



**CONGRESS OF NEUROLOGICAL SURGEONS SYSTEMATIC REVIEW AND
EVIDENCE-BASED GUIDELINES ON THE EVALUATION AND TREATMENT OF
PATIENTS WITH THORACOLUMBAR SPINE TRAUMA:
OPERATIVE VERSUS NONOPERATIVE TREATMENT**

Sponsored by: Congress of Neurological Surgeons and the Section on Disorders of the Spine and Peripheral Nerves in collaboration with the Section on Neurotrauma and Critical Care

Endorsed by: Joint Guidelines Committee of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS)

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Abbreviation:

PLC - Posterior ligamentous complex

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ABSTRACT

Background: There is a lack of consensus regarding the approach to treatment of a neurologically intact patient with a thoracic or lumbar burst fracture. Similarly, a widely adopted treatment paradigm for nonburst fractures, a diverse group, remains elusive.

Objective: We sought to determine the optimal treatment protocol for burst and nonburst fractures of the thoracic and lumbar spine.

Methods: A systematic review of the literature was performed using the National Library of Medicine PubMed database and the Cochrane Library for studies relevant to thoracolumbar fractures, including burst fractures and nonburst fractures. Clinical studies specifically comparing nonsurgical to surgical treatment for neurologically intact patients harboring burst and nonburst fractures were selected for review.

Results: The literature search yielded 836 abstracts. The task force selected 144 articles for full-text review, and 6 were selected for inclusion in this systematic review. Of these, 3 articles were level II and specifically studied burst fractures in neurologically intact patients. One article indicated the superiority of surgery, and 2 articles showed equivalence. There were 3 level III studies that provided conflicting evidence. There were no studies meeting the inclusion criteria that studied nonburst fractures.

Conclusion: With regard to patient outcomes, there is conflicting evidence for and against surgery in the management of neurologically intact patients with thoracolumbar burst fractures. Therefore, the task force recommends (grade insufficient) that the discretion of the treating provider should be used to determine if the presenting thoracic or lumbar burst fracture in the neurologically intact patient warrants surgical intervention. Similarly, because of the lack of studies specifically investigating nonburst fractures, this guideline provides a grade insufficient recommendation that the discretion of the treating provider should be used to determine if the presenting nonburst thoracolumbar fracture warrants surgical intervention.

RECOMMENDATIONS

Question 1

Does the surgical treatment of burst fractures of the thoracic and lumbar spine improve clinical outcomes compared to nonoperative treatment?

Recommendation 1

There is conflicting evidence to recommend for or against the use of surgical intervention to improve clinical outcomes in patients with thoracolumbar burst fracture who are neurologically intact. Therefore, it is recommended that the discretion of the treating provider be used to determine if the presenting thoracic or lumbar burst fracture in the neurologically intact patient warrants surgical intervention.

Strength of Recommendation: Grade Insufficient

Question 2

Does the surgical treatment of nonburst fractures of the thoracic and lumbar spine improve clinical outcomes compared to nonoperative treatment?

Recommendation 2

There is insufficient evidence to recommend for or against the use of surgical intervention for nonburst thoracic or lumbar fractures. It is recommended that the decision to pursue surgery for such fractures be at the discretion of the treating physician.

Strength of Recommendation: Grade Insufficient

INTRODUCTION

Goals and Rationale

This clinical guideline was created to improve patient care by outlining the appropriate information gathering and decision-making processes involved in the evaluation and treatment of patients with thoracolumbar spine trauma. The surgical management of these patients often takes place under a variety of circumstances and by various clinicians. This guideline was created as an educational tool to guide qualified physicians through a series of diagnostic and treatment decisions in an effort to improve the quality and efficiency of care.

The decision as to whether or not neurologically intact patients with thoracolumbar fractures require surgical intervention remains controversial. A consensus regarding the treatment of burst fractures, in particular, has been difficult to obtain. With the advent of modern spinal instrumentation, the options for surgical intervention have been refined considerably. The evolution of imaging techniques, such as magnetic resonance imaging (MRI) and reformatted computed tomography (CT) scans, has led to a better understanding of these injuries.

The most concerning complication related to nonoperative treatment of a patient with thoracolumbar fractures has been neurologic deterioration due to a failure to surgically decompress and/or stabilize the injured spine.¹ More recently, physicians electing nonoperative care for neurologically intact patients are recognizing the potential for the progressive development of chronic pain and deformity. By contrast, surgeons should strive to determine the best treatment option for each individual patient, so as to avoid unnecessary surgery.

Historical treatment for thoracic and lumbar spine injuries has often been nonsurgical.^{2,3} Early discussions as to which fractures require surgical stabilization centered over the question of whether or not the injury was stable or unstable.⁴ White and Panjabi define clinical instability as “the loss of the ability of spine under physiologic loads to maintain relationships between vertebra in such a way that there is neither damage nor subsequent irritation to the spinal cord or nerve roots and, in addition, there is no development of incapacitating deformity or pain due to structural changes.” In determining which fractures require open stabilization, they were early advocates of determining whether the anterior and/or posterior elements were destroyed or unable to function. Denis⁵ later proposed via a case series further subdividing the anterior column by introducing the concept of a middle column, which included the posterior portion of the vertebral body, the posterior annulus, and posterior longitudinal ligament. The primary implication discussed was that posterior column injury is insufficient alone to cause instability. In 1998, Hitchon et al⁶ were among the first to propose that surgery was best reserved for patients with >20° of kyphosis, >50% height loss, or >50% canal stenosis. This study contained

highly heterogeneous patient groups, including both intact patients and patients with spinal cord injuries. Moreover, diverse injury types were also included.

Over the past 20 years, the rapid evolution of both diagnostic imaging and spinal stabilization techniques has complicated interpretation of the literature, such that adequate determination of which patients would benefit most from surgical stabilization and/or decompression is difficult. For example, a number of early papers were based upon the use of Harrington instrumentation,⁷⁻¹⁰ which makes contemporary application of their findings challenging. Moreover, while few will argue that decompression and stabilization is appropriate for patients with neurologic deficits, the heterogeneity of patient samples, e.g., the presence or absence of neurologic deficits, has further complicated analysis of the literature.⁶ In addition, many older studies were performed before the widespread use of MRI, which may alter treatment decisions. A comprehensive assessment of the published literature devoted to this subject is critical to assist clinicians with decision-making as to which injuries require operative versus nonoperative treatment.

METHODS

The guidelines task force initiated a systematic review of the literature relevant to the diagnosis and treatment of patients with thoracolumbar trauma. Through objective evaluation of the evidence and transparency in the process of making recommendations, this evidence-based clinical practice guideline was developed for the diagnosis and treatment of adult patients with thoracolumbar injury. These guidelines are developed for educational purposes to assist practitioners in their clinical decision-making processes. Additional information about the

methods used in this systematic review can be found in the [introduction and methodology chapter](#).

Literature Search

The task force members identified search terms/parameters, and a medical librarian implemented the literature search, consistent with the literature search protocol (see Appendix I), using the National Library of Medicine PubMed database and the Cochrane Library (which included the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effect, the Cochrane Central Register of Controlled Trials, the Health Technology Assessment Database, and the National Health Service Economic Evaluation Database) for the period from January 1, 1946, to March 31, 2015, using the search strategies provided in Appendix I.

RESULTS

The literature search yielded 836 abstracts. Task force members reviewed all abstracts yielded from the literature search and identified the literature for full-text review and extraction, addressing the clinical questions in accordance with the literature search protocol (Appendix I). Task force members identified the best research evidence available to answer the targeted clinical questions. When level I, II, and/or III literature was available to answer specific questions, the task force did not review level IV studies.

The task force selected 144 articles for full-text review. Of these, 138 were rejected for not meeting inclusion criteria or for being off- topic. Six were selected for inclusion in the systematic review (Appendix II).

Inclusion/Exclusion Criteria

Articles were retrieved and included only if they met specific inclusion/exclusion criteria. These criteria were also applied to articles provided by guideline task force members who supplemented the electronic database searches with articles from their own files. To reduce bias, these criteria were specified before conducting the literature searches.

Articles that do not meet the following criteria were, for the purposes of this evidence-based clinical practice guideline, excluded. To be included as evidence in the guideline, an article had to be a report of a study that:

- Investigated patients with thoracolumbar injuries;
- Included patients ≥ 18 years of age;
- Enrolled $\geq 80\%$ of thoracolumbar injuries (studies with mixed patient populations were included if they reported results separately for each group/patient population);
- Was a full article report of a clinical study;
- Was not an internal medical records review, meeting abstract, historical article, editorial, letter, or commentary;
- Appeared in a peer-reviewed publication or a registry report;
- Enrolled ≥ 10 patients per arm per intervention (20 total) for each outcome;
- Included only human subjects;
- Was published in or after 1946 through March 31, 2015;
- Quantitatively presented results;
- Was not an in vitro study;
- Was not a biomechanical study;

- Was not performed on cadavers;
- Was published in English;
- Was not a systematic review, meta-analysis, or guideline developed by others*;

Rating Quality of Evidence

The guideline task force used a modified version of the North American Spine Society's evidence-based guideline development methodology. The North American Spine Society methodology uses standardized levels of evidence (Appendix III) and grades of recommendation (Appendix IV) to assist practitioners in easily understanding the strength of the evidence and the recommendations within the guidelines. The levels of evidence range from level I (high-quality randomized controlled trial) to level IV (case series). Grades of recommendation indicate the strength of the recommendations made in the guideline based on the quality of the literature. Levels of evidence have specific criteria and are assigned to studies prior to developing recommendations. Recommendations are then graded based upon the level of evidence. To better understand how levels of evidence inform the grades of recommendation and the standard nomenclature used within the recommendations, see Appendix IV.

Guideline recommendations were written using a standard language that indicates the strength of the recommendation. "A" recommendations indicate a test or intervention is "recommended"; "B" recommendations "suggest" a test or intervention; "C" recommendations indicate a test or intervention or "is an option." "Insufficient evidence" statements clearly indicate that "there is

*The guideline task force did not include systematic reviews, guidelines, or meta-analyses conducted by others. These documents are developed using different inclusion criteria than those specified in this guideline; therefore, they may include studies that do not meet the inclusion criteria specific in this guideline. In cases where these types of documents' abstract suggested relevance to the guideline's recommendations, the task force searched their bibliographies for additional studies.

insufficient evidence to make a recommendation for or against” a test or intervention. Task force consensus statements clearly state that “in the absence of reliable evidence, it is the task force’s opinion that” a test or intervention may be considered. Both the levels of evidence assigned to each study and the grades of each recommendation were arrived at by consensus of the workgroup employing up to three rounds of voting when necessary.

In evaluating studies as to levels of evidence for this guideline, the study design was interpreted as establishing only a potential level of evidence. For example, a therapeutic study designed as a randomized controlled trial would be considered a potential level I study. The study would then be further analyzed as to how well the study design was implemented, and significant shortcomings in the execution of the study would be used to downgrade the levels of evidence for the study’s conclusions (see Appendix V for additional information and criteria).

Revision Plans

In accordance with the Institute of Medicine’s standards for developing clinical practice guidelines and criteria specified by the National Guideline Clearinghouse, the task force will monitor related publications following the release of this document and will revise the entire document and/or specific sections “if new evidence shows that a recommended intervention causes previously unknown substantial harm; that a new intervention is significantly superior to a previously recommended intervention from an efficacy or harms perspective; or that a recommendation can be applied to new populations.”¹¹ In addition, the task force will confirm within 5 years from the date of publication that the content reflects current clinical practice and

the available technologies for the evaluation and treatment for patients with thoracolumbar trauma.

DISCUSSION

Question 1

Does the surgical treatment of burst fractures of the thoracic and lumbar spine improve clinical outcomes compared to nonoperative treatment?

Recommendation 1

There is conflicting evidence to recommend for or against the use of surgical intervention to improve clinical outcomes in patients with thoracolumbar burst fractures who are neurologically intact. Therefore, it is recommended that the discretion of the treating provider be used to determine if the presenting thoracic or lumbar burst fracture in the neurologically intact patient warrants surgical intervention.

Strength of Recommendation: Grade Insufficient

Level II Evidence

None of the studies met the criteria to be considered level I evidence. There were 3 class II studies.⁸⁻¹⁰ While these studies were randomized controlled trials (RCTs), various flaws led to downgrading them to level II evidence. In the study by Shen et al¹² outcomes were similar at 2 years, when comparing nonoperative treatment to short-segment posterior pedicle screw fixation. Siebenga et al¹³ also compared operative versus nonoperative management; however, this study suffers from a small sample size (34 patients). The authors looked at patients with AO type A fractures who were neurologically intact and, by analyzing subgroups, they concluded that

patients with AO type A3 (burst) fractures fare better with short-segment posterior fixation, in terms of both radiographic and functional assessment. In the surgically treated group, more patients returned to work than in the nonoperatively treated group. The study by Wood et al,¹⁴ although considered an RCT, fell short of being considered level I evidence. The authors specifically excluded cases thought to have posterior ligamentous disruption. In addition, <80% of the patients had adequate follow-up. There were 24 patients treated operatively and 23 treated nonoperatively. No significant differences were found regarding return to work, pain scores, or kyphosis. The authors were unable to confirm their hypothesis that surgery (performed via a posterior approach) was superior to nonoperative treatment.

Level III Evidence

Some comparative studies met inclusion criteria but were downgraded to level III. Landi et al¹⁵ performed a retrospective comparative study (25 patients in each arm). Follow-up was conducted at 3 and 6 months, comparing percutaneous screw fixation to bracing for Magerl type A3 fractures. Patients had better satisfaction with surgery. Another study included patients with A1 and A2 fractures (including nonburst fractures) and concluded that outcomes with surgery were superior.¹⁶

Wood conducted a long-term follow-up study of patients previously studied in 2003.^{14,17} This study included a small number of patients, who were consecutively assigned and randomized to operative treatment or nonoperative treatment, but the method of randomization was not reported. Therefore, the study was downgraded to level II. There was also a lack of blinding,

small cohorts, and no power analysis was performed. The study was further downgraded to level III, showing an advantage to nonoperative care over surgery.

Question 2

Does the surgical treatment of nonburst fractures of the thoracic and lumbar spine improve clinical outcomes compared to nonoperative treatment?

Recommendation 2

There is insufficient evidence to recommend for or against the use of surgical intervention for nonburst thoracolumbar fractures. It is recommended that the decision to pursue surgery for such fractures be at the discretion of the treating physician.

Strength of Recommendation: Grade Insufficient

Level IV Evidence

None of the studies examined met the criteria for inclusion. The literature search located a number of retrospective comparative studies of surgical versus nonsurgical treatment of thoracic and lumbar fractures.¹⁸⁻²⁰ The studies included patients with varying degrees of neurologic deficits and/or instability. In addition, fractures that the authors considered “unstable” underwent surgery. These patients were not consistently classified by any standard manner to deem them “unstable,” thereby calling into question the possible heterogeneity of the comparison groups.

One study of patients presenting with paraplegia compared nonoperative treatment to laminectomy with or without fusion and to patients receiving Harrington instrumentation. The authors concluded that laminectomy was inferior to either Harrington instrumentation or conservative treatment, and that pain complaints were worse in the laminectomy group and in the

conservatively treated group.²¹ An additional key issue that caused these papers to be downgraded is that many older retrospective comparative studies involved patients who underwent surgical procedures using outdated instrumentation (e.g., Harrington rod fixation) and noncurrent diagnostic imaging (e.g., plain x-ray). Therefore, the relevance of these studies in the modern era is questionable. As a result, unfortunately, adequate studies in this area are currently lacking.

Future Research

As this literature review has demonstrated, there is a need for further research regarding operative versus nonoperative treatment of patients with burst or nonburst thoracolumbar fractures. With respect to burst fractures, given the rapid evolution of imaging, a focus on the posterior ligamentous complex (PLC) in neurologically intact patients should be more thoroughly investigated. An RCT of neurologically intact patients with and without disruption of the PLC may help to more definitively answer this question.

Heterogeneity of thoracolumbar injuries has hindered the interpretation of the literature with regard to nonburst fractures, as no high-quality randomized controlled trials exist in this area. It may prove to be too challenging ethically to try to perform such studies. A trial specifically dedicated to classic bony Chance fractures, for example, could shed some light on this subject, but in all probability, it may not be feasible. Likewise, comparing the likelihood of developing posttraumatic cord tethering and/or syringomyelia in spinal cord injury patients who received either operative or nonoperative treatment would be of interest. It may prove that prospective

registries of patients treated for various nonburst thoracolumbar fractures provide the greatest amount of information to guide treatment decisions.

Conclusions

Most surgeons today use surgical intervention for patients with thoracolumbar fractures who present with neurologic deficits, owing to assumed instability, and the desire to restore alignment, decompress neural elements, and stabilize the spine to reduce pain, prevent deformity, and allow for early mobilization. There is little research available for the neurologically intact patient. Relatively high-quality studies have been performed for patients with burst fractures, but have yielded conflicting conclusions, such that either surgery or nonoperative treatment remain viable options. Unfortunately, high-quality studies have yet to be performed to investigate which option results in the best outcomes for nonburst fractures. As such, it must be left to the discretion of the treating surgeon as to which treatment option is best for a given patient.

Potential Conflicts of Interest

The task force members were required to report all possible conflicts of interest (COIs) prior to beginning work on the guideline, using the COI disclosure form of the AANS/CNS Joint Guidelines Committee, including potential COIs that are unrelated to the topic of the guideline. The CNS Guidelines Committee and Guideline Task Force Chairs reviewed the disclosures and either approved or disapproved the nomination. The CNS Guidelines Committee and Guideline Task Force Chairs are given latitude to approve nominations of Task Force members with possible conflicts and address this by restricting the writing and reviewing privileges of that

person to topics unrelated to the possible COIs. The conflict of interest findings are provided in detail in the companion [introduction and methods manuscript](#).

Disclaimer of Liability

This clinical systematic review and evidence-based guideline was developed by a multidisciplinary physician volunteer task force and serves as an educational tool designed to provide an accurate review of the subject matter covered. These guidelines are disseminated with the understanding that the recommendations by the authors and consultants who have collaborated in their development are not meant to replace the individualized care and treatment advice from a patient's physician(s). If medical advice or assistance is required, the services of a competent physician should be sought. The proposals contained in these guidelines may not be suitable for use in all circumstances. The choice to implement any particular recommendation contained in these guidelines must be made by a managing physician in light of the situation in each particular patient and on the basis of existing resources.

Disclosures

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Appendix I. Literature Searches

Search Strategies

PubMed

1. Lumbar vertebrae [MeSH] OR Thoracic vertebrae [MeSH]
2. Spinal Injuries [MeSH] OR Spinal Cord Injuries [MeSH]
3. #1 AND #2
4. Thoracolumbar [TIAB] OR thoraco-lumbar [TIAB] OR thoraco lumbar [TIAB] OR burst [Title]
5. Injur* [TIAB] OR trauma* [TIAB] OR fractur* [TIAB] OR dislocation* [TIAB]
6. #4 AND #5
7. Lumbar vertebrae/injuries [MeSH] OR Thoracic vertebrae/injuries [MeSH] (3150 results)
8. #3 OR #6 OR #7
9. Braces [MeSH] OR Casts, Surgical [MeSH] OR Bed rest [MeSH] OR Physical Therapy Modalities[MeSH] OR Rehabilitation [MeSH] OR rehabilitation[SH]
10. Drug therapy[sh] OR Analgesics[mh] OR analgesics[pa] OR "Muscle Relaxants, Central"[mh] OR Steroids[mh] OR Glucocorticoids[mh] OR Glucocorticoids[pa]
11. Brace OR braces OR bracing OR orthos* OR orthotic* OR cast OR casts OR casting OR TSLO [TIAB]
12. Bed rest OR bedrest OR “physical therapy” OR physiotherap* OR rehabilitation [TIAB]
13. NSAID[tiab] OR opioid*[tiab] OR (muscle[tiab] AND relax*[tiab]) OR acetaminophen[tiab] OR naproxen[tiab] OR ibuprofen[tiab] OR hydrocodone[tiab] OR oxycodone[tiab] OR oxycontin[tiab] OR morphine[tiab] OR benzodiazepine*[tiab] OR tramadol[tiab] OR steroid*[tiab] OR prednisone[tiab] OR solumedrol[tiab] OR fentanyl[tiab] OR lidoderm[tiab] OR aspirin[tiab] OR codeine[tiab] OR drug* [TIAB] OR medication* [TIAB]
14. (Conservative[tiab] OR non-operat*[tiab] OR nonoperat*[tiab] OR non-surg*[tiab] OR nonsurg*[tiab]) AND (treatment*[tiab] OR therap*[tiab] OR management[tiab])
15. #9 OR #10 OR #11 OR #12 OR #13 OR #14
16. Orthopedic Procedures [MeSH] OR Neurosurgical Procedures [MeSH] OR Decompression, surgical [MeSH] OR Orthopedic Fixation Devices [MeSH] OR surgery [SH] OR instrumentation [SH]
17. surgery[tiab] OR surgical[tiab] OR operati*[tiab] OR repair*[tiab] OR stabiliz*[tiab] OR fixation[tiab] OR reconstruct*[tiab] OR fusion[tiab] OR decompress*[tiab] OR spondylodes*[tiab] OR spondylosyndes*[tiab] OR arthrodes*[tiab] OR laminectomy[tiab] OR discectomy[tiab] OR discectomy OR “percutaneous vertebral augmentation”[tiab] OR “bone screw”[tiab] OR "bone screws"[tiab] OR “bone plate”[tiab] OR "bone plates"[tiab] OR “pedicle screw”[tiab] OR "pedicle screws"[tiab]
18. #16 OR #17
19. #8 AND (#15 AND #18)
20. (animal [MeSH] NOT human [MeSH]) OR cadaver [MeSH] OR cadaver* [Titl] OR comment [PT] OR letter [PT] OR editorial [PT] OR addresses [PT] OR news [PT] OR “newspaper article” [PT] OR case reports [PT]
21. #19 NOT #20

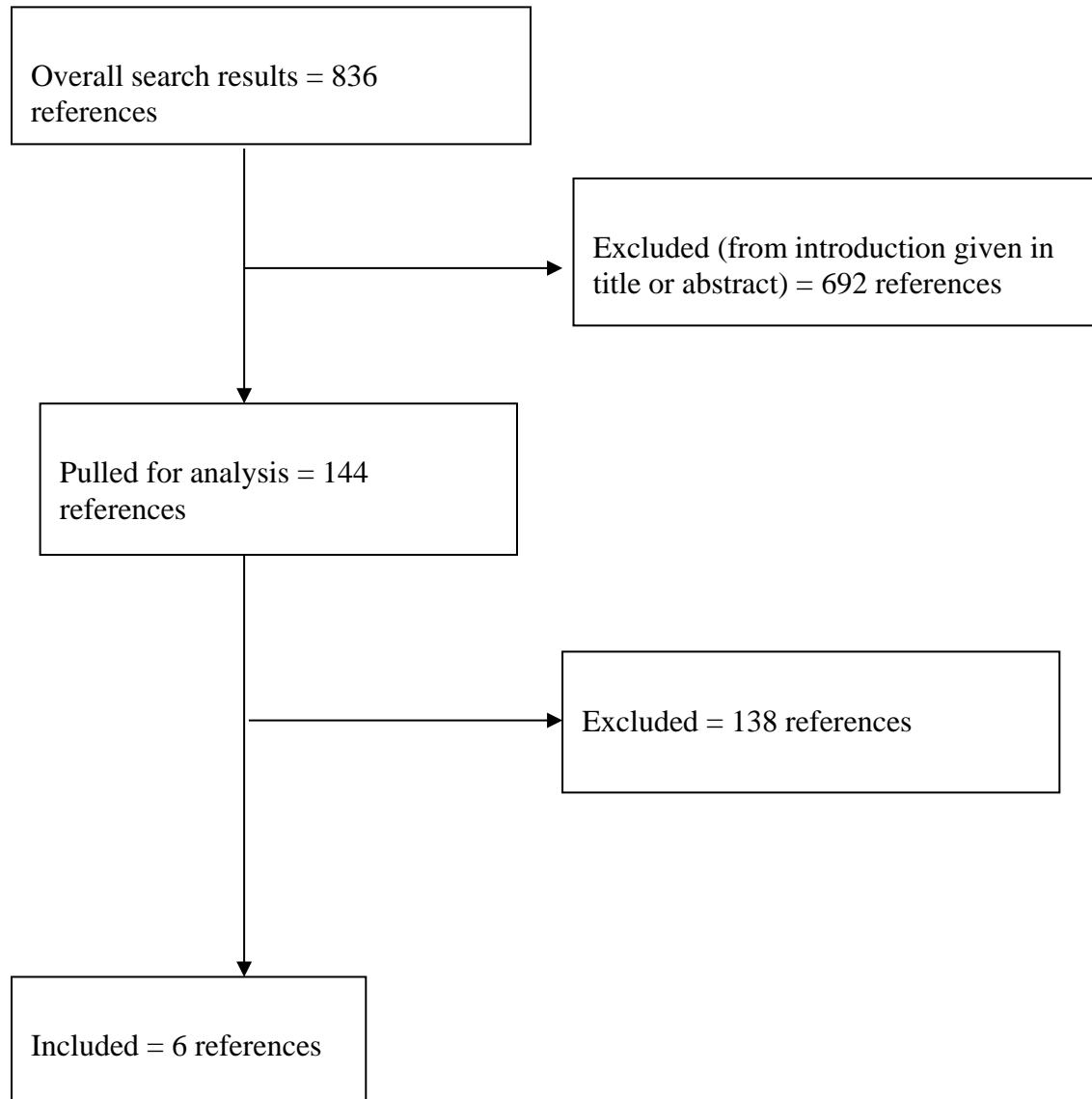
22. osteoporosis [MH] OR osteoporotic fractures [MH] OR osteopor* [TITLE] OR spinal neoplasms [MH] OR tumor* [TITLE] OR tumour* [TITLE] OR malignan* [TITLE]
23. #21 NOT #22
24. #23 AND English [Lang]

Cochrane Library

1. Lumbar vertebrae: MeSH descriptor, explode all trees
2. Thoracic vertebrae: MeSH descriptor, explode all trees
3. #1 OR #2
4. Spinal Injuries: MeSH descriptor
5. Spinal Cord Injuries: MeSH descriptor
6. #4 OR #5
7. #3 AND #6
8. (Thoracolumbar OR thoraco-lumbar OR thoraco lumbar OR burst) NEAR/4 (Injur* OR trauma* OR fractur* OR dislocation*):ti,ab,kw
9. Lumbar vertebrae/injuries: MeSH descriptor, explode all trees
10. Thoracic vertebrae/injuries: MeSH descriptor, explode all trees
11. #9 OR #10
12. #7 OR #8 OR #11
13. mh osteoporosis or mh osteoporotic fractures or mh spinal neoplasms
14. osteopor* or tumor* or malignan*:ti
15. #13 OR #14
16. #12 NOT #15

Appendix II. Article Inclusions and Exclusions

Included and Excluded Articles Flowchart



Appendix III. Rating Evidence Quality

Levels of Evidence for Primary Research Question^a

Types of studies				
	Therapeutic studies – Investigating the results of treatment	Prognostic studies – Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic studies – Investigating a diagnostic test	Economic and decision analyses – Developing an economic or decision model
Level I	<ul style="list-style-type: none"> • High-quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals • Systematic review^b of level I RCTs (and study results were homogenous^c) 	<ul style="list-style-type: none"> • High-quality prospective study^d (all patients were enrolled at the same point in their disease with $\geq 80\%$ follow-up of enrolled patients) • Systematic review^b of level I studies 	<ul style="list-style-type: none"> • Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference “gold” standard) • Systematic review^b of level I studies 	<ul style="list-style-type: none"> • Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses • Systematic review^b of level I studies
Level II	<ul style="list-style-type: none"> • Lesser quality RCT (e.g., $\leq 80\%$ follow-up, no blinding, or improper randomization) • Prospective^d comparative study^e • Systematic review^b of level II studies or level I studies with inconsistent results 	<ul style="list-style-type: none"> • Retrospective^f study • Untreated controls from an RCT • Lesser quality prospective study (e.g., patients enrolled at different points in their disease or $\leq 80\%$ follow-up) • Systematic review^b of level II studies 	<ul style="list-style-type: none"> • Development of diagnostic criteria on consecutive patients (with universally applied reference “gold” standard) • Systematic review^b of level II studies 	<ul style="list-style-type: none"> • Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses • Systematic review^b of level II studies

Level III	<ul style="list-style-type: none"> • Case control study^g • Retrospective comparative study^e • Systematic review^b of level III studies 	<ul style="list-style-type: none"> • Case control study^g 	<ul style="list-style-type: none"> • Study of non consecutive patients; without consistently applied reference “gold” standard • Systematic review^b of level III studies 	<ul style="list-style-type: none"> • Analyses based on limited alternatives and costs; and poor estimates • Systematic review^b of level III studies
Level IV	Case series ^h	Case series	<ul style="list-style-type: none"> • Case-control study • Poor reference standard 	<ul style="list-style-type: none"> • Analyses with no sensitivity analyses

RCT, Randomized controlled trial.

^aA complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.

^bA combination of results from ≥ 2 previous studies.

^cStudies provided consistent results.

^dStudy was started before the first patient enrolled.

^ePatients treated one way (e.g., instrumented arthrodesis) compared with a group of patients treated in another way (e.g., unsinstrumented arthrodesis) at the same institution.

^fThe study was started after the first patient enrolled.

^gPatients identified for the study based on their outcome, called “cases” (e.g., pseudoarthrosis) are compared to those who did not have outcome, called “controls” (e.g., successful fusion).

^hPatients treated one way with no comparison group of patients treated in another way.

Appendix IV. Linking Levels of Evidence to Grades of Recommendation

Grade of Recommendation	Standard Language	Levels of Evidence	
A	Recommended	Two or more consistent level I studies	
B	Suggested	One level I study with additional supporting level II or III studies	Two or more consistent level II or III studies
C	Is an option	One level I, II, or III study with supporting level IV studies	Two or more consistent level IV studies
Insufficient (insufficient or conflicting evidence)	Insufficient evidence to make recommendation for or against	A single level I, II, III, or IV study without other supporting evidence	>1 study with inconsistent findings ^a

^aNote that in the presence of multiple consistent studies, and a single outlying, inconsistent study, the Grade of Recommendation will be based on the level of the consistent studies.

Appendix V. Criteria Grading the Evidence

The task force used the criteria provided below to identify the strengths and weaknesses of the studies included in this guideline. Studies containing deficiencies were downgraded one level (no further downgrading allowed, unless so severe that study had to be excluded). Studies with no deficiencies based on study design and contained clinical information that dramatically altered current medical perceptions of topic were upgraded.

1. Baseline study design (i.e., therapeutic, diagnostic, prognostic) determined to assign initial level of evidence.
2. Therapeutic studies reviewed for following deficiencies:
 - Failure to provide a power calculation for an RCT;
 - High degree of variance or heterogeneity in patient populations with respect to presenting diagnosis/demographics or treatments applied;
 - <80% of patient follow-up;
 - Failure to utilize validated outcomes instrument;
 - No statistical analysis of results;
 - Cross over rate between treatment groups of >20%;
 - Inadequate reporting of baseline demographic data;
 - Small patient cohorts (relative to observed effects);
 - Failure to describe method of randomization;
 - Failure to provide flowchart following patients through course of study (RCT);
 - Failure to account for patients lost to follow-up;
 - Lack of independent post-treatment assessment (e.g., clinical, fusion status, etc.);
 - Utilization of inferior control group:
 - Historical controls;
 - Simultaneous application of intervention and control within same patient.
 - Failure to standardize surgical/intervention technique;
 - Inadequate radiographic technique to determine fusion status (e.g., static radiographs for instrumented fusion).
3. Methodology of diagnostic studies reviewed for following deficiencies:
 - Failure to determine specificity and sensitivity;
 - Failure to determine inter- and intraobserver reliability;
 - Failure to provide correlation coefficient in the form of kappa values.
4. Methodology of prognostic studies reviewed for following deficiencies:
 - High degree of variance or heterogeneity in patient populations with respect to presenting diagnosis/demographics or treatments applied;
 - Failure to appropriately define and assess independent and dependent variables (e.g., failure to use validated outcome measures when available).

Appendix VI. Evidence Tables

Author, Year	Level of Evidence	Task Force Conclusions Relative to Question and Rationale for Evidence Grading
Landi et al, ¹⁵ 2014	III	This paper provides evidence that patients had better satisfaction with percutaneous screw fixation surgery. Retrospective comparative study (25 patients in each arm). Follow-up was conducted at 3 and 6 months, comparing percutaneous screw fixation to bracing for Magerl type A3 fractures
Medici et al, ¹⁶ 2014	III	This paper provides evidence that patients who had percutaneous fixation had better functional outcomes than patients treated nonoperatively with a 3-point orthopedic corset. This study included patients with A1 and A2 fractures (including nonburst). This study is a level III study; authors are assuming retrospective. This is the only study that includes nonburst fractures
Shen et al, ¹² 2001	II	This paper provides evidence that short-segment posterior fixation provides partial kyphosis correction and earlier pain relief, but the functional outcome at 2 years is similar. This is a prospective study, not an RCT. This study was assigned a level II, with equivalent outcomes
Siebenga et al, ¹³ 2006	II	This paper provides evidence that patients with a type A3 thoracolumbar spine fracture without neurologic deficit should be treated by short-segment posterior stabilization. This study included 34 patients and concluded the opposite of what has been shown previously, with longer follow-up (4-year follow-up), but at a lower rate. This is an RCT but was downgraded from level I to II because of the small number of patients
Wood et al, ¹⁴ 2003	II	This paper provides evidence that operative treatment of patients with a stable thoracolumbar burst fracture and normal findings on the neurological examination provided no major long-term advantage compared with nonoperative treatment. This study was downgraded from level I to II, showing no difference between operative vs. nonoperative patients

Wood et al, ¹⁷ 2015	III	<p>This paper provides evidence that while early analysis (4 years) revealed few significant differences between the 2 groups, at long-term follow-up (16–22 years), those patients with a stable burst fracture who were treated nonoperatively reported less pain and better function compared with those who were treated surgically. This study is an RCT, but guideline authors question if the loss of more patients to follow-up can skew the data. It includes a small number of patients, who were consecutively assigned and randomized to operative treatment or nonoperative treatment, but the method of randomization was not reported. Therefore, the study should be downgraded from level I to level II. There was also a lack of blinding, small cohorts, and no power analysis was performed. Therefore, the study was further downgraded to level III, showing an advantage to nonoperative care</p>
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RCT = randomized controlled trial.