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Effect of Brace to Osteoporotic Vertebral Fracture: A Meta-Analysis

Yuan Zhe Jin[1] and Jae Hyup Lee[1,2]

[1]Department of Orthopedic Surgery, College of Medicine, Seoul National University, Seoul, Korea; [2]Department of Orthopedic Surgery, SMG-SNU Boramae Medical Center, Seoul, Korea

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Address for Correspondence:
Jae Hyup Lee, MD
Department of Orthopedic Surgery, Seoul National University College of Medicine, Seoul Metropolitan Government Seoul National University Boramae Medical Center, 20 Boramae-ro 5-gil, Dongjak-gu, Seoul 07061, Korea
E-mail: spinelee@snu.ac.kr

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Brace is one of the most commonly used interventions to manage osteoporotic vertebral fracture. However, its authentic effectiveness remains unclear. The aim of this study was to investigate the efficacy of brace in patients with osteoporotic vertebral fractures. We conducted a literature review and meta-analysis following the guideline and handbook of the Cochrane collaboration. Ten published articles were included in this study and data from 4 randomized controlled trials were analyzed. Low quality evidence proved using Spinomed brace could bring large and significant beneficial effect to patients with subacute osteoporotic vertebral fractures. Very low quality evidence proved no significant difference between Spinomed orthosis, rigid brace and soft brace when they were used in patients with acute fractures. Therefore, it might be applicable to recommend middle term use of Spinomed orthosis to patients with subacute fracture. In addition, this study emphasized the need for high quality randomized controlled trials.

Keywords: Spine; Osteoporosis; Fracture; Brace; Meta-Analysis

INTRODUCTION

Osteoporotic vertebral fracture (OVF) is one of the most severe osteoporotic fractures, which causes severe pain, disability, dyspnea, deformity and raises the risk of subsequent fracture and death (1,2). Among the conservative treatments to OVF, multifarious orthoses are used and expected to immobilize the fracture site, diminish pain and improve quality of life. However, their authentic effectiveness to patients with OVF remains unclear (1). Several trials investigated the efficacy of orthoses, but quality of them varied a lot and their outcome parameters were not standardized. Conclusions from previously published systematic reviews had limited generalizability, due to their indirectness in participants or limited number of included studies (3,4). Additionally, strength of recommending orthoses to patients with OVF remained inconclusive in reviews or guidelines (5,6).

In order to explore the efficacy of orthoses, we conducted this study through a systematic literature search and meta-analysis. We focused on patients with osteoporotic vertebral fracture and analyzed the outcomes of pain, kyphosis angle and quality of life. Furthermore, we discussed the reasons why some orthoses were effective and some were not.

MATERIALS AND METHODS

Data source and searching strategy

We searched electronic databases, including Medline, EMBASE, Central Register of Controlled Trials (CENTRAL) and Web of science, from May, 2015 and updated weekly until March, 2016. A search strategy included keywords of "clinical trial", "osteoporotic fracture", "spine", "orthosis", and "brace" was used. Details of the search strategy were presented in Supplementary 1. Reference lists of other reviews were also checked for relevant articles.

Study selection

Initially, one author identified the potentially relevant articles by screening titles and abstracts, and then two authors evaluated their eligibility for being included in this study through full text assessment. The evaluation mainly focused on characteristics of the studies. English published articles that recruited participants who had at least one diagnosed OVF and implemented orthoses as interventions were included. Trials were excluded if they recruited subjects with traumatic vertebral fractures or pooled participants with and without fracture together but did not separately report their outcomes. Disagreements were solved by discussion between two authors.

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Data extraction

We extracted information with standardized tables which described characteristics of participants, interventions and outcomes. Unclear information and data in studies was clarified by contacting their authors through e-mails. Outcomes of pain, kyphosis angle and quality of life (Oswestry disability index, Well-being and Functional independence measure-motor score) were statistically analyzed.

Methods used for extracting and handling data were slightly different according to studies. In studies reported outcomes at multiple time points, data from the last visit was extracted; in cross-over designed trials, data before the cross-over procedure was extracted. When synthesized the data from studies with 3 arms, the number of participants in control group was separated evenly, and each compared with one intervention group, with the value of mean and standard deviation (SD) unchanged.

Measurement of risk of bias

We assessed the quality of included randomized controlled trials (RCTs) with a method recommended by Cochrane back and neck group (CBN) (7). The method measured the risk of bias in 6 domains: selection, performance, detection, attribution, reporting and others.

Data synthesis and analysis

We pooled data using the Review Manager (Revman 5.3) and implemented the meta-analysis with the random effect model. Change value from baseline was used because most trials reported outcomes in that data type. If value of SD was not reported and needed to be estimated, the formula presented as follows was used,

$$\text{SDchange} = \sqrt{(SDbaseline^2 + SDfinal^2 - (2 \times Corr \times SD\text{baseline} \times \text{SDfinal})}$$

with an assignment of 0.5 as correlation value. The standardized mean difference (SMD) was used to synthesize the outcomes because the measuring scales were different between studies. Some mean values were multiplied by -1 to ensure results from different scales could point in the same direction. Expression of the magnitude of the results followed the rules of thumb (< 0.2, small effect; 0.2 to 0.8, moderate effect; > 0.8, large effect) (8). Statistical heterogeneity between studies was measured with the chi-squared test. The heterogeneity was considered as significant when P value was not bigger than 0.10 and was recognized as considerable when I^2 value was bigger than 75% (7). To explore the heterogeneity, subgroup analysis was conducted. To prove our results were not depended on arbitrary decisions on including studies or assigning values, we conducted several sensitivity analyses. The analyses included estimating SD with the different correlation value (0.4), excluding some "dubious" articles and estimating results with the fixed effect model.

Measurement of quality of evidence

To reflect our confidence in truthfulness of the results, we measured quality of evidence with the GRADE approach. The approach measures the limitations of results in 5 domains: study limitation (risk of bias), inconsistency, indirectness, imprecision and publication bias. Each item was downgraded 1 or 2 points if the result failed to meet the criteria (9). "Study limitation" was downgraded 1 point if 1 to 3 categories of risk of bias were rated as high or unclear. "Inconsistency" was downgraded 1 point if large statistical heterogeneity ($P \leq 0.10$, $I^2 > 80\%$) existed, downgraded 2 points if both large statistical heterogeneity and obvious clinical heterogeneity existed. "Indirectness" was downgraded 1 to 2 points if we detected indirectness in domains of population, intervention, comparator, comparison and outcome. "Imprecision" was downgraded 1 point if the total sample size was smaller than 400 and was downgraded 2 points if there were few events and wide confidence intervals (CIs). "Publication bias" was downgraded by 1 point only when we strongly suspected the existence of publication bias.

RESULTS

Initially we identified 649 relevant citations and then remained 28 articles for full-text assessment. Eventually, 10 articles were included in this study (10-19) and 4 RCTs, with 281 participants, were included in meta-analysis (10-12,14) (Fig. 1).

Description of included studies

As summarized in Table 1 and 2, 6 RCTs (10-15), 1 non-randomized controlled trial (19) and 3 observational studies (16-18)

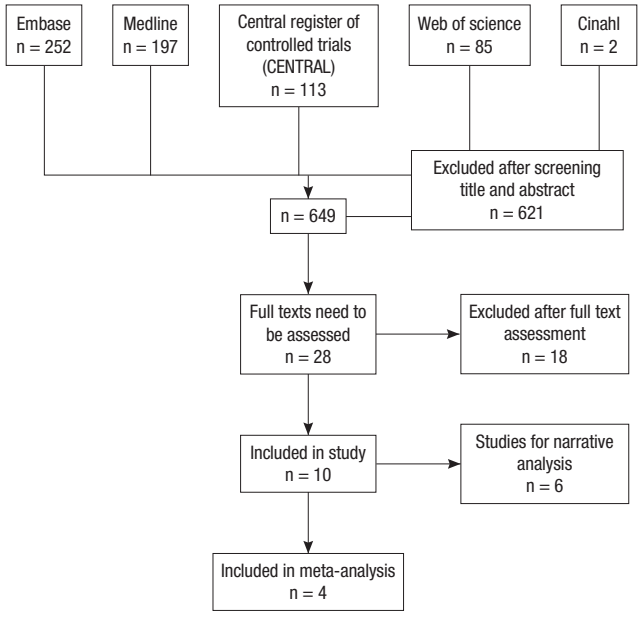

Fig. 1. Flow diagram of selection process.

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Table 1. Characteristics of studies included in MA

Study ID	Study design	Participants number	Phase of fracture	Participants source	Intervention	Follow up duration
Kim et al. (14), 2014	RCT	60	Acute	Hospital	Soft brace: 8 wk Rigid brace: 8 wk Control group: no brace	12 wk
Li et al. (10), 2014	RCT	51	Acute	Hospital	Group 1: TLSO, the1st week; SpinoMed, the 2nd and the 3rd week Group 2: TLSO, the 1st week; Soft brace, the 2nd and the 3rd week	3 wk
Pfeifer et al. (12), 2011*	RCT	108	Subacute	Community	Group 1: Spinomed orthosis, 12 mon Group 2: Spinomed active orthosis, 12 mon Group 3: no brace	12 mon
Pfeifer et al. (11), 2004*	RCT	62	Subacute	Community	Group 1: Spinomed, 12 mon Group 2: no brace	12 mon

MA, meta-analysis; RCT, randomized controlled trial; TLSO, thoracolumbar sacral orthosis.
*This trial was designed as a cross-over study. We extracted the data before cross-over procedure, on the 6th month.

Table 2. Characteristics of studies included in study but excluded from MA

Study ID	Study type	Participants number	Phase of fracture	Participants source	Interventions	Follow up duration	Conclusion
Dionyssiots et al. (13), 2015*	RCT	50	Subacute	Hospital	Group 1: Semi-rigid orthosis Group 2: Elastic orthosis Group 3: Control group	6 mon	Wearing Spinomed orthosis decreased back pain significantly and increased trunk muscle strength significantly.
Sinaki and Lynn (15), 2002	Pilot RCT	7	NA	Hospital	Group 1: PTS + Exercise Group 2: Exercise	1 mon	Subjects who had abnormal balance had the most significant improvement in balance.
Valentin et al. (16), 2014	Case series study	13	NA	NA	Spinomed III	3 mon	The improvement in the back extensor strength was significant; but not in pain or physical function.
Talic et al. (19), 2012	N-RCT	59	NA	Hospital	Group 1: Three-point orthosis Group 2: Plaster corset	1-4 mon	Plaster corset offered stability; but patients with orthoses were more mobile. Duration of immobilization was significantly longer in orthosis group.
Murata et al. (18), 2012	Retrospective study	55	Acute	Hospital	Plastic TLSO orthosis	6 mon	TLSO promoted the healing of OVF. Mean kyphosis angle deteriorated from 11.4° to 17.2°.
Liaw et al. (17), 2009	Case series study	47	NA	Hospital	Knight-Taylor orthosis	Immediately	Knight-Taylor brace improved in static and dynamic motor balance but decreased the directional control.

MA, meta-analysis; RCT, randomized controlled trial; PTS, posture training support; NA, not available; TLSO, thoracolumbar sacral orthosis; N-RCT, non-randomized controlled trial.
*The data reported in this article was insufficient to be included in meta-analysis.

were included. Characteristics of studies varied a lot but all had limited number of participants and only one trial had a sample size merely above 100 (12). Phase of fracture and recruiting sources of participants were different between studies. Participants had acute fractures in 3 trials (10,14,18) while those from another 3 trials had sub-acute fractures (11-13). Most of the studies recruited participants in hospital environment (10,13-15,17-19), while two trials recruited in community environment (11,12).

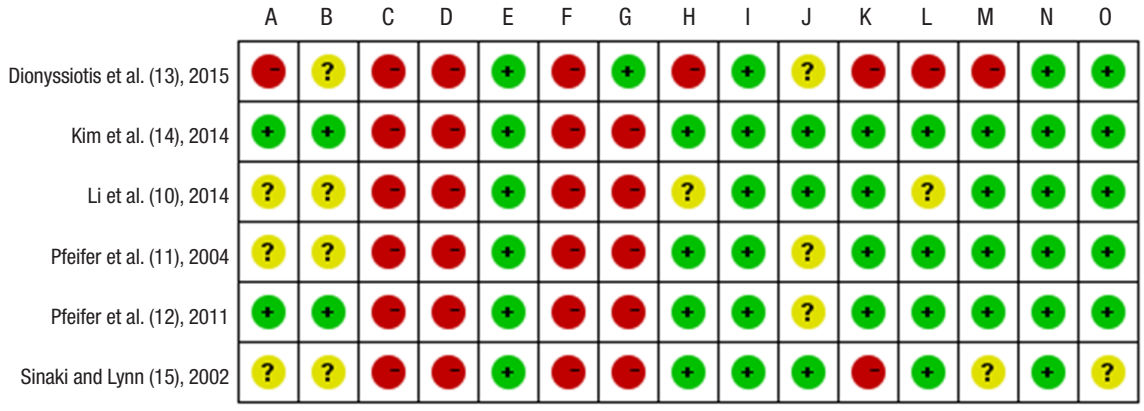
Most of the trials implemented semi-rigid brace (Spinomed orthosis) and rigid brace for middle to long term. Efficacy of the Spinomed orthosis was investigated in 4 RCTs (10-13) and 1 case series study (16). Three of the 4 RCTs were included in the meta-analysis (10-12) (Table 1), while Dionyssiotis et al.'s study (13) was excluded due to their insufficiently reported data. Efficacy of rigid brace was investigated in 2 observational studies (17,18) and 2 controlled trials (14,19), one of which evaluated the efficacy of thoracolumbar sacral orthosis (TLSO) was included in meta-analysis (14) (Table 1). Implementation and follow-up periods ranged from 1 to 6 months in most studies, except one case series study that immediately measured effect of the Knight-Taylor brace after it was implemented (17).

Risk of bias of included RCTs

All trials had high risk of bias in at least 1 category (Fig. 2). Most trials had unclear risk of selection bias, due to their briefly reported procedures of random sequence generation and allocation concealment. All trials had high risk of performance bias because it was relatively difficult to maintain double blind while implemented braces. Risk of detection bias was evaluated separately in different outcomes, and only the measurement of the kyphosis angle was rated as low risk. Risk of attribution bias was rated as low in 4 trials (11,12,14,15). Risk of reporting bias was rated as unclear in half of the trials (11-13). Risk of other bias was evaluated as low in 5 trials that clarified no conflict of interest in conducting and publishing the researches (10-14). We presented the rationales for the judgements of risk of bias in Supplementary 2.

Effects of intervention: results from meta-analysis

Three studies investigated the efficacy of braces by comparing



A. Random sequence generation (selection bias)
B. Allocation concealment (selection bias)
C. Blinding to patients (performance bias)
D. Blinding to care providers (performance bias)
E. Blinding to outcome assessors (detection bias): kyphosis angle
F. Blinding to outcome assessors (detection bias): pain
G. Blinding to outcome assessors (detection bias): quality of life
H. Incomplete outcome data (attribution bias): drop-out
I. Incomplete outcome data (attribution bias): ITT or modified ITT
J. Selective reporting (reporting bias)
K. Group similarity at baseline (selection bias)
L. Influence of co-interventions (performance bias)
M. Compliance with interventions (performance bias)
N. Timing of outcome assessments (detection bias)
O. Other sources of bias

Fig. 2. Risk of bias table of included randomized controlled trials. Green represents "low risk of bias"; yellow, "unclear risk of bias"; red, "high risk of bias".

Table 3. Summary of findings (SOF) table of brace vs. no brace

Outcomes	Anticipated absolute effects (95% CI)	No. of participants (studies)	Overall quality of evidence (GRADE)
Pain reduction-pooled data	SMD 1.1 fewer (1.61 fewer to 0.59 fewer)	212 (3 studies)	⊕⊕◯◯ LOW*,†
Pain reduction-TLSO	SMD 0.57 fewer (1.48 fewer to 0.34 more)	23 (1 study)	⊕◯◯◯ VERY LOW‡,§
Pain reduction-soft brace	SMD 0.37 fewer (1.31 fewer to 0.57 more)	19 (1 study)	⊕◯◯◯ VERY LOW‡,§
Pain reduction-Spinomed group	SMD 1.46 fewer (1.81 fewer to 1.11 fewer)	170 (2 studies)	⊕⊕◯◯ LOW‖,†
Kyphosis angle-pooled data	SMD 0.91 fewer (1.21 fewer to 0.61 fewer)	209 (3 studies)	⊕⊕◯◯ LOW¶,†
Kyphosis angle-TLSO	SMD 0.72 fewer (1.69 fewer to 0.26 more)	21 (1 study)	⊕◯◯◯ VERY LOW**,§
Kyphosis angle-soft brace	SMD 0.38 fewer (1.42 fewer to 0.66 more)	18 (1 study)	⊕◯◯◯ VERY LOW**,§
Kyphosis angle-Spinomed group	SMD 0.99 fewer (1.32 fewer to 0.65 fewer)	170 (2 studies)	⊕⊕◯◯ LOW†,††
Quality of life-pooled data	SMD 1.24 fewer (2.1 fewer to 0.38 fewer)	212 (3 studies)	⊕◯◯◯ VERY LOW*,†,‡‡
Quality of life-TLSO	SMD 0.49 fewer (1.39 fewer to 0.41 more)	23 (1 study)	⊕◯◯◯ VERY LOW‡,§
Quality of life-soft brace	SMD 0.2 fewer (1.13 fewer to 0.07 more)	19 (1 study)	⊕◯◯◯ VERY LOW‡,§
Quality of life-Spinomed brace	SMD 1.96 fewer (2.34 fewer to 1.58 fewer)	170 (2 studies)	⊕⊕◯◯ LOW‖,†

CIs, confidence intervals; SMD, standardized mean difference; RCT, randomized controlled trial; TLSO, thoracolumbar sacral orthosis.
*Serious study limitation: three trials were included, with high risk of performance bias and detection bias; †Serious imprecision: sample size was smaller than 400; ‡Serious study limitation: one trial was included, with high risk of detection bias and performance bias; §Very serious imprecision: sample size was too small and CIs was wide; ‖Serious study limitation: two trials were included, with high risk of performance bias and detection bias; ¶Serious study limitation: three trials were included, with high risk of performance bias; **Serious study limitation: one trial was included, with high risk of performance bias; ††Serious study limitation: two trials were included, with high risk of performance bias; ‡‡Very serious inconsistency: the statistical heterogeneity was large (I^2 > 80%) and the clinical heterogeneity existed.

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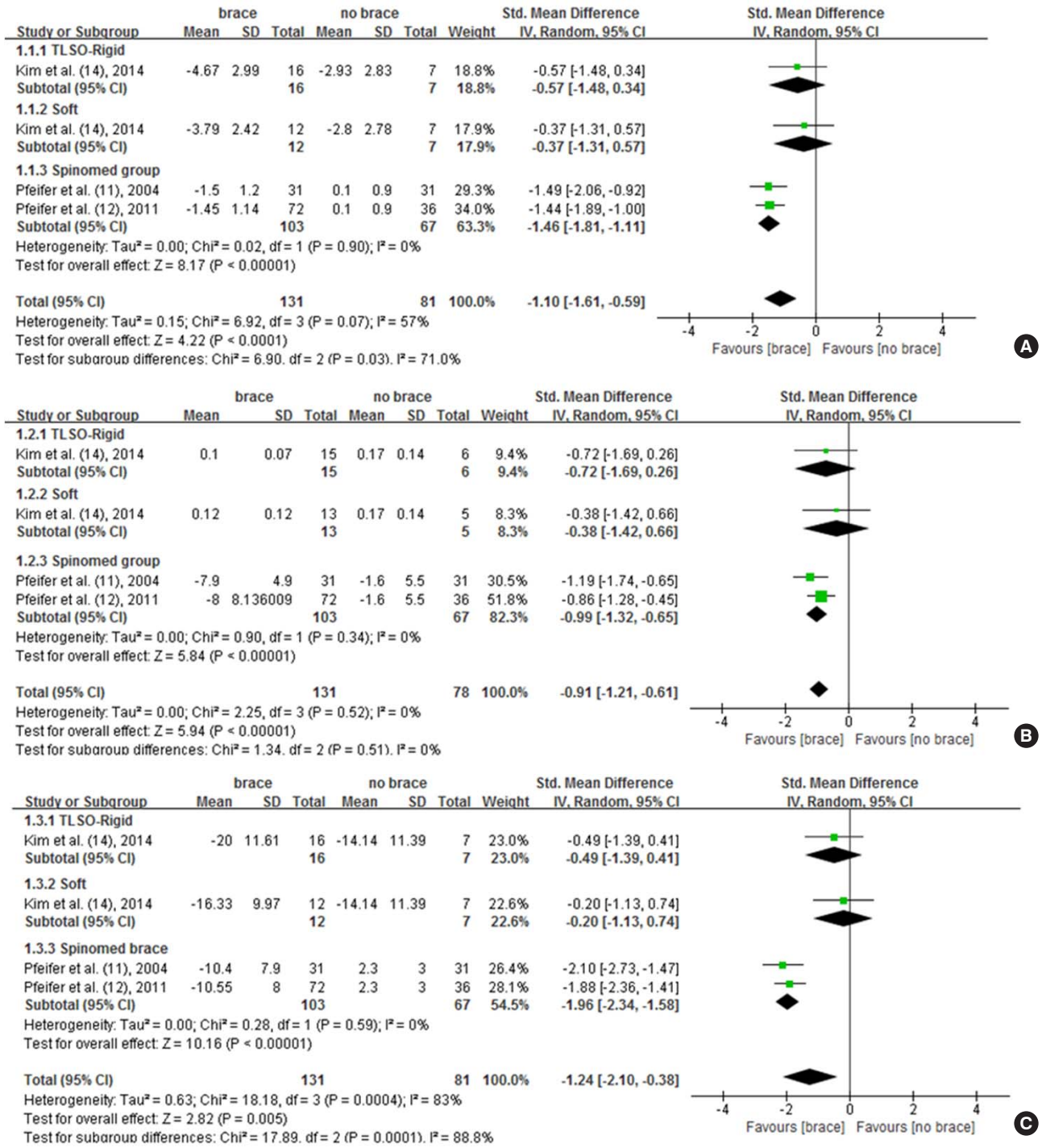

Fig. 3. Forest plot. Comparison between brace group and no brace group. Use of brace showed significant efficacy on pain (**A**), kyphosis angle correction (**B**), and quality of life (**C**).

to no brace groups, including 230 participants (11,12,14). We analyzed the outcomes of pain, kyphosis angle and quality of life with subgroup analysis.

In the outcome of pain, the pooled data showed large and significant beneficial effect brought by using brace (SMD, -1.10; 95% CIs, -1.61 to -0.59; $P < 0.001$, Fig. 3A). The heterogeneity was significant but its magnitude was acceptable ($P = 0.070$, $I^2 = 57\%$, Fig. 3A). However, the overall quality of the result was rated as low, due to the serious study limitation and serious imprecision (Table 3). From the subgroup analysis, we noticed only the efficacy of Spinomed was significant ($P < 0.001$, Fig. 3A); and so was the difference between subgroups ($P = 0.030$, Fig. 3A).

In the outcome of kyphosis angle, pooled data was similar to that of pain: the efficacy brought by brace was large and signifi-

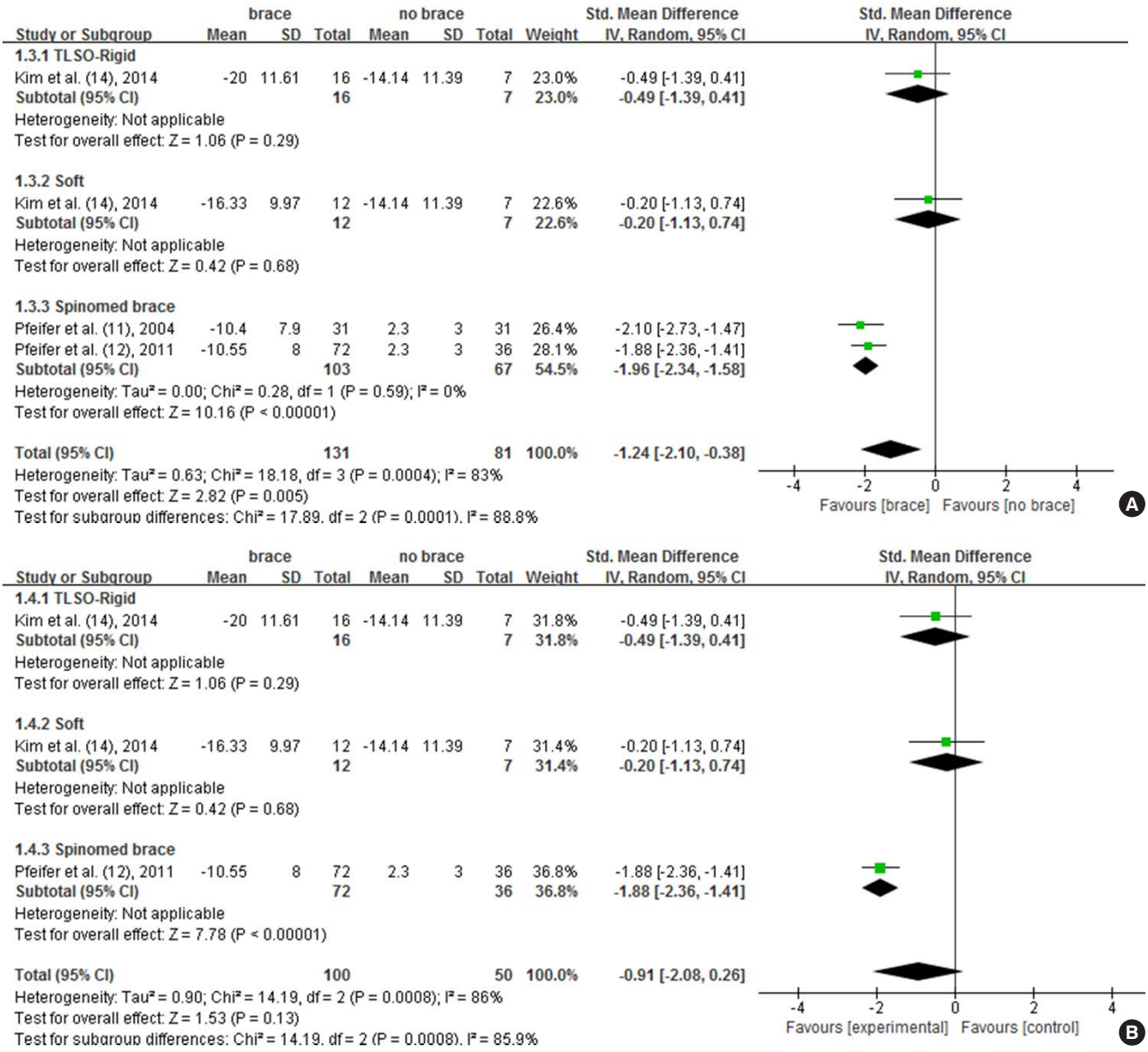

Fig. 4. Result of the sensitivity analysis of excluding one of the two trials with unclear risk of reporting bias. The outcome of quality of life became insignificant after excluding data of Pfeifer et al., 2004 (**A** → **B**).

cant (SMD, -0.91; 95% CIs, -1.21 to -0.61; $P < 0.001$, Fig. 3B). Still, the overall quality of this evidence was rated as low for the serious study limitation and serious imprecision (Table 3). The difference between subgroups was insignificant ($P = 0.510$, Fig. 3B), though only the Spinomed orthosis showed significant efficacy (Fig. 3B). The consistency between subgroups might be a result of the similarity in their effect sizes and the relatively well overlapped CIs (Fig. 3B).

Very low quality evidence indicated large and significant beneficial effect on quality of life brought by bracing (SMD, -1.24; 95% CIs, -2.10 to -0.38; $P = 0.005$, Fig. 3C). The heterogeneity and the difference between subgroups were significant ($P <$ 0.001, Fig. 3C). The large magnitude of I2 and the existence of clinical heterogeneity suggested downgrading 2 scores for the inconsistency (Fig. 3). Thus, quality of this evidence was rated as very low, due to the serious study limitation, serious imprecision and the very serious inconsistency (Table 3). The untrustworthy of this outcome was also reflected by the result of sensitivity analysis, in which the pooled outcome changed to insignificant after excluding one of the two trials that had unclear risk of reporting bias (11) (Fig. 4).

Analysis that compared soft brace with un-soft brace included two RCTs whose participants had acute vertebral fractures (10,14). The pooled data showed un-soft brace had no signifi-

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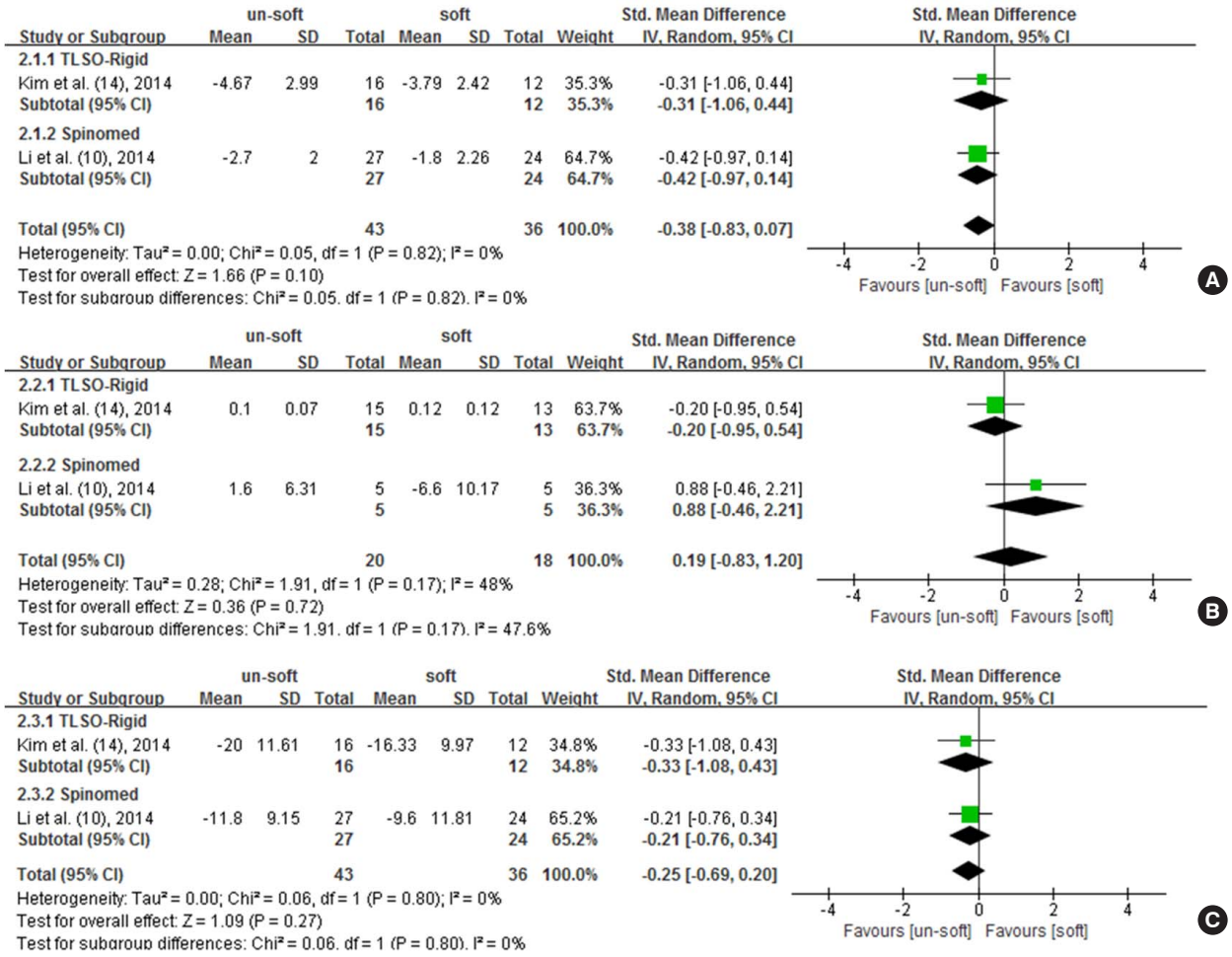

Fig. 5. Forest plot. Comparison between un-soft brace group and soft brace group. The results showed no significant difference between braces in pain (**A**), kyphosis angle (**B**) and quality of life (**C**).

cant difference compared with soft brace (Fig. 5). The result was different from the one previously observed, in which Spinomed brace showed significantly better efficacy compared to soft brace (Fig. 3). The quality of evidence of pooled data was rated as very low in all outcomes, due to the serious study limitation and very serious imprecision (Table 4).

Results from narrative analysis

The narrative results were summarized in Table 2. Though most of the results showed benefits from using brace, the strength of them was relatively weak. Two RCTs had limitations in their methodologies: one had high risk of bias (13) and the other one had a small sample size (15). Also, we had limited confidence in conclusions of observational studies, because they might lack the power of proving causal relationship between the utilization of orthoses and the benefit.

Publication bias

The publication bias cannot be detected through the funnel plot because the number of trials included in our meta-analysis was less than 10.

DISCUSSION

We included 10 trials in this study and 4 RCTs in meta-analysis. All trials had high risk of performance bias and most of them had unclear risk of selection bias. Low to very low quality evidence proved that using brace was effective in reducing pain, preventing kyphosis angle deterioration and improving quality of life. However, as observed in the subgroup analyses, only middle term use of Spinomed orthosis could bring significant improvement to the patients who had subacute fractures. Very low quality evidence indicated there was no significant difference between the efficacy of TLSO, Spinomed and soft brace, when they were implemented to the patients with acute fractures.

The pooled results were difficult to interpret and were relatively unreliable due to the limited information. Therefore, rather than solving the prescribe questions, current evidence might

Table 4. Summary of findings (SOF) table of un-soft brace vs. soft brace

Outcomes	Anticipated absolute effects (95% CIs)	No. of participants (studies)	Overall quality of evidence (GRADE)
Pain reduction-pooled data	SMD 0.38 fewer (0.83 fewer to 0.07 more)	79 (2 studies)	⊕◯◯◯ VERY LOW*,†,‡
Pain reduction-TLSO	SMD 0.31 fewer (1.06 fewer to 0.44 more)	28 (1 study)	⊕◯◯◯ VERY LOW§,‖
Pain reduction-Spinomed orthosis	SMD 0.42 fewer (0.97 fewer to 0.14 more)	51 (1 study)	⊕⊕◯◯ LOW¶,‡
Kyphosis angle-pooled data	SMD 0.19 fewer (0.83 fewer to 1.2 more)	38 (2 studies)	⊕◯◯◯ VERY LOW**,†,‖
Kyphosis angle-TLSO	SMD 0.2 fewer (0.95 fewer to 0.54 more)	28 (1 study)	⊕◯◯◯ VERY LOW††,‖
Kyphosis angle-Spinomed orthosis	SMD 0.88 more (0.46 fewer to 2.21 more)	10 (1 study)	⊕◯◯◯ VERY LOW‡‡,‖
Quality of life-pooled data	SMD 0.25 fewer (0.69 fewer to 0.02 more)	79 (2 studies)	⊕◯◯◯ VERY LOW*,†,‡
Quality of life-TLSO	SMD 0.33 fewer (1.08 fewer to 0.43 more)	28 (1 study)	⊕◯◯◯ VERY LOW§,‖
Quality of life-Spinomed brace	SMD 0.21 fewer (0.76 fewer to 0.34 more)	51 (1 study)	⊕⊕◯◯ LOW¶,‡

CIs, confidence intervals; SMD, standardized mean difference; RCT, randomized controlled trial; TLSO, thoracolumbar sacral orthosis.
*Serious study limitation: two trials were included, with high risk of performance bias and detection bias; †Serious inconsistency: measurement time was different between studies; ‡Serious imprecision: sample size was smaller than 400; §Serious study limitation: one study was included, with high risk of performance bias and detection bias; ‖Very serious imprecision: sample size was too small and CIs was wide; ¶Serious study limitation: one study was included, with high risk of performance and detection bias; **Serious study limitation: two trials were included, with high risk of performing bias; ††Serious study limitation: one study was included, with high risk of performance bias; ‡‡Serious study limitation: one study was included, with high risk of performance and unclear risk of selection bias.

be more proper to find possible explanations or patterns of the efficacy. The result showed Spinomed orthosis could bring large and significant beneficial effects to patients with sub-acute fracture, but it was relatively unreliable because of the interference from chance and the limited detective ability in our study. Nevertheless, it also might be a result of the special mechanism of this brace. Unlike most of the braces that offer immobilization to the fracture site, the Spinomed orthosis worked with a concept of improving the strength of users' trunk muscle. The stronger muscle of the users might subsequently reduce their pain and kyphosis angle deterioration, and improve their quality of life (12).

TLSO is one of the most widely used braces and should have shown beneficial effects in trials, but there was little evidence proving it in our study. The main reason for this contradiction should be the limited detective ability of our study. Other reasons might include the inadequate immobilization and the poor compliance of the brace (13,18). The inadequate immobilization might cause by the skin and soft tissues lie between orthosis and skeletal (6); while the poor compliance might cause by inappropriate implementation of the brace or complications like skin ulceration (6).

We noticed improvement in a single outcome cannot guarantee the improvements in others. Some equipment could reduce the kyphosis angle by exerting backward force to shoulders and forward force in thoracic region. But their efficacy in deformity was not always associated with improvement in mobility or quality of life (16,20). Also, the significant improvement in back muscle strength does not always accompany with relief of pain or improvement in physical function (16).

Two reviews investigated the subject recently, which had minor differences with ours. Newman et al. included osteoporosis and osteopenia participants and stated a descriptive review (3). Compared with theirs, our study focused on patients with OVF and conducted statistical analysis, which should bring more direct conclusions. Rzewuska et al. (4) investigated the efficacy of conservative treatments to OVF patients and included 3 RCTs about orthoses. Compared with them, we included 1 more trial that investigated the efficacy of rigid and soft braces. Also, we had different conclusions in the outcome of functional independence, while ours was more consistent with that of original article (10). Additionally, we analyzed the outcome of kyphosis angle, which was another critical parameter related to OVF patients. Excluding those differences, our results all revealed the need for high quality clinical trials.

There are several limitations in this study. The existence of publication bias might be covered by the absence of ongoing studies, grey literatures and trials from regional databases. The estimation of the treatment efficacy might be influenced by the language restriction in our inclusion criteria. The generalizability of results might be diminished by our relatively stringent criteria for evaluating the quality of evidence. Besides them, the biggest limitations were the limited number of included trials and the inconsistency between studies. All the limitations raised the difficulty in interpreting the results to some extent and fairly lowered the quality of evidence.

To obtain more dependable evidence, more RCTs with low risk of bias and big sample size are needed. Authors could low-

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er the risk of selection bias through adequate description of the random sequence generation and allocation concealment. A cross-over study might be a proper design to minimize the risk of performance bias, since it might be inevitable for a trial about orthoses (12).

In conclusion, it might be appropriate to recommend middle term use of Spinomed orthoses to patients with subacute fractures. The evidence that could prove the efficacy of other brace was insufficient.

DISCLOSURE

The authors have no potential conflicts of interest to disclose.

AUTHOR CONTRIBUTION

Study conception and design: Lee JH. Data acquisition: Jin YZ. Data analysis, interpretation: Jin YZ, Lee JH. Writing manuscript: Jin YZ, Lee JH. Revision: all authors. Approval of final manuscript: all authors.

ORCID

Yuan Zhe Jin http://orcid.org/0000-0001-9068-2778
Jae Hyup Lee http://orcid.org/0000-0002-2141-0266

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Supplementary 1. Search strategy for MEDLINE (via PubMed)

Randomized controlled trial[pt]
Controlled clinical trial[pt]
Randomized controlled trials[mh]
Random allocation[mh]
Double-blind method[mh]
Single blind method[mh]
Clinical trial[pt]
Clinical trials[mh])
Clinical trial"[tw]
Latin square[tw])
Placebos[mh]
Placebo*[tw]
Random*[tw]
Research design[mh:noexp]
Placebos[mh]
Evaluation studies[mh]
Follow-up studies[mh]
Prospective studies[mh]
Cross-over studies[mh]
Control*[tw]
Prospective*[tw]
Volunteer*[tw]) not ((animal[mh] not human[mh])
#1 Or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22
Osteoporosis compression fracture
Osteoporotic fracture
#24 Or #25
Spine
Spinal
Vertebral
Vertebrae
#27 Or #28 or #29 or #30
Brace
Protective gear
Protection
Orthosis
Orthoses
Taping
32 OR #33 OR #34 OR #35 OR #36 OR #37
#23 AND #26 AND #31 AND #38

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Supplementary 2. Rationales for the judgement of the risk of bias

Study ID: Kim, 2014	Level	Quote
Random sequence generation (Selection bias)	Low risk of bias	"This randomization was performed using a computer-generated randomization list, which was concealed from the first author (H.-J.K.) before the randomized allocation." Criteria quote: A random (unpredictable) assignment sequence. Examples of adequate methods are coin toss (for studies with 2 groups), rolling a dice (for studies with 2 or more groups), drawing of balls of different colors, drawing of ballots with the study group labels from a dark bag, computer-generated random sequence, preordered sealed envelopes, sequentially-ordered vials, telephone call to a central office, and preordered list of treatment assignments.
Allocation concealment (Selection bias)	Low risk of bias	"This randomization was performed using a computer-generated randomization list, which was concealed from the first author (H.-J.K.) before the randomized allocation." Criteria quote: Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient.
Blinding to patients (Performance bias)	High risk of bias	The character of intervention. Criteria quote: Index and control groups are indistinguishable for the patients or if the success of blinding was tested among the patients and it was successful.
Blinding to care provider (Performance bias)	High risk of bias	The character of intervention. Criteria quote: Index and control groups are indistinguishable for the care providers or if the success of blinding was tested among the care providers and it was successful.
Blinding to outcome assessors (Detection bias) - kyphosis angle	Low risk of bias	The outcome measurement was objective, which means it was less likely to be influenced by the failure of blinding. Criteria quote: for outcome criteria that do not suppose a contact with participants (e.g., radiography, magnetic resonance imaging): the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed when assessing the main outcome.
Blinding to outcome assessors (Detection bias) - pain	High risk of bias	The outcome measurement was subjective and was easily influenced by the failure of blinding. Criteria quote: for patient-reported outcomes in which the patient is the outcome assessor (e.g., pain, disability): the blinding procedure is adequate for outcome assessors if participant blinding is scored "yes".
Blinding to outcome assessors (Detection bias) - quality of life	High risk of bias	The outcome measurement was subjective and was easily influenced by the failure of blinding. Criteria quote: for patient-reported outcomes in which the patient is the outcome assessor (e.g., pain, disability): the blinding procedure is adequate for outcome assessors if participant blinding is scored "yes".
Incomplete outcome data (Attribution bias): drop-out	Low risk of bias	The lost ratio is 13.3%. Criteria quote: The number of participants who were included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and drop-outs does not exceed 20% for short-term follow-up and 30% for long-term follow-up and does not lead to substantial bias a "yes" is scored.
Incomplete outcome data (Attribution bias) - ITT* or modified ITT	Low risk of bias	"All data were evaluated with use of intention-to treat analysis." Criteria quote: All randomized patients are reported/analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values) irrespective of noncompliance and co-interventions.
Selective reporting (Reporting bias)†	Low risk of bias	Undetected. Criteria quote: The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Group similarity at baseline (Selection bias)	Low risk of bias	"The baseline characteristics of the participants were similar among the three groups." Criteria quote: Groups have to be similar at baseline regarding demographic factors, duration and severity of complaints, percentage of patients with neurological symptoms, and value of main outcome measure(s).
Influence of co-interventions (Performance bias)	Low risk of bias	"There was no significant difference in opioids use among the three groups at twelve weeks." Criteria quote: If there were no co interventions or they were similar between the index and control groups.
Compliance with interventions (Performance bias)	Low risk of bias	"On the basis of self-reported compliance, one patient in the soft-brace group and one patient in the rigid-brace group admitted to not wearing the brace in the sitting position during the twelve-week follow-up period; however, these patients wore the rigid or soft brace in the standing or walking positions." Criteria quote: The reviewer determines if the compliance with the interventions is acceptable, based on the reported intensity, duration, number and frequency of sessions for both the index intervention and control intervention(s). For example, physiotherapy treatment is usually administered for several sessions; therefore it is necessary to assess how many sessions each patient attended. For single-session interventions (e.g., surgery), this item is irrelevant.
Timing of outcome assessments (Detection bias)	Low risk of bias	"At the twelve-week assessment, complete data were available for forty-nine (81.7%) of the sixty participants." Criteria quote: Timing of outcome assessment should be identical for all intervention groups and for all primary outcome measures.
Other sources of bias	Low risk of bias	"The funds were used to pay for salaries and conference expenses. The funder had no role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript." Criteria quote: 1. When the outcome measures were not valid. There should be evidence from a previous or present scientific study that the primary outcome can be considered valid in the context of the present. 2. Industry-sponsored trials. The conflict of interest (COI) statement should explicitly state that the researchers have had full possession of the trial process from planning to report without funders with potential COI having any possibility to interfere in the process. If, for example, the statistical analyses have been done by a funder with a potential COI, usually "unsure" is scored.

ITT, intention to treat.
*Three principles of "intention to treat": 1. Keep participants in the intervention groups to which they were randomized, regardless of the intervention they actually received, 2. Measure outcome data on all participants, 3. Include all randomized participants in the analysis. The first one is widely acceptable, the second one is impossible, the third one is contentious. — in our review our criteria for ITT is the trial which fulfill the first principle, which means no matter with or without missing data; †Reporting bias should be examined by comparison between protocol and published article but no protocol was found, so we compared the outcomes in method section with those whose results were reported.

Study ID: Li, 2014	Risk of bias	Quote
Random sequence generation (Selection bias)	Unclear risk of bias	Not mentioned.
Allocation concealment (Selection bias)	Unclear risk of bias	Not mentioned.
Blinding to patients (Performance bias)	High risk of bias	The character of intervention.
Blinding to care providers (Performance bias)	High risk of bias	The character of intervention.
Blinding to outcome assessors (Detection bias) - kyphosis angle	Low risk of bias	The outcome measurement was objective, which means it was less likely to be influenced by the failure of blinding.
Blinding to outcome assessors (Detection bias) - pain	High risk of bias	The outcome measurement was subjective and easily influenced by the failure of blinding.
Blinding to outcome assessors (Detection bias) - quality of life	High risk of bias	The outcome measurement was subjective and easily influenced by the failure of blinding.
Incomplete outcome data (Attribution bias): drop-out	Unclear risk of bias	Kyphosis outcome only reported in 10 subjects.
Incomplete outcome data (Attribution bias) - ITT* or modified ITT	Low risk of bias	Outcomes of participants were reported as their allocation.
Selective reporting (Reporting bias)	Low risk of bias	Undetected.
Group similarity at baseline (Selection bias)	Low risk of bias	"The levels of vertebral fracture were different among patients." But the difference was deemed tolerable by reviewer.
Influence of co-interventions (Performance bias)	Unclear risk of bias	Participants were worn TLSO for 1st week and wore soft and Spinomed for the 2nd and the 3rd weeks. Did not mention the compliance of interventions.
Compliance with interventions (Performance bias)	Low risk of bias	"This study had evaluated the efficacy of SpinoMed® orthosis by a prospective and randomized control trial, with the subjects' compliance monitored by clinicians in hospital."
Timing of outcome assessments (Detection bias)	Low risk of bias	3 weeks (1 week TLSO, 2 weeks Spinomed orthosis or soft brace).
Other sources of bias	Low risk of bias	"This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors."

ITT, intention to treat; TLSO, thoracolumbar sacral orthosis.

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Study ID: Pfeifer, 2004	Risk of bias	Quote
Random sequence generation (Selection bias)	Unclear risk of bias	Not mentioned.
Allocation concealment (Selection bias)	Unclear risk of bias	Not mentioned.
Blinding to patients (Performance bias)	High risk of bias	The character of intervention.
Blinding to care providers (Performance bias)	High risk of bias	The character of intervention.
Blinding to outcome assessors (Detection bias) - kyphosis angle	Low risk of bias	The outcome measurement was objective, which means it was less likely to be influenced by the failure of blinding.
Blinding to outcome assessors (Detection bias) - pain	High risk of bias	The outcome measurement was subjective and was easily influenced by the failure of blinding.
Blinding to outcome assessors (Detection bias) - quality of life	High risk of bias	The outcome measurement (questionnaire) was subjective and easily influenced by the failure of blinding.
Incomplete outcome data (Attribution bias): drop-out	Low risk of bias	No lost data on the 6th month.
Incomplete outcome data (Attribution bias) - ITT* or modified ITT	Low risk of bias	The baseline data and change value from baseline on the 6th months was reported according to participants' initial allocation.
Selective reporting (Reporting bias)	Unclear risk of bias	Seemed to have identical data with the article published on 2011.
Group similarity at baseline (Selection bias)	Low risk of bias	"Both groups were comparable concerning age, height, weight, number of vertebral fractures, loss of height since the age of 25, number of non-vertebral fractures, and falls within the previous 2 yrs. In addition, concomitant diseases and concomitant medications were distributed similarly. Specifically, the use of analgesics was sporadic in both groups."
Influence of co-interventions (Performance bias)	Low risk of bias	"Specifically, the use of analgesics was sporadic in both groups. Five women in group A took analgesics two or three times a weeks, whereas three women in group B used analgesics two or three times a week."
Compliance with interventions (Performance bias)	Low risk of bias	"The overall compliance of the study participants was excellent: all 62 study subjects completed at least 6 mos of intervention each, and another 28 subjects continued for a 12-mo period."
Timing of outcome assessments (Detection bias)	Low risk of bias	6 months.
Other sources of bias	Low risk of bias	"Medi-Bayreuth had no control over the decision to approve or submit the manuscript for publication."
ITT, intention to treat.		
Study ID: Pfeifer, 2011	Risk of bias	Quote
Random sequence generation (Selection bias)	Low risk of bias	"The randomization of study subjects was performed externally by a statistical consultant bureau."
Allocation concealment (Selection bias)	Low risk of bias	"The randomization of study subjects was performed externally by a statistical consultant bureau."
Blinding to patients (Performance bias)	High risk of bias	The character of intervention.
Blinding to care providers (Performance bias)	High risk of bias	The character of intervention.
Blinding to outcome assessors (Detection bias) - kyphosis angle	Low risk of bias	The outcome measurement was objective, which means it was less likely to be influenced by the failure of blinding.
Blinding to outcome assessors (Detection bias) - pain	High risk of bias	The outcome measurement was subjective and easily influenced by the failure of blinding.
Blinding to outcome assessors (Detection bias) - quality of life	High risk of bias	The outcome measurement (questionnaire) was subjective and easily influenced by the failure of blinding.
Incomplete outcome data (Attribution bias): drop-out	Low risk of bias	Data remains intact.
Incomplete outcome data (Attribution bias) - ITT* or modified ITT	Low risk of bias	"All study subjects, who were initially randomized and received an orthosis, had been included into the analysis (intention-to-treat analysis)."
Selective reporting (Reporting bias)	Unclear risk of bias	Seemed to have identical data with article reported on 2004.
Group similarity at baseline (Selection bias)	Low risk of bias	Concomitant diseases and concomitant medications were distributed similarly.
Influence of co-interventions (Performance bias)	Low risk of bias	"Specifically, the use of analgesics was sporadic in all groups. Only five women in group A (14%) took analgesics on a daily basis, three women in group B (8%) used analgesics, and five (14%) women in group C took medications for pain relief."
Compliance with interventions (Performance bias)	Low risk of bias	"The overall compliance of the study participants was excellent: 105 study subjects completed at least 6 mos of intervention each, and another 100 subjects continued over a 12-mo period."
Timing of outcome assessments (Detection bias)	Low risk of bias	6 months.
Other sources of bias	Low risk of bias	"Financial disclosure statements have been obtained, and no conflicts of interest have been reported by the authors or by any individuals in control of the content of this article."

ITT, intention to treat.

Study ID: Dionyssiotis, 2015	Risk of bias	Quote
Random sequence generation (Selection bias)	High risk of bias	"As controls, women who denied wearing the prescribed orthosis were enrolled."
Allocation concealment (Selection bias)	Unclear risk of bias	Not mentioned.
Blinding to patients (Performance bias)	High risk of bias	The character of intervention.
Blinding to care providers (Performance bias)	High risk of bias	The character of intervention.
Blinding to outcome assessors (Detection bias) - kyphosis angle	Low risk of bias	The outcome measurement was objective, which means it was less likely to be influenced by the failure of blinding.
Blinding to outcome assessors (Detection bias) - pain	High risk of bias	The outcome measurement was subjective and easily influenced by the failure of blinding.
Blinding to outcome assessors (Detection bias) - quality of life	Low risk of bias	The computer measuring system minimized the influence caused by failure of blinding.
Incomplete outcome data (Attribution bias): drop-out	High risk of bias	Only reported part of participants' data.
Incomplete outcome data (Attribution bias) - ITT* or modified ITT	Low risk of bias	Outcomes of participants were reported as their allocation.
Selective reporting (Reporting bias)	Unclear risk of bias	No protocol found but result was significantly insufficiently reported according to their study design. Quote: "Our purpose was to repeat a clinical trial using similar methods but various orthoses in order to determine generalizability."
Group similarity at baseline (Selection bias)	High risk of bias	"Women of group A (Spinomed) were significantly older, and at the beginning of the study, they felt more pain compared with the control group."
Influence of co-interventions (Performance bias)	High risk of bias	"The effect of some drugs on back pain was not analyzed as controls also took drugs."
Compliance with interventions (Performance bias)	High risk of bias	"The compliance was highest for Spinomed (90%) followed by Osteomed and Spinomed active (50%), while Spine-X showed the lowest compliance of 30%."
Timing of outcome assessments (Detection bias)	Low risk of bias	6 months.
Other sources of bias	Low risk of bias	"This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors."

ITT, intention to treat.

Study ID: Sinaki, 2002	Risk of bias	Quote
Random sequence generation (Selection bias)	Unclear risk of bias	Not mentioned.
Allocation concealment (Selection bias)	Unclear risk of bias	Not mentioned.
Blinding to patients (Performance bias)	High risk of bias	The character of intervention.
Blinding to care providers (Performance bias)	High risk of bias	The character of intervention.
Blinding to outcome assessors (Detection bias) - kyphosis angle	Low risk of bias	The outcome measurement was objective, which means it was less likely to be influenced by the failure of blinding.
blinding to outcome assessors (Detection bias) - pain	High risk of bias	The outcome measurement was subjective and easily influenced by the failure of blinding.
Blinding to outcome assessors (Detection bias) - quality of life	Low risk of bias	In this study, the clinician performing CDP was blind to the study group assignment of the subjects.
Incomplete outcome data (Attribution bias): drop-out	Low risk of bias	No lost.
Incomplete outcome data (Attribution bias) - ITT* or modified ITT	Low risk of bias	Outcomes of participants were reported as their allocation.
Selective reporting (Reporting bias)	Low risk of bias	Undetected.
Group similarity at baseline (Selection bias)	High risk of bias	There was significant difference in important parameters between groups at the baseline.
Influence of co-interventions (Performance bias)	Low risk of bias	All participants had the exercise.
Compliance with interventions (Performance bias)	Unclear risk of bias	Not mentioned.
Timing of outcome assessments (Detection bias)	Low risk of bias	4 weeks.
Other sources of bias	Unclear risk of bias	Participation in this study was strictly voluntary, and no remuneration was offered or provided to participants.

ITT, intention to treat; PDP, proprioceptive dynamic posture; CDP, computerized dynamic posturography.

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