

Lumbar Spinal Fusion

Effective: November 1, 2018

Next Review: March 2019

Last Review: September 2018

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Lumbar fusion is a surgical procedure that joins two or more lumbar vertebrae together into one solid bony structure.

MEDICAL POLICY CRITERIA

- I. Lumbar spinal fusion may be considered **medically necessary** in patients with any of the following conditions:
 - A. Spinal fracture with instability or neural compression
 - B. Spinal repair surgery for dislocation, tumor, or infection (including abscess, osteomyelitis, discitis, or fungal infection) when debridement is necessary and the extent of the debridement to help eradicate the infection creates or could create an unstable spine.
 - C. Spinal stenosis with *all* of the following (1-2):
 1. Same-level spondylolisthesis demonstrated on plain x-rays or high likelihood of post-operative instability;
 2. At least *one* of the following criteria are met:

- a. Neurogenic claudication or radicular pain when *all* of the following criteria (i.-iv.) are met:
 - i. There is either clinical documentation of significant functional impairment or disability, *or* severe disability as measured by the Oswestry Disability Index
 - ii. There is clinical documentation that a minimum of three months of conservative nonoperative therapy failed to adequately treat the patient's symptoms including all of the following criteria:
 - a.) Trial of at least two prescription analgesics or non-steroidal antiinflammatories unless contraindicated; and
 - b.) Documented participation in nonoperative modalities which may include physical therapy, home exercise program, massage, yoga, acupuncture, and/or injections (Note: this policy requirement may be waived with progression or worsening of the condition); and
 - c.) There are no documented cognitive, behavioral, or analgesic dependence issues OR if present, a psychiatric/behavioral evaluation documents appropriate management.
 - iii. Documented central, lateral recess, or foraminal stenosis on MRI or other imaging consistent with the patient's symptoms
 - iv. The patient is not a tobacco user OR there is clinical documentation that the patient has been abstinent from tobacco use for at least six weeks prior to fusion
 - b. Documented progressive symptoms of motor loss, or cauda equina syndrome confirmed by advanced diagnostic imaging studies.
- D. Single- or multi-session (staged) fusion for severe, progressive idiopathic scoliosis (i.e., lumbar or thoracolumbar) with Cobb angle greater than 40 degrees.
- E. Single- or multi-session (staged) fusion for severe degenerative scoliosis or severe spinal deformities when one or more of the following criteria are met:
- 1. Documented progression of deformity with persistent (daily) axial (non-radiating) pain when both of the following criteria are met:
 - a. There is either clinical documentation of significant functional impairment or disability, *or* severe disability as measured by the Oswestry Disability Index; and
 - b. There is clinical documentation that a minimum of three months of conservative nonoperative therapy failed to adequately treat the patient's symptoms including all of the following criteria:
 - i. Trial of at least two prescription analgesics or non-steroidal antiinflammatories unless contraindicated; and
 - ii. Documented participation in nonoperative modalities which may include physical therapy, home exercise program, massage, yoga,

- acupuncture, and/or injections (Note: this policy requirement may be waived with progression or worsening of the condition); and
 - iii. There are no documented cognitive, behavioral, or analgesic dependence issues OR if present, a psychiatric/behavioral evaluation documents appropriate management.
2. Persistent (daily) and significant neurogenic claudication or radicular pain when both of the following criteria are met:
- a. There is either clinical documentation of significant functional impairment or disability, *or* severe disability as measured by the Oswestry Disability Index; and
 - b. There is clinical documentation that a minimum of three months of conservative nonoperative therapy failed to adequately treat the patient's symptoms including all of the following criteria:
 - i. Trial of at least two prescription analgesics or non-steroidal antiinflammatories unless contraindicated; and
 - ii. Documented participation in nonoperative modalities which may include physical therapy, home exercise program, massage, yoga, acupuncture, and/or injections (Note: this policy requirement may be waived with progression or worsening of the condition); and
 - iii. There are no documented cognitive, behavioral, or analgesic dependence issues OR if present, a psychiatric/behavioral evaluation documents appropriate management.
- F. Isthmic spondylolisthesis when all of the following criteria (1 – 4) are met:
- 1. Either congenital (Wiltse type I) or acquired pars defect (Wiltse II), documented on x-ray
 - 2. Persistent (daily) back pain, with or without neurogenic claudication or radicular pain, with either clinical documentation of significant functional impairment or disability, *or* severe disability as measured by the Oswestry Disability Index.
 - 3. Symptoms have been unresponsive to at least three months of conservative nonsurgical care including all of the following criteria:
 - a. Trial of at least two prescription analgesics or non-steroidal antiinflammatories unless contraindicated; and
 - b. Documented participation in nonoperative modalities which may include physical therapy, home exercise program, massage, yoga, acupuncture, and/or injections (Note: this policy requirement may be waived with progression or worsening of the condition); and
 - c. There are no documented cognitive, behavioral, or analgesic dependence issues OR if present, then a psychiatric/behavioral evaluation documents appropriate management.

- d. The patient is not a tobacco user OR there is clinical documentation that the patient has been abstinent from tobacco use for at least six weeks prior to fusion
- G. Recurrent, same level, disc herniation when all of the following criteria (1-5) are met:
- 1. Previous disc surgery was performed at least six months ago and resulted in significant interval relief of prior symptoms
 - 2. Recurrent neurogenic claudication or radicular pain that has been unresponsive to at least three months of conservative nonsurgical care including all of the following criteria:
 - a. Trial of at least two prescription analgesics or non-steroidal antiinflammatories unless contraindicated; and
 - b. Documented participation in nonoperative modalities which may include physical therapy, home exercise program, massage, yoga, acupuncture, and/or injections (Note: this policy requirement may be waived with progression or worsening of the condition); and
 - c. There are no documented cognitive, behavioral, or analgesic dependence issues OR if present, then a psychiatric/behavioral evaluation documents appropriate management.
 - 3. There is either clinical documentation of significant functional impairment or disability, *or* severe disability as measured by the Oswestry Disability Index.
 - 4. Neural structure compression documented by recent imaging consistent with signs and symptoms
 - 5. The patient is not a tobacco user OR there is clinical documentation that the patient has been abstinent from tobacco use for at least six weeks prior to fusion
- H. Adjacent segment degeneration when all of the following criteria are met:
- 1. Previous fusion was performed at least 12 months ago and resulted in significant interval relief of prior symptoms
 - 2. There is either clinical documentation of significant functional impairment or disability, *or* severe disability as measured by the Oswestry Disability Index
 - 3. Recurrent neurogenic claudication or radicular pain that has been unresponsive to at least three months of conservative nonsurgical care including all of the following criteria:
 - a. Trial of at least two prescription analgesics or non-steroidal antiinflammatories unless contraindicated; and
 - b. Documented participation in nonoperative modalities which may include physical therapy, home exercise program, massage, yoga, acupuncture, and/or injections (Note: this policy requirement may be waived with progression or worsening of the condition); and

- c. There are no documented cognitive, behavioral, or analgesic dependence issues OR if present, a psychiatric/behavioral evaluation documents appropriate management.
 - 4. Neural structure compression documented by recent imaging consistent with signs and symptoms
 - 5. The patient is not a tobacco user OR there is clinical documentation that the patient has been abstinent from tobacco use for at least six weeks prior to fusion
 - I. Radiologically documented pseudarthrosis (nonunion of prior fusion) when all of the following criteria are met:
 - 1. Previous fusion was performed at least six months ago and resulted in significant interval relief of prior symptoms
 - 2. Persistent (daily) axial back pain with or without neurogenic claudication or radicular pain
 - 3. There is either clinical documentation of significant functional impairment or disability, *or* severe disability as measured by the Oswestry Disability Index
 - 4. The patient is not a tobacco user OR there is clinical documentation that the patient has been abstinent from tobacco use for at least six weeks prior to fusion
 - J. Iatrogenic or degenerative flatback syndrome with significant sagittal imbalance; when fusion is performed with spinal osteotomy.
- II. Lumbar spine arthrodesis (fusion) surgery is considered **not medically necessary** in the following circumstances:
- A. When the above criteria are not met
 - B. If the sole indication is any one or more of the following conditions:
 - 1. Disc herniation
 - 2. Degenerative disc disease with no radicular symptoms
 - 3. Initial discectomy/laminectomy for neural structure decompression
 - 4. Facet joint arthritis as a singular problem
 - 5. Low back pain that does not meet the criteria above
 - 6. Non-instrumented fusion (except in cases of in-situ instrumented spinal fusion surgery with bone grafting)
- III. Staged, multi-session (see Policy Guidelines for a definition) spinal fusions are considered **not medically necessary** for conditions other than severe scoliosis or severe spinal deformities that meet criteria I.D. or I.E. above. The current standards of care for lumbar spinal fusions are single-session including multiple approach techniques.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

POLICY GUIDELINES

SUBMISSION OF DOCUMENTATION

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and physical/chart notes
- Indication for the requested service
- Clinical documentation of minimum of three months of conservative, nonoperative therapy as applicable to the policy criteria.
- If associated cognitive, behavioral, or analgesic dependence issues are present, provide psychiatric/behavioral evaluation documenting appropriate management as applicable to the policy criteria.
- X-rays and/or MRI and/or applicable imaging reports as appropriate to policy criteria testing.
- If current tobacco user, documented length of abstinence
- Evaluation and documentation of functional impairment or disability, or documentation of severe disability as measured by the Oswestry Disability Index.
- Documentation if staged, multi-sessions spinal fusion is to be performed.

MULTI-SESSION DEFINITION

Multi-session is defined as procedures occurring on different days or requiring an additional anesthesia session.

CROSS REFERENCES

1. [Electrical Bone Growth Stimulators \(Osteogenic Stimulation\)](#), Durable Medical Equipment, Policy No. 83.11
2. [Artificial Intervertebral Disc](#), Surgery, Policy No. 127
3. [Dynamic Stabilization of the Spine](#), Surgery, Policy No. 143
4. [Interspinous and Interlaminar Stabilization/Distractor Devices \(Spacers\)](#), Surgery, Policy No. 155
5. [Percutaneous Axial Anterior Lumbar Fusion](#), Surgery, Policy No. 157
6. [Total Facet Arthroplasty](#), Surgery, Policy No. 171
7. [Interspinous Fixation \(Fusion\) Devices](#), Surgery, Policy No. 172
8. [Image-Guided Minimally Invasive Spinal Decompression \(IG-MSD\) for Spinal Stenosis](#), Surgery, Policy No. 176
9. [Sacroiliac Joint Fusion](#), Surgery, Policy No. 193

BACKGROUND

Low back pain is a common affliction that can be caused by a variety of conditions including degenerative disc disease, muscle strain, skeletal trauma, infection, and tumor. It may be associated with radiculopathy or neurogenic claudication. Radiculopathy is caused by lumbar nerve root compression that may be due to disc protrusion, and/or osteophytes. Radicular pain is in the buttock, thigh, or calf areas. In addition to pain, this nerve root compression may be associated with sensory impairment, weakness, or diminished deep tendon reflexes. Neurogenic claudication is associated with spinal stenosis, with symptoms of leg pain, occasionally with weakness, brought on by walking or standing. Most cases of low back pain improve with conservative therapy including physical therapy, exercise, and/or analgesics.

If the spine becomes unstable due to spondylolisthesis, trauma, infection or tumor, and for certain other identified causes of chronic, unremitting back pain, a lumbar fusion (arthrodesis) procedure is often recommended to provide stability or pain relief to the affected portion of the spine. Lumbar fusion is primarily used to treat spine instability, traumatic injury, disease (e.g., malignancy; infection), or congenital deformities (e.g., severe scoliosis). It is occasionally used for pain caused by degenerative changes (e.g., degenerative disc disease). Surgical approaches include the following:

- The posterior lumbar approach, which is the most common approach.
- The anterior/anterolateral approach through the abdomen.
- The anterior/posterior approach through the abdomen and from the back.
- The lateral extracavitary approach from the side or laterally.

After the vertebrae are exposed, pressure on the nerve roots and/or spinal cord is removed (“decompressed”). This usually includes removing part or all of the lamina bone, facet joints, any free disc fragments, filing down any nearby bone spurs, and/or foraminotomy. Bone grafts using the patient’s own bone or cadaver bone are placed across the spaces between the vertebral bodies. Instrumentation (i.e., metal screws, rods, cages, and/or plates) may be used to prevent movement of the vertebrae during the bone healing process. The standard surgical technique is to perform lumbar fusion during a single operative session, except in some cases of severe scoliosis which may require staged repair.

EVIDENCE SUMMARY

SPINAL STENOSIS

The primary surgical intervention for spinal stenosis is decompressive surgery (ie, laminectomy or related procedures). Spinal fusion is not a primary treatment for spinal stenosis, but rather can be performed in addition to decompressive surgery with the intent of decreasing spinal instability. Therefore, the most relevant comparison for patients with spinal stenosis is decompressive surgery alone compared to decompressive surgery plus fusion.

There are 2 published RCTs that assessed the benefit of adding fusion to laminectomy, ie decompressive surgery alone compared to decompressive surgery plus fusion, both of these were published in 2016. These trials reported somewhat different results concerning benefit for the combined procedure.^[1,2] In the Swedish Spinal Stenosis Study (SSS), 247 patients between 50 and 80 years of age who had lumbar spinal stenosis at 1 or 2 levels were randomized to undergo decompression plus fusion surgery or decompression surgery alone.^[1] The specific surgical method for decompression and fusion was determined by the surgeon. Randomization was stratified by the presence of degenerative spondylolisthesis, which was present in about half of the patients. The addition of fusion to laminectomy resulted in longer operating time, more bleeding, higher surgical costs, and longer hospitalization. The primary outcome measure, the Oswestry Disability Index (ODI) score, did not differ significantly between groups at the 2- or 5-year follow-ups. Mean scores were also analyzed separately for patients with or without spondylolisthesis. In patients with degenerative spondylolisthesis (range, 7.4-14.3 mm), the mean ODI score at 2 years was 25 in the fusion group and 21 in the decompression-alone group. The distance walked in 6 minutes (6-minute walk test) did not differ significantly between groups. Additional lumbar spine surgery during 6.5 years of follow-

up was performed in a similar percentage of patients in the fusion group (22%) and the decompression-alone group (21%).

In the Spinal Laminectomy versus Instrumented Pedicle Screw (SLIP) trial, all 66 patients randomized to decompression plus fusion or decompression alone had stable degenerative spondylolisthesis (grade I, 3-14 mm) and symptomatic lumbar spinal stenosis.^[2] Decompression was performed by laminectomy with partial removal of the medial facet joint. The fusion group, which underwent posterolateral instrumented fusion (PLF), had more blood loss and longer hospital stays. The primary outcome measure, change in 36-Item Short-Form Health Survey (SF-36) Physical Component Summary score at 2 years, was significantly greater in the fusion group (15.2) than in the decompression-alone group (9.5; $p=0.046$). The minimally important difference (MID) for SF-36 score was prespecified at 5 points, and was achieved in 86% of the fusion group and 69% of the decompression group. At 2 years, ODI scores had improved by 26.3 points in the fusion group and by 17.9 points in the decompression-alone group ($p=0.06$). The MID for ODI score was prespecified as a 10-point improvement, but the percentages of patients who achieved the MID were not reported. The rate of reoperation in the fusion group was 14% compared with 34% in the decompression-alone group ($p=0.05$), although only 68% of patients were available for follow-up at 4 years. All reoperations in the fusion group were for adjacent-level degeneration, while reoperations in the decompression-alone group were performed for instability at the index level. In addition to the low follow-up rate, there are questions about risk of surgeon bias in the recommendation for additional fusion surgery in patients who had undergone decompression alone.

A 1991 quasi-randomized study by Herkowitz et al evaluated decompression, with or without fusion, in 50 patients with spondylolisthesis and spinal stenosis.^[3] All patients had failed a trial of nonoperative treatment. This study used alternating assignment to the 2 treatment groups. At a mean follow-up of 3 years (range, 2.4-4.0 years), patients who had posterolateral lumbar fusion (PLF) together with limited decompression had significantly improved outcomes, as measured by overall outcomes and numeric rating scales, compared with the patients who underwent decompression alone. An increase in postoperative olisthesis was also observed in the decompression-alone group.

In 2007 and 2009, Weinstein et al reported findings from the widely cited multicenter controlled trial (Spine Patient Outcomes Research Trial [SPORT]). The primary comparison in this study was decompressive surgery plus fusion compared to nonsurgical treatment for patients with lumbar spinal stenosis and degenerative spondylolisthesis.^[4,5] All patients had neurogenic claudication or radicular leg pain associated with neurologic signs, spinal stenosis shown on cross-sectional imaging, and degenerative spondylolisthesis shown on lateral radiographs with symptoms persisting for at least 12 weeks. There were 304 patients in a randomized cohort and 303 patients in an observational cohort. About 40% of the randomized cohort crossed over in each direction by 2 years of follow-up. At the 4-year follow-up, 54% of patients randomized to nonoperative care had undergone surgery. Five percent of the surgically treated patients received decompression only and 95% underwent decompression with fusion. Analysis by treatment received was used due to the high percentage of crossovers. This analysis, controlled for baseline factors, showed a significant advantage for surgery at up to 4 years of follow-up for all primary and secondary outcome measures.

Summary

Two RCTs that specifically assessed the benefit of adding fusion to decompression in patients

with grade I spondylolisthesis reached different conclusions. Both trials reported more frequent operative and perioperative adverse outcomes with the addition of fusion. The SSS trial found no benefit of surgery on clinical outcomes measured by ODI score, while the SLIP trial reported a small benefit measured by SF-36 score, a difference in the ODI score that was not statistically significant, and a reduction in subsequent surgeries when fusion was added to decompression. In the SPORT trial, 95% of patients in the surgical group underwent decompression with fusion and had improved outcomes compared to nonoperative therapy. Although this is an important trial of surgical therapy in patients with spinal stenosis, it evaluates whether the combination of decompressive surgery plus fusion is superior to nonsurgical therapy. It does not isolate the effect of fusion, therefore it is not possible to determine whether the benefit of surgery derived from decompression, fusion, or both. An earlier quasi-randomized study (Herkowitz et al) reported that lumbar spinal fusion improved outcomes in patients with spinal stenosis associated with spondylolisthesis. Methodologic limitations of this evidence base include high loss to follow-up in the SLIP and SPORT trials, the lack of information on the surgical procedures in the SSS trial, and the variation in outcome measures used. The current evidence does not permit conclusions whether the addition of fusion to decompressive surgery for patients with spinal stenosis improves outcomes.

JUVENILE IDIOPATHIC SCOLIOSIS

Scoliosis is an abnormal lateral and rotational curvature of the vertebral column. Treatment of scoliosis currently depends on 3 factors: the cause of the condition (idiopathic, congenital, secondary), severity of the condition (degrees of curve), and the remaining growth expected for the patient at the time of presentation. Children who have vertebral curves measuring between 25 and 40 degrees with at least 2 years of growth remaining are considered at high risk of curve progression. Because severe deformity may lead to compromised respiratory function and is associated with back pain in adulthood, in the United States, surgical intervention with spinal fusion is typically recommended for curves that progress to 45 or more degrees.^[6]

In 2001, Danielsson and Nachemson reported long-term follow-up on 283 consecutive patients who had been treated with a brace or with surgical treatment for adolescent idiopathic scoliosis in Sweden.^[7] Lumbar curves of less than 60 degrees were treated with a brace worn for an average of 2.7 years. Curves of 60 degrees or more were treated with fusion using bone grafts from the iliac crest. An average of 9.5 vertebrae were fused. Clinical and radiologic follow-up data were obtained in 89% of patients at a mean of 22 years (range, 20-28 years). Curve progression was 3.5 degrees for surgically treated curves and 7.9 degrees for brace-treated curves. Five (4%) patients treated surgically and 39 (36%) treated with bracing had an increase in the Cobb angle of more than 10 degrees.

Summary

Long-term follow-up of a large comparative cohort has indicated that spinal fusion can reduce curve progression compared to bracing in patients with large Cobb angles. In this study the populations are not comparable, as curves less than 60 degrees were treated with a brace and curves of 60 degrees or greater were treated with spinal fusion. Although supportive of the use of spinal fusion in juveniles with large Cobb angles and remaining growth, studies are needed that compare curve progression following fusion or bracing in a comparable population.

ADULT DEGENERATIVE SCOLIOSIS

In 2009, Bridwell et al reported a prospective multicenter cohort study that compared operative versus nonoperative treatment of adult symptomatic lumbar scoliosis (defined as a minimum Cobb angle of 30 degrees) in 160 consecutively enrolled patients.^[8] Operative versus nonoperative treatment was decided by the patient and medical team. Nonoperative treatment included observation (21%), medications (26%), medications plus physical therapy and/or injections (40%), and other treatment without medications (13%). For analysis, patients were matched using propensity scores that included baseline Cobb angle, ODI, Scoliosis Research Society subscore, and a numerical rating scale for back and leg pain. The percentage of patients who returned for follow-up at 2 years was higher for operative (95%) than nonoperative patients (45%), although baseline measures for patients lost to follow-up were similar to those who were followed for 2 years. At the 2-year follow-up, nonoperative treatment had not improved quality of life or any other outcome measures, while the operative group showed significant improvement in all outcomes.

Summary

Evidence includes a prospective comparative cohort study, which evaluated outcomes in adults with symptomatic scoliosis who were treated either with spinal fusion surgery or nonoperatively. Using propensity matching, the study found that nonoperative treatment did not improve outcomes whereas surgical treatment improved all outcome measures. There is a potential for bias in this study due to the self-selection of treatment and high loss to follow-up in the conservatively managed group.

ISTHMIC SPONDYLOLISTHESIS

In 2000, Moller and Hedlund reported a study of 111 patients with adult isthmic spondylolisthesis who were randomly assigned to posterolateral fusion (with or without instrumentation, n=77) or to an exercise program (n=34).^[9] Inclusion criteria were lumbar isthmic spondylolisthesis of any grade, at least 1 year of low back pain or sciatica, and severely restricted functional ability. Mean age of patients was 39 years, with a mean age at onset of symptoms of 26 years. At 1- and 2-year follow-ups, functional outcome (assessed by the Disability Rating Index) had improved in the surgery group but not in the exercise group. Pain scores improved in both groups, but were significantly better in the surgically treated group.

Summary

One RCT was identified that compared fusion to an exercise program for patients with symptomatic isthmic spondylolisthesis. Functional outcomes and pain relief were significantly better following fusion surgery. Results of this trial support the use of fusion for this condition, but should be corroborated in a larger number of patients.

SPINAL FRACTURE

A 2006 qualitative systematic review identified 2 RCTs that compared operative and nonoperative treatment for thoracolumbar burst fractures in patients without neurologic deficit.^[10] The larger study, by Wood et al in 2003, is described next. The other study identified in the systematic review had only 20 patients.

The trial by Wood et al randomized 53 consecutive patients with a stable burst fracture and no neurologic deficit or loss of structural integrity to fusion with instrumentation or to nonoperative treatment with application of a body cast or orthosis for approximately 16 weeks.^[11] At an

average follow-up of 44 months (24-month minimum), patients completed assessments of pain and function. At follow-up, the 2 groups were similar in average fracture kyphosis, canal compromise, and return to work. Patients treated nonoperatively reported less disability on the ODI and 36-Item Short-Form Health Survey physical function, lower pain scores, and had fewer complications.

Summary

Results of a small RCT indicate that, compared to conservative care, spinal fusion may be associated with worse outcomes in patients with spinal fracture without instability or neural compression.

LUMBAR DISC HERNIATION WITH RADICULOPATHY

Spinal fusion can be performed in addition to discectomy for herniated disc. Therefore, the most relevant comparison is discectomy plus fusion compared to discectomy alone. No RCTs were identified with that specific comparison.

The largest trial on surgery for herniated disc is the SPORT discectomy trial, which reported on randomized (n=501) and observational (n=743) cohorts of patients with lumbar disc herniation and radiculopathy who received either discectomy or nonoperative care.^[12,13] There was no mention of any patient undergoing fusion following discectomy. Intention-to-treat analysis for the randomized cohort found a small advantage for patients assigned to discectomy with no significant differences between groups for the primary outcome measures (bodily pain, physical function, ODI score). Analysis by treatment received found significant advantages for discectomy on the primary outcome measures.

Summary

Current evidence is lacking on whether the addition of fusion to discectomy improves outcomes compared to discectomy alone. One large RCT has indicated that surgical treatment with discectomy improves outcomes for lumbar disc herniation with radiculopathy compared to nonsurgical care. However, there is no evidence that the addition of spinal fusion to discectomy improves outcomes in patients with lumbar disc herniation undergoing discectomy.

CHRONIC LOW BACK PAIN WITHOUT RADICULOPATHY

Nonspecific chronic low back pain (CLBP) is persistent low back pain not attributable to a known specific pathology such as infection, tumor, osteoporosis, fracture, structural deformity (eg, spondylolisthesis, scoliosis), inflammatory disorder, radiculitis, or cauda equine syndrome. Surgical interventions, including fusion and disc arthroplasty, have been used on the assumption that abnormal intersegmental movement or degenerative pathology may be the cause of CLBP.^[13]

A 2013 systematic review assessed studies on surgical fusion for CLBP.^[14] As of September 2012, 4 RCTs (total N=981 patients) had compared surgical and nonsurgical approaches for CLBP. In contrast, 33 RCTs (total N=3790 patients) had compared variations of surgical techniques. A 2015 systematic review identified many of the same RCTs that evaluated fusion for CLBP attributed to degenerative disc disease (DDD); a number of the included studies compared fusion with total disc replacement for presumed DDD.^[15]

A 2014 meta-analysis compared lumbar fusion to conservative treatment in patients with

CLBP.^[15] Meta-analysis of 4 trials (total N=666 patients) reported a reduction in the ODI score that was -2.91 in favor of lumbar fusion. However, this improvement was not statistically significant nor reached the minimal clinically significant 10-point difference in ODI score. There was evidence of publication bias that favored placebo. The meta-analysis concluded that there is strong evidence that lumbar fusion does not lead to a clinically significant reduction in perceived disability compared with conservative treatment in patients with CLBP and degenerative spinal disease. The meta-analysis also noted it is unlikely that further research on the subject would alter this conclusion.

One of the studies that compared surgical and nonsurgical treatment for CLBP was a 2001 multicenter trial by the Swedish Lumbar Spine Study Group.^[16] In this trial, 294 patients with CLBP for at least 2 years, sick leave or disability for at least 1 year (mean, 3 years), and radiologic evidence of disc degeneration were randomized into 1 of 3 types of spinal fusion or to physical therapy supplemented by other nonsurgical treatment. Patients were excluded if they had specific radiologic findings such as spondylolisthesis, new or old fractures, infection, inflammatory process, or neoplasm. With intention-to-treat analysis, the surgical group showed greater reductions than the nonsurgical group in back pain (33% vs 7%), disability according to ODI score (25% reduction vs 6% reduction), Million visual analog scale (VAS) score (28% vs 8%), and General Function Score (31% vs 4%). Significantly more surgical patients were also back to work (36% vs 13%) and more reported their outcome as better or much better (63% vs 29%).

A 2005 pragmatic multicenter randomized trial from the Spine Stabilization Trial Group compared spinal fusion with an intensive (approximately 75 hours) physical and cognitive-behavioral rehabilitation program.^[17] Patients (N=349) who had back pain for at least 1 year and were considered candidates for surgical stabilization by the treating physician were randomized if the clinician and patient were uncertain which study treatment strategies were best. Radiologic findings were not part of the inclusion criteria. By the 2-year follow-up, 48 (28%) of patients randomized to rehabilitation had undergone surgery. Results for 1 of the 2 primary outcome measures (ODI score) showed a modest but significantly greater improvement (4.1 points) in the surgery group. There were no significant differences between groups for the walking test or any of the secondary outcome measures.

In 2010, Brox et al reported 4-year follow-up from 2 randomized trials that compared surgery to cognitive intervention and exercises in 124 patients with disc degeneration.^[18] One of the trials enrolled patients with CLBP and radiographic evidence of disc degeneration; the other enrolled patients with chronic back pain after previous surgery for disc herniation. The criteria for symptomatic DDD were based on imaging without other diagnostic tests to identify the source of the CLBP. The combined 4-year follow-up rate was 92% in the surgical group and 86% in the nonsurgical group. In the nonsurgical group, 24% had undergone surgery by 4 years. In the surgical group, 15 (25%) had reoperation for persistent complaints or deterioration of the condition. In the intention-to-treat analysis, there were no significant differences between groups in ODI scores or in percentages of patients on disability at 4 years. For the secondary outcomes, the only treatment effect identified was a reduction of fear-avoidance beliefs favoring cognitive-behavioral therapy (CBT) and exercises. Results of this study are confounded by the high percentage of crossovers from nonsurgical to surgical treatment.

In 2013, Mannion et al^[19] reported 11-year follow-up (range, 8-15 years) on 3 RCTs, including the 2 RCTs by Brox and Fairbanks described above. Of 473 patients originally enrolled in the trials, 261 (55%) agreed to participate in long-term follow-up and completed the outcome

questionnaires. When controlling for baseline factors, both intent-to-treat and as-treated analysis showed no significant advantage for fusion over multidisciplinary CBT and exercise rehabilitation for patient-reported outcomes. However, only 40% had ODI scores in the normal range (ODI score \leq 22/100) for either group. In addition, 40% of patients randomized to CBT and exercise rehabilitation had crossed over to fusion by the long-term follow-up.

Frequently cited, the smaller 2011 trial by Ohtori et al assessed patients with discogenic low back pain for at least 2 years (without radiculopathy), who were selected following demonstration of disc degeneration at 1 level based on MRI, pain provocation on discography, and pain relief following intradiscal injection of anesthetic.^[20] Forty-six patients did not agree to undergo discography or intradiscal anesthetic injection, and 11 patients were excluded (negative results). Most patients (70%) were categorized with a bulging disc; the remainder had evidence of disc degeneration on MRI. The 41 patients included in the trial were divided into a walking and stretching group (over 2 years, n=20) and a discectomy and fusion group (n=21). The surgical approach was anterior lumbar interbody fusion (ALIF; n=15) or posterolateral fusion (PLF; n=6) if the anterior approach was technically difficult due to blood vessel anatomy. At 2-year follow-up, there was improvement for all groups for VAS scores, Japanese Orthopedic Association Score, and ODI scores. The 2 surgical groups scored significantly better than the exercise group on all measures, with some advantage of ALIF over PLF. For example, VAS scores improved from 7.7 to 4.7 in the walking and stretching group, from 7.4 to 1.3 in the ALIF group, and from 6.5 to 3.5 in the PLF group. A limitation of this trial is the nature of the treatment provided to the control group.

Summary

The results of trials comparing fusion to nonsurgical management in this population are mixed. A meta-analysis assessing 4 RCTs found no clinically significant advantage for lumbar fusion over conservative therapy in patients with CLBP not attributable to a known specific pathology (eg, infection, tumor, osteoporosis, fracture, structural deformity, inflammatory disorder, radiculitis, cauda equine syndrome). The strongest benefits of surgery were reported in a trial of patients who had been on sick leave or disability for more than 1 year, but no advantage of surgery was found when patients or surgeon were unsure of whether surgery or conservative therapy would be the best treatment strategy. Interpretation of these studies is limited by the high percentages of patients who crossed over to surgery, variances in the type of spinal fusion used (eg, posterolateral vs interbody), and uncertainty in establishing whether the source of CLBP was DDD.

STAGED, MULTI-SESSION FUSION

The following summary on staged lumbar fusion does not include repair of scoliosis or severe spinal deformities in which staged repair may be required.

Staged, multi-session lumbar fusion generally involves a circumferential (anterior and posterior) procedure performed at two separate operative sessions several days apart. Assessment of the safety and effectiveness of staged lumbar fusion requires data from well-designed clinical trials that compare the peri- and post-operative health outcomes of the staged fusion with single session fusion, the current standard of care. Therefore, this literature review was limited to comparative trials.

Current comparative evidence on the peri- and postoperative outcomes of single- and multi-session lumbar spinal fusion in patients with non-scoliosis lumbar spinal conditions and no

severe spinal deformity is limited to one prospective inpatient study^[21], two retrospective reviews^[22,23], and one large database^[24] with 3,243 2-stage and 8,022 same-day circumferential fusions.^[24]

- All four studies reported significantly greater incidence and severity of complications with the staged technique. Complications included but were not limited to surgical site infection, venous thrombosis, and adult respiratory distress syndrome.
- The three studies that reported inpatient length of stay found longer total hospitalization time for the staged procedure.
- The staged technique did not provide any beneficial effect in any of the studies for surgery-related mortality, total operative time, or blood loss during surgery.
- The inpatient registry reported that significantly more patients were discharged directly home rather than to inpatient rehabilitation following a same-day procedure.

EFFECT OF SMOKING ON FUSION RATES

A systematic review of the effects of smoking on spine surgery was published by Jackson and Devine in 2016.^[25] Four large retrospective comparative studies were included; they evaluated fusion rates in smokers and nonsmokers. The greatest difference in fusion rates was observed in a study of 100 patients by Brown et al (1986) with a 32% difference in fusion rates between smokers and nonsmokers ($p=0.001$).^[26] Bydon et al (2014) found no significant difference in fusion rates between smokers and nonsmokers for single-level fusion, but an 18% lower fusion rate in smokers for 2-level fusions ($p=0.019$).^[27] A retrospective analysis by Andersen et al (2001) of 232 smokers and 194 nonsmokers found that patients who smoked more than 10 cigarettes per day within 3 months of surgery had a 9% decrease in fusion rates^[28] and a fourth study (Glassman et al, 2000) of 188 nonsmokers and 169 smokers found that smokers had a 7% reduction in fusion rates ($p=0.05$), but fusion success improved with postoperative smoking cessation.^[29]

PRACTICE GUIDELINE SUMMARY

AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS/CONGRESS OF NEUROLOGICAL SURGEONS (AANS/CNS)

In 2014 the AANS/CNS updated their 2005 guidelines^[30-35] for lumbar spinal fusion, stating that there was no evidence that conflicted with those initial recommendations. The updated guidelines were based on a systematic review of the evidence published since the initial review (July 2003) through December 2011. The following are the updated AANS/CNS recommendations related to lumbar spinal fusion:

Intractable low back pain (LBP) without stenosis or spondylolisthesis^[36]

- Lumbar fusion or a comprehensive rehabilitation program with cognitive therapy are recommended treatment alternatives for patients with chronic LBP due to one- or two-level degenerative disc disease without stenosis or spondylolisthesis that is refractory to traditional conservative treatment. (Grade B recommendation, based on multiple level II studies).

Degenerative disease with stenosis and spondylolisthesis^[37]

- Surgical decompression and fusion is recommended as an effective treatment

alternative for symptomatic stenosis associated with a degenerative spondylolisthesis in patients who desire surgical treatment. (Grade B recommendation, Level II evidence)

- There is insufficient evidence to recommend a standard fusion technique; however, the patient's anatomy, desires, and concerns as well as surgeon experience should all be factored into the decision-making process when determining the optimal strategy for an individual patient to maximize fusion potential while minimizing risk of complications. (Grade B recommendation)

Degenerative disease with stenosis without spondylolisthesis^[38]

- Surgical decompression is recommended for patients with symptomatic neurogenic claudication due to lumbar stenosis without spondylolisthesis who elect to undergo surgical intervention. (Grade B recommendation, Level II/III evidence)
- In the absence of deformity or instability, lumbar fusion is not recommended because it has not been shown to improve outcomes in patients with isolated stenosis. (Grade C recommendation, Level IV evidence)

Disc herniation and radiculopathy^[39]

- Lumbar spinal fusion is not recommended as routine treatment following primary disc excision for isolated herniated lumbar discs causing radiculopathy (Grade C recommendation, Level IV evidence)
- Lumbar spinal fusion is considered a potential option in patients with herniated discs when there is preoperative evidence of any of the following (Grade C recommendation, Level IV evidence):
 - Spinal instability, or
 - Significant chronic axial LBP, or
 - Work as manual laborer, or
 - Severe degenerative changes
- Reoperative discectomy with fusion is recommended for recurrent disc herniation associated with lumbar instability or chronic axial LBP (Grade C recommendation, Level III evidence)

Instrumentation^[40]

- Pedicle screw (PS) fixation is recommended when PLF is used to manage LBP in patients who are at high risk for pseudoarthrosis. (Grade B recommendation)
- Routine use of PS fixation is an option as an adjunct to PLF in patients with degenerative disc disease because there is consistent evidence that the use of PS fixation enhances fusion rate; however, a positive correlation with respect to clinical outcome has not been consistently demonstrated. (Grade B recommendation)

NORTH AMERICAN SPINE SOCIETY (NASS)

In 2014, North American Spine Society (NASS) published coverage policy recommendations for lumbar fusion.^[41] Specific criteria were described for infection, tumor, traumatic injuries, deformity (eg, scoliosis), stenosis, disc herniations, synovial facet cysts, discogenic low back pain, and pseudoarthrosis. NASS isolated situations where lumbar fusion would not be indicated: disc herniation in the absence of instability or spondylolisthesis; stenosis in the

absence of instability; foraminal stenosis or spondylolisthesis; and discogenic low back pain not meeting the recommended criteria.

The 2014 guidelines from NASS addressed the diagnosis and treatment of degenerative lumbar spondylolisthesis.^[42] NASS gave a grade B recommendation for surgical decompression with fusion for the treatment of patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis to improve clinical outcomes compared with decompression alone. A grade C recommendation was given for decompression and fusion as a means to provide satisfactory long-term results for the treatment of patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis.

The 2011 NASS guidelines (updated in 2013) addressed multidisciplinary spine care for adults with a chief complaint of degenerative lumbar spinal stenosis.^[43,44] The guidelines indicated that the nature of the pain and associated patient characteristics should be more typical of a diagnosis of spinal stenosis than herniated disc. NASS addressed whether the addition of lumbar fusion to surgical decompression improved surgical outcomes in the treatment of spinal stenosis compared with treatment by decompression alone. NASS gave a grade B recommendation (fair evidence) for decompression alone for patients with leg predominant symptoms without instability

The 2012 NASS guidelines (updated in 2014) addressed multidisciplinary spine care for the diagnosis and treatment of lumbar disc herniation with radiculopathy.^[45,46] The guidelines indicated that “there is insufficient evidence to make a recommendation for or against fusion for specific patient populations with lumbar disc herniation with radiculopathy whose symptoms warrant surgery. Recommendation: I (Insufficient Evidence).”

AMERICAN PAIN SOCIETY (APS)^[47]

- For nonradicular LBP with common degenerative spinal changes and persistent and disabling symptoms, the APS made a weak recommendation based on moderate-quality evidence that surgery may provide improved outcomes compared with non-interdisciplinary rehabilitation, but not for intensive interdisciplinary rehabilitation. The APS further recommended that clinicians discuss with patients the risks and benefits of surgery versus intensive interdisciplinary nonsurgical therapy since the majority of these patients do not experience an optimal outcome with surgery.
- Instrumented fusion is associated with enhanced fusion rates but insufficient evidence exists to determine whether it improves clinical outcomes, and additional costs are substantial. In addition, there is insufficient evidence to recommend a specific fusion method, though more technically difficult procedures may be associated with higher complication rates.
- The benefits of fusion versus nonsurgical therapy have only been demonstrated in a relatively narrow group of patients with at least moderately severe pain or disability unresponsive to nonsurgical therapies for at least one year and without serious psychiatric or medical comorbidities or other risk factors for poor surgical outcomes.
- The evidence is insufficient to determine whether concurrent fusion improves outcomes when laminectomy is performed for spinal stenosis with persistent disabling leg pain.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

In 2017, the U.K.’s National Institute for Health and Care Excellence (NICE) provided clinical guidelines on lateral interbody fusion in the lumbar spine low back pain.^[48] NICE states that

lumbar fusion may be appropriate for people with severe, life-limiting, chronic low back pain that does not respond to conservative treatments. The evidence on lateral interbody fusion was considered adequate in quality and quantity. Also in 2017, NICE reexamined lumbar disc replacement and reported higher complication rates were found in patients who underwent fusion.^[49] The conclusion was that disc replacement was not warranted and spinal fusion for nonspecific low back pain should only be performed as part of a randomized controlled study.

AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS (AAOS)

The AAOS has endorsed the above APS guidelines.^[50] In a position statement, the AAOS provided educational information related to the effects of tobacco smoking on the musculoskeletal system.^[51] “The American Academy of Orthopaedic Surgeons (AAOS) is concerned that the American public is not fully aware that the use and exposure to tobacco products has harmful effects on the musculoskeletal system. The AAOS strongly recommends avoiding use and exposure to tobacco products due to the severe and negative impact on the musculoskeletal system.” Key associations were decreased bone mineral density, impaired bone healing including following bone surgery, poor wound healing and delayed fracture healing. The statement also noted that “quitting smoking before surgery can help improve postoperative wound healing, and decrease recovery time.”

SUMMARY

The current research for lumbar spinal fusion has shown improvement in health outcomes resulting in reduced pain and improved function in select patients. Therefore, lumbar spinal fusion is considered medically necessary in patients who meet the policy criteria. In those patients that don't meet policy criteria, the use of lumbar fusion is considered not medically necessary.

The current standard technique for lumbar spinal fusion for low back pain due to conditions other than severe scoliosis and severe spinal deformity is completion of all aspects of the fusion in a single operative session. Staged, multi-session spinal fusion is a technique in which the same surgical procedure is performed in separate operative sessions several days apart. Current evidence comparing these two techniques is limited, but consistently reported that the staged technique resulted in a higher rate of complications while providing no significant beneficial effects. In addition, the total number of days in the hospital is higher for the staged procedure. Therefore, multi-stage fusion is considered not medically necessary for all conditions other than severe scoliosis or severe spinal deformity.

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CODES

Codes	Number	Description
CPT	20930	Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)
	20931	Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure)
	20936	Autograft for spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or laminar fragments) obtained from same incision (List separately in addition to code for primary procedure)
	20937	;morselized (through separate skin or fascial incision) (List separately in addition to code for primary procedure)
	20938	;structural, bicortical or tricortical (through separate skin or fascial incision) (List separately in addition to code for primary procedure)
	20939	Bone marrow aspiration for bone grafting, spine surgery only, through separate skin or fascial incision (list separately in addition to code for primary procedure)
	22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
	22534	;thoracic or lumbar, each additional vertebral segment (List separately in addition to code for primary procedure)
	22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar

Codes	Number	Description
	22585	Anterior approach for Lumbar Fusion (Anterior Retroperitoneal Exposure); each additional interspace (List separately in addition to code for primary procedure)
	22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)
	22614	;each additional vertebral segment (List separately in addition to code for primary procedure)
	22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar
	22632	;each additional interspace (List separately in addition to code for primary procedure)
	22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar
	22634	;each additional interspace and segment (List separately in addition to code for primary procedure)
	22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments
	22802	;7 to 12 vertebral segments
	22804	;13 or more vertebral segments
	22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments
	22810	;4 to 7 vertebral segments
	22812	;8 or more vertebral segments
	22840	Posterior non-segmental instrumentation (eg, Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)
	22841	Internal spinal fixation by wiring of spinous processes (List separately in addition to code for primary procedure)
	22842	Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments (List separately in addition to code for primary procedure)
	22843	;7 to 12 vertebral segments (List separately in addition to code for primary procedure)
	22844	;13 or more vertebral segments (List separately in addition to code for primary procedure)
	22845	Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure)
	22846	;4 to 7 vertebral segments (List separately in addition to code for primary procedure)
	22847	;8 or more vertebral segments (List separately in addition to code for primary procedure)
	22848	Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum (List separately in addition to code for primary procedure)
	22849	Reinsertion of spinal fixation device
	22853	Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody

Codes	Number	Description
		arthrodesis, each interspace (List separately in addition to code for primary procedure)
	22854	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
	22859	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
HCPCS	None	

Date of Origin: March 2013