Potential Clinical Benefit

Blood loss was significantly lower for MIS fusion.

Blood loss during spine surgery may lead to postoperative hematoma, neurologic compromise or an increased risk of infection. In the three prospective studies, mean intraoperative blood loss ranged from 150 to 456 ml for MIS fusion versus from 517 to 961 ml for open fusion (Figure 1). These differences were statistically significant (p < 0.05).

Figure 1 – Intraoperative Blood Loss, MIS versus Open Posterior Lumbar Fusion

Note: The studies referenced within this value analysis sought to quantify the clinical and economic merits of MIS posterior fusion, rather than those attributable to a particular brand. Though DePuy Spine’s VIPER® MIS Spine System is among the technologies represented in two of the three prospective studies, data specific to individual brands are not provided.

Methods

This value analysis brief presents information on the relative clinical and economic benefits of minimally invasive surgery (MIS) versus open approaches to posterior fusion of the lumbar spine. The referenced data were obtained through a search of MEDLINE for all peer-reviewed studies published prior to September 2010 that compared clinical or economic outcomes between MIS and open posterior interbody lumbar fusion (transforaminal lumbar interbody fusion [TLIF] or posterior lumbar interbody fusion [PLIF]). Unpublished conference proceedings, retrospective reviews, and noncomparative studies were excluded from review unless higher level evidence was lacking. This search yielded three prospective cohort studies, one meta analysis, and two conference proceedings.

Note: The studies referenced within this value analysis sought to quantify the clinical and economic merits of MIS posterior fusion, rather than those attributable to a particular brand. Though DePuy Spine’s VIPER® MIS Spine System is among the technologies represented in two of the three prospective studies, data specific to individual brands are not provided.

Background

Standard open approaches to fusion of the spine can be associated with significant muscle trauma and blood loss, which can increase postoperative pain and hospital length of stay. MIS techniques for spine fusion 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.

In the reviewed studies, MIS lumbar fusion reduced blood loss, hospital length of stay, and hospital costs when compared to open posterior lumbar fusion during the perioperative period. Results from a meta analysis suggest that fusion rates are comparable for the two approaches. Data on surgical complications—including surgical site infection—show trends favoring MIS versus open fusion. Due to the learning effect, operative time may be longer for MIS fusion.
In two of three prospective studies, MIS lumbar fusion was associated with less postoperative pain.

Shunwu et al. found patients who received MIS fusion to experience greater relief of postoperative back pain than those who received open fusion.\(^3\) Peng and colleagues noted patients who received MIS fusion to have less pain and require less analgesia (morphine) during the immediate post-operative period than those who received open fusion.\(^1\) In this study, improvements in pain and function for all patients endured to two years, but were not statistically different between MIS and open cohorts. Shizas et al. observed no differences in improvements in pain, function, and analgesic use for the two approaches.\(^2\)

In the two studies that reported time to ambulation, patients who received MIS fusion were able to more rapidly ambulate than those who had open fusion.\(^1,3\)

Rates of complications, including postoperative infection, showed a trend favoring MIS fusion.

Dural tear/cerebrospinal fluid leak, new onset radiculopathy, and surgical site infection were the most commonly reported complications in meta analysis comparison of MIS to open TLIF.\(^4\) The pooled frequency of these and complications for all represented studies was 7.5% and 12.6% for MIS and open fusion, respectively.\(^4\) These differences were not statistically significant.

Surgical site infection (SSI) after lumbar fusion warrants specific attention, given the significant patient morbidity and associated costs of this complication. No statistical differences in infection rates were observed between MIS and open cohorts in the three prospective studies. However, differences in infection rates were observed in a retrospective, population-based study of 5,170 patients who received posterior lumbar fusion.\(^6\) In this study, the incidence of post-operative infection was similar for one-level fusions, but was significantly lower for 2-level MIS versus open fusions (30/652 [4.6%] vs. 151/2,157 [7.0%], respectively, \(p = 0.030\)).\(^6\)

Fusion rates were found to be comparable for open and MIS approaches.

Fusion rates for open and MIS posterior lumbar fusion were comparable in a meta analysis representing more than 1,000 patients.\(^4\) The fusion rate for open TLIF was 90.9% (95% confidence interval [CI] of 86.4% to 94.0%). This compared to 94.8% (95% CI of 85.4% to 98.3%) for patients who received MIS fusion.\(^3\)

Potential Economic Benefit

MIS lumbar fusion has been shown to reduce length of stay.

Mean length of stay in the three prospective studies was shorter for patients who received MIS fusion, ranging from 4 to 9 days versus 7 to 13 days for patients who received open lumbar fusion.\(^1,3\) In all cases these differences were statistically significant.

Figure 2 – Hospital Length of Stay, MIS versus Open Posterior Lumbar Fusion\(^1,3\)
MIS lumbar fusion has been shown to reduce hospital costs. In a study of 6,106 patient visits within a nationwide database, total adjusted hospital costs were $2,106 lower for two-level MIS lumbar fusions ($33,879 for two-level MIS fusions versus $35,984 for open lumbar fusions, p = 0.0023). Data from a US National Database with 6,106 patients found costs with MIS fusion to be lower in most areas except for the cost center for supplies (Table 1). Lower total costs were attributable primarily to lower room and board ($857), operating room ($359), pharmacy ($304), and laboratory ($166) costs in the MIS group. Costs were comparable for one-level MIS and open fusions.

Table 1 – Mean Hospital Costs For Two-level T/PLIF Procedures, MIS versus OPEN Procedures (n = 3,351)

<table>
<thead>
<tr>
<th>Variable</th>
<th>MIS</th>
<th>OPEN</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>CARDIOLOGY EKG</td>
<td>$26</td>
<td>$34</td>
<td>0.215</td>
</tr>
<tr>
<td>LAB</td>
<td>$279</td>
<td>$442</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>OR</td>
<td>$5,779</td>
<td>$6,140</td>
<td>0.005</td>
</tr>
<tr>
<td>OTHER</td>
<td>$506</td>
<td>$530</td>
<td>0.616</td>
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<tr>
<td>PHARMACY</td>
<td>$743</td>
<td>$1,043</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>RADIOLOGY</td>
<td>$374</td>
<td>$462</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>ROOM AND BOARD</td>
<td>$2,122</td>
<td>$2,979</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>SUPPLY</td>
<td>$24,268</td>
<td>$23,744</td>
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</tr>
<tr>
<td>THERAPY</td>
<td>$341</td>
<td>$416</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>RESPIRATORY</td>
<td>$60</td>
<td>$93</td>
<td>0.005</td>
</tr>
<tr>
<td>ER</td>
<td>$7</td>
<td>$5</td>
<td>0.449</td>
</tr>
</tbody>
</table>

*two-sample t-test

Operating Room Time

Operating room time was higher for MIS lumbar fusion.

As with other minimally invasive procedures, MIS lumbar fusion requires mastering new techniques, which can increase operative duration due to the learning curve. In the three prospective studies combined, operative time ranged from 16 to 46 minutes longer for MIS versus open lumbar fusions.¹³

Introduction to VIPER MIS Spine System

DePuy Spine has a robust platform of solutions for MIS fusion, including VIPER MIS Spine System. The VIPER System provides adaptable MIS solutions for every step of an evolving practice. VIPER empowers surgeons to treat an unparalleled range of pathologies with a single platform solution. Providing comprehensive instrument and implant options for a variety of surgical techniques, VIPER provides control and confidence for MIS approaches.

- VIPER streamlines rod placement and simplifies rod reduction through a truly percutaneous technique.
- For patients with complex pathologies—including deformity, trauma, or tumor—VIPER provides surgeons with secure, versatile solutions.
- By offering a wide range of rod options for kyphotic and lordotic curves, VIPER provides surgeons with the ability to percutaneously instrument the entire thoracolumbar spine.
- Full compatibility with DePuy Spine’s EXPEDIUM® 5.5 Spine System allows surgeons to provide hybrid construct options where necessary.

Citations

The VIPER® 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 VIPER Systems 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 percutaneous approach with MIS Instrumentation, the VIPER Systems 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.

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

CAUTION: USA Law restricts these devices to sale by or on the order of a physician. To order in the US, call DePuy Spine Customer Service (1-800-227-6633).

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