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Title	Efficacy, safety and economics of bracing after spine surgery: a systematic review of the literature
Authors	Zhu, Mary P.;Tetreault, Lindsay A.;Sorefan-Mangou, Fatimah;Garwood, Philip;Wilson, Jefferson R.
Publication date	2018-01-17
Original Citation	Zhu, M. P., Tetreault, L. A., Sorefan-Mangou, F., Garwood, P. and Wilson, J. R. (2018) 'Efficacy, safety and economics of bracing after spine surgery: a systematic review of the literature', Spine Journal, 18(9), pp. 1513-1525. doi: 10.1016/j.spinee.2018.01.011.
Type of publication	Article (peer-reviewed)
Link to publisher's version	http://www.thespinejournalonline.com/article/S1529-9430(18)30014-7/abstract - 10.1016/j.spinee.2018.01.011
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Download date	2026-11-06 11:49:09
Item downloaded from	https://hdl.handle.net/10468/5356

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PII: S1529-9430(18)30014-7
DOI: https://doi.org/10.1016/j.spinee.2018.01.011
Reference: SPINEE 57576

To appear in: *The Spine Journal*

Received date: 14-9-2017
Revised date: 28-11-2017
Accepted date: 10-1-2018

Please cite this article as: Mary P. Zhu, Lindsay A. Tetreault, Fatimah Sorefan-Mangou, Philip Garwood, Jefferson R. Wilson, Efficacy, safety and economics of bracing after spine surgery: a systematic review of the literature, *The Spine Journal* (2018), https://doi.org/10.1016/j.spinee.2018.01.011.

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Efficacy, Safety and Economics of Bracing after Spine Surgery: A Systematic Review of the Literature

Mary P. Zhu[1]*, Lindsay A. Tetreault[2,3]*, Fatimah Sorefan-Mangou[3], Philip Garwood[3], Jefferson R. Wilson[1,4]

[1]Division of Neurosurgery, St. Michael's Hospital, Toronto, Canada

[2]Division of Neurosurgery, Toronto Western Hospital, Toronto, Canada

[3]Graduate Entry Medicine, University College Cork, Cork, Ireland

[4]Li Ka Shing Knowledge Institute, St. Michael's Hospital, Toronto, Canada

* Contributed equally to this paper

Corresponding author: Jefferson R. Wilson, jeffersonwilson7@gmail.com, 30 Bond Street, Toronto, Ontario, Canada M5W 1W8

Abstract

Background Context: Bracing is often used after spinal surgery to immobilize the spine, improve fusion, and relieve pain. However, controversy exists regarding the efficacy, necessity and safety of various bracing techniques in the post-surgical setting.

Purpose: In this systematic review, we aimed to compare the effectiveness, safety and cost-effectiveness of postoperative bracing versus no postoperative bracing following spinal surgery in patients with several common operative spinal pathologies.

Study Design/Setting: Systematic Review

Patient Sample: N/A

Outcome Measures: N/A

Methods: A systematic search was conducted of MEDLINE, Embase and the Cochrane Collaboration Library from 1970 to May 2017, supplemented by manual searching of the reference list of relevant studies and previously published reviews. Studies were included if they compared disability, quality of life, functional impairment, radiographic outcomes, cost-effectiveness and/or complications between patients treated with postoperative bracing versus those not receiving any postoperative bracing. Each article was critically appraised independently by 2 reviewers, and the overall body of evidence was rated using guidelines outlined by the Grading of Recommendation Assessment, Development and Evaluation (GRADE) Working Group.

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Results: Of the 858 retrieved citations, 5 studies met inclusion criteria and were included in this review, consisting of 4 randomized controlled trials and 1 prospective cohort study. Low to moderate evidence suggests that there are no significant differences in most measures of disability, pain, quality of life, functional impairment, radiographic outcomes, and safety between groups. Isolated studies reported statistically significant and inconsistent differences between groups with respect to Neck Disability Index at 6 weeks postoperatively and/or Short Form-36 Physical Component Score at 1.5, 3, 6, and 12 months postoperatively.

Conclusions: Based on limited evidence, postoperative bracing does not result in improved outcomes following spinal surgery. Future high quality randomized trials will be required to confirm these findings.

Keywords: outcomes; postoperative bracing; surgery; spinal pathology; complications.

Introduction

Bracing is routinely used after surgery for a number of spinal pathologies, including degenerative disease of the lumbar and cervical spine, thoracolumbar fractures and scoliosis.[1] The intended goal of this practice is to immobilize the spine, relieve pain, improve fusion rates, and remind patients to avoid certain activities that may compromise their recovery.[1, 2] However, a number of important complications can arise from bracing, including dysphagia, nerve palsies, pressure ulcers, and skin rashes.[1] Furthermore, braces can be uncomfortable for some patients as well as costly.[2]

Given the paucity of high-quality comparative studies, it is unclear whether postoperative bracing can effectively limit and restrict spinal movements, reduce rates of pseudoarthrosis and optimize patient recovery. Certain advances in spinal surgery have allowed for rigid internal stabilization of the spine and, arguably, have decreased the requirement for external immobilization. Although these techniques may be sufficient to achieve successful fusion, there may still be a role for postoperative bracing in higher risk patients, including those who smoke, suffer from osteoporosis or require an extensive multilevel surgery.

As a result of the limited body of evidence available, spine surgeons often base their decision to use postoperative bracing on their own clinical experience and training.[1] This finding is supported by a survey that highlighted substantial disagreement among spinal surgeons with respect to the appropriate type, duration and indication for use of postoperative bracing after anterior cervical spine surgery.[3] Given the heterogeneity in management strategies, there is a need to synthesize results from high quality studies and establish recommendations surrounding care following spinal surgery.

This systematic review addresses 4 key questions (KQs). KQ1: What is the efficacy and effectiveness of postoperative bracing compared with no bracing based on disability, pain,

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quality of life and functional outcomes? KQ2: What is the impact of postoperative bracing compared with no bracing on radiographic outcomes? KQ3: What is the safety profile of postoperative bracing compared with no bracing? KQ4: What is the cost-effectiveness of postoperative bracing? **Importantly, this systematic review will assess the overall strength of the evidence using methodology developed by the Grading of Recommendation Assessment, Development and Evaluation (GRADE) working group.**

Methods

Eligibility Criteria

Population

Our review targeted studies including patients undergoing surgery for any spinal pathology, including cervical and lumbar degenerative disease, trauma, oncology and adolescent idiopathic scoliosis. Studies were excluded if patients under study were treated non-operatively (Table 1).

Intervention and Comparison

This review focused on studies that had an intervention group who received postoperative bracing, and a control group who received standard of care and no postoperative bracing (Table 1).

Outcomes

For KQ1, we sought studies that considered the clinical efficacy of postoperative bracing by measuring patient disability, pain, quality of life, and/or functional outcomes. For KQ2, we focused on studies that assessed radiographic outcomes, including fusion rate, sagittal alignment, and range of motion. For KQ3, we sought studies that compared complication rates and adverse events between the intervention and control groups. For KQ4, we focused on studies that examined various measures of cost-effectiveness including incremental cost-effectiveness ratio and cost per unit of outcome (Table 1).

Study Characteristics

For KQ1, 2 and 3, we sought comparative studies (i.e. randomized controlled trials, cohort studies) designed to evaluate differences between a postoperative bracing group and a control group. To be included, studies needed to have at least 10 patients per group. Case reports, nonclinical studies, and animal studies were excluded. For KQ4, we focused on full economic studies. For all KQs, abstracts, editorials, letters, narrative and systematic reviews were excluded. Duplicate publications of the same study that did not report on different outcomes were also excluded.

Information Sources

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A systematic search of MEDLINE, Embase and Cochrane Collaboration Library was conducted to identify relevant studies. Manual searching of the reference lists of included studies and previously published reviews was also conducted to ensure all relevant studies were located.

Search Strategy

The search strategy was first developed in MEDLINE and then appropriately modified for the other databases. We used the following search terms to search all databases: Orthotic Devices AND Spinal Diseases AND Postoperative Complications/Care AND Treatment Outcome or Outcome Assessment. Only studies involving humans, written in English and published in peer-review journals between 1970 and May 2017 were considered for inclusion, with no other limits applied. **A detailed search strategy is provided in the supplemental digital material.**

Study Selection

All abstracts and titles were reviewed and sorted by our predefined inclusion criteria. Studies were classified as relevant, possibly relevant, or irrelevant. Full text investigation of all relevant and possibly relevant studies was done for further clarification.

Data Extraction and Synthesis

The following data were extracted from each included article: study design; patient sample and characteristics, including diagnosis, surgical summary and type of bracing; outcome assessment tools; follow-up schedule; drop-out rate; and results of association, including standard deviation, odds ratio, confidence intervals, and p-values.

Risk of Bias in Individual Studies

The class of evidence for each article was rated (Class I, II, III, IV) independently by 2 reviewers using criteria outlined by the Journal of Bone and Joint Surgery for therapeutic studies and modified to encompass both methodological quality and risk of bias. Randomized controlled trials were rated based on patient allocation, intention to treat analysis, independent or blinded assessment, whether co-interventions were applied equally, rates of follow-up, statistical power, and control for possible confounding. Prospective cohort studies were rated based on independent or blinded assessment, whether co-interventions were applied equally, rates of follow-up, statistical power, and control for possible confounding. Due to the nature of the intervention, studies were rated as having independent or blinded assessment if surgeons were blinded to the randomization group until after surgery, patients were blinded to the randomization group until day of admission of surgery or after surgery, and/or radiologists reviewing radiographs were blinded to the randomization group.

Risk of Bias Across Studies

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The overall body of evidence was assessed using a scoring system developed by the **GRADE** working group with recommendations from the Agency for Healthcare Research and Quality (AHRQ). **This methodology allows for an assessment of the overall strength of the evidence and is particularly valuable for highlighting critical knowledge gaps.**

The initial strength of the overall body of evidence was graded as "high" if half or more of the studies were randomized controlled trials and "low" if the majority of studies were observational studies. The body of evidence was downgraded 1, 2, or 3 levels if there was risk of bias, results were inconsistent or consistency was unknown, the evidence was indirect, the effect estimates were imprecise (e.g. wide confidence intervals), or if there was publication bias. If no downgrades were made, the body of evidence was upgraded 1, 2 or 3 levels based on large magnitude of effect, dose-response gradient or if all plausible biases would decrease the magnitude of an apparent effect.

The final rating of the body of evidence expresses our confidence in the estimate of effect and the impact of further research on this topic. An overall strength of "high" means we have high confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect. The overall strength of "moderate" means we have moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate. A grade of "low" means we have low confidence that the evidence reflects the true effect. Further research is likely to change the confidence in the estimate of effect and likely to change the estimate. A grade of "insufficient" means that evidence is either unavailable or does not permit a conclusion.

Results

Study Selection

The initial electronic search yielded a total of 853 citations. Five additional citations were identified through reference scanning. After initial review of abstracts and titles, 841 studies did not meet our inclusion criteria. Following full text investigation, an additional 12 studies were excluded because 1) they were not comparative studies; 2) patients were not treated surgically; 3) there was no postoperative comparison of intervention and control groups; 4) they had a different outcome of interest; 5) they had no control group; 6) they were a duplicate publication with no new results; and/or 7) they were not in English. A total of 5 studies were deemed relevant following this review process.

Study Characteristics

For KQ1, we identified 4 studies (3 randomized controlled trials, 1 prospective cohort) discussing the effect of postoperative bracing on disability, pain, quality of life and functional outcomes.[4-7] Sample sizes ranged from 33 to 257 surgical patients with mean ages between 43.9 and 72.7 years. All patients were diagnosed with degenerative cervical myelopathy or

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radiculopathy, or degenerative disease of the lumbar spine. Bracing included Philadelphia collars, cervical collars, and lumbar corsets for differing lengths of time. Various outcome measures were used across the studies, with the Short Form-36 (SF-36) Physical Component Score (PCS) reported the most frequently (n = 4),[4-7] followed by the SF-36 Mental Component Score (MCS) (n = 3),[4, 6, 7] SF-36 subscales (n = 3),[4, 6, 7] Neck Disability Index (NDI) (n = 2),[4, 5] neck pain (n = 2),[4, 5] and arm pain (n = 2).[4, 5]

For KQ2, a total of 5 studies (4 randomized controlled trials, 1 prospective cohort) met our inclusion criteria.[4-8] These studies were designed to assess the impact of postoperative bracing compared with no bracing on radiographic outcomes. Sample sizes ranged from 33 to 257 surgical patients with mean ages between 14.3 and 72.7 years. Patients were diagnosed with degenerative cervical myelopathy or radiculopathy, degenerative disease of the lumbar spine, or adolescent idiopathic scoliosis. Bracing included Philadelphia collars, cervical collars, body casts, and lumbar corsets for various lengths of time. Fusion rate was the most frequently reported outcome measure (n = 3).[4, 5, 7]

For KQ3, we identified 3 studies (2 randomized controlled trials, 1 prospective cohort) examining the safety profile of postoperative bracing compared with no bracing.[5-7] Sample sizes ranged from 50 to 257 surgical patients with mean ages between 43.9 and 72.7 years. Patients were diagnosed with degenerative cervical myelopathy or radiculopathy, or degenerative disease of the lumbar spine. Bracing included Philadelphia collars, cervical collars, and lumbar corsets for various lengths of time. Outcome measures included complications (n = 3)[5-7] and revision surgery or second procedure (n = 2).[5, 7]

No studies met our inclusion criteria for KQ4 on the cost-effectiveness of postoperative bracing.

Risk of Bias

We critically appraised the 5 studies included in our review. **The inter-rater reliability was 80%; disagreement on the fifth study, by Yee et al., surrounding the "intention to treat" analysis was resolved through discussion. It was noted that although 90 patients were randomized, only 72 were included in their analysis, and therefore the study did not use intention to treat analysis.[7]** Of **the studies included**, 4 were considered Class II and 1 was rated Class III. The 4 Class II studies were randomized controlled trials, and were downgraded from Class I because they did not include intent-to-treat analysis, independent or blind assessment, adequate sample size, random sequence generation and/or statement of concealed allocation, had unreported follow-up rates or follow-up rates < 80%, and/or did not control for possible confounders. The Class III study was a prospective cohort study that was downgraded from Class II because co-interventions were not applied equally and follow-up was not reported.

Results of Individual Studies

KQ1: What is the efficacy and effectiveness of postoperative bracing compared with no bracing based on disability, pain, quality of life and functional outcomes?

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Degenerative cervical myelopathy or radiculopathy

Three studies compared disability, pain, quality of life and/or functional outcomes between the postoperative bracing and non-bracing groups in patients with degenerative cervical myelopathy or radiculopathy.[4-6]

According to Abbott et al., patients who received postoperative bracing had better NDI scores at 6 weeks after surgery compared to patients who did not receive postoperative bracing (mean difference between groups -4.4, 95% CI -8.6 to -0.2, p = 0.042).[4] However, Campbell et al., reported that patients in the non-braced group had better NDI scores at 6 weeks after surgery compared to patients in the braced group (p = 0.008).[5]

Abbott et al. also found that patients in the control group had better SF-36 PCS scores at 6 weeks (mean difference between groups 5.8, 95% CI 0.8-10.7, p = 0.025), 3 (mean difference between groups 6.8, 95% CI 0.4-13.1, p = 0.038), 6 (mean difference between groups 7.4, 95% CI 1.4-13.4, p = 0.017), and 12 months (mean difference between groups 7.5, 95% CI 0.3-14.6, p = 0.041) after surgery compared to patients in the postoperative bracing group.[4] In contrast, Campbell et al. and Hida et al. found no significant differences in SF-36 PCS scores between the two groups at all time points assessed (Campbell et al. 6 months p = 0.481, 12 months p = 0.260, 24 months p = 0.279; Hida et al. p = 0.537).[5, 6]

Two studies evaluated differences in various subscales of the SF-36 between a postoperative bracing and a control group.[4, 6] A single study by Abbott et al. reported significantly better SF-36 Bodily Pain (BP) scores in the postoperative bracing group at 6 (mean difference between groups 21.4, 95% CI 4.4-38.5, p=0.016) and 12 (mean difference between groups 17.5, 95% CI 1.7-33.2, p=0.031) months, as well as better SF-36 Social Functioning (SF) scores at 12-months (mean difference between groups 16.5, 95% CI 0.1-32.9, p=0.049) than in the non-bracing group.[4] The other six subscales (Physical Functioning (PF), General Health (GH), Role Limitations Physical (RP), Vitality (VT), Role Limitations Emotional (RE) and Mental Health (MH)) were not significantly different between treatment groups at all time points assessed (1.5, 3, 6, 12 and 24 months).[4] A second study by Hida et al., identified no differences between the collar-fixation group and the control group with respect to SF-36 BP subscale (p=0.848).[6]

Other measures of disability, pain, quality of life, and functional impairment, including SF-36 MCS, Visual Analog Scale (VAS), Japanese Orthopedic Association (JOA) recovery rate, Falls Efficacy Scale (FES), unipedal balance standing test, and neck and arm pain were not significantly different between the postoperative bracing and non-bracing groups (Table 3).[4-6]

Degenerative disease of the lumbar spine

A single study by Yee at al. examined pain and quality of life outcomes for patients with a degenerative disease of the lumbar spine.[7] There were no significant differences in the Dallas Pain Questionnaire (DPQ, daily activity category p = 0.34, work/leisure category p = 0.67,

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anxiety-depression category p = 0.17, social category p = 0.40), SF-36 PCS (p = 0.30), SF-36 MCS (p = 0.57) and SF-36 subscales (PF p = 0.38, BP p = 0.28, GH p = 0.23, RP p = 0.41, VT p = 0.25, SF p = 0.79, RE p = 0.86, MH p = 0.30) between the braced and non-braced groups at all time points assessed.[7]

KQ2: What is the impact of postoperative bracing compared with no bracing on radiographic outcomes?

Degenerative cervical myelopathy or radiculopathy

Three studies assessed the radiographic outcomes between the postoperative bracing and non-bracing groups in patients with degenerative cervical myelopathy or radiculopathy.[4-6]

Abbott et al. reported no significant differences in cervical range of motion (ROM) (p > 0.05), fusion rate (p = NR), and sagittal alignment (p = NR) between the two groups.[4] Campbell et al. also found no significant differences in fusion success between the bracing and non-bracing groups (p = NR).[5] Similarly, Hida et al. concluded that there were no significant differences in ROM (p = 0.61) or decrease in lordotic angle C2-7 (p = 0.82) between groups.[6]

Degenerative disease of the lumbar spine

Yee at al. found no significant differences in fusion rate at 12 months (p = 0.8) or 24 months (p = 0.9) postoperatively between patients who wore a lumbar corset and those who did not.[7]

Adolescent idiopathic scoliosis

Based on a single study, there was no significant difference in mean loss of spinal curve correction between the braced and non-braced groups at all time points assessed in patients with adolescent idiopathic scoliosis (p = NR).[8]

KQ3: What is the safety profile of postoperative bracing compared with no bracing?

Degenerative cervical myelopathy or radiculopathy

Campbell et al. reported rates of instrumentation failure, graft extrusion, and second procedures including revisions, removals, reoperations, supplemental fixations, and external bone growth stimulators,[5] while Hida et al. considered all perioperative complications including surgical site infection, epidural hematoma, and C5 palsy.[6]

Both Campbell et al. and Hida et al. identified no significant differences in the incidence of complications between the bracing and non-bracing groups (Campbell et al. no events of instrumentation failure or graft extrusion in either group, p = NC; Hida et al. p = 0.53).[5, 6] In addition, Campbell et al. found no significant differences between groups in the rate of revision surgery (p=0.653), removals (p=0.724), reoperations (p=1.000), supplemental fixations (p=0.286) or any second operation (p = 0.184).[5]

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Degenerative disease of the lumbar spine

Based on a single study, there were no significant differences in rates of revision surgery, a second procedure or complications between the braced and non-braced groups at all time points assessed (p = 0.8).[7] Revision surgery included later-stage revision surgery due to symptomatic nonunion or later-stage hardware removal due to prominence/bursitis, and complications included intraoperative incidental durotomy, intraoperative pedicle-screw-placement issues, new postoperative radiculopathy, early postoperative pulmonary embolism, wound seroma/hematoma, deep wound infection or persistent lumbar radiculopathy postoperatively.

KQ4: What is the cost-effectiveness of postoperative bracing?

No studies were identified that evaluated the cost-effectiveness of postoperative bracing.

Summary of Evidence

The overall quality of evidence ranged from "insufficient" to "moderate". Evidence was downgraded due to risk of bias, unknown or inconsistent consistency of results, and/or imprecise effect estimates (e.g. wide confidence intervals).

Based on low evidence, postoperative bracing in patients with degenerative cervical myelopathy or radiculopathy does not result in improved SF-36 MCS, VAS, JOA recovery rate, sagittal alignment, ROM, decrease in lordotic angle C2-7, and rate of revision surgery or second procedure outcomes. Based on moderate evidence, postoperative bracing does not result in improved neck or arm pain, fusion rate, and incidence of complications in this patient population.

Low evidence suggests no improvement in DPQ, SF-36 PCS, SF-36 MCS, SF-36 subscales, fusion rate, incidence of complications, and rate of revision surgery or second procedure following postoperative bracing in patients with a degenerative disease of the lumbar spine.

Based on low evidence, postoperative bracing is not associated with improved loss of spinal curve correction in adolescents with idiopathic scoliosis.

Discussion

The use of bracing after surgery for a variety of spinal pathologies remains controversial with limited evidence available to the surgeon to make an informed decision. Historically cited reasons to use bracing include to limit mobility and stabilize the spine, improve fusion rates, prevent graft dislodgement or subsidence, reduce postoperative pain and optimize outcomes. Bracing, however, can be uncomfortable, lead to social isolation and be associated with complications such as dysphagia, nerve palsies and pressure ulcers. This review summarizes the current literature on the efficacy, safety and cost-effectiveness of bracing after spinal surgery **using rigorous methodology and is the first to synthesize results using methodology**

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proposed by the GRADE working group. This knowledge is valuable in a clinical setting, and can be used by clinicians to determine the most appropriate postoperative management strategies. Clinical judgement, however, is still required to determine whether a patient may benefit from additional external immobilization.

Degenerative cervical myelopathy or radiculopathy

Based on this review, postoperative bracing of the cervical spine has no impact on 1) most measures of pain, disability, functional impairment, and quality of life; 2) radiographic outcomes such as fusion rate and range of motion; and 3) rates of complications and reoperations. In the study by Abbott et al., patients who received postoperative bracing exhibited superior improvements in neck disability (NDI at 6 weeks) and various metrics of quality of life (SF-36 PCS at 6 weeks to 12 months, SF-36 SF at 12-months and SF-36 BP at 6 to 12 months) than those who did not.[4] These findings can be partly explained by psychological factors, including a sense of security provided by the brace, increased coping mechanisms, improved functional self-efficacy, and less fear avoidance.[4] In contrast, Campbell et al identified that patients with postoperative bracing had worse NDI scores, likely due to the discomfort and disability associated with wearing a brace.[5]

Previous studies in healthy subjects have demonstrated that cervical bracing reduces velocity of eye movements and causes deterioration in the anterior to posterior body sway induced by vibration of the calf muscles.[9, 10] Given these findings, it is hypothesized that restricting cervical motion through external immobilization may significantly impair static postural control and disturb balance during dynamic movement. In the study by Abbott et al., however, there were no differences between a bracing group and a control group with respect to the unipedal balance standing test.[4]

Biomechanical studies have indicated that cervical collars help to restrict motion during routine activities and stabilize the spine.[11-13] However, early mobilization exercises can prevent spine contracture and improve range of motion after surgery.[6] In studies by Hida et al. and Abbott et al., there were no significant differences in cervical range of motion between the postoperative bracing group and the control group.[4, 6] Although range of motion often decreases following surgery, this is more likely due to fusion and fixation techniques, damage to the cervical flexors and extensors and injury to the facet joints. Postoperative bracing may also help to decrease the risk of graft or cage migration, maintain spinal alignment and improve fusion rates. Advancements in surgical procedures, however, have allowed for internal stabilization of the spine and may have decreased the requirement for external immobilization. For example, the use of anterior plates has shown to increase fusion and decrease subsidence rates by limiting motion between the graft and vertebral bodies.[14, 15] This finding was confirmed by Campbell et al. who reported no significant difference in rates of fusion between a bracing and non-bracing group;[5] these results question the need for postoperative bracing, especially in patients undergoing internal stabilization. There may still be a role for postoperative bracing in patients at

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a higher risk of pseudoarthrosis and disease progression, including those who smoke, have had a previous spine operation, and/or are treated without rigid internal fixation.[16-21] Furthermore, surgeons are more likely to use postoperative bracing following a multilevel anterior cervical discectomy and fusion (ACDF) (76%) compared to a single level ACDF (55%).[3]

Degenerative Disease of the Lumbar Spine

Based on this review, the use of a lumbar corset following surgery for degenerative lumbar disease has no impact on pain, disability, functional impairment, quality of life, radiographic outcomes, incidence of complications, and rate of reoperations. Postoperative bracing is often used in this population to relieve pain, limit mobility, improve fusion rates and optimize outcomes; however, the study by Yee et al. indicated no advantage or disadvantage to the use of a lumbar corset.[7] There may still be a role for bracing in patients at a higher risk of nonunion or pseudoarthrosis, such as those who smoke or require a multilevel fusion.

Adolescent Idiopathic Scoliosis

Historically, molded plaster braces were used to correct the curve following posterior fusions without instrumentation and maintain this correction until solid bony fusion. Techniques proposed in the study by Christodoulou et al., including the use of Harrington distraction rods, however, has decreased the need for postoperative external bracing due to more rigid internal fixation.[8] In this review, a single study examined postoperative bracing in an adolescent idiopathic scoliosis population and found no differences in radiographic outcomes between patients who received bracing versus those who did not. Further investigation, however, is needed to determine the effectiveness of bracing in this population based on other outcome measures.

Our finding that bracing may not confer additional benefits following spine surgery will have relevant applications in a clinical setting. First, complications such as skin reactions, dysphagia, pressure ulcers and nerve palsies, as well as costs associated with bracing can be eliminated. Second, if postoperative bracing is not required, there may be less of an impact on activities of daily living, decreased social isolation, body anxiety, self-perception and body image issues and an improved ability to return to work or school following surgery.

Strengths and Limitations

To our knowledge, no other reviews have evaluated the merits of bracing in the post-surgical setting for patients with various spinal pathologies **using the GRADE approach**. **This methodology allows for rigorous evaluation of the overall strength of the evidence and helps to identify critical knowledge gaps in the literature (e.g** a lack of high-quality comparative studies and limited data on the cost-effectiveness of postoperative bracing). Furthermore, the majority of current studies published on this topic have moderately high to high

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risk of bias and imprecise estimates of effect (or estimates with unknown precision). Consistency of results is also largely unknown as results are based on single studies.

Our review also has its limitations. First, our search was restricted to studies published in English and, as a result, some articles with relevant titles or abstracts were excluded. Second, although results were separated based on patient population, the type and length of bracing, as well as surgical technique varied substantially among studies, preventing pooling of data and meta-analysis.

Conclusions

Based on the results of this review, postoperative bracing does not result in improved outcomes after spine surgery in patients with various spinal pathologies. Although some outcomes were significantly different between bracing and non-bracing groups, firm conclusions cannot be made due to small sample sizes, risk of bias and low quality of evidence. Finally, given the paucity of studies available, no conclusions can be made regarding the cost-effectiveness of bracing after surgery.

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Figure 1. Flow diagram of study selection

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Table 1. Inclusion and exclusion criteria for studies reviewed

Characteristic	Inclusion	Exclusion
Population	Patients w/ any spinal pathology treated surgically and followed postoperatively (e.g. scoliosis, spinal trauma, cervical myelopathy)	Patients treated non-operatively
Intervention	Postoperative bracing	
Comparison	No postoperative bracing Standard of care	
Outcome	KQ1: Efficacy and effectiveness • Disability (e.g. NDI) • Pain (e.g. VAS) • Quality of life (e.g. SF-36) • Functional outcomes (e.g. JOA, mJOA, Nurick) KQ2: Radiographic Outcomes • Fusion rate • Sagittal alignment • ROM KQ3: Safety • Complications or adverse events (e.g. dysphagia, hardware, skin complications, reoperation, revision	KQ1: Subjective neurological status, patient satisfaction, improvement of symptoms

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	surgery, infection, hematoma) KQ4: Cost-effectiveness • Incremental cost-effectiveness ratio (or similar) • Cost per unit of outcome	
Study design	KQ1, 2, 3: Comparative studies (e.g. RCT, prospective cohort, case-control studies) designed to compare a postoperative bracing group with a control group; n ≥ 10 per group. KQ4: Full economic studies	Case reports Nonclinical studies Animal studies
Publication	Studies published in peer-review journals and in English	Abstracts, editorials, letters Duplicate publications of the same study that do not report on different outcomes Narrative or systematic reviews

JOA = Japanese Orthopedic Association; mJOA = modified Japanese Orthopedic Association; NDI = neck disability index; ROM = range of motion; SF-36 = short form-36; VAS = visual analog scale

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1 **Table 2. Characteristics of included studies**

Authors & Year	Population, n	Sex, %	Mean Age (Range, SD)*	Diagnosis	Surgery	Bracing	Outcome Factors Assessed	Follow-up	Drop-out, n†
Abbott et al., 2013 (RCT, pilot)	Brace (n = 17)	M, 53%	53.4 (NR, 13)	Cervical spondylosis (n = 8), Cervical disk herniation (n = 4), Cervical degenerative disc disease (n = 5)	ACDF with interbody cage	Philadelphia Collar daytime only for 6 weeks	KQ1: Borg CR-10 (neck and arm pain), NDI, SF-36 (PCS and MCS), FES, unipedal balance standing test KQ2: CROM, fusion rate,	1.5, 3, 6, 12, and 24 months postoperative	55% (n = 18)
	Control (n = 16)	M, 69%	47.3 (NR, 11)	Cervical spondylosis (n = 5), Cervical disk herniation (n = 4),					

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Authors & Year	Population, n	Sex, %	Mean Age (Range, SD)*	Diagnosis	Surgery	Bracing	Outcome Factors Assessed	Follow-up	Drop-out, n†
				Cervical degenerative disc disease (n = 7)			sagittal alignment KQ3: None KQ4: None		
Campbell et al., 2008 (Prospective cohort)‡	Brace (n = 149)	M, 43.6 %	44.3 (NR, 8.8)	Single-level radiculopathy or myelopathy	Decompression and arthrodesis using allograft and anterior cervical plate or	Cervical collar	KQ1: NDI, neck and arm pain scales, SF-36 KQ2: Fusion success KQ3: Second procedure§,	1.5, 3, 6, 12, and 24 months postoperative	NR
	Control (n = 108)	M, 49.1 %	43.3 (NR, 9.0)						

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Authors & Year	Population, n	Sex, %	Mean Age (Range, SD)*	Diagnosis	Surgery	Bracing	Outcome Factors Assessed	Follow-up	Drop-out, n†
					arthoplasty		instrumentation failure, graft extrusion KQ4: None		
Christodoulou et al., 1987 (RCT)	Brace (n = 25) Control (n = 25)	NA NA	NR NR	Adolescent idiopathic scoliosis with thoracic curves ≥ 35°	Posterior decompression and fusion with Harrington instrumentation augmented	Plaster body cast for 6 months	KQI: None KQ2: Spinal curve KQ3: None KQ4: None	3, 6, 12, and 24 months postoperative	NR

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Authors & Year	Population, n	Sex, %	Mean Age (Range, SD)*	Diagnosis	Surgery	Bracing	Outcome Factors Assessed	Follow-up	Drop-out, n†
					by a Cotrel bar or by sublaminal Luque wires				
Hida et al., 2017 (RCT)	Brace (n = 45)	M, 73%	72.0 (NR, 8.7)	Cervical myelopathy secondary to multisegmental cervical spondylotic stenosis	Double-door cervical laminoplasty without instrumentation	Philadelphia collar for 2 weeks	KQ1: VAS, JOA, SF-36 (PCS and MCS) KQ2: ROM (total, extension and flexion),	0.5, 3, 6, and 12 months postoperative	18% (n = 16)
	Control (n = 45)	M, 62%	71.6 (NR, 9.6)						

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Authors & Year	Population, n	Sex, %	Mean Age (Range, SD)*	Diagnosis	Surgery	Bracing	Outcome Factors Assessed	Follow-up	Drop-out, n†
							lordotic angle C2-7 KQ3: Perioperative complications ¶ KQ4: None		
Yee et al., 2008 (RCT)	Brace (n = 46)	M, 43% **	52 (NR, 15.2) **	Spondylosis/stenosis (n = 11), degenerative spondylolisthesis (n = 13), isthmic	Posterior lumbar spinal arthrodesis	Canvas lumbar corset full-time for 8	KQ1: DPQ, SF-36 KQ2: Fusion rate KQ3: Revision	12 and 24 months postoperative	20% (n = 18)

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Authors & Year	Population, n	Sex, %	Mean Age (Range, SD)*	Diagnosis	Surgery	Bracing	Outcome Factors Assessed	Follow-up	Drop-out, n†
				spondylolisthesis (n = 8), junctional syndrome (n = 1), pseudarthrosis (n = 2), iatrogenic/post-op instability (n = 2) ††		weeks	surgery††, complications ‡‡ KQ4: None		
	Control (n = 44)	M, 54% **	53 (NR, 15.4) **	Spondylosis/stenosis (n = 12), degenerative spondylolisthesis					

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Authors & Year	Population, n	Sex, %	Mean Age (Range, SD)*	Diagnosis	Surgery	Bracing	Outcome Factors Assessed	Follow-up	Drop-out, n†
				(n = 12), isthmic spondylolisthesis (n = 5), junctional syndrome (n = 2), pseudarthrosis (n = 2), iatrogenic/post-op instability (n = 1), congenital stenosis (n = 1) ††					

ACDF = anterior cervical discectomy and fusion; CROM = cervical range of motion; DPQ = Dallas pain questionnaire; FES = falls efficacy scale; JOA = Japanese Orthopedic Association; MCS = mental component score; NDI= neck disability index; NR = not

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reported; PCS = physical component score; ROM = range of motion; SD = standard deviation; SF-36 = short form-36; VAS = visual analog scale

* Age in years

† Drop-out before end of follow-up

‡ Postoperative care, including immobilization techniques and activity restrictions, was left to the discretion of the attending surgeon

§ Included revisions, removals, reoperations, supplemental fixations, and external bone growth stimulators

¶ Included surgical site infection, epidural hematoma, and C5 palsy

** Based on patients who completed follow-up

†† Included later-stage revision surgery due to symptomatic nonunion or later-stage hardware removal due to prominence/bursitis

‡‡ Included intraoperative incidental durotomy, intraoperative pedicle-screw-placement issues, new postoperative radiculopathy, early postoperative pulmonary embolism, wound seroma/hematoma, deep wound infection or persistent lumbar radiculopathy postoperatively

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Table 3. Results of statistical analysis

Authors & Year	Statistical Analysis	Differences at Baseline	Postoperative Differences
Abbott et al., 2013	ANCOVA with adjustment for covariates, repeated measure analysis of covariance	There were no significant differences between the cervical collar group and the control group with respect to gender, age, diagnosis, level of operation, cervical range of motion, unipedal balance and baseline NDI, SF-36 (subscales, PCS and MCS), FES and Borg CR-10 (neck and arm pain) scores (p = NR)	ANCOVA*:* *NDI Scores at 1.5 months (p = 0.042)** Mean difference between groups: -4.4 (95% CI: -8.6 to -0.2); Cohen's effect size: -0.77 *SF-36 BP scores* *6 months (p = 0.016)** Mean difference between groups: 21.4 (95% CI: 4.4 to 38.5); Cohen's effect size: 0.73 *12 months (p = 0.031)** Mean difference between groups: 17.5 (95% CI: 1.7 to 33.2); Cohen's effect size: 0.57 *SF-36 SF scores at 12 months (p = 0.049)**

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	Mean difference between groups: 16.5 (95% CI: 0.1 to 32.9); Cohen's effect size: 0.45 *SF-36 PCS* *1.5 months (p = 0.025)** Mean difference between groups: 5.8 (95% CI: 0.8 to 10.7); Cohen's effect size: 0.84 *3 months (p = 0.038)** Mean difference between groups: 6.8 (95% CI: 0.4 to 13.1); Cohen's effect size: 0.63 *6 months (p = 0.017)** Mean difference between groups: 7.4 (95% CI: 1.4 to 13.4); Cohen's effect size: 0.80 *12 months (p = 0.041)** Mean difference between groups: 7.5 (95% CI: 0.3 to 14.6); Cohen's effect size: 0.66

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	There were no significant differences between the cervical collar group and the control group with respect to 1) neck pain, arm pain, FES, SF-36 PF, SF-36 RP, SF-36 GH, SF-36 VT, SF-36 RE, SF-36 MH, SF-36 MCS at all time points assessed (1.5, 3, 6, 12, and 24 months) ($p > 0.05$) 2) all components of the unipedal balance test (right/ foot, right/left foot soft surface, right/left foot eyes closed) at all time points assessed (1.5, 3, 6, 12, and 24 months) ($p > 0.05$) 3) all components of CROM (right/left lateral flexion, flexion, extension, right/left rotation) at all time points assessed (1.5, 3, 6, 12, and 24 months) ($p > 0.05$) 4) fusion rates and sagittal alignment (p = NR)

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			Repeated measures analysis of covariance showed that controlling for the combined effects of all prospective measures gave significantly better outcome for the cervical collar group in neck pain (p = 0.038), SF-36 PCS (p = 0.010) and SF-36 BP (p = 0.029).
Campbell et al., 2008	ANOVA, ANCOVA, Fisher exact test, Student t test	SF-36 PCS was higher in the control group (31.1±7.2) than in the braced group (33.4±7.8) (p = 0.019) There were no significant differences between the braced group and the control group with respect to age (p = 0.367), gender (p = 0.447), worker's compensation (p = 0.458), litigation (p = 1.000), smoking status (p = 1.000)	*Mean improvement in NDI Scores at 1.5 months (p = 0.008)* Braced: 21.6±18.4 Not Braced: 28.4±19.0 There were no significant differences between the braced group and the control group with respect to NDI scores at 3-months (p = 0.468), 6-months (p = 0.169), 12-months (p = 0.415) and 24-months (p = 0.693), SF-36 PCS at 6-months (p = 0.481), 12-months (p = 0.260)

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		and occupational status (p = 0.695), and baseline NDI (p = 0.141), neck pain (p = 0.523) and arm pain (p = 0.710) scores.	and 24-months (p = 0.279), average neck pain scores at 24-months (p = 0.622), and average arm pain scores at 24-months (p = 0.260). There were no significant differences in fusion success at any time period between groups, though higher rates of fusion were reported in the non-braced group (p = 0.552 at 24-months). There were no significant differences in rates of secondary surgeries or procedures between the braced group and the control group: revisions (p = 0.653), removals (p = 0.724), reoperations (p = 1.000), supplemental fixations (p = 0.286), any surgery (p = 0.184).
Christodoulou	NR	*Mean curves* (p = NR)	*Postoperative mean curves* (p = NR)

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et al., 1987		Braced: 58.0° Not Braced: 54.0°	Braced: 23.0° Not Braced: 22.8° There was no significant difference between the braced group and the control group with respect to the mean loss of correction at 24 months (7.0° for braced group, 6.3° for control group, p = NR).
Hida et al., 2017	Two-way repeated ANOVA, Fisher exact test, Student t test, x^2 test,	There were no significant differences between the collar-fixation group and the control group with respect to age (p = 0.73), gender (p = 0.26), height (p = 0.59), weight (p = 0.66), operation time (p = 0.57), intraoperative blood loss (p = 0.69), number of operated levels (p = 0.67), VAS (p = 0.33), JOA (p = 0.67), lordotic angle (p =	There were no significant differences between the collar-fixation group and the control group with respect to 1) VAS (p = 0.487), JOA recovery rates (p = 0.80), SF-36 PCS (p = 0.537), SF-36 MCS (p = 0.504), and SF-36 BP subscores (p = 0.848) at 12 months follow-up. 2) the decrease in the C2-7 lordotic angle (p = 0.82) and ROM (p = 0.61).

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		0.84), ROM (p = 0.88) and SF-36 PCS (p = 0.68), MCS (p = 0.80) and BP (p = 0.57).	3) incidence of complications (p = 0.53).
Yee et al., 2008	Mann-Whitney U test, chi-square test, Fisher exact test, two-way ANOVA	There were no significant differences between the brace group and the control group with respect to age (p = 0.97), gender (p = 0.35), CCI (p = 0.6), number of levels included in the arthrodesis (p = 0.42), smoking status (p = 0.89), worker's compensation or litigation (p = 0.48), revision surgery (p = 0.88), BMI (p = 0.74), diagnosis (p = 0.8), and preoperative SF-36 MCS (p = 0.9), SF-36 PCS (p = 0.19), SF-36 domain scores (p > 0.05) and DPQ category scores (p > 0.05)	There were no significant differences between the brace group and the control group with respect to 1) the distribution of surgical complications or subsequent revision rates (p = 0.8) 2) postoperative DPQ category scores (p = 0.34 for the daily activity category, p = 0.67 for the work/leisure category, p = 0.17 for the anxiety-depression category and p = 0.40 for the social category) 3) postoperative SF-36 domain and component scores (p = 0.38 for PF, p = 0.28 for BP, p = 0.23 for GH, p = 0.41 for RP, p = 0.25 for VT, p = 0.79 for SF, p = 0.86 for RE, p = 0.30 for MH,

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			p = 0.30 for PCS and p = 0.57 for MCS) 4) rates of fusion seen radiographically at 12 months (p = 0.8) or 24 months (p = 0.9) postoperatively. 5) Rates of revision surgery due to symptomatic non-union (p = 0.43)

ANCOVA = analysis of covariance; ANOVA = analysis of variance; BMI = body mass index; BP = bodily pain; CCI = Charlson comorbidity index; CI = confidence interval; CROM = cervical range of motion; DPQ = Dallas pain questionnaire; FES = falls efficacy scale; GH = general health; JOA = Japanese Orthopedic Association; MCS = mental component score; MH = mental health; NDI = neck disability index; NR = not reported; OR = odds ratio; PCS = physical component score; PF = physical functioning; RE = role limitations emotional; ROM = range of motion; RP = role limitations physical; SF = social functioning; SF-36 = short form-36; VAS = visual analog scale; VT = vitality

* No significant differences at all other time points assessed (1.5, 3, 6, 12, and 24 months postoperative)

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1 **Table 4. Summary and Strength of Evidence**

Patient Population and Outcome of Interest	Studies	Strength of Evidence	Overall Effect and Conclusions
KQ1: What is the efficacy and effectiveness of postoperative bracing compared with no bracing based on disability, pain, quality of life and functional outcomes?			
Degenerative cervical myelopathy or radiculopathy			Results were inconsistent across studies: 1) a prospective cohort study reported that patients in the non-braced group had better NDI scores at 6 weeks after surgery compared to patients in the braced group,(Campbell, Carreon et al. 2009) whereas 2) a pilot randomized controlled trial indicated that patients in the braced group had better NDI scores at 6 weeks after surgery compared to patients in the non-braced group.(Abbott, Halvorsen et al. 2013)
NDI	n = 2(Campbell, Carreon et al. 2009, Abbott, Halvorsen et al. 2013)	Insufficient	
SF-36 PCS		Insufficient	
SF-36 MCS		Low	
SF-36 BP subscale	n = 3(Campbell, Carreon et al. 2009, Abbott, Halvorsen et al. 2013, Hida, Sakai et al. 2017)	Insufficient	
SF-36 SF subscale		Insufficient	
SF-36 other subscales		Insufficient	
VAS	n = 2(Abbott, Halvorsen et al. 2013, Hida, Sakai et al. 2017)	Low	
JOA recovery rate		Low	Results were inconsistent across studies: 1) a pilot randomized controlled trial indicated that patients in the non-
FES	n = 2(Abbott, Halvorsen et al.	Insufficient	

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Patient Population and Outcome of Interest	Studies	Strength of Evidence	Overall Effect and Conclusions
Unipedal balance standing test	2013, Hida, Sakai et al. 2017)	Insufficient	braced group had better SF-36 PCS scores at 6 weeks, 3, 6,
Neck pain	n = 1(Abbott, Halvorsen et al.	Moderate	and 12 months after surgery compared to patients in the
Arm pain	2013)	Moderate	braced group,(Abbott, Halvorsen et al. 2013) whereas 2) two
	n = 1(Abbott, Halvorsen et al.		studies (a prospective cohort study and a randomized
	2013)		controlled trial) reported no significant differences in SF-36
	n = 1(Hida, Sakai et al. 2017)		PCS scores between the braced and non-braced groups at all
	n = 1(Hida, Sakai et al. 2017)		time points assessed.(Campbell, Carreon et al. 2009, Hida,
	n = 1(Abbott, Halvorsen et al.		Sakai et al. 2017)
	2013)		
	n = 1(Abbott, Halvorsen et al.		Results were inconsistent across studies: 1) a pilot
	2013)		randomized controlled trial indicated that patients in the
	n = 2(Campbell, Carreon et al.		braced group had better SF-36 BP subscale scores at 6 and
	2009, Abbott, Halvorsen et al.		12 months after surgery compared to patients in the non-
	2013)		braced group,(Abbott, Halvorsen et al. 2013) whereas 2) a
	n = 2(Campbell, Carreon et al.		randomized controlled trial reported no significant

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Patient Population and Outcome of Interest	Studies	Strength of Evidence	Overall Effect and Conclusions
	2009, Abbott, Halvorsen et al. 2013)		differences in SF-36 BP subscale scores between the braced and non-braced groups at all time points assessed.(Hida, Sakai et al. 2017) Patients in the braced group had better SF-36 SF subscale scores at 12 months after surgery compared to patients in the non-braced group.(Abbott, Halvorsen et al. 2013) There were no significant differences in SF-36 MCS and other subscales, VAS, JOA recovery rate, FES, unipedal balance standing test, neck pain, and arm pain between the braced and non-braced groups at all time points assessed.
Degenerative disease of the lumbar spine DPQ	n = 1(Yee, Yoo et al. 2008)	Low	There were no significant differences in DPQ, SF-36 PCS,

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Patient Population and Outcome of Interest	Studies	Strength of Evidence	Overall Effect and Conclusions
SF-36 PCS	n = 1(Yee, Yoo et al. 2008)	Low	MCS and subscales between the braced and non-braced groups at all time points assessed.
SF-36 MCS	n = 1(Yee, Yoo et al. 2008)	Low	
SF-36 subscales	n = 1(Yee, Yoo et al. 2008)	Low	
KQ2: What is the impact of postoperative bracing compared with no bracing on radiographic outcomes?			
Degenerative cervical myelopathy or radiculopathy			There were no significant differences in ROM, fusion rate, sagittal alignment, and decrease in lordotic angle C2-7 between the braced and non-braced groups at all time points assessed.
ROM	n = 2(Abbott, Halvorsen et al. 2013, Hida, Sakai et al. 2017)	Low	
Fusion rate		Moderate	
Sagittal alignment	n = 2(Campbell, Carreon et al. 2009, Abbott, Halvorsen et al. 2013)	Low	
Lordotic angle C2-7	n = 1(Abbott, Halvorsen et al. 2013)	Low	
	n = 1(Hida, Sakai et al. 2017)		
Degenerative disease of the			There was no significant difference in fusion rate between

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Patient Population and Outcome of Interest	Studies	Strength of Evidence	Overall Effect and Conclusions
lumbar spine			the braced and non-braced groups at all time points assessed.
Fusion rate	n = 1(Yee, Yoo et al. 2008)	Low	
Adolescent idiopathic scoliosis with thoracic curves ≥ 35°			There was no significant difference in mean loss of spinal curve correction between the braced and non-braced groups at all time points assessed.
Spinal curve	n = 1(Christodoulou, Prince et al. 1987)	Low	
KQ3: What is the safety profile of postoperative bracing compared with no bracing?			
Degenerative cervical myelopathy or radiculopathy			There were no significant differences in rate of revision surgery, second procedure or complications between the braced and non-braced groups at all time points assessed.
Revision surgery or second procedure	n = 1(Campbell, Carreon et al. 2009)	Low	
Complications	n = 2 (Campbell, Carreon et al. 2009, Hida, Sakai et al. 2017)	Moderate	
Degenerative disease of the			There were no significant differences in rate of revision

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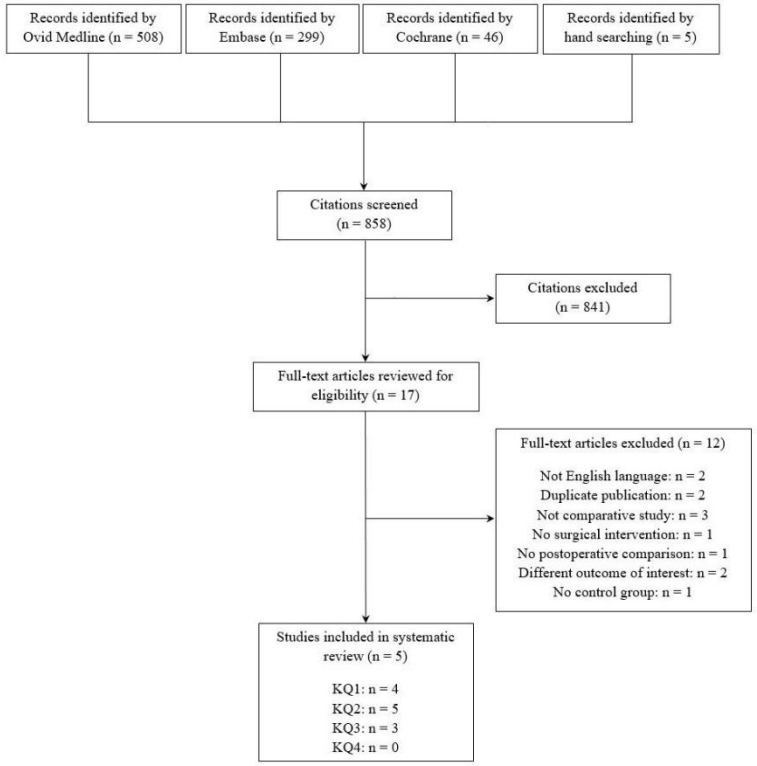
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Patient Population and Outcome of Interest	Studies	Strength of Evidence	Overall Effect and Conclusions
lumbar spine			surgery, second procedure or complications between the
Revision surgery or second procedure	n = 1(Yee, Yoo et al. 2008)	Low	braced and non-braced groups at all time points assessed.
Complications	n = 1(Yee, Yoo et al. 2008)	Low	
KQ4: What is the cost-effectiveness of postoperative bracing?			
None	n = 0	NA	None

CROM = cervical range of motion; DPQ = Dallas pain questionnaire; FES = falls efficacy scale; JOA = Japanese Orthopedic Association; MCS = mental component score; NDI = neck disability index; NA = not applicable; PCS = physical component score; ROM = range of motion; SF-36 = short form-36; VAS = visual analog scale

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