

MINIMALLY INVASIVE LUMBAR SPINAL FUSION

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COVERAGE RATIONALE

The following spinal fusion techniques are unproven:

- laparoscopic anterior lumbar interbody fusion (LALIF)
- minimally invasive transforaminal lumbar interbody fusion (MITLIF)
- axial lumbar interbody fusion via a presacral approach (AxiaLIF)

Current clinical evidence on these techniques is from small, uncontrolled studies. Randomized, controlled trials comparing them to standard procedures are needed to determine impact on health outcomes and long-term efficacy.

BACKGROUND

Spinal fusion, also called arthrodesis, is a surgical technique that may be done as an open or minimally invasive procedure. Open procedures require larger incisions, muscle stripping, longer hospitalization and subsequent increased recovery time. Minimally invasive surgical techniques utilize portals or smaller incisions through which small, specialized instruments are inserted. In theory, the advantages of using less invasive approaches are reduced postoperative pain, diminished blood loss, faster recovery and reduced hospital stays.

There are many different approaches to spinal fusion, but all techniques involve removing the disc between two or more vertebrae and fusing the adjacent vertebrae together using bone grafts and/or spacers placed where the disc used to be. Spacers can be made of bone or bone substitutes, metal (titanium), carbon fiber, polymers or bioresorbable materials and are often supported by plates, screws, rods and/or cages.

CLINICAL EVIDENCE

In a review article by German et al. (2005) the author provides an overview of current minimally invasive lumbar fusion techniques. Pertinent literature and the authors' clinical experience were reviewed. Minimally invasive techniques have been developed for intertransverse process, posterior lumbar interbody, and transforaminal lumbar interbody fusions. It is emphasized that while these less-invasive procedures appear promising, the clinical results of these techniques remain preliminary with few long-term studies available for critical review. The author concluded that preliminary clinical evidence suggests that minimally invasive lumbar fusion techniques will benefit patients with spinal disorders. This study has a relatively short follow-up period. More long-term studies are still indicated.

Laparoscopic anterior lumbar interbody fusion (LALIF)

Laparoscopic anterior lumbar interbody fusion (LALIF) is a minimally invasive alternative to an open surgical approach to spinal fusion. The vertebrae are reached through an incision in the lower abdomen or side.

A few small, uncontrolled studies reported relatively high rates of fusion and good symptomatic relief in patients who underwent LALIF for treatment of degenerative disc disease. However, there is insufficient evidence from the available studies to conclude that the laparoscopic approach provides overall health outcomes that are equivalent or superior to those obtained with open surgical approaches to spinal fusion. Although there are some data to indicate that intraoperative blood loss and postoperative morbidity may be reduced in patients who undergo laparoscopic rather than open ALIF for single-level, uncomplicated disc disease, the long-term efficacy of the laparoscopic procedure has not been proven, and there is very limited evidence regarding magnitude of pain relief, fusion rates or frequency of return to work following LALIF. Moreover, there is a significant learning curve associated with LALIF, and a number of technical difficulties are associated with laparoscopic technique in patients with multilevel disease, in obese patients, in patients with intra-abdominal scarring or adhesions, and in patients with L4- L5 disc disease (Hayes, 2002).

Frantzides et al. (2006) completed a retrospective analysis of consecutive patients who underwent L5-S1 laparoscopic ALIF between February 1998 and August 2003. Twenty-eight patients underwent L5-S1 LAIF (15 males and 13 females). The mean age was 43 years (range, 26 to 67). The authors concluded that ALIF is feasible and safe with all the advantages of minimally invasive surgery. Fusion rates and pain improvement were comparable to those with an open repair. However, the small numbers of patients in the study, and the specific experience of the surgeons with this procedure would make it difficult to generalize this result to a larger population

Inamasu and Guiot (2005) reviewed the literature on the outcomes of LALIF. Several comparative

studies showed that at the L5-S1 disc level, there was no marked difference between LALIF and the open or mini-open ALIF in terms of short-term efficacy, i. e., operative time, blood loss and length of hospital stay. With regard to the complication rate, however, there was a higher incidence of retrograde ejaculation in LALIF. At the L4-L5 and L4-L5/L5-S1 disc levels, the complication rate and conversion rate to open surgery was high in LALIF, and many authors were not impressed with the LALIF at these levels. Several case series showed that the LALIF yielded excellent perioperative outcomes in the hands of experienced endoscopic spine surgeons at both the L5-S1 and L4-L5 disc levels. No conclusion regarding either the superiority or inferiority of LALIF to the open or mini-open ALIF can be drawn, because of the lack of data with a high-level of evidence.

Chung et al. (2003) compared perioperative parameters and minimum 2-year follow-up outcome for laparoscopic and open anterior surgical approach for L5-S1 fusion. The data of 54 consecutive patients who underwent anterior lumbar interbody fusion (ALIF) of L5-S1 from 1997 to 1999 were collected prospectively. More than 2-years' follow-up data were available for 47 of these patients. In all cases, carbon cage and autologous bone graft were used for fusion. Twenty-five patients underwent a laparoscopic procedure and 22 an open mini-ALIF. Three laparoscopic procedures were converted to open ones. For perioperative parameters only, the operative time was statistically different ($P=0.001$), while length of postoperative hospital stay and blood loss were not. The incidence of operative complications was three in the laparoscopic group and two in the open mini-ALIF group. After a follow-up period of at least 2 years, the two groups showed no statistical difference in pain, measured by visual analog scale, in the Oswestry Disability Index or in the Patient Satisfaction Index. The fusion rate was 91% in both groups. The laparoscopic ALIF for L5-S1 showed similar clinical and radiological outcome when compared with open mini-ALIF, but significant advantages were not identified.

Kaiser et al. (2002) conducted a retrospective review of 98 patients who underwent ALIF procedures between 1996 and 2001 in which either a mini-open or a laparoscopic approach was used. Patient demographics, intraoperative parameters, length of hospitalization, and technique-related complications associated with the use of these two approaches were compared. The subset of patients who underwent L5-S1 ALIF procedures was analyzed separately. A laparoscopic approach was used in 47 of these patients, and the mini-open technique was used in the other 51 patients. The authors concluded that both the laparoscopic and mini-open techniques are effective approaches to use when performing ALIF procedures. On the basis of the data obtained in this retrospective review, the laparoscopic approach does not seem to have a definitive advantage over the mini-open exposure, particularly in an L5-S1 ALIF procedure. In the author's opinion, the mini-open approach possesses a number of theoretical advantages; however, the individual surgeon's preference ultimately is likely to be the dictating factor.

In a multicenter study, prospective study by Regan et al. (1999), 240 patients underwent LALIF. This cohort was compared with 591 consecutive patients undergoing open anterior fusion using a retroperitoneal approach. The laparoscopy group had shorter hospital stays and reduced blood loss but had increased operative time. Operative time improved in the laparoscopy group as surgeons' experience increased. Operative complications were comparable in both groups, with an occurrence of 4.2% in the open approach and 4.9% in the laparoscopic approach. Overall, the device-related reoperation rate was higher in the laparoscopy group (4.7% vs. 2.3%), primarily as a result of intraoperative disc herniation. Conversion to open procedure in the laparoscopy group was 10%, with most cases predictable and preventable. The laparoscopic procedure is associated with a learning curve, but once mastered it is effective and safe when compared with open techniques of fusion.

Minimally Invasive Transforaminal Interbody Fusion (MITLIF)

Minimally invasive TLIF (MITLIF) is essentially the same as TLIF except that it is performed through smaller incisions using specialized retractors that gradually open an operative corridor through the muscles rather than pulling the muscles aside as with conventional open surgery. Endoscopes are used to visualize the spine and TLIF is performed with specialized instruments

through the retractors with less trauma to soft tissues, which may result in reduced operative time and hospitalization. The operation is performed using fluoroscopic guidance.

Although operative time, blood loss and hospitalization were lower for MITLIF compared with more traditional procedures, there was little difference between MITLIF and open TLIF in the single study that compared them, except for lower blood loss and a higher number of complications in the MITLIF group. Overall, due to deficiencies in study design and the relatively small numbers of patients studied, the evidence is insufficient to demonstrate long-term efficacy and safety of the minimally invasive TLIF technique, or to determine whether this technique is equivalent to open TLIF or more established surgeries such as APLIF and PLIF. It is also unknown how the various techniques for MITLIF compare with one another (Hayes, 2007).

Park and Foley (2008) discussed their retrospective review study results in 40 consecutive patients who underwent MI-TLIF for symptomatic spondylolisthesis utilizing this approach. Thirty cases involved a degenerative spondylolisthesis while the remaining 10 were isthmic. The minimum follow-up was 24 months with a mean of 35 months. The authors conclude that MI-TLIF for symptomatic spondylolisthesis appears to be an effective surgical option with results that compare favorably to open procedures. Results are limited by study design, small patient numbers and lack of a control.

This retrospective study by Scheufler et al. (2007) reports technique, clinical outcomes, and fusion rates of percutaneous transforaminal lumbar interbody fixation (pTLIF). Results are compared with those of mini-open transforaminal lumbar interbody fixation (oTLIF) using a muscle splitting (Wiltse) approach. pTLIF was performed in 43 patients with single-level and 10 patients with bi- or multilevel lumbar discopathy or degenerative pseudolisthesis resulting in axial back pain and claudication, pseudoradicular, or radicular symptoms. Postoperative pain was significantly lower after pTLIF after the second postoperative day ($P < 0.01$). The overall clinical outcome was not different from oTLIF at 8 and 16 months. The authors concluded that pTLIF allows for safe and efficient minimally invasive treatment of single and multilevel degenerative lumbar instability with good clinical results. Further prospective studies investigating long-term functional results are required to assess the definitive merits of percutaneous instrumentation of the lumbar spine.

Villavicencio et al. (2006) retrospectively compared outcomes in 167 consecutive patients with DDD treated with anterior-posterior lumbar interbody fusion MITLIF (73), open TLIF (51), or APLIF (43). MITLIF recipients had fewer previous surgeries (18%) compared with TLIF (39%) or APLIF (49%) recipients. Few details were provided as to surgical techniques or procedures. Mean operative time was 255 min for MITLIF compared with 222 min in open TLIF versus 455 min in APLIF ($P < 0.0001$ for both TLIF procedures versus APLIF). Mean estimated blood loss (EBL) was 231 mL for MITLIF patients, 424 mL for open TLIF patients, and 550 mL for APLIF patients (MITLIF was $P < 0.0001$ versus APLIF and open TLIF was $P < 0.03$ versus APLIF). The mean HLOS was 3.1 days for MITLIF, 4.1 for open TLIF, and 7.2 days for APLIF (both TLIF procedures were $P < 0.0001$ versus APLIF). Only mean EBL showed a statistically significant decrease in MITLIF versus TLIF patients ($P < 0.006$). For MITLIF, open TLIF, and APLIF, major complications occurred in 6 (8.2%), 0, and 27 (62.8%) patients respectively, with minor complications in 16 (21.9%), 18 (35.3%), and 6 (13.9%), respectively.¹⁵ This study is limited by its retrospective design.

In a case series, Deutsch and Musacchio (2006) prospectively evaluated 20 patients with DDD (all of whom had failed conservative therapy) who received MITLIF with unilateral pedicle screw placement. Mean operative time was 246 minutes, mean EBL was 100 mL and mean HLOS was 2.5 days. At follow-up from 6 to 12 months, a good result ($> 20\%$ decrease in ODI) was observed in 17/20 (85%) patients with no improvement in 3 (15%). Mean ODI decreased from 57% to 25%, VAS score decreased from 8.3 to 1.4 ($P < 0.005$) and 13/20 (65%) patients displayed some degree of fusion at 6 months. Cerebrospinal fluid (CSF) leaks occurred in 2 patients, and one new postoperative radiculopathy was observed, which resulted in further surgery to readjust a pedicle

screw.

Isaacs et al. (2005) retrospectively compared 20 patients receiving MITLIF with 24 patients receiving traditional PLIF. All patients had grade I or II spondylolisthesis or mechanical lower back pain and radiculopathy (pain involving the nerve root) and had failed conservative therapy. Two interbody grafts were placed with bilateral pedicle screws using Medtronic instrumentation in the MITLIF group. One senior surgeon supervised all MITLIF operations, while 5 surgeons performed the PLIF operations. Mean operative time was 300 min in MITLIF recipients versus 276 min in PLIF recipients. For the MITLIF and PLIF groups, respectively, the mean EBL was 226 and 1147 mL ($P < 0.001$); mean HLOS was 3.4 versus 5.1 days ($P < 0.02$) and complications occurred in 1 versus 6 patients in these groups, respectively. The retrospective nature of this design limits the ability to draw firm conclusions regarding efficacy.

Axial Lumbar Interbody Fusion

Axial lumbar interbody fusion (AxiaLIF) is a minimally invasive technique used in L5-S1 spinal fusions. The technique provides access to the spine along the long axis of the spine, as opposed to anterior, posterior or lateral approaches. The surgeon enters the back through a very small incision next to the tailbone and the abnormal disc is taken out. Then a bone graft is placed in where the abnormal disc was and is supplemented with a large metal screw. Sometimes, additional, smaller screws are placed through another small incision higher on the back for extra stability. In the literature, the procedure is also referred to as a presacral, transsacral, transaxial or paracoccygeal approach. No randomized controlled trials were found in the peer-reviewed, published clinical literature addressing the safety and efficacy of this technique.

The AxiaLIF (Axial Lumbar Interbody Fusion) System includes surgical instruments for creating a safe and reproducible presacral access route to the L5-S1 vertebral bodies. The AxiaLIF technique features novel instrumentation to enable standard of care fusion principles, distraction and stabilization of the anterior lumbar column while mitigating the soft tissue trauma associated with traditional lumbar fusion through open surgical incisions. The lumbar spine is accessed through a percutaneous opening adjacent to the sacral bone. This atraumatic tissue plane alleviates the need for the surgeon to cut through soft tissues like muscles and ligaments, thus lessening patient pain and the likelihood of complications (TranS1 website).

A Hayes search found a very small body of published literature related to the AxiaLIF system and concluded that there was insufficient evidence to assess the safety and efficacy of AxiaLIF for percutaneous minimally invasive anterior lumbosacral surgery. This technique cannot be recommended for adoption or use at this time (Hayes, 2008).

Aryan et al. (2008) retrospectively reviewed 35 patients with L5-S1 degeneration who underwent percutaneous paracoccygeal axial fluoroscopically-guided interbody fusion (axiaLIF). Twenty-one patients underwent axiaLIF followed by percutaneous L5-S1 pedicle screw-rod fixation. Two patients underwent axiaLIF followed by percutaneous L4-L5 extreme lateral interbody fusion (XLIF) and posterior instrumentation. Ten patients had a stand-alone procedure. Unfavorable anatomy precluded access to the L5-S1 disc space during open lumbar interbody fusion in 2 patients who subsequently underwent axiaLIF at this level as part of a large construct. Thirty-two patients (91%) had radiographic evidence of stable L5-S1 interbody cage placement and fusion at the last follow-up. Average follow-up was 17.5 months. The authors concluded that this approach was safe to perform alone or in combination with minimally invasive or traditional open fusion procedures. While these results are promising, the study is limited by its retrospective design, small sample size and lack of randomization and control.

A technical note by Marotta et al. (2006) described a new paracoccygeal approach to the L5-S1 junction for interbody fusion with transsacral instrumentation. The authors report that this novel technique of interbody distraction and fusion via a truly percutaneous approach corridor allows for circumferential treatment of the lower lumbar segments with minimal risk to the anterior organs and dorsal neural elements.

In a review, Ledet et al. (2006) reported that preliminary results of a novel transaxial approach to lumbosacral fixation appear promising.

Cragg et al. (2004) reported preliminary results of cadaver, animal and human studies performed to determine the feasibility of axial anterior lumbosacral spine access using a percutaneous, presacral approach. Custom instruments were directed under fluoroscopic guidance along the midline of the anterior sacrum to the surface of the sacral promontory where an axial bore was created into the lower lumbar vertebral bodies and discs. Imaging and gross dissection were performed in cadavers and animals. The procedure was used for lumbosacral biopsy in human subjects guided by intraoperative imaging and clinical monitoring. All procedures were technically successful. The authors concluded that this study demonstrated the feasibility of the axial access technique to the anterior lower lumbar spine.

Professional Societies

American Association of Neurological Surgeons (AANS)/Congress of Neurological Surgeons (CNS): The AANS/CNS guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine state that future studies focusing on patient outcomes are required to establish whether the increased fusion rates seen with interbody techniques are truly associated with improved functional outcomes. Application of reliable, valid, and responsive outcome measures in a multi-center randomized trial would serve to answer this question. In terms of the techniques used to achieve an interbody arthrodesis, it is likely that certain techniques will be more applicable to different patient populations. Future studies should be focused on evaluating the individual techniques within specific patient populations. Well-designed cohort studies would provide needed Class II medical evidence. Randomized studies would need to include adequate numbers of patients to ensure sufficient power to be able to assess whether the incremental improvement achieved with interbody techniques is clinically significant (Resnick, 2005).

Additional Search Terms

ruptured disc, slipped disc

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

The FDA has approved numerous devices and instruments used in lumbar spinal fusion. Additional information, using product codes HRX, KWQ and MAX, is available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. Accessed January 20, 2010.

The FDA issued 510(k) approval (K050965) for the TranS1 AxiaLIF System on June 14, 2005. AxiaLIF is an anterior spinal fixation device intended for patients requiring spinal fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (Grade I or 2), or degenerative disc disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is not intended to treat severe scoliosis, severe spondylolisthesis (Grades 3 and 4), tumor or trauma. Its usage is limited to anterior supplemental fixation of the lumbar spine at L5-S1 in conjunction with legally marketed facet and pedicle screw systems.

Additional 510K approvals were received on January 11, 2008 (K073514) and April 28, 2008 (K073643). See the following web site for more information: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. Accessed January 20, 2010.

Additional Products

Atavi, AxiaLIF Interbody Fusion System, MaXcess System, PathFinder

Cages - BAK Interbody Fusion System, INTERFIX RP, INFUSE Bone Graft/LT-CAGE, Lumbar I/F Cage, Ray TFC

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for minimally invasive spinal fusion procedures. Local Coverage Determinations (LCDs) do not exist at this time. Accessed January 21, 2010.

APPLICABLE CODES

The codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

CPT [®] Code	Description
0195T	Arthrodesis, pre-sacral interbody technique, including instrumentation, imaging (when performed), and discectomy to prepare interspace, lumbar; single interspace
0196T	Arthrodesis, pre-sacral interbody technique, including instrumentation, imaging (when performed), and discectomy to prepare interspace, lumbar; each additional interspace (List separately in addition to code for primary procedure)
22899	Unlisted procedure, spine

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Coding Clarification

The North American Spine Society (NASS) recommends that anterior or anterolateral approach techniques performed via an open approach should be billed with CPT codes 22554 – 22585. These codes should be used to report the use of extreme lateral interbody fusion (XLIF) and direct lateral interbody fusion (DLIF) procedures. (NASS, 2010)

Laparoscopic approaches should be billed with an unlisted procedure code.

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
02/26/2010	<ul style="list-style-type: none">• Revised coverage rationale; removed extreme lateral interbody fusion (XLIF) from list of unproven spinal fusion techniques• Added statement of coding clarification for the reporting of XLIF and DLIF procedures• Archived previous policy version 2009T0458D