

**Table 1. Summary of Recommendations for Evaluating and Managing Low Back Disorders**

Clinical Measure	Treatment with Evidence Rating/Recommendation Level		
	Recommended	No Recommendation	Not Recommended
<b>Surgical Considerations</b>	<p>Lumbar discectomy for patients with radiculopathy due to ongoing nerve root compression who continue to have significant pain/functional limitation after 4 to 6 weeks and appropriate conservative treatment (B)</p> <p>Decompressive surgery for symptomatic spinal stenosis intractable to conservative management (B)</p> <p>Lumbar fusion for isthmic spondylolisthesis (C)</p> <p>Lumbar fusion for degenerative spondylolisthesis (C)</p> <p>If patient having third lumbar discectomy on same disc, spine fusion at time of discectomy is an option (I)</p>	<p>Vertebroplasty for highly select patients with low back or thoracic pain due to unusual vertebral compression fractures – e.g., more than 2 compression fractures or pathological fractures (I)</p> <p>Kyphoplasty for patients with low back or thoracic pain due to vertebral compression fractures (I)</p>	<p>Percutaneous discectomy (nucleoplasty), laser discectomy, and discoblation therapy for any back or radicular pain syndrome (B)</p> <p>Discectomy for acute, subacute, or chronic LBP without radiculopathy (B)</p> <p>Lumbar fusion for spinal stenosis unless concomitant instability or deformity proven (C)</p> <p>Lumbar fusion for radiculopathy from disc herniation or chronic LBP after lumbar discectomy (C)</p> <p>Lumbar fusion for chronic non-specific LBP (B)</p> <p>Artificial disc replacement for chronic non-specific LBP or other spinal pain syndrome (I)</p> <p>Sacroiliac joint fusion surgery and other sacroiliac joint surgical procedures for any LBP condition (I)</p> <p>Spinal cord stimulators for acute, subacute, chronic LBP, radicular pain, failed back surgery syndrome (I)</p> <p>Adhesiolysis for acute, subacute, chronic LBP, spinal stenosis, or radicular pain syndromes (I)</p> <p>Vertebroplasty for routine treatment of patients with low back or thoracic pain due to vertebral compression fractures (A)</p>
<b>Rehabilitation/ Behavioral/ Education</b>	<p>Chronic pain management or functional restoration program for chronic pain (I)</p> <p>Chronic pain management or functional restoration program for subacute LBP (I)</p> <p>Work conditioning/hardening programs for chronic LBP (C)</p> <p>Work conditioning/hardening programs for subacute LBP (I)</p> <p>Participatory ergonomic programs for highly select subacute or chronic LBP (C)</p>		<p>Back school for acute LBP (I)</p> <p>Back school/education for preventing LBP (C)</p> <p>Cognitive behavioral therapy for acute LBP (I)</p> <p>Chronic pain management or functional restoration program for acute spinal disorders (I)</p> <p>Work conditioning and work hardening programs for acute LBP (I)</p> <p>Biofeedback for acute or subacute LBP (I)</p>

<b>Rehabilitation/ Behavioral/ Education</b> <i>(cont.)</i>	<p>Biofeedback for select chronic LBP as component of an interdisciplinary approach (I)</p> <p>Multidisciplinary rehabilitation programs combined with aerobic exercise and other conditioning exercise for chronic LBP (C)</p> <p>Multidisciplinary rehabilitation program with participatory ergonomics team for subacute or chronic LBP with lost-time injuries (C)</p> <p>Smoking cessation and weight loss programs to prevent LBP (I)</p> <p>FABT for acute, subacute, or chronic LBP (B)</p> <p>Back school/education for select chronic LBP and chronic radicular pain syndromes (B)</p> <p>Cognitive behavioral therapy as component of interdisciplinary program for chronic LBP; subacute if combined with other therapies (C)</p>		<p>Multidisciplinary rehabilitation program with primary focus on LBP interventions (I)</p>
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**Table 2. Summary of Recommendations by Low Back Disorder**

Low Back Disorder	Treatment with Evidence Rating/Recommendation Level		
	Recommended	No Recommendation	Not Recommended
<b>Spinal Stenosis</b>	<p>Cytoprotective medications if contraindications for NSAIDs (C)</p> <p>Acetaminophen if contraindications for NSAIDs (C)</p> <p>Discuss risks/benefits of NSAID therapy with patients with known or multiple risk factors for cardiovascular disease (I)</p> <p>Acetaminophen or aspirin as 1st-line therapy for patients with known or multiple risk factors for cardiovascular disease (A)</p> <p>Gabapentin for severe neurogenic claudication with limited walking distance from spinal stenosis (C)</p> <p>Opioid trial – both function and pain must improve to continue (I)</p>	<p>Camphora molmol, Maleluca alternifolia, Angelica sinensis, Aloe vera, Thymus officinalis, Menthe peperita, Arnica Montana, Curcuma longa, Tancaetum parthenium, Zingiber officinalis (I)</p> <p>Shoe insoles (I)</p> <p>Mattress firmness (I)</p> <p>Other optimal sleeping surfaces – e.g., bedding, water beds, hammocks (I)</p> <p>Infrared therapy for home use (I)</p> <p>Ultrasound (I)</p> <p>Botulinum injections (I)</p>	<p>Willow bark (salix) (I)</p> <p>Spiroflor (I)</p> <p>Complementary or alternative treatments or dietary supplements, etc., other than those discussed in chapter (I)</p> <p>Bed rest (I)</p> <p>Shoe insoles and lifts except if leg length discrepancy &gt;2 cm (I)</p> <p>Reflexology (I)</p> <p>Shoe insoles and lifts for primary prevention (C)</p> <p>Lumbar supports (C)</p> <p>Magnets (I)</p> <p>Routine use of cryotherapies in health care provider offices or home use of high-tech device (I)</p>

<p><b>Spinal Stenosis (cont.)</b></p>	<p>Alteration of sleep posture (I)</p> <p>Epidural glucocorticosteroid injections as 2nd-line treatment of acute flare-ups (I)</p> <p>Decompressive surgery for symptomatic spinal stenosis that is intractable to conservative management (B)</p>		<p>Diathermy (C)</p> <p>Low-level laser therapy (I)</p> <p>Mechanical devices for administering massage (C)</p> <p>Interferential therapy (C)</p> <p>Taping and kinesiotaping (I)</p> <p>Myofascial release (I)</p> <p>High voltage galvanic (I)</p> <p>Iontophoresis (I)</p> <p>Adjustments/manipulation of neck/cervical spine or areas outside lumbopelvic region (I)</p> <p>Acupuncture (I)</p> <p>Radiofrequency neurotomy, neurotomy, facet rhizotomy (C)</p> <p>IDET (I)</p> <p>Lumbar fusion unless concomitant instability or deformity proven (C)</p> <p>Artificial disc replacement (I)</p> <p>Sacroiliac joint fusion surgery and other sacroiliac joint surgical procedures (I)</p> <p>Percutaneous discectomy (nucleoplasty), laser discectomy, and disc coblation therapy (B)</p> <p>Adhesiolysis (I)</p>
<p><b>Spinal Fractures</b></p>	<p>Bed rest for unstable spinal fractures (I)</p> <p>NSAIDs (I)</p> <p>Acetaminophen for patients with contraindications for NSAIDs (C)</p> <p>Gabapentin for perioperative pain management (A)</p> <p>Limited use (2 to 3 weeks) of opioids with longer periods for more severe fractures (C)</p> <p>Skeletal muscle relaxants as 2nd- or 3rd-line agents for more severe pain (I)</p>	<p>Gabapentin for chronic radicular pain syndromes (I)</p> <p>Mattress firmness (I)</p> <p>Other optimal sleeping surfaces (e.g., bedding, water beds, hammocks) (I)</p> <p>Infrared therapy for home use (I)</p> <p>Ultrasound (I)</p> <p>Neuroreflexotherapy (I)</p> <p>Botulinum injections (I)</p>	<p>Bed rest for stable spinal fractures (I)</p> <p>Vitamins (I)</p> <p>Willow bark (salix) (I)</p> <p>Spiroflor (I)</p> <p>Complementary or alternative treatments or dietary supplements, etc., other than those discussed in chapter (I)</p> <p>Reflexology (I)</p> <p>Lumbar supports (I)</p> <p>Magnets (I)</p>

<b>Spinal Fractures (cont.)</b>	<p>Alteration of sleep posture (I)</p> <p>Gradual introduction of aerobic exercises during and to facilitate recovery (I)</p> <p>Strengthening exercises after aerobic exercises instituted and after healed (I)</p> <p>Stretching exercises to regain normal range of motion (I)</p> <p>Inclusion of FABT during course of rehabilitation (I)</p>	<p>Vertebroplasty for highly select patients with low back or thoracic pain due to unusual vertebral compression fractures – e.g., more than 2 compression fractures or pathological fractures (I)</p> <p>Kyphoplasty for patients with low back or thoracic pain due to vertebral compression fractures (I)</p>	<p>Routine use of cryotherapies in health care provider offices or home use of high-tech device (I)</p> <p>Diathermy (I)</p> <p>Low-level laser therapy (I)</p> <p>Mechanical devices for administering massage (I)</p> <p>Interferential therapy (I)</p> <p>Taping and kinesiotaping (I)</p> <p>Myofascial release (I)</p> <p>High-voltage galvanic (I)</p> <p>Iontophoresis (I)</p> <p>Adjustments/manipulation (I)</p> <p>Acupuncture (I)</p> <p>Aggressive stretching (I)</p> <p>Strengthening of abdominal muscles (I)</p> <p>Vertebroplasty as a routine treatment of patients with low back or thoracic pain due to vertebral compression fractures (A)</p>
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**Strength-of-Evidence Ratings:**

A = **Strong evidence-base:** Two or more high-quality studies.\*

B = **Moderate evidence-base:** At least 1 high-quality study/multiple moderate-quality studies\*\* relevant to topic/working population.

C = **Limited evidence-base:** At least one study of moderate quality.

I = **Insufficient Evidence:** Evidence is insufficient or irreconcilable.

\*For therapy and prevention, RCTs with narrow confidence intervals and minimal heterogeneity. For diagnosis and screening, cross sectional studies using independent gold standards. For prognosis, etiology or harms, prospective cohort studies with minimal heterogeneity.

\*\*For therapy and prevention, well-conducted cohort studies. For prognosis, etiology or harms, well-conducted retrospective cohort studies or untreated control arms of RCTs.

## Vertebroplasty

Vertebroplasty, first reported in 1987,<sup>802</sup> involves using image guidance to inject polymethylmethacrylate within the vertebral body, in order to stabilize vertebral fractures caused by osteoporosis, vertebral osteonecrosis, or malignancies of the spinal column.<sup>803-809</sup> This procedure is most common among elderly osteoporotic patients who have delayed healing of compression fractures of the vertebral body(ies),<sup>810</sup> but it is sometimes performed on younger patients with acute vertebral fractures due to osteoporosis. A work-related minor trauma may be the event that caused the osteoporotic pathologic fracture.

1. *Recommendation: Vertebroplasty for Low Back or Thoracic Pain Due to Vertebral Compression Fractures*  
**Vertebroplasty is strongly not recommended as a routine treatment for patients with low back or thoracic pain due to vertebral compression fractures.**<sup>811,812</sup>

*Strength of Evidence – Strongly Not Recommended, Evidence (A)*

2. *Recommendation: Vertebroplasty for Select Patients with Low Back or Thoracic Pain Due to Vertebral Compression Fractures*

**There is no recommendation for or against the use of vertebroplasty for treatment of highly select patients with low back or thoracic pain due to unusual vertebral compression fractures.**

*Indications* – Patients who are not included in the two available high-quality trials. These include patients who have had fractures despite bisphosphonate therapy, pathologic fractures due to neoplasms in the vertebral body, or multiple simultaneous compression fractures (three or more). Candidates for vertebroplasty should have these types of unusual vertebral body compression fractures, should generally have severe pain, passage of at least 2 months, and failure of other treatment options including medical management.

*Strength of Evidence – No Recommendation, Insufficient Evidence (I)*

### *Rationale for Recommendations*

There are two recent (2009) high-quality, sham-controlled RCTs available that evaluated the efficacy of vertebroplasty and both failed to find any significant improvements in the patients who underwent vertebroplasty compared with a sham procedure.<sup>811,812</sup> These results are in contrast with other low-quality studies that had reported pain relief and other functional improvements that had appeared promising.<sup>806,813-819</sup> There is one other quality trial which reported pain relief and increased mobility; however, that trial is of lower quality, was short term (2 weeks), and had a substantially lower sample size than both of the 2009 studies, and appears biased against pain treatment.<sup>820</sup> In addition, substantial complications occur with this procedure including deaths.<sup>806,811,821,822</sup> The results of the two high-quality RCTs indicate that vertebroplasty is strongly not recommended for nearly all patients with vertebral compression fractures. It remains unclear whether there are highly selected unusual patients – such as severely affected patients, patients with 3 or more simultaneous compression fractures, or patients with pathologic fractures due to neoplasms<sup>823</sup> – who were outside the scope of these two quality trials, who might still derive benefit from this procedure. This procedure is invasive, has complications,<sup>824,825</sup> and is costly. Therefore, vertebroplasty is not recommended other than for highly select patients who have failed other interventions (including quality medical management) and for whom there are no other options available, whose significant pain is not resolving, and especially those for whom bisphosphonate therapy has failed.

### *Evidence for the Use of Vertebroplasty*

There are 2 high-quality and 1 moderate-quality RCTs incorporated in this analysis for vertebroplasty. There are 3 systematic reviews in the Appendix.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
<b>Vertebroplasty vs. Sham</b>						
Buchbinder 2009 RCT	9.5	N = 78  1 to 2 painful compression fractures up to 12 months old	Vertebroplasty vs. sham (blunt needle)	Overall pain score changes (1 week/1 month/3 months/6 months): vertebroplasty (1.5±2.5/2.3±2.6/2.6±2.9/2.4±3.3) vs. placebo (2.1±2.8/1.7±3.3/1.9±3.3/2.1±3.3), all p >0.05. Perceived status at 1 week: vertebroplasty 6 (16%) better, 5 (14%) worse vs. placebo 13 (35%) better, 1 (3%) worse; 1 month vertebroplasty 12 (34%) better, 2 (6%) worse vs. placebo 9 (24%) better, 9 (24%) worse. At 6 months, vertebroplasty 16 (46%) better, 7 (20%) worse vs. sham 15 (42%) better and 5 (14%) worse.	“We found no beneficial effect of vertebroplasty as compared with a sham procedure in patients with painful osteoporotic vertebral fractures, at 1 week or at 1, 3, or 6 months after treatment.”	Co-interventions unclear, as noted usual care. Overall 141/468 declined to participate. Data suggest no benefit.
Kallmes 2009 RCT	9.0	N = 131  1 to 3 painful compression fractures T4-L5 up to 12 months old	Vertebroplasty vs. control group (sham, no needle)	At 14 days, 63% vertebroplasty vs. 51% controls correctly guessed assignment; 1 patient hospitalized with thecal sac injury. Rolland-Morris Disability scores (baseline/3 days/14 days/1 month): vertebroplasty (16.6±3.8/13.0±5.2/12.4±5.8/12.0±6.3) vs. sham (17.5±4.1/12.5±5.5/12.3±5.9/13.0±6.4), p = 0.30, 0.35, 0.49. Pain intensity scores: vertebroplasty (6.9±2.0/4.2±2.8/4.3±2.9/3.9±2.9) vs. sham (7.2±1.8/3.9±2.9/4.5±2.8/4.6±3.0), p = 0.37, 0.77, 0.19. Post-hoc analyses found no significant differences by pain duration (<13 weeks, 14 to 26 weeks, 27 to 52 weeks).	“Improvements in pain and pain-related disability associated with osteoporotic compression fractures in patients treated with vertebroplasty were similar to the improvements in a control group.”	Co-interventions not mentioned but appear likely; 300 of 1682 exclusions were declinations. Allowed cross-over after 1 month for both groups [8 (12%) of vertebroplasty vs. 27 (43%) controls crossed over], precluding assessment of long-term effects. Data suggest no benefit.
<b>Vertebroplasty vs. Pain Treatment</b>						
Voormolen 2007 RCT	5.5	N = 34  compression fractures and “refractive to medical therapy for at least 6 weeks and no longer than 6 months.”	Vertebroplasty vs. pain management (NSAID or opioid). Study terminated early as nearly all pain management patients asked to be treated with vertebroplasty after 2 weeks (suggesting bias).	VAS pain scores (baseline/Day 1/2 weeks): PV 7.1/4.7/4.9 vs. OPM 7.6/7.1/6.4. Analgesic use: PV 1.9/1.1/1.2 vs. OPM 1.7/2.5/2.6.	“Pain relief and improvement of mobility, function, and stature after PV is immediate and significantly better in the short term compared with OPM treatment.”	Short-term 2-week trial after which able to crossover. Small sample size; some baseline differences. Requirement to have at least 6 weeks prior treatment (likely including pain management) appears to bias in favor of other intervention as pain management would then be “more of the same.”

## Kyphoplasty

Kyphoplasty, first introduced in 1998, has been used similarly to vertebroplasty to restore vertebral body height and improve sagittal alignment of the spine.<sup>826,827</sup> Kyphoplasty involves injection of polymethylmethacrylate within a cavity in the vertebral body that has been created by percutaneously insertion of a balloon through the involved pedicle(s).<sup>828</sup> It has been suggested that kyphoplasty may be appropriate as a prophylactic procedure.<sup>829</sup>

*Recommendation: Kyphoplasty for Low Back and Thoracic Pain Due to Vertebral Compression Fractures*

**There is no recommendation for or against the use of kyphoplasty as a treatment for patients with low back or thoracic pain due to vertebral compression fractures.**

*Indications* – Vertebral body compression fractures among patients with severe pain; patients who have had fractures despite bisphosphonate therapy may also be candidates.

*Strength of Evidence* – **No Recommendation, Insufficient Evidence (I)**

### *Rationale for Recommendations*

There are no quality studies comparing kyphoplasty with a sham procedure. There is one moderate-quality study comparing kyphoplasty with an unstructured, unblinded, non-interventional control that included cancer patients.<sup>830,831</sup> That study also differentially utilized passive treatments between the two groups, such as bed rest and braces, that may have confounded the results. The other moderate-quality study compared two types of cement and found the calcium phosphate cement to be inferior for burst fractures.<sup>828</sup> There are comparative clinical trials and other low-quality studies suggesting benefit.<sup>832,833,834</sup> These have been compiled into meta-analyses with a conclusion of efficacy (as well as efficacy of vertebroplasty).<sup>835,836,837</sup> Yet, as kyphoplasty is similar to vertebroplasty, and two high-quality, sham-controlled trials for vertebroplasty are now reported documenting a lack of benefit,<sup>811,812</sup> and despite the Wardlaw study which included patients with neoplasia, it appears reasonable to assume the same lack of benefit will eventually be shown for kyphoplasty for treatment of non-cancer patients. It remains unclear whether there are highly selected, unusual patients such as those severely affected, patients with 3 or more simultaneous compression fractures, or patients with pathologic fractures due to neoplasms,<sup>823</sup> who may derive benefit from this procedure. Kyphoplasty is invasive, has complications, and is costly. There is no recommendation for or against kyphoplasty other than for highly selected patients who have failed other interventions (including quality medical management), and in whom there are no other options available, whose significant pain is not resolving, and especially those for whom bisphosphonate therapy has failed.

### *Evidence for the Use of Kyphoplasty*

There are 2 moderate-quality RCT incorporated in this analysis for kyphoplasty. There are 3 systematic reviews in the Appendix.

Author/Year Study Type	Score (0-11)	Sample Size	Comparison Group	Results	Conclusion	Comments
<b>Comparison of Two Methods of Kyphoplasty</b>						
Blattert 2009  RCT	4.5	N = 56  osteoporotic with 60 fractures (excluded those over age 65)	Kyphoplasty with poly- methylmeth- acrylate (PMMA) vs. calcium phosphate cement (CaP)	VAS pain ratings (pre/1 year): A1.3 fractures CaP (7.9/2.1) vs. PMMA (8.2/2.3). A3 fractures CaP (8.2/7.4) vs. PMMA (8.1/2.5).	“The routine use of the CaP tested is not currently recommended for kyphoplasty.”	Baseline data not well described. Long-term dropout rate unclear. Results worse for CaP A3 fractures.  Study does not compare kyphoplasty with sham procedure, non-interventional control or control group with known success/failure rate.

**Kyphoplasty Plus Non-operative Care vs. Non-operative Care Alone**

Wardlaw 2009  RCT	6.0	N = 300  1 to 3 compression fractures T5-L5, less than 3 month fracture age; included malignancies  12 month follow-up	Kyphoplasty plus non-operative care vs. non-operative alone. Non-operative care unstructured, included analgesics, bed rest, back braces, physiotherapy, rehabilitation programs, walking aids, vitamin D, calcium, anti-resorptive or anabolic agents.	Mean improvement in SF-36 physical component at 1 month 5.2 points more than non-operative group (p < 0.0001). Differences decreased over time (4.0, 3.2, 1.5 at 3, 6, 12 months); not different at 12 months. Roland Morris improved 4.0 points at 1 month, 2.6 at 12 months (p < 0.0001 and p = 0.0012); 2.9 fewer days of restricted activity per 2 weeks than non-operative at 1 month (p = 0.0004).	“[C]ompared with non-surgical management, balloon kyphoplasty resulted in improvements in quality of life and disability measures and reduction of back pain in patients with acute painful vertebral fractures; however, differences in improvement...diminished by 1 year.”	No sham treatment arm. Somewhat more multiple fractures in kyphoplasty group (32.9% vs. 23.8%). Heterogeneous and unstructured non-operative care precludes assessment of comparison with specific treatments. Some non-operative treatments more utilized in non-operative group and were questionable [e.g., bed rest (42 vs. 23%), back braces (20 vs. 7%), walking aides (42 vs. 24%)], possibly worsening clinical case, potentially confounding results.
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