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An attempt at clinically defining and assessing minimally invasive surgery compared with traditional "open" spinal surgery

Editorial

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Abstract

Background: The goal of this editorial and literature review is to define the term "minimally invasive surgery" (MIS) as it relates to the spine and characterize methods of measuring parameters of a spine MIS technique.

Methods: This report is an analysis of 105,845 cases of spinal surgery in unmatched series and 95,161 cases in paired series of open compared with MIS procedures performed by the same surgeons to develop quantitative criteria to analyze the success of MIS.

Results: A lower rate of deep infection proved to be a key differentiator of spinal MIS. In unmatched series the infection rate for 105,845 open traditional procedures ranged from 2.9% to 4.3%, whereas for MIS, the incidence of infection ranged from 0% to 0.22%. For matched paired series with the open and MIS procedures performed by the same surgeons, the rate of infection in open procedures ranged from 1.5% to 10%, but for spine MIS, the rate of deep infection was much lower, at 0% to 0.2%. The published ranges for open versus MIS infection rates do not overlap or even intersect, which is a clear indication of the superiority of MIS for one specific clinical outcome measure (MIS proves superior to open spine procedures in terms of lower infection rate).

Conclusions: It is difficult, if not impossible, to validate that an operative procedure is "less invasive" or "more minimally invasive" than traditional surgical procedures unless one can establish a commonly accepted definition of MIS. Once a consensus definition or precise definition of MIS is agreed upon, the comparison shows a higher infection rate with traditional spinal exposures versus MIS spine procedures. © 2011 SAS - The International Society for the Advancement of Spine Surgery. Published by Elsevier Inc. All rights reserved.

Keywords: MIS; Minimally invasive surgery; Infection

Minimally invasive surgery (MIS) of the spine should produce clinical, radiographic, and functional outcomes that are similar to or better than those of comparable, open, more extensile surgeries designed to achieve the same goals. "The primary goal of minimally invasive spinal surgery is to minimize paraspinal muscle retraction and dissection in the *hope* that this will lead to reduced blood loss and postoperative pain, acceleration of the recovery period, and improved clinical outcomes." [italics added].¹ These goals are true of all spinal surgical techniques and are not unique to spine MIS. The first published articulation of the phrase "minimally invasive surgery" is credited to John E. Wickham in the *British Medical Journal* in 1987.² He was a urologist who founded the first clinical department of MIS and defined it as "minimal damage of biologic tissue at the point of entrance of surgical instruments." From 1987 to the present, MIS has undergone a continuous evolution, evidenced by the increasing number of patents using descriptions such as "trocar," "expandable trocar," "endoscopic," "microendoscopic," "percutaneous expandable retractor," "three- and four-blade retractors," and "less invasive surgery." It is difficult to precisely define the exact limits of spine MIS because (1) the goals and outcomes of open surgery are to diminish the muscle damage, estimated blood loss, and length of stay (ie, the same metrics of MIS) and (2) MIS is in evolution, with continuous, incremental innovation addressing

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specific approach and surgically related challenges. Although it is difficult to precisely outline the limits of where MIS begins and where open surgery ends, it is essential to understand this to (1) evaluate the results of MIS, (2) compare outcomes, (3) evaluate the cost-effectiveness of MIS, and (4) analyze the incidence of MIS complications.

It is generally recognized that MIS principles are predicated on using "smaller incisions" during access of an MIS surgical corridor: (1) avoiding surgically induced muscle damage from the approach as well as retraction; (2) decreasing disruption of tendon attachments (eg, for posterior lumbar surgery, the multifidus muscle); (3) using natural anatomic planes when possible; and (4) minimizing collateral soft-tissue injury, particularly in adjacent segments. Successful perioperative spine MIS, relative to more invasive or traditional open approaches, would potentially decrease blood loss, postoperative pain, postoperative complications, surgical time (not by itself an absolute goal), and length of hospital stay, the anticipated result of which is a speedier return to normal function. All of these factors should enhance the risk-benefit ratio of spine surgery and improve overall outcomes, leading to more substantial gains in quality-adjusted life-years and incremental cost-effectiveness ratios.

The first requirement is a reference point. MIS has to be minimally invasive compared with something: Is it compared with current conventional open surgery? Is it compared with the standard of care 5 years previously?

MIS does not necessarily mean percutaneous surgery or surgery through a tube, but it does imply less extensile and less disruptive surgery than conventional, comparable surgeries that are currently performed. All investigators probably agree that "percutaneous surgery" includes placing the working instruments through small skin openings, but what is "miniopen" surgery? Although MIS should not be defined simply as making a smaller incision, a small incision is often a characteristic of MIS procedures. In addition, a surgical procedure is not MIS simply because it is performed by working through a tube, although specialized instrumentation for access and creation of a surgical corridor are commonly features of MIS. O'Toole et al.3 defined MIS as "any spinal procedure performed through a tubular retractor system." This definition is probably not precise enough now that thousands of MIS procedures have been reported using expandable tube systems with sections of a single tube that divide into 3 or 4 sections of semilunar tubes that spread apart (eg, far lateral-approach retractor systems, such as extreme lateral interbody fusion [XLIF], direct lateral interbody fusion [DLIF], and lateral lumbar interbody fusion [LLIF]). With modern innovations, it is not straightforward as to what exactly defines a "tube." What are the objective reproducible metrics of how one quantitates a more minimally invasive approach? Most likely, they are a combination of approach- and surgery-related variables and include the size of the skin incision as well as the extent of the local and collateral tissue injury during the approach and surgical procedure.

Methods

How do we evaluate the procedural, clinical, and long-term effectiveness of an innovative procedure and decide whether it is favorable from an MIS perspective? One metric is not sufficient (length of incision, global cost decrease, and so on). The evaluation requires a balanced scorecard-type approach with 4 equally weighted criteria.⁴ We propose 4 major perspectives that can be used to differentiate current spine MIS (including mini-open procedures) and traditional open procedures. They all should be viewed together in a composite approach. The factors involved are (1) local zone of injury (cytokine elevation, muscle creatine phosphokinase elevation (CPK), and so on), which are primarily measures of collateral damage of muscle injury; (2) operative patient demographics that are directly dependent on the surgery/approach (estimated blood loss, length of surgery, fluoroscopy time, radiation exposure, wound drainage, postoperative seroma formation, and so on); (3) hospitalization demographics that are indirectly related to the surgery approach (length of hospital stay, length of stay in an intensive care unit, transfusion rates, discharge to a skilled nursing facility, or length of stay in a rehabilitation hospital); and (4) econometrics or global cost (direct and indirect) to society (implant costs, cost of hospitalization, navigation costs, radiographic imaging costs, return to work, cost of patient being lost to the workforce) (Table 1).

First, open procedures are easily identified by nearly every spine surgeon and need not be further defined but can simply be explained as any traditional approach and/or dissection of any and all anatomic structures required by the operative surgeon in an open fashion, enabling him or her to identify all elements of the surgical pathology in question and subsequently safely address that pathology with acceptable means of treatment, whether decompression, stabilization, reconstruction, or otherwise.

Second, for MIS versus an open technique, there should be a distinction in definitions. Strictly defined, "minimally invasive" implies that the approach is less invasive than open approaches. "Less invasive" may or may not be minimally invasive, because "minimally invasive" implies that the approach to the spinal pathology was the least invasive based on available techniques and technology. Instead of a strict definition, it can be a continuum, such that MIS includes all techniques where a less invasive approach was performed on this continuum. We can then define where each technique falls on this continuum relative to its open counterpart. For example, anterior lumbar interbody fusions at the thoracolumbar junction through a far lateral approach can be compared with their counterpart of an open, thoracoabdominal approach, which crosses the diaphragm and has significant associated morbidities.

Finally, the econometrics of MIS and open techniques may need to be further substratified into acute/perioperative (including in-hospital stay data), subacute, and chronic or long-term. This is especially advantageous when looking at the impact of MIS on cost-effectiveness and future studies. The data thus far suggest that a favorable impact of MIS occurs mainly on changes occurring during the in-hospital stay, or acute stage, and possibly during the Table 1

Quantitative criteria to define MIS of spine: four major categories

1. Local zone of injury—less extensive collateral damage or muscle injury because of the approach	
Less area or zone of injury as assessed by postoperative cross-sectional MRI	
Less selective type II fiber atrophy on postoperative muscle biopsy	
Lower physiologic cross-sectional area reflecting less muscle strength	
Lower incidence of postoperative intracompartmental pressure, decreased perfusion, and lower oxygen saturation of the paraspinal muscl	le compartment
Less intramuscular edema	
Less postoperative muscle atrophy of the multifidus, interspinales, intertransversarii, longissimus, and iliocostalis documented on r	muscle biopsy or less
denervation by EMG	in the second
Postoperative muscle biopsy specimens showing a lower incidence of denervation, fibrosis, and fatty infiltration	
Lower incidence of local neurologic injury (free-running EMG, MEP, SSEP) and less denervation of paraspinal musculature	
Lower incidence of intercostal neuralgia, less decrease of sympathetic trunk function, and less development of reflex sympathetic	dystrophies
Lower incidence of epidural scar formation	5 1
Reduced anterior abdominal dissection and less vascular retraction particularly with multilevel procedures	
2. Operative patient demographics that are directly dependent on the approach	
Less intraoperative estimated blood loss	
Shorter length of surgical time	
Shorter fluoroscopy time and less radiation exposure	
Lower amounts of wound drainage	
Lower incidence of postoperative seroma formation	
Fewer intraoperative complications or adverse events (dural tears, medical complications, and so on)	
Greater preservation of spinal stability by preservation of anterior and posterior longitudinal ligaments	
No or acceptable loss of sagittal or coronal balance	
Smaller zone of muscle injury or necrosis measured by creatine kinase and aldolase levels. Is there a decrease in levels of inflammed and aldolase levels.	matory cytokines
(IL-6, IL-8, IL-10, IL-1) compared with previous techniques?	5 5
Lower incidence of SSIs (Table 2)	
3. Patient and hospitalization demographics that are indirectly related to the approach	
Shorter length of hospital stay	
Shorter length of stay in intensive care unit	
Shorter length of stay in rehabilitation hospital or skilled nursing facility	
Shorter length of time in medically supervised physical therapy before transition to self-motivated physical fitness	
Timing of neurologic decompression, particularly with staged front and back procedures	
Outcome instruments (VAS, ODI, ZCQ, SF-36, ASIA score)	
Fewer intrahospital complications, including medical and comorbidities	
Lower incidence of reoperations	
4. Econometrics or global cost to society	
Faster return to work with less economic expenditures	
Improved QALYs with shorter estimated blood loss, LOS, and hospital time, without sacrificing patient outcome instruments (NDI, ODI	I. VAS, and so on)
More favorable incremental cost-effectiveness ratios (ie, change in cost/change in effectiveness or cost per QALY)	, , ,
MIS is a procedure that requires more dependence on radiographic imaging and intraoperative navigation for intraoperative orienta	ation for the surgeon
Lower cost of spinal instrumentation and spinal implants	anon for the surgeon
Less costs for intraoperative surgical navigation	
Cost of radiographic imaging and intraoperative CT scanning	
Cost of optical magnification, endoscopes, and microscopes	
Cost of patient being lost to the workforce	
Lost opportunity costs	
Learning curve of MIS and time spent adopting new MIS techniques in instructional cadaveric courses	
Ability to expand indications to include additional surgical treatment groups, such as the elderly (higher BMI, more immunocomp	promised, more
osteoporotic, more comorbidities)	
Abbreviations: ASIA, American Spinal Injury Association; BMI, body mass index; CT, computed tomography; EMG, electromyography; IL, inter	
stay; MEP, motor evoked potentials; MRI, magnetic resonance imaging; NDI, Neck Disability Index; ODI, Oswestry Disability Index; QALY, qu	ality-adjusted life-year
SF-36, Short Form 36; SSEP, somatosensory evoked potentials; VAS, visual analog scale; ZCQ, Zurich Claudication Questionnaire.	
subacute stages of surgical recovery and resource utilization. Al- Results	

subacute stages of surgical recovery and resource unitization. Although this may lower the number of days off from work and has substantial societal implications for productivity and the like, only when MIS is correlated with durable improvements in validated outcome measures (Oswestry Disability Index, Visual Analog Scale, Short Form 36, and so on) will the incremental cost-benefit ratios of MIS versus open surgery become apparent. If outcomes fall over a period of 2 to 4 years compared with stable or improving outcomes with open or nonsurgical treatments, a reassessment of MIS would be required.

Criteria example: Lower infection rate as a key differentiator of spinal MIS

One of the clearest advantages of spinal MIS has been reports of lower infection rates compared with open procedures (Table 1, section 2 [operative patient demographics]). O'Toole et al.³ reported 1,338 spinal MIS procedures in 1,274 patients with only 3 postoperative surgical-site infec-

Authors	N	Predominant type of spine surgery	No. of postoperative spine infections	Ratio	Incidence of infection
Open spine procedures					
Spangfort ¹⁴	10,104	Lumbar laminectomies	290	290/10,104	2.9%
Smith et al. ¹⁵	94,115	Posterior spinal fusions	2,280	2,280/94,115	2.4%
Daubs et al. ¹⁶	46	Spinal deformity posterior instrumentation	2	2/46	4.3%
MIS spine procedures					
Perez-Cruet et al. ¹⁷	150	Microendoscopic discectomy (MED)	0	0/150	0%
Schwender et al. ¹⁸	49	MIS TLIF	0	0/49	0%
Selznick et al. ¹⁹	43	MIS TLIF	0	0/43	0%
O'Toole et al. ³	1,338	Mixed—78% simple decompressions, 20%	3	3/1,338	0.22%
		instrumented arthrodesis			
Matched series (open + MIS)					
Rodgers and Michitsch ¹²	144	Instrumented posterior lumbar fusions	6	6/144	4.2%
Rodgers et al. ¹³	313	XLIF	0	0/313	0%
Rovner et al. ²⁰	251	Open TLIF	9	9/251	3.6%
Rovner et al. ²⁰	196	MIS TLIF	0	0/196	0%
Isaacs et al. ²¹	29	XLIF with open posterior instrumentation	3	3/29	10%
Isaacs et al. ²¹	78	XLIF and XLIF with MIS posterior instrumentation	0	0/78	0%
Smith et al. ¹⁵	94,115	Deep infections, all open cases	1,414	1,414/94,115	1.5%
Smith et al. ¹⁵	35	Deep infections, all MIS cases	14,301	35/14,301	0.2%

 Table 2

 Incidence of postoperative wound infections: "Open" compared with MIS procedures

Abbreviations: TLIF, transforaminal lumbar interbody fusion; XLIF, extreme lateral interbody fusion.

tions (SSIs); 2 were superficial and 1 deep. They reported a procedural rate of SSIs for simple decompressive procedures of 0.1% and a rate of only 0.7% for MIS fusion/ fixation. The total SSI rate for the overall group was 0.2%. They compared this with a reported rate of SSIs of 2% to 6% for non-MIS spinal procedures in large clinical series.

Poelstra et al.^{5–10} reported a large series of MIS trauma procedures performed at the University of Maryland Shock Trauma Hospital as life-saving measures in extreme polytrauma cases called "damage control spine surgery." They have an ongoing prospective series comprised of 80 multilevel cases with 2 infections (2.5% incidence). This is better than their historical infection rate of 4% to 18% with the same surgical protocols but using an open surgical approach for the comparative spinal surgery.

In documenting a differential infection rate with MIS versus conventional surgery, Andreshak et al.¹¹ reported a 13% infection rate for obese patients (defined as >20% over ideal body weight) with traditional open spinal procedures. Rodgers and Michitsch¹² analyzed a subset of obese patients. They reported a 4.2% infection rate in 144 obese patients undergoing instrumented open posterior lumbar fusions. Rodgers et al.¹³ performed a retrospective review of 313 patients operated on from October 2006 to July 2008 undergoing MIS far lateral interbody fusions—156 were obese (defined as body mass index >30) and 157 were nonobese. There were no SSIs in this group. Within the same institution, with the same surgeons, this was an improvement from a 4.2% infection rate in 144 open procedures to 0% in 156 MIS procedures in obese patients.

Perhaps the most compelling argument in documenting a lower infection rate of MIS compared with open procedures is shown in Table 2. Three large series comprising over 110,000 open spine procedures resulted in an infection rate range of 2.9% to 4.3%. The infection rates for 4 independent MIS procedures varying from microendoscopic discectomy to MIS transforaminal lumbar interbody fusion ranged from 0% to 0.22%. Separately, there are 4 reported matched series of open versus MIS procedures. All show a lower infection rate for the MIS alternative procedure: Rodgers et al., 0% versus 4.2%; Rovner et al., 0% versus 3.6%; Isaacs et al., 0% versus 10%; and Smith et al. 0.1% versus 1.5%. The matched series are the most compelling argument that the lower infection rate seen with MIS cannot be attributed to less severe pathology in the presenting patients. Table 3 shows the differential infection rate for additional clinical series of legacy procedures compared with MIS spine procedures and correlates this with the clinical parameters, such as number of levels, vertebral location, and whether instrumentation was used. This comparison also shows a higher infection rate with traditional spinal exposures versus MIS spine procedures.

Discussion

It is difficult, if not impossible, to validate that an operative procedure is "less invasive" or "more minimally invasive" than traditional surgical procedures unless one can establish a commonly accepted definition of MIS. Once a consensus definition or precise definition of MIS is agreed upon, we can develop a common language and common objective metrics to statistically validate the advantages of minimally invasive techniques in spinal surgery. At present, the key concepts of MIS rest on efforts to avoid muscle crush injury by avoiding self-retaining retractors and instead using tubular-type table-mounted retractors combined with

	rates
	infection
Table 3	Historical

								Infections			
					No. of			Simple	Instrumented	Instrumented	
Author	Exposure	Approach	Procedure	Indication	levels	Levels	Z	decompression	decompression	fusion	Total
Rodgers et al. ²³	MIS	Lateral, posterior	XLIF	Stenosis with	1-4	L1-L5	600		I	0.0%	0.0%
				instability							
Dakwar et al. ²⁴	MIS	Lateral, posterior	XLIF	Scoliosis	1-6	T10-S1	25	I	I	0.0%	0.0%
O'Toole et al. ³	MIS	Mixed	Mixed	Mixed	<u>1</u> 4	C, T, L	1,338	0.0%	0.44%	0.74%	0.22%
Dhall et al. ²²	MIS	Posterior	TLIF	DDD	1	L	21	I	I	0.0%	0.0%
Villavicencio et al. ²⁵	MIS	Posterior	TLIF	DDD	1-2	L	73	I	I	1.3%	1.3%
McAfee et al. ²⁶	Endoscopic	Anterior	Decompression/fusion	Mixed	Mixed	L	100	I	I	0.0%	0.0%
Brau et al. ²⁷	MIS	Anterior	ALIF	DDD	1	L	686	I	I	0.4%	0.4%
Dhall et al. ²²	Open	Posterior	TLIF	DDD	0	L	21			0.0%	0.0%
Rihn et al. ²⁸	Open	Posterior	TLIF	DDD	1	L	119			6.1%	6.1%
Fasciszewski et al. ²⁹	Open	Anterior	Anterior surgery	Mixed	Mixed	C, T, L	1,223				Р. 1.6%
Villavicencio et al. ²⁵	Open	Posterior	TLIF	DDD	1–2	L	51			1.6%	
Jutte et al. ³⁰	Open	Posterior	PLF	DDD	1 - 7	L	105		4.7%		
Villavicencio et al. ²⁵	Open	Anterior	ALIF	DDD	1-2	L	43			9.3%	0
Epstein et al. ³¹	Open	Posterior	PLF	DDD	Mixed	L	128			10.9%	10.9%
Abbreviations: ALJF, anterior lumbar interbody fusion; C, cervical; DDD, c TLJF, transforaminal lumbar interbody fusion; XLJF, extreme lateral interb	aterior lumbar in mbar interbody	terbody fusion; C, cerv fusion; XLIF, extreme	Abbreviations: ALJF, anterior lumbar interbody fusion; C, cervical; DDD, degenerative disc disease; L, lumbar; MIS, minimally invasive spine surgery; N, sample size; PLF, posterolateral fusion; T, thoracic: TLJF, transforaminal lumbar interbody fusion; XLJF, extreme lateral interbody fusion.	sc disease; L, lum	bar; MIS, r	minimally inv	asive spi	ne surgery; N, sam	nple size; PLF, poste	rolateral fusion; 7	thoracic;

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