Title: Axial Lumbosacral Interbody Fusion

Population: Individuals
- With degenerative spine disease at the L4-S1 disc spaces

Interventions of interest are:
- Axial lumbosacral interbody fusion

Comparators of interest are:
- Standard lumbar interbody fusion surgery

Relevant outcomes include:
- Symptoms
- Functional outcomes
- Quality of life
- Treatment-related morbidity

Description

Background
Axial lumbosacral interbody fusion (LIF; also called presacral, transsacral or paracoccygeal interbody fusion) is a minimally invasive technique designed to provide anterior access to the L4-S1 disc spaces for interbody fusion, while minimizing damage to
muscular, ligamentous, neural, and vascular structures. It is performed under fluoroscopic guidance.

The procedure for 1-level axial LIF is as follows: Under fluoroscopic monitoring, a blunt guide pin introducer is passed through a 15- to 20-mm incision lateral to the coccyx and advanced along the midline of the anterior surface of the sacrum. A guide pin is introduced and tapped into the sacrum. A series of graduated dilators are advanced over the guide pin, and a dilator sheath attached to the last dilator is left in place to serve as a working channel for the passage of instruments. A cannulated drill is passed over the guide pin into the L5-S1 disc space to rest on the inferior endplate of L5. It is followed by cutters alternating with tissue extractors, and the nucleus pulposus is debulked under fluoroscopic guidance. Next, bone graft material is injected to fill the disc space. The threaded rod is placed over the guide pin and advanced through the sacrum into L5. The implant is designed to distract the vertebral bodies and restore disc and neural foramen height. Additional graft material is injected into the rod, where it enters into the disc space through holes in the axial rod. A rod plug is then inserted to fill the cannulation of the axial rod. Percutaneous placement of pedicle or facet screws may be used to provide supplemental fixation. An advantage of axial LIF is that it preserves the annulus and all paraspinous soft tissue structures. However, there is an increased need for fluoroscopy and an inability to address intracanal pathology or visualize the discectomy procedure directly. Complications of the axial approach may include perforation of the bowel and injury to blood vessels and/or nerves.

Regulatory Status
The AxiaLIF® and AxiaLIF II Level systems (TranS1) consist of techniques and surgical instruments for creating a presacral access route to perform percutaneous fusion of the L5-S1 or L4-S1 vertebral bodies. (In 2013, TranS1 acquired Baxano and changed the company name to Baxano Surgical. Quandry Medical acquired the TranS1 technology in 2014 and re-established distribution of AxiaLIF in 2015.) The instruments were cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process to provide anterior stabilization of the spinal segments as an adjunct to spinal fusion and to assist in the treatment of degeneration of the lumbar disc; to perform lumbar discectomy; or to assist in the performance of interbody fusion.2,3 The AxiaLIF systems are indicated for patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, grade 1 or 2 spondylolisthesis, or degenerative disc disease, defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. They are not intended to treat severe scoliosis, severe spondylolisthesis (grades 3 and 4), tumor, or trauma. The devices are not meant to be used for vertebral compression fractures or any other condition in which the mechanical integrity of the vertebral body is compromised. Their usage is limited to anterior supplemental fixation of the lumbar spine at L5-S1 or L4-S1 disc spaces in conjunction with legally marketed facet or pedicle screw systems. FDA product code: KWQ.
POLICY

Axial lumbosacral interbody fusion (axial LIF) is considered experimental / investigational.

RATIONALE
This evidence review has been updated using the MEDLINE database. The most recent literature review was performed through February 12, 2016.

Assessment of efficacy for therapeutic interventions involves a determination of whether the intervention improves health outcomes. The optimal study design for a therapeutic intervention is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as noncomparability of treatment groups, the placebo effect, and variable natural history of the condition.

The literature on axial lumbosacral interbody fusion (axial LIF) includes case series and 1 retrospective comparison of axial LIF versus anterior lumbar interbody fusion (ALIF). No prospective RCTs have been identified that compare outcomes of axial LIF with other approaches to LIF.

Single-Level Axial LIF
The largest case series published to date is a 2011 retrospective analysis of 156 patients from 4 clinical sites in the United States.4 Patients were selected for inclusion if they underwent a L5-S1 interbody fusion via the axial approach and had both presurgical and 2-year radiographic or clinical follow-up. The number of patients who underwent axial LIF but were not included in the analysis was not reported. The primary diagnosis was degenerative disc disease (61.5%), spondylolisthesis (21.8%), revision surgery (8.3%), herniated nucleus pulposus (8.3%), spinal stenosis (7.7%), or other (8.3%). Pain scores on a numeric rating scale improved from a mean of 7.7 to 2.7 (n=155), while the Oswestry Disability Index (ODI) scores improved from a mean of 36.6 preoperatively to 19.0 (n=78) at 2-year follow-up. Clinical success rates, based on an improvement of at least 30%, were 86% (n=127/147) for pain and 74% (n=57/77) for the ODI scores. The overall radiographic fusion rate at 2 years was 94% (145/155). No, neural, urologic, or bowel injuries were reported in this study group. Limitations of this study include the retrospective analysis, lack of controls, and potential for selection bias by only reporting on patients who had 2 years of follow-up.

Zeilstra et al conducted a retrospective review of 131 axial LIF procedures (L5-S1) performed at their institution over a period of 6 years.5 All patients had undergone a minimum of 6 months (mean, 5 years) of unsuccessful nonsurgical management and had magnetic resonance imaging (MRI), radiography, provocative discography, and anesthetization of the disc. MRI of the sacrum and coccyx was performed to identify vascular anomalies, tumor, or surgical scarring that would preclude safe access through the presacral space, and patients followed a bowel preparation protocol the night before surgery. Percutaneous facet screw fixation was used in all patients beginning mid-2008. No intraoperative complications were reported. At a mean follow-up of 21...
months (minimum 1 year), back pain had decreased by 51% (change in visual analog score [VAS] score, from 70 to 39), leg pain decreased by 42% (from 45 to 26), and back function scores (ODI) improved by 50% compared with baseline. With clinical success defined as improvement of 30% or more, 66% of patients were improved in back and leg pain severity. Employment increased from 47% to 64% at follow-up. The fusion rate was 87.8%, with 9.2% indeterminate on radiograph and 3.1% showing pseudoarthrosis. There were 8 (6.1%) reoperations at the index level.

Whang et al reported a multicenter, retrospective comparison of axial LIF versus ALIF of the L5-S1 disc space in 96 patients with a minimum of 2 years of follow-up. Most procedures were performed for degenerative disc disease or spondylolisthesis and included the use of bilateral pedicle screws. Various graft materials were used, including recombinant human bone morphogenetic protein-2 (in 29 axial LIF and 11 ALIF procedures). Fusion, assessed at 24 months by 2 independent evaluators based on radiographs and multiplanar CT images, was similar for the 2 procedures (85% for axial LIF, 79% for ALIF, p>0.05). The incidence of adverse events was also similar, with no cases of rectal perforation. Interpretation of this study is uncertain given the retrospective nature of the study, variability in procedures, absence of validated clinical outcome measures, and lack of randomization.

In 2012, Gerszten et al reported a series of patients who had a minimum 2-year follow-up after axial LIF with percutaneous fixation with pedicle screws for the stabilization of grade 1 or 2 lumbosacral isthmic spondylolisthesis.7 There were no perioperative procedure-related complications. The spondylolisthesis grade in the 26 consecutive patients was significantly improved at follow-up, with 50% of patients showing a reduction of at least 1 grade. Axial pain severity improved from a VAS score of 8.1 to 2.8, and 81% of patients had excellent or good results based on Odom criteria. At 2 years posttreatment, all patients showed solid fusion.

Additional series with fewer than 100 patients were reviewed by Zeilstra et al.5 Improvement in back pain in these studies ranged from 49% to 67% and improvement in ODI scores ranged from 50% to 56%.

Two-Level Axial LIF
Marchi et al reported prospective 2-year follow-up on 27 patients who underwent 2-level axial LIF at the L4-5 and L5-S1 disc spaces. Average back pain decreased from a VAS score of 8.08 to 4.04 and ODI scores improved from 51.7 to 31.4. Although no intraoperative complications occurred, the authors reported malpositioned rods in 3 cases due to difficulty in attaining an adequate route for the double-level access. In one of these cases, the rod eventually migrated and perforated the bowel. Five (18.5%) patients underwent additional surgery for malpositioned rods, broken posterior screws, failure of the rods, or collapse of spine levels. Total complications observed at follow-up included screw breakage (14.8%), transsacral rod detachment (11.1%), radiolucency around the transsacral rod (52%), and disc collapse with cephalic rod migration (24%). A gain in disc height was observed 1 week after surgery, but, by the 24-month follow-up, the disc space was less than that of the preoperative state. Only 22% of levels had solid fusion at the 24-month radiologic evaluation, and only 2 patients had solid fusion at both levels.

Axial LIF Combined With Another Procedure
In 2010, Patil et al reported a retrospective review of 50 patients treated with axial LIF.9 Four (8%) patients underwent 2-level axial LIF and 16 (32%) patients underwent a combination of
axial LIF with another procedure for an additional level of fusion. There were 3 reoperations due to pseudoarthrosis (n=2) and rectal injury (n=1). Other complications included superficial infection (n=5), hematoma (n=2), and irritation of a nerve root by a screw (n=1). At 12- to 24-month follow-ups, VAS scores had decreased from 8.1 to 3.6 (n=48). At an average 12-month follow-up, 47 (96%) of 49 patients with postoperative radiographs achieved solid fusion. There were no significant differences between pre- and postoperative disc space height and lumbar lordosis angle.

Adverse Events
An industry-sponsored 5-year voluntary postmarketing surveillance study of 9152 patients was reported by Gundanna et al in 2011. A single-level L5-S1 fusion was performed in 8034 (88%) patients and a 2-level (L4-S1) fusion was performed in 1118 (12%) patients. A predefined database was designed to record device- or procedure-related complaints through spontaneous reporting. Several procedures, including the presence of a TransS1 representative during every case, were implemented to encourage complication reporting. Complications recorded included bowel injury, superficial wound and systemic infections, transient intraoperative hypotension, migration, subsidence, presacral hematoma, sacral fracture, vascular injury, nerve injury, and ureter injury (pseudoarthrosis was not included). Follow-up period ranged from 3 months to 5 years 3 months. Complications were reported in 120 (1.3%) patients at a median of 5 days (mean, 33 days; range, 0-511 days). Bowel injury was the most commonly reported complication (0.6%), followed by transient intraoperative hypotension (0.2%). All other complications had an incidence of 0.1% or lower. There were no significant differences in complication rates for single-level (1.3%) and 2-level (1.6%) fusion procedures. Although this study included a large number of patients, it depended on spontaneous reporting, which could underestimate the true incidence of complications.

Lindley et al found high complication rates in a retrospective review of 68 patients who underwent axial LIF between 2005 and 2009. Patient diagnoses included degenerative disc disease, spondylolisthesis, spinal stenosis, degenerative lumbar scoliosis, spondyloysis, pseudoarthrosis, and recurrent disc herniation. Ten patients underwent 2-level axial LIF (L4-S1) and 58 patients underwent a single-level axial LIF (L5-S1). A total of 18 complications in 16 (23.5%) patients were identified at a mean 34-month follow-up (range, 17-61 months). Complications included pseudoarthrosis (8.8%), superficial infection (5.9%), sacral fracture (2.9%), pelvic hematoma (2.9%), failure of wound closure (1.5%), and rectal perforation (2.9%). Both patients with rectal perforation underwent emergency repair and had no long-term sequelae. Patients with nonunion underwent additional fusion surgery with an anterior or posterior approach. The 2 patients with sacral fractures had preexisting osteoporosis. Because of the potential complications, the authors recommended full bowel preparation and preoperative MRI before an axial LIF procedure to assess the size of the presacral space, to determine rectal adherence to the sacrum, to rule out vascular abnormalities, and to determine a proper trajectory.

A search of the U.S. Food and Drug Administration's MAUDE database in April 2016 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm) identified 134 adverse event reports for axial LIF, including possible and confirmed bowel injuries.
Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

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NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

Summary of Evidence
The evidence for axial lumbosacral interbody fusion (LIF) in individuals who have degenerative spine disease at the L4-S1 disc spaces includes case series and 1 retrospective comparative study. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence is insufficient to evaluate whether axial LIF is as effective or as safe as other surgical approaches to LIF, due to the variable nature of the disorder and the subjective nature of the main outcomes. In addition, there are a relatively large number of adverse event reports in the MAUDE database for axial LIF, which raises the possibility of an increased risk of complications. Controlled trials are needed to better define the benefits and risks of this procedure compared with treatment alternatives. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical Input Received From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 2 specialty medical societies and 3 academic medical centers while this policy was under review in 2011. The input considered axial LIF to be investigational.

Practice Guidelines and Position Statements
North American Spine Society
The North American Spine Society (NASS) published a guideline on the treatment of degenerative spondylolisthesis in 2014.12 NASS gave a Grade B recommendation for surgical decompression with fusion in patients with spinal stenosis and spondylolisthesis. The guideline discussed posterolateral fusion, 360° fusion, and minimally invasive fusion, but did not address axial LIF.

American Association of Neurological Surgeons
The American Association of Neurological Surgeons published guidelines for interbody techniques for lumbar fusion in 2005 (part 11).13 There was insufficient evidence to recommend a treatment standard. Minimally invasive procedures were not reviewed.
National Institute for Health and Clinical Excellence
The U.K.’s National Institute for Health and Clinical Excellence (NICE) provided guidance on transaxial interbody fusion in the lumbosacral spine in 2011.14 The guidance states that current evidence on the efficacy of transaxial interbody lumbosacral fusion is “limited in quantity but shows symptom relief in the short term in some patients. Evidence on safety shows that there is a risk of rectal perforation. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.” NICE encouraged “further research into transaxial interbody lumbosacral fusion. Research outcomes should include fusion rates, pain and functional scores, quality of life measures, and the frequency of both early and late complications. NICE may review this procedure on publication of further evidence.”

U.S. Preventive Services Task Force Recommendations
Not applicable.

CODING
The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS
22586 Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed; L5-S1 interspace
0195T Arthrodesis, pre-sacral interbody technique, disc space preparation, discectomy, without instrumentation, with image guidance, includes bone graft when performed; L5-S1 interspace
0196T Arthrodesis, pre-sacral interbody technique, disc space preparation, discectomy, without instrumentation, with image guidance, includes bone graft when performed; L4-L5 interspace (list separately in addition to code for primary procedure
0309T Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft, when performed, lumbar, L4-L5 interspace (List separately in addition to code for primary procedure)

- There is a CPT category I code for this procedure and a category III add-on code for the additional interspace: 22586 and 0309T respectively.
- The category III codes used previously for this procedure were revised in 2013 to indicate that they represent the procedure without instrumentation: 0195T and 0196T.

DIAGNOSIS
Experimental / Investigational for all diagnoses related to this policy.
REVISIONS

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REFERENCES


