Value Analysis Brief – MIS Lateral Approach to Interbody Fusion

Methods

This value analysis brief presents information on the clinical and economic benefits of the minimally invasive lateral approach to interbody fusion. The referenced data were obtained through a search of MEDLINE for all peer-reviewed studies published prior to August 2010 that included the lateral interbody approach to spinal fusion for degenerative disease of the lumbar spine. Conference proceedings were excluded from review. Our search yielded one single-center case series and one single-center, prospective chart review – both of which are summarized herein.

Note: The published studies referenced within this document evaluated the clinical and economic merits of the minimally invasive lateral approach to interbody fusion, rather than those attributable specifically to DePuy Spine’s MIS Lateral Platform.

Background

Standard open approaches to spinal fusion can be associated with significant muscle trauma and blood loss. These can increase postoperative pain and hospital length of stay.1 Minimally invasive surgical (MIS) techniques to fuse the anterior spinal column have been introduced with the aim of reducing the size of surgical incisions, decreasing tissue trauma, and allowing for more rapid recovery than possible with traditional open fusion.2, 3

Built upon the fundamentals of spine surgery, the lateral interbody technique has emerged as a minimally invasive approach to accessing the lumbar spine from the patient’s side (Figure 1). The lateral interbody approach allows for clear access to the intervertebral disc while minimizing muscular disruption and trauma to nearby structures (e.g., posterior muscle groups or anterior organs and blood vessels). Neuromonitoring may be used during lateral interbody fusion in an attempt to protect the neural elements that exit the spinal foramen (nerve roots) and travel within the psoas muscle (lumbar plexus). For patients who require fusion of both the posterior and anterior columns of the spine, the lateral interbody approach may be supplemented with open or MIS (percutaneous) pedicle screw fixation.

Potential Clinical Benefits of MIS Lateral Approach to Interbody Fusion

The lateral interbody approach decreases tissue disruption when compared to open approaches to lumbar fusion.

Access to the spine for a lateral interbody fusion is achieved through a small incision in the patient’s side, obviating the need to strip posterior spinal musculature, which has been implicated as a source of morbidity after open posterior fusion (Figures 2a and 2b).4, 5 In contrast to traditional anterior approaches to spinal fusion (e.g., anterior interbody lumbar fusion), the lateral interbody approach allows surgeons to minimize disruption of vital organs and blood vessels (Figures 2a and 2c). Hence, patients who receive fusion via a MIS lateral interbody approach may not only have a smaller scar (Figures 3a-3c), but also may experience less post-operative morbidity when compared to open approaches.
Figure 2a: Incisions for 2-level MIS lateral interbody fusion

Figure 2b: Incision for 2-level open posterior lumbar interbody fusion

Figure 2c: Incision for 2-level open anterior lumbar interbody fusion

Figure 3a: Scars from 2-level MIS lateral interbody fusion

Figure 3b: Scar from 2-level open posterior lumbar interbody fusion

Figure 3c: Scar from 2-level open anterior lumbar interbody fusion
Lateral interbody fusion may reduce intraoperative blood loss when compared to open fusion.

Blood loss during spine surgery may lead to postoperative hematoma, neurologic compromise, or an increased risk of infection. One study compared blood loss for a cohort of 58 patients who received lateral interbody fusion to that for a historic cohort of 40 patients treated with open, posterolateral fusion. Estimated blood loss was statistically lower for patients who received lateral interbody fusion versus those in the open control group (136 mL vs. 489 mL, respectively \[p < 0.0001]\)).

Data from one study suggests complication rates after lateral interbody fusion may be similar for obese and non-obese patients.

Obese patients have been shown to be at greater risk than non-obese patients for experiencing complications, predominantly postoperative wound infection, after lumbar fusion. Data on complication rates from a single-center study are promising for obese (body-mass index \(\geq 30\)) relative to non-obese (body-mass index \(\leq 30\)) patients who receive lateral interbody fusion. Among 313 patients followed for a minimum of 3 months after lateral interbody fusion, the overall incidence of complications was below 8.6% and similar between obese and non-obese patients. No patients in this series had a wound infection.

Nerve irritation is the most commonly occurring complication after lateral interbody fusion.

As with all surgical procedures, lateral interbody fusion poses the risk of complications. Versus a historical control of patients treated with open, posterolateral fusion, the incidence of overall complications in the lateral interbody cohort (22.4%) was comparable to that for the open cohort (22.5%). Among patients who received lateral interbody fusion, 9/58 (16%) experienced approach-related complications, the majority of which were nerve irritation. Major adverse events approximated 8.6%.

Potential Economic Benefits of MIS Lateral Approach to Interbody Fusion

Mean hospital length of stay (LOS) for lateral interbody fusion ranged from 1.24 days to 5 days in the reviewed studies.

Among 432 patients who received lateral interbody fusion in a single institution from 2006 to 2008, mean hospital length of stay was 1.24 days. Knight et al. observed mean length of stay to be 5 days for 58 patients who received lateral interbody fusion between 2004 and 2006, which was comparable to LOS observed in an historical cohort of patients who received open lumbar fusion.

DePuy Spine’s MIS Lateral Platform may be used with a hospital’s existing neuromonitoring system, potentially reducing procedural costs.

Unlike other technology platforms for lateral interbody fusion, DePuy Spine’s MIS Lateral Platform does not require a proprietary neuromonitoring system. The complete platform provides surgeons and hospitals with flexibility to choose the neuromonitoring equipment and staffing model which best meet hospitals’ clinical and economic requirements. Such flexibility may contribute further to the clinical and economic benefits of an MIS lateral approach to spinal fusion.
DePuy Spine has developed a budget impact model that your hospital can use to compare per-patient and annual costs for different lateral interbody fusion platforms. The budget impact model is depicted in Figure 4, below. (Click on the figure for access)

The following two scenarios outline potential differences between DePuy Spine’s MIS Lateral Platform and competitor systems, of which the components may have a significant impact on procedural costs.

**Scenario #1:** DePuy Spine’s MIS Lateral Platform + hospital or third-party neuromonitoring may require:

- COUGAR® LS Interbody Cage
- Probes
- Monitoring Leads
- Costs of Hospital or Third-Party NM

**Scenario #2:** Competitive lateral platform with proprietary neuromonitoring system may require:

- Interbody Cage
- Usage Fees
  - Retractor and/or Lateral Set
  - Monitoring Equipment
- Disposable Light Source
- Disposable Dilators
  - Disposable Shims, Scalpels, and Guidewires
- Probes
- Monitoring Leads

![Figure 4: Budget Impact Model for MIS Lateral Interbody Fusion of the Lumbar Spine. (Click above to access.)](image-url)

If you have any questions about the Budget Impact Model, please contact your DePuy Spine sales representative.
With DePuy Spine’s MIS Lateral Platform, access to the disc space is accomplished with the PIPELINE® LS Lateral Access System and anterior column support is achieved with the COUGAR® LS Lateral Cage System. DePuy Spine’s VIPER® MIS Spine System provides surgeons with a secure, versatile solution for MIS pedicle screw fixation to supplement MIS lateral interbody fusion.

The following are among the benefits of DePuy Spine’s MIS Lateral Platform:

- DePuy Spine’s MIS Lateral Platform may be used with a hospital’s existing neuromonitoring system, potentially reducing procedural costs.
- The independent blades on the PIPELINE LS retractor offer controlled distal expansion and clear visibility in the working area.
- The COUGAR LS cage, composed of Carbon Fiber Reinforced Polymer (CFRP), has a self-distracting tip to facilitate streamlined insertion into collapsed disc spaces.
- The strength of CFRP meets the structural requirements of anterior column support, while optimizing the fusion environment through an open, load-sharing environment.

The PIPELINE LS retractor provides excellent visibility for the surgeon in the working area without expanding the patient’s incision size.

The PIPELINE LS retractor blades have two key features to aid in the access to the interbody space. First, the telescoping feature allows for intraoperative blade depth adjustment to conform to the patient’s anatomy and prevent muscle creep. This is critical to keep the working area clear of any excess tissue that might impair visualization of the disc space. Second, the toeing capability allows for expansion in the working area within the incision rather than at the skin level. With this feature, surgeons have improved visibility without expanding the size of the patient’s incision (Figures 5 and 6).
The COUGAR LS interbody cage has a self-distracting tip for simplified insertion into collapsed disc spaces.

The bulleted nose on the COUGAR LS implant was designed specifically to streamline insertion of the cage into the disc space (Figure 7). This may be particularly useful for treatment of patients who have extremely collapsed disc spaces.

Figure 7: Close-up view of bulleted nose of COUGAR LS interbody cage

Made from CFRP, the COUGAR LS interbody cage has the strength to support the anterior column with an open architecture design.

CFRP is composed of 30% carbon fiber and 70% PEEK and has 2x the strength of pure PEEK. It provides COUGAR LS with the strength to support the anterior column while offering an open-architecture design to maximize the area for bone graft, lateral vascularization, and load-sharing. CFRP implants have over a decade of use in the spine and are strong enough to withstand in vivo loads with an optimized stiffness for load-sharing.

Citations

INDICATIONS

The PIPELINE® LS Lateral Access System is intended for use with the COUGAR® LS Lateral Cage System, which is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The COUGAR LS Lateral Cage System is also indicated for treating fractures of the thoracic and lumbar spine. It is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. When used as a vertebral body replacement device, this system is intended for use with DePuy Spine supplemental internal fixation. The COUGAR LS Lateral Cage System is also indicated for intervertebral body fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive lateral approach. When used as an interbody fusion device, this system is intended for use with DePuy Spine supplemental internal fixation.

The EXPEDIUM® and VIPER® Spine Systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The EXPEDIUM and VIPER Spine System are intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudarthrosis; and failed previous fusion in skeletally mature patients.

When used in a posterior percutaneous approach with MIS instrumentation, the VIPER System are intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudarthrosis; and failed previous fusion in skeletally mature patients.

LIMITED WARRANTY AND DISCLAIMER: DePuy Spine products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

To order, call DePuy Spine Customer Service (1-800-227-6633).