an increase of kyphosis, 5 patients had new fracture in 1 year follow up.

(continued)

Table 9. (continued)

Study name	Orthosis type	Orthosis structures	Orthotic treatment duration	Daily wearing time	Wearing circumstances	Orthosis goals and participants condition	Affected outcome measures	Adverse effects or new OVFs
Valentin et al., 2014[27] (experimental follow up)	Spinomed III	An active back orthosis with belts. Adjustable by patients or physiotherapists.	12 weeks	15 min in first 14 days and 2 h daily in the next 14 days. In the next 8 weeks orthosis is worn for 2–4 h daily.	After 2 and 6 weeks, the orthosis adjusted if needed.	Maintaining upright position and improve trunk muscles proprioceptive in at least one OVF started in last 3 months in osteoporotic patient more than 50 years. Anterior body collapse more than 20%.	Isometric back extensors strength, back pain, SF-36.	One patient after 10 weeks excluded due to paine that get worsen by wearing orthosis.
Dionyssiotis et al., 2014[28] (clinical trial)	1) Spinomed 2) Osteomed 3) Spinomed active 4) Name-hidden orthosis	1) Spinomed include abdominal pad, spinal rod, back pad, and belts with hook and loops. 2) Include velcro tabs for pressure on the lumbosacral region and air chamber pads in spinal region, are filled by 2/3 and 3/4 of full capacity.	6 months	At least 2 h daily	Not mentioned	Alleviate back pain by exerting force on the trunk (extensors–abdominal) muscles. Used in osteoporotic patients more than 60 years, with at least one OVFs, more than 20% collapse, thoracic kyphosis angle more than 55°.	Isometric back extensors and abdominal flexors strength, VAS.	No

Table 10. Orthoses were used for hyperkyphosis or back extensor muscle strength improvement.

Study name	Orthosis type	Orthosis structure and function	Treatment duration	Daily wearing time	Wearing circumstance	Orthosis goals and participants characteristics	Affected outcome measures	Adverse effects or new OVFs
Kaplan et al., 1993[33] (prospective nonrandomized clinical trial)	Posture training support (PTS)	Include shoulder straps and back pocket, positioned beneath the scapula filled with a weight for proprioception improvement and unloading anterior column of vertebral bodies.	3 months	2 times daily and 4 h for each time.	Orthosis weight varied from 0.25 to 2.5 pound mostly 1.75 pound based on patient's characteristics	Improving back pain and posture in osteoporotic or osteopenia patients with or without OVFs	Pain and posture.	2 patients faced with pain in PTS group
Kaplan et al., 1996[1] (prospective randomized controlled study)	1) PTS 2) Conventional TLSO	1) Include shoulder straps and back pocket, positioned beneath the scapula filled with a weight (0.79 kg). 2) A stomach pad, shoulder straps, waist straps and pelvic straps based on article image.	16 weeks	1) 2 times daily and 4 h for each time. 2) Wore ceaselessly while up and about.	Deep breathing and seated back extension exercises were instructed in all groups.	Both orthoses were used as a supplementary part of a posture improvement plan in females with osteoporosis or osteopenia (mean age 64.2 years)	Isometric back extensor muscle strength, hand grip strength, physical activity.	Seven subjects before, and one person after 8 weeks, due to TLSO discomfort excluded and remained faced with back muscle weakness.
Sinaki et al., 2002[34] (prospective clinical trial)	PTS	A 2-pound weighted kypho-orthosis with weights positioned at the level of the scapulae in back. Incentive for back extensor muscles. Reposition the center of gravity and spine to maintain possible upright posture.	4 weeks	2 house daily	Orthosis wore only during activity with back extensor muscles exercise and (PDP) proprioceptive dynamic posture training	To improve balance in osteoporotic kyphotic patient. Used in osteoporotic older adults with thoracic kyphosis angle more than 50°.	Balance (computerized dynamic posturography), pain, back extensor muscles strength, physical activity scale.	Not mentioned

(continued)

Table 10. (continued)

Study name	Orthosis type	Orthosis structure and function	Treatment duration	Daily wearing time	Wearing circumstance	Orthosis goals and participants characteristics	Affected outcome measures	Adverse effects or new OVFs
Sinaki et al., 2005[3] (prospective clinical trial)	Weighted kypho-orthosis (WKO)	A 1 kg weight, positioned between T10 to L4, was fitted with a harness for improving spinal joints position sense.	4 weeks	1 h daily, 30 min in morning and 30 min in evening	WKO was a part of spinal proprioceptive extension exercise dynamic (SPEED) and the gait programs.	To decrease the risk of falls in ambulatory older adults with osteoporosis and hyperkyphosis. Used in osteoporotic community-dwelling, and physically active older adults with thoracic kyphosis angle more than 50°.	Balance (computerized dynamic posturography), fall, spatiotemporal gait parameters, back extensor muscles strength, physical activity, mini mental state scale	No
Fink et al., 2007[20] (prospective uncontrolled clinical trial)	Osteomed (Thaemert Ltd, Germany)	Include velcro tabs for pressure on the lumbosacral region and air chamber pads in spinal region filled about 67%-75%. No rigid part. Pain reduction effect will happen by stimulation of mechanoreceptors with air movements.	10 weeks	Wore all day continuously	Osteomed used with physiotherapy in some cases.	An adjuvant therapy for pain relief in osteoporotic patients with or without OVFs. Used in patients with typical osteoporosis-related back pain syndrome. The number of OVFs was different from none to more than three.	Pain, activities of daily living, compliance.	No
Raeissadat et al., 2014[16] (nonrandomized clinical trial)	WKO	An orthosis (made by techno-tan company) with a harness and a 2-pound weight positioned at T10 to L4.	4 weeks	1 h daily, 30 min in morning and 30 min in evening	WKO was a part of spinal proprioceptive extension exercise dynamic (SPEED) and 30 min daily walking.	Balance improvement in osteoporotic patients with no OVFs in last 6 months.	Timed up and go test, functional reach test, unilateral stance.	2 Patients excluded due to orthosis discomfort

(continued)

Table 10. (continued)

Study name	Orthosis type	Orthosis structure and function	Treatment duration	Daily wearing time	Wearing circumstance	Orthosis goals and participants characteristics	Affected outcome measures	Adverse effects or new OVFs
Shariatzadeh et al., 2017[17] (randomized clinical trial)	Dynamic hyperkyphosis orthosis (DHB)	Handmade orthosis includes shoulder straps and strap around the thorax and a pocket filled with 1 kg weight. Repetitive loading stimulates actuate osteogenesis in osteoporotic patients. Orthosis make stabilization, offloading and long-term extension force in spin.	12 months	12 h daily during activity	DHB were used with hyper extension exercise for 20 min three times daily. Patients are informed to remove orthosis in resting, lying and sleeping positions.	Deceleration of osteoporosis and inhabitation of hyperkyphosis in osteoporotic patients with thoracic kyphosis angle between 50 and 65°.	Spinal kyphosis, lumbar bone mineral density and T-score, serum alkaline phosphonate.	2 new OVFs
Alin et al., 2019[12] (randomized controlled trial)	Activating spinal orthosis spinomed	A backpack like orthosis includes a steel back rod from the C7 to the sacrum adjusted on spine in upright position, straps around the shoulders. Straps and rod making feedback for activating back extensor muscles.	6 months	Started with 15 min daily then participants during the 16 days gradually reached the 2 h or more daily wearing time that could divide to half hours during a day.	Realignment of orthosis done if patients asked by orthopedic technician.	Used in older adults diagnosed with osteoporosis and back pain with or without OVFs.	Isometric back extensor muscles strength, thoracic kyphosis angle, VAS.	One new OVFs

(continued)

Table 10. (continued)

Study name	Orthosis type	Orthosis structure and function	Treatment duration	Daily wearing time	Wearing circumstance	Orthosis goals and participants characteristics	Affected outcome measures	Adverse effects or new OVFs
Hosseinabadi et al., 2020[13] (prospective parallel group randomized controlled trial)	Spinomed IV AP orthosis (medi-bayreuth, bayreuth, Germany)	Semi-rigid thoracolumbar support includes moldable metallic back pad and belts with hook and loops. The shoulder straps forces and the total contact of the back pad help correction of hyperkyphosis.	13 weeks	30 min a day in the first 2 weeks and 2 hours a day in the next 5 weeks and then wore 2 to 4 h that varied between cases to the end.	Orthotist fit the orthoses based on the manufacturer's instructions and in accordance with individuals' anatomy. Correction force adjusted monthly.	Improve proprioception, enhance muscle performance and correct spinal alignment and balance in ambulatory older adults with thoracic kyphosis angle more than 50°.	Berg balance scale, timed up and go test, thoracic kyphosis angle, ito test, spine joint position sense.	No
Rahimi et al., 2021[14] (prospective randomized controlled trial study)	1) Spinomed IV AP orthosis (medi-bayreuth, bayreuth, Germany) 2) Elderly spinal orthosis	1) Include abdominal pad, moldable metallic upright, and shoulder straps for retraction. 2) Include back metallic upright, pelvic belt, abdominal pad. Fastened by velcro.	3 months	30 min a day in the first 2 weeks and 2 h a day in the remaining weeks for both orthosis	The dorsal metallic back part shaped by the orthotist based on patient spine for both orthoses and adjustment happened every 2 weeks.	Managing older people hyperkyphosis in ambulatory older adults with thoracic kyphosis angle more than 50°.	Thoracic kyphosis angle, VAS, SF-36.	No
Keshavarzi et al., 2022[15] (randomized controlled trial - parallel group)	Semi-rigid backpack type orthosis	Include two paravertebral metallic bars that moldable and adjustable by spanner based on patients' spine shape, a two-layer elastic stomach pads that increase abdominal pressure and neoprene shoulder straps.	12 weeks	30 min in first week then increased 15 min every day in second week. After 2 weeks, participants should wear orthosis for 2 h daily.	Orthosis wore only in walking and standing conditions and realignments happened every month.	Treatment of age related hyperkyphosis in older adults without OVFs in last 6 months. Used in older adults with kyphosis angle more than 50 by photogrammetry that could walk without assistance and could wear orthosis independently.	Isometric extensor muscle strength, thoracic kyphosis angle, extensor muscle endurance, ito test, spinal joint position sense.	No

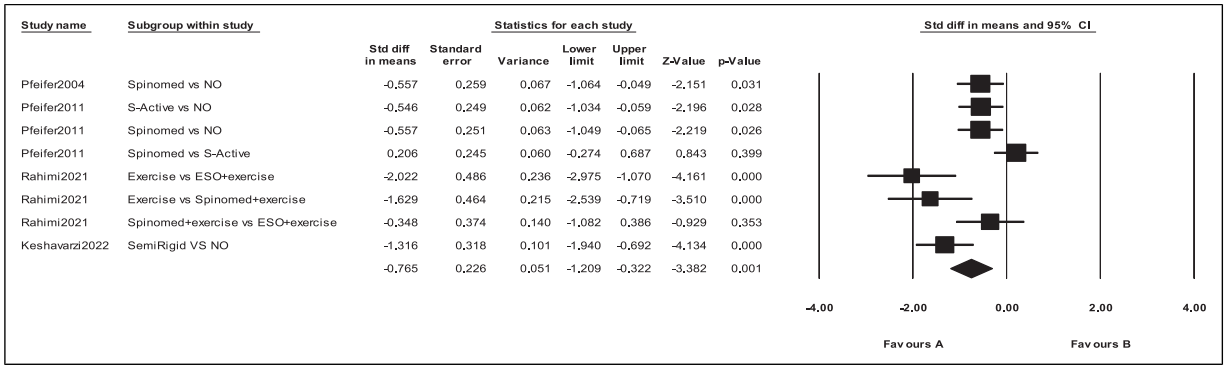

Figure 4. Effect of an orthosis on thoracic kyphosis angle.

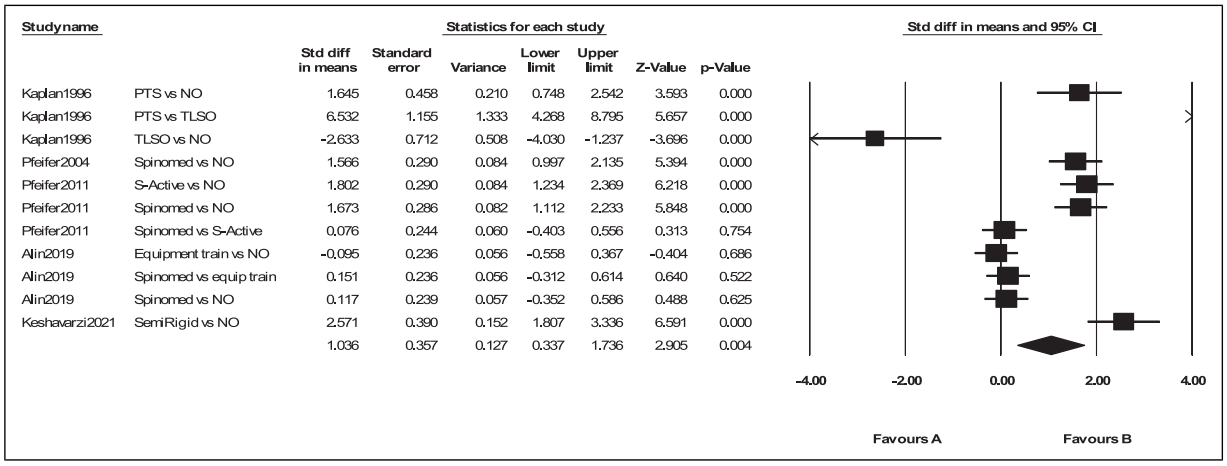

Figure 5. Effect of an orthosis on back extensor muscles strength.

inclusion criteria,[25,61,63] and two had patients with pain and OVFs in the last 6 months.[61,63]

In one article a WKO orthosis wore 1 h daily for 4 weeks and in another article, WKO wore 2 h daily only during activity for 4 weeks.[48,67] One study used PTS 8 h daily while up and about for 16 weeks.[24] Five articles used Spinomed orthosis for different durations between 3 and 12 months, two to 4 h daily.[60–63,65] One study used a semirigid TLO orthosis 2 h daily for 12 weeks.[25]

Immediate effects of orthoses in osteoporotic patients

Five articles that evaluated the effect of an orthosis directly after the first-time use included in this part (Table 11). Two of them had low methodological quality[68,69] and didn't enter into meta-analysis.

Sensory organization test. Three articles that used the Neurocom system and reported SOT test data before and after orthosis were included in the meta-analysis.[67,70,71] There was heterogeneity (p = .000, I2 = 87.594, and Tau2 = 1.200). Therefore, a subgroup analysis was conducted. Significant differences in the comparison of WKO versus no orthosis (SDM = −1.442, p = .001, and CI = 95%), PTS versus no orthosis (SDM = 1.704, p = .004, and CI = 95%), and spinomed versus no orthosis (SDM = 1.628, p = .002, and CI = 95%) indicated. There were no significant differences between spinomed versus PTS and Knight Taylor versus no orthosis in the SOT test (Figure 6). Two articles had hyperkyphosis as inclusion criteria,[67,70] and one study's participants had OVFs.[71] Two studies reported LOS test data that evaluated directional control and reaction time and showed no significant difference between the orthosis and without orthosis conditions.[70,71]

Gait parameters. Two articles measured spatiotemporal gait parameters before and after orthosis use in both first use and long duration after using orthosis,[51,67] and one other article measured walking speed.[72] Walking speed was measured in two studies,[51,72] entered into a meta-analysis, and there were no significant differences between the orthosis and no orthosis groups immediately (Figure 7).

Table 11. Orthoses were analyzed their immediate effect.

Study name	Orthosis type	Orthosis structures	Patient characteristics	Orthosis goals	Outcome measures
Vogt et al., 2008[18] (prospective uncontrolled clinical trial)	1) Osteomed 2) Osteomed without air chamber 3) Simple body wear as a placebo	1) A body suit includes constructively cut by velcro tabs making pressure on the lumbosacral region and air chamber pads positioned on the paravertebral and lumbosacral region. Pads filled with air between 2/3 and 3/4 of full capacity. No rigid element.	Osteoporotic patients	Posture correction	Maximum possible active straightening of spine
Liaw et al., 2009[4] (clinical trial)	Rigid knight-taylor (K-T)	Include two aluminum thoracolumbosacral posterior uprights, tow lateral uprights, two axillary straps, thoracic and abdominal pads, interscapular band, thoracic band, lumbar band, and pelvic band. Orthosis is controlling trunk motions in all plates. Increase abdominal pressure and correct spine alignment.	Older adults recently faced with OVFs and had tolerable pain.	An Immobilization of fracture and relieve back pain.	Balance (computerized dynamic posturography)
Azadinia et al., 2013[7] (single blinded clinical trial)	1) Spinomed 2) PTS (made by trulife)	1) Include abdominal pad, back metal upright, and straps. Metal upright extends up to the 1–5 cm under C7 and down to the end of spine. Back upright adjusted based on patient's spine. 2) Include posterior pocket with 10–20 cm length and 5–10 cm width. Pocket positioned under the scapula inferior angle. Filled with three 110 g and a 440 g weight. Weights were adjusted.	Hyperkyphotic older adults	Improving balance in hyperkyphotic older adults	Balance (computerized dynamic posturography)

(continued)

Table 11. (continued)

Study name	Orthosis type	Orthosis structures	Patient characteristics	Orthosis goals	Outcome measures
Namdar et al., 2017[9]	1) Spinomed 2) PTS	1) Include abdominal pad, back metal upright, and straps. Metal upright extends up to the 1–5 cm under C7 and down to the end of spine. Back upright adjusted based on patient's spine. 2) Include posterior pocket with 10–20 cm length and 5–10 cm width. Pocket positioned under the scapula inferior angle. Filled with three 110 g and a 440 g weight. Weights were adjusted.	Hyperkyphotic older patients that had not new OVFs in one last year.	Improving walking ability in hyperkyphotic older adults.	10-M walk test, 2 min' walk test, elderly mobility scale.
Karimian et al., 2021[19] (cross over trial)	1) The semi-rigid TLSO orthosis (kypho-Support, Teknotan, tehran, Iran) 2) The soft TLSO orthosis (custom fitted) 3) The rigid TLSO orthosis (custom fitted)	1) Include shoulder straps, abdominal pad and backside flexible metal frame. (900 gr) 2) Include an anterior opening one piece textile corset with shoulder straps and abdominal pad with four thermoplastic uprights. (800 gr) 3) A bivalve thermoplastic orthosis fitted with eight straps with a subclavian element for more forward flexion restriction. (1200 gr)	Ambulatory community doweling osteoporotic older adults without any OVFs. Thoracic kyphosis angle was more than 45 by kyphometer, experienced at least two falls last year.	Positioning spin in true alignment	Thoracic kyphosis angle, timed up and go test, forward reach test, anteroposterior mean velocity of center of pressure, mediolateral mean velocity of center of pressure.

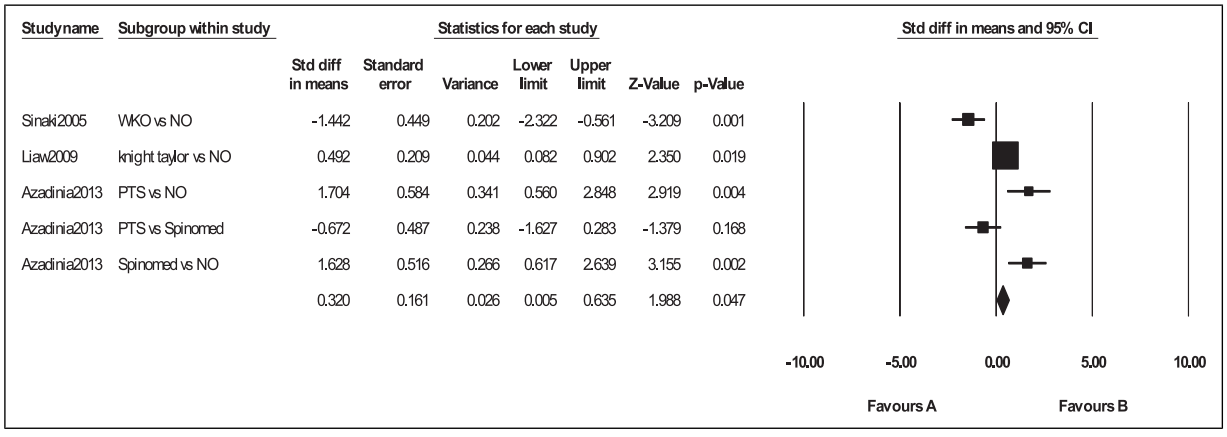

Figure 6. Effect of an orthosis on sensory organization test (SOT).

Figure 7. Immediate effect of an orthosis on walking speed.

Discussion

Quality

While four articles got more than 20 points on the QI scale,[52,53,61,63] about six Articles with a quality score of less than 15 were excluded from the meta-analyses.[47,58,60,68,69,73] The lowest scores, respectively, related to Internal validity confounding (selection bias) include random allocation, concealing the allocation of participants and evaluators, and reporting or evaluating confounding factors. Internal validity bias includes blinding and undefined sample sources. External validity includes distribution of confounding in the sample and treatment of most patients, reporting, and power-providing sample size calculation.

Even though 13 articles randomized intervention assignments and five concealed them from patients and examiners,[24,49,53,70,72] the randomization still weakens the included studies' quality. Some studies were multicentral,[52,58] and some did not describe the source of the included participants.[15,51,52,54,56,60,68,69,74] While blinding patients about orthosis is impossible, blinding them about the type of orthosis via placebo orthosis,[69] blinding examiners about the intervention group[23–25,52,53,75] is possible. Only three studies reported the proportion of the sample to the source.[14,52,53] 11 articles reported power based on the primary outcome measure of effect size.[13,23–25,52,53,61,63,65,70,72] A part of quality deficiencies relates to the nature of orthotic interventions that are usually optional and not the intervention for most patients. The score of the quality scale in two studies with the largest sample size[52,58] decreased because they had a multicentral design. Considering reports from various studies mentioned in results, it is crucial to prioritize the evaluation of adverse effects in orthotic studies. Results of the QI score showed that 27 points on this scale are achievable in studies with orthotic interventions. Incomplete reports of results data and details of the method, more than the absence of randomization and blindness, made included studies to review inappropriate for the meta-analysis. In any trial, data before and after intervention always shows effectivity but without correlation of these data, the effect can't compare with other studies in meta-analysis.

The design of some studies fails to distinguish the effect of physiotherapy or training from the effect of orthosis.[14,15,49,55,66,75] There is evidence indicating that the impact of physiotherapy on healing during the acute phase of osteoporotic vertebral fractures (OVFs)[76] and supervised training on kyphosis angle[19] is greater than what is reported in studies on orthotics. Comparing exercise with orthoses using precise methodology can lead to different results.[65]

Effect of orthoses in the acute phase of OVFs

Vertebral body compression ratio and Lumbar function quality were the most frequent variables reported in the studies included in this part of the review. Two studies, which only involved one level OVF participants, included in the meta-analysis based on quality score[52,53] showed no significant difference in the anterior vertebral body compression ratio between patients who used orthoses and those who did not. One of these studies had a control group with no brace, and the baseline score of the ODI in this group was lower than that of two other groups with orthotic intervention,[53] mentioned in a review before.[21] So, it seems a full-time use of an orthosis in one-level acute phase OVF patients has no harmful effect on lumbar function based on the ODI scale score. Reported data for pain wasn't enough for inclusion in the meta-analysis.[53] Besides participants have different sensitivity to analgesic drugs that aren't measurable,[13] so pain assessments had a not enough quality to compare. Also, existing and prescribed orthoses only

protect the spine from inadvertent flexions and movements that may hurt the spine again and cause pain. Evaluation of the effect of orthotics on pain debating when control group patients are conscious about body movements that may cause more pain. Orthoses can alleviate the pain of the fracture and improve healing if it has stimulators.[76] On the other hand, in most studies, orthosis wearing was full-time. Full-time immobilization of the spine for 3 months[24] or a long period of bed rest has irreversible effects on older patients' lifetime, which increases the risk of disability and mortality.[77,78] Any intervention that can help them ambulate independently in a shorter time after OVFs is a priority, and long durations of bed rest[79] or long duration of rigid orthosis wear is not the choice in unnecessary cases like one-level OVFs. If orthotic treatments are chosen, soft or semi-rigid designs while walking may eliminate adverse effects.

Conservative treatment in five studies includes physiotherapy or targeted muscle training[14,15,55–57] and only two studies explained the details of the training. In this review, we excluded any studies that did not provide detail about the type of orthosis. These criteria may lead to the exclusion of studies that focus on training or physiotherapy.

Effects of orthoses in OVFs happened in the last 6 months

The inclusion criteria in the studies may significantly influence the outcomes. Five studies recruited osteoporotic patients who had OVFs in the last 6 months[15,60–63] and two of them got the highest quality score of the QI tool in this review, showing the effectiveness of Spinomed in pain relief and kyphosis angle and trunk muscle strength and body sway improvements[61,63] However, there is some debate around these findings because the exact age of the vertebral fractures was not reported in these studies[61,63] and the ability of patients to contract muscles for strength tests may influenced by the nature of their fracture pain that is improving during the time. Also, participants of these studies[61,63] had thoracic kyphosis angles higher than 60° in baseline evaluation. There is a relation between thoracic kyphosis angle and back muscle strength.[8] Patients with Hyperkyphosis probably had lower trunk muscle strength. It can be one of the reasons for the inability of other studies to prove their[61,63] results. By the way, the results of these two articles confirm that wearing Spinomed according to the manner of use (2–4 h daily) is a beneficial treatment for osteoporotic patients with VAS pain score of fewer than five points that had one level OVFs in the last 6 months and Hyperkyphosis that affirmed before.[30] Orthoses with spring-like bars meet both the needs of movement limitation and moveability for patients and demonstrated a semi-rigid orthosis[17,25] revealed significant improvement. In all studies, orthosis wearing time was 2–4 h daily.

Effect of orthoses in osteoporotic and hyperkyphotic older adults

There is a relation between back muscle strength, number of OVFs, degree of hyperkyphosis, and the number of falls in older adults.[6,8] So, the prevention of OVFs and hyperkyphosis should be targeted.[80] The strength of back extensor muscles and thoracic kyphosis angle are vital variables that can prohibit osteoporotic vertebral fractures and falls in older adults. Based on this evidence, some orthoses are designed to improve spinal muscle strength and decrease kyphosis angle in osteoporotic patients.

Effect of orthoses on kyphosis angle. The thoracic kyphosis angle was measured in six studies before and after orthotic intervention.[23,25,49,61,63,66] Two of them were not included in the meta-analysis due to heterogeneity or involving participants with new osteoporotic vertebral fracture (OVF).[23,49] Based on the meta-analysis results, it was found that exercises designed by a specialist and tailored to each patient's condition, with changes every 14 days, are more effective in reducing the thoracic kyphosis angle compared to orthosis and constant exercise.[66]

A previous meta-analysis compared the effect of Spinomed orthosis with other conservative treatments, mostly different types of exercises, on kyphosis angle in patients of various ages.[19] Only one study compared two orthoses plus constant exercise with developing exercise based on patient condition. In Jenkins and colleagues' study, only two studies of Pfeifer[61,63] with osteoporotic patients experiencing pain due to OVF were included. Other studies in this part had no pain or OVF. Semi-rigid backpack-type orthoses, with no exercise, were found to have a significant effect on decreasing kyphosis angle in hyperkyphotic seniors compared to a control group with no treatments. This effect may be due to the periodic realignments of spring-like spinal bars and two-layer elastic stomach pads that increase abdominal pressure.[25]

The number of studies that used an orthosis in age-related hyperkyphosis or osteoporosis isn't sufficient to judge their effect on the thoracic kyphosis angle compared with other type of conservative treatments.[19] It is suggested that mixing exercise with an orthosis should be examined in a meta-analysis with groups that have exercise only, orthosis only, exercise and concomitant orthosis, and a group without any treatments, especially in a study that employs a crossover design for ethical reasons.

Effect of orthoses on back extensor muscles strength. According to a meta-analysis, PTS, Spinomed, and semi-rigid backpack-type orthoses showed a notable positive impact on back extensor muscles when compared to no intervention. Two studies[48,67] were not included in the meta-analysis because they did not report a control

groups or correlation between before and after the intervention.[48,67] Additionally, one study that compared Spinomed with equipped exercise and no orthosis[65] showed no significant effect on none of the interventions. In this study, the thoracic kyphosis angle was not reported and hyperkyphosis was reported via flexible ruler index. The same orthosis in patients with OVFs happened in the past 6 months with a Kyphosis angle of more than 60°, and pain after the same intervention duration showed significant improvement in trunk extensor and flexure muscle strength.[61,63] The decrease in thoracic kyphosis angle may be related to changes in back muscle structural variables.[8] Another study found that the use of a semi-rigid orthosis improved thoracic kyphosis angle in patients without pain and osteoporotic vertebral fractures (OVFs) within 3 months, leading to significant improvement in back muscle strength.[25] Some patients may prefer to keep using orthosis for more than 3 months,[43] but there is no evidence for the more beneficial effect of orthosis for longer-duration use.[61]

Only one study compared the effect of Weighted orthoses on back muscle strength with a control group[24] and one compared thoracic kyphosis angle.[49] Kaplan et al. compared conventional TLO with no orthosis and PTS orthosis group in which only five participants were in the TLO group. Based on five patients' data in this study, movement limitation with a soft TLO with complex inlays in osteoporotic patients makes back muscles weaker.[24] The Weighted orthoses were developed to improve posture and strengthen back muscles in osteoporotic patients. One study compared the effect of these orthoses on back muscle strength with a control group,[24] and another study compared the thoracic kyphosis angle[49] while both group participants had spinal extension training simultaneously.

Effect of orthoses in osteoporotic or hyperkyphotic patients on gait and balance

Effect of orthoses on dynamic balance. Three studies evaluated the effect of orthoses on dynamic balance in patients with hyperkyphosis, osteoporosis, or both.[67,70,71] Orthoses types were a weighted orthosis (PTS, WKO),[67,70] a semi-rigid orthosis (Spinomed),[70] and a movement restriction design (Knight Taylor).[71] Effects of initial and after 4 weeks of orthosis use on sensory organization test (SOT),[67] and the effect of one-time use of the orthoses on directional control and reaction time were reported.[70,71] Osteoporotic patients with pain due to recent OVFs with a Knight Taylor orthosis compared with no orthosis showed a decrease in overall directional control and no significant differences for SOT and reaction time.[71] Besides, patients had increased average stability, percentage of ankle strategy and decreased average velocity of the center of gravity target sway, and a lower frequency of falls.[71] Another study compared the effects of a weighted orthosis (PTS) and a semi-rigid orthosis (Spinomed) in hyperkyphotic older adults and showed that both orthoses had a significant positive impact on SOT tests compared with no orthosis condition. Still, there were no significant differences in directional control or reaction time.[70] One study showed improvement in the SOT test after 4 weeks of 1 h's daily use of WKO plus speed program exercise in osteoporotic hyperkyphotic patients.[67] It needs to be made clear whether the balance tests in this study were conducted with or without an orthosis.

Effect of an orthosis on static balance. One study analyzed the effect of the one-time use of three different TLSOs on hyperkyphotic older adults' center of pressure (COP) displacement velocity.[68] Results showed an increase in the anteroposterior mean velocity of COP displacement, respectively, for rigid TLSO, soft TLSO, and semi-rigid TLSO and an increase in the mediolateral mean velocity of COP displacement for soft TLSO, rigid TLSO, and semi-rigid TLSO.[68] Mohebi et al. compared COP displacement velocity between Hyperkyphotic patients with or without osteoporosis and a healthy young group. Higher COP displacement velocity for anteroposterior displacement in hyperkyphotic patients versus the young group and higher velocity for mediolateral displacement in osteoporotic patients versus the young group were reported.[81] So, it seems a semi-rigid TLSO is a better choice than a rigid and soft TLSO in static balance, as a study reported a larger average, anteroposterior COP range in faller elderly that experienced hard damages after a fall compared with non-faller elderly.[82] Sinaki et al. showed hyperkyphotic patients have a more mediolateral and less Antero-posteriorly center of mass displacement compared with healthy older adults.[67] It can show that this population balance system tends to decrease anteroposterior displacement, and can lead to harmful falls. Fall prediction based on one variable of static balance is not possible.[83] Pfeifer et al. reported a decrease in body sway Velocity after 6 months of using spinomed as a semi-rigid orthosis.[61,63] The Foot pressure of osteoporotic patients immediately after wearing a semi-rigid orthosis showed a pressure decrease in the forefoot region.[42] COP trajectory can be more explicator of elderly falls by variables like Sway area per unit time and anteroposterior and radial mean velocity.[84]

Effect of an orthosis on gait spatiotemporal parameters. Three studies measured spatiotemporal gait parameters,[51,67,72] and two of them included meta-analyses.[51,72] Cadence improved after using a weighted and semi-rigid orthosis, but there was no significant difference in first-time or long-duration use of the orthosis on spatiotemporal gait parameters.[51,67]

Orthosis designs, goals, and manner of use

The design of each orthosis reflects the goals of the orthosis and the expectations of the medical profession. With respect

to the effect of an orthosis on joints' range of motion (ROM) and muscles' electrical activations (EMG),[85] The orthoses's designs transformed the logic of movement inhibition to movement restriction and also movement motivation in some situations.[63] As orthoses's designs progress, our outlook on spinal orthotics in osteoporotic or age-related hyperkyphotic patients will be changed. In this part we have a look on the effect of different design of orthosis and the thru manner of use for each orthosis.

Semi-rigid designs. Orthoses made from spring-like or plastic uprights fitted into elastic or non-elastic soft structures like polychloroprene fabrics, elastic, and non-elastic fabrics that are enclosed by hook-and-loop fasteners. With this explanation, some of the orthoses used in articles as soft orthosis is a semi-rigid orthosis.[52] Spring uprights allow some flection while keep its constant alignments. The wearing time and manner of use ignored in some studies[15] and adverse effects that reported in one study may relate to manner of use. In this study, semi-rigid orthosis wore in sitting and standing positions and the exact wearing time during the day is not clear[56] The true manner of use for this type is, 2–4 h daily during simple upright activities.

Weighted designs. This orthosis consists of a non-elastic rucksack or backpack with 0.2 to 1 kg weights positioned at a specific distance from the scapula's inferior angle and adjacent to defined vertebrae. The position, number of weights and wearing time varied across different studies. The PTS orthosis is used in patients with osteoporosis, kyphosis, scoliosis, etc.[47] Some studies reported the effects of WKO orthosis on back extensor muscle strength in osteoporotic patients with 4 h of daily use,[24] while others reported the impact of PTS on hyperkyphosis with 1-h daily use combined with an exercise program during activity.[67] 11 studies utilized a weighted orthosis, with two not meeting the inclusion criteria.[44,46]

Movement restrictor designs. Five types of rigid spinal designs body jacket (full body orthosis made from two pieces of plaster or thermoplastic or sometimes made from one-piece lighter thermoplastics with an anterior opening design that covers Thoracolumbosacral region and shoulders), rigid TLSO (anterior opening thermoplastic and cover the Thoracolumbosacral regions but not shoulders), Taylor (steel rods shaped base on body size, covered with soft materials and restrict flexion, extension and lateral bending of the trunk), three-point pressure orthoses (steel bars making force on the sternum, pubis and back to restrict flexion and extension and some amounts of lateral bending of trunk mostly named Jewett or CASH or C35 orthosis), rigid TLO (light anterior opening thermoplastic and cover the Thoracolumbar regions), were commonly used in patients with vertebral fractures[86] and were used in some studies for osteoporotic vertebral fracture patients too.

Soft designs. These types are made from polychloroprene fabric or elastic or non-elastic fabrics and may include some plastic bars used for orthosis shaping. Some restrictions are due to increased abdominal pressure and the length of shoulder straps. The coverage of soft orthoses commonly is a thoracolumbar or lumbar region. Some designs have shoulder straps covering the thoracic region. Some designs may include different parts like air chambers of Osteomed. Commonly wore full-time.

Discussion summary

Only four high-quality studies are not enough to compare orthotic interventions with other treatments. In some studies, it is impossible to distinguish the effect of orthosis from other conservative treatments. Comorbidities are an important aspect of any research. The included studies reported comorbidities as a baseline distribution to show normality or excluded participants with comorbidities via inclusion criteria. It's not possible to evaluate the effect of comorbidities on the result of intervention. We suggest that future studies consider common comorbidities such as diabetes, osteopenia, and progressive degenerative joint diseases in different groups.

The high-quality studies in the acute phase of vertebral fractures had single-level fracture inclusion criteria, which limited our results to single-level vertebral fractures. After the acute phase and 6 months post-fracture, back extensor muscle strength and the kyphosis angle improve in individuals with over 60 degrees of hyperkyphosis and less than five-point pain with a semi-rigid brace. The kyphosis angle and back muscle strength can improve in osteoporotic patients who do not have vertebral fractures or are not in the acute phase of fractures with weighted or semi-rigid orthosis.

The orthosis effect on dynamic balance is well defined, but static balance can be evaluated with variables representing the balance situation. The number of studies assessing walking parameters is insufficient for discussion. Any type of orthosis has a prescription and manner of use that should be considered for utilization.

Limitations and future directions

In this study, we aimed to investigate the true effect of spinal orthotic interventions in osteoporotic patients. However, due to low methodological quality or lack of reported data, our meta-analysis is based on less than 10 articles, which limits the strength of our conclusions. We found that only one of three studies in the acute phase of osteoporotic vertebral fractures (OVFs) had a control group, and one of them was a multicenter study. Other studies in this group used orthosis combined with other treatments, making it difficult to isolate the effect of the orthotic intervention. We

recommend that future studies use better methods, including control groups with no treatment or separable groups with enough reporting of results. Additionally, we encourage future studies to report correlations between before and after intervention data, as these correlations are critical for evaluating the effectiveness of interventions and allow for comparisons with studies that have no control group.

Conclusion

This systematic review and meta-analysis propose that using soft or rigid orthoses solely has no beneficial effect on interventions in the acute phase of OVFs compared with no orthoses in one-level fractures. Besides, using semi-rigid or weighted orthoses in osteoporotic or hyperkyphotic older adults with or without OVFs significantly affects thoracic kyphosis angle, back muscle strength, and balance improvements.

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