SYMPOSIUM: MINIMALLY INVASIVE SPINE SURGERY

Complications Associated With the Initial Learning Curve of Minimally Invasive Spine Surgery

A Systematic Review

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Abstract

Background There is an inherently difficult learning curve associated with minimally invasive surgical (MIS) approaches to spinal decompression and fusion. The association between complication rate and the learning curve remains unclear.

Questions/purposes We performed a systematic review for articles that evaluated the learning curves of MIS procedures for the spine, defined as the change in frequency of complications and length of surgical time as case number increased, for five types of MIS for the spine.

Methods We conducted a systematic review in the Pub-Med database using the terms "minimally invasive spine surgery AND complications AND learning curve" followed by a manual citation review of included manuscripts. Clinical outcome and learning curve metrics were categorized for analysis by surgical procedure (MIS lumbar

All ICMJE Conflict of Interest Forms for authors and *Clinical Orthopaedics and Related Research* editors and board members are on file with the publication and can be viewed on request. *Clinical Orthopaedics and Related Research* neither advocates nor endorses the use of any treatment, drug, or device. Readers are encouraged to always seek additional information, including FDA approval status, of any drug or device before clinical use. decompression procedures, MIS transforaminal lumbar interbody fusion, percutaneous pedicle screw insertion, laparoscopic anterior lumbar interbody fusion, and MIS cervical procedures). As the most consistent parameters used to evaluate the learning curve were procedure time and complication rate as a function of chronologic case number, our analysis focused on these. The search strategy identified 15 original studies that included 966 minimally invasive procedures. Learning curve parameters were correlated to chronologic procedure number in 14 of these studies.

Results The most common learning curve complication for decompressive procedures was durotomy. For fusion procedures, the most common complications were implant malposition, neural injury, and nonunion. The overall postoperative complication rate was 11% (109 of 966 cases). The learning curve was overcome for operative time and complications as a function of case numbers in 20 to 30 consecutive cases for most techniques discussed within this review.

Conclusions The quantitative assessment of the procedural learning curve for MIS techniques for the spine remains challenging because the MIS techniques have different learning curves and because they have not been assessed in a consistent manner across studies. Complication rates may be underestimated by the studies we identified because surgeons tend to select patients carefully during the early learning curve period. The field of MIS would benefit from a standardization of study design and collected parameters in future learning curve investigations.

Introduction

The ability to treat conditions of the spine through minimally invasive surgical (MIS) techniques has garnered

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increased interest from spine surgeons and their patients over the past two decades [17]. MIS for the spine includes a wide variety of procedures designed to achieve decompression and stabilization of the cervical, thoracic, or lumbar spine while minimizing soft tissue damage. The principle of soft tissue preservation in MIS for the spine is largely accomplished by way of a carefully planned approach to the surgical target site. MIS fusion of the lumbar spine utilizes multiple paramedian incisions with tubular dilation to prevent crush injury or detachment of the stabilizing muscles of the spine. Important structures spared with this approach, as well as with lateral approaches to lumbar fusion, include the spinous process, the tendinous attachments of the multifidus muscle, and the supraspinous and interspinous ligaments [7, 9, 13]. Similarly, an anterior approach to MIS cervical decompression is utilized to prevent damage to the posterior cervical paraspinal musculature [5]. These techniques may result in less postoperative instability, less intraoperative blood loss, a shorter hospital stay, and a lower infection rate than traditional open procedures [5, 10, 14, 22]. Potential longterm benefits include less postoperative instability, which could lead to improved patient function.

A major challenge of MIS for the spine is the technical difficulty of working through a narrow surgical corridor with limited visualization of anatomic landmarks. A spine surgeon trained in traditional open methods must overcome a learning curve on the way to mastering MIS techniques for the spine [2, 9, 26, 28]. Specialized retraction systems, computer-assisted navigation technologies, and focused

cadaveric training courses have been developed to decrease the MIS learning curve [28]. However, surgeons who adopt these techniques must be prepared for a higher complication rate and prolonged operative times during the initial experience with MIS procedures [20].

This systematic review evaluated the learning curves of MIS procedures for the spine, defined as the change in frequency of complications and length of surgical time as case number increased, for five types of MIS for the spine.

Search Strategy and Criteria

We used the Cochrane methodology [4] to perform a systematic review of PubMed for the learning curve of five categories of MIS procedures for the spine: MIS lumbar decompression procedures, MIS transforaminal lumbar interbody fusion (TLIF), percutaneous pedicle screw insertion, laparoscopic anterior lumbar interbody fusion (ALIF), and MIS cervical procedures. We used three successive searches: "minimally invasive spine surgery" (1960 results), "AND complications" (reduced to 986 articles), "AND learning curve" (reduced to 37 articles) (Fig. 1).

All manuscripts returned from this search strategy were reviewed in full for inclusion. Additionally, a manual review of the citation sections within included articles was performed. All case reports, case series, and clinical learning curve studies that pertained to decompression or fusion procedures of the cervical, thoracic, or lumbar spine

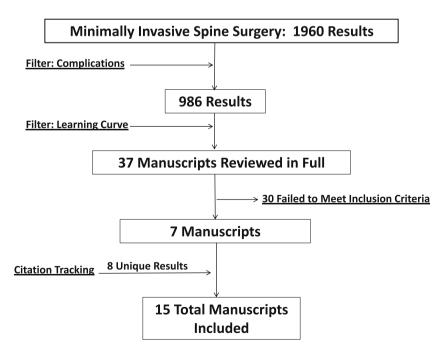


Fig. 1 A flow diagram illustrates the search and selection process.

were included. Studies that focused on revision procedures. corpectomy, or treatment of traumatic fracture or malignancy were excluded. The search strategy identified 37 total manuscripts that were reviewed in full. Twenty of these articles were excluded for not discussing complications during the learning curve period. An additional eight publications were excluded because they focused on treatment for fracture, malignancy, revision surgery, corpectomy, or cervical disc replacement. Two articles were excluded for only presenting cadaveric data. Manual review of the reference sections of included studies yielded eight additional publications that met inclusion criteria and were included in this review. Thus, a total of 15 articles were included in our systematic review, none of which were case reports [1, 3, 6, 8, 11, 12, 15, 16, 18, 19, 21, 23– 25, 27] (Table 1).

The mean publication year was 2007 (median 2008). We included three microendoscopic decompression studies, two tubular microdiscectomy studies, one percutaneous endoscopic lumbar discectomy study, one percutaneous pedicle screw study, four MIS TLIF studies, one laparoscopic ALIF study, one endoscopic anterior cervical decompression study, one MIS posterior cervical decompression study, and one imaging technology study in this review.

Of 966 MIS procedures for the spine included in this review, data were collected prospectively on 827 cases and retrospectively on 139 cases. We included nine publications with Level IV evidence (case series without comparison group) [3, 6, 12, 15, 16, 21, 23, 24, 27], four with Level III evidence (retrospective comparative study) [1, 8, 11, 18], and two with Level II evidence (prospective comparative study) [19, 25].

MIS learning curve parameters that were assessed relative to chronologic case number were operative time (n = 11), complication type/frequency (n = 10), and estimated blood loss (n = 2). The overall postoperative complication rate was 11% (109 of 966 cases).

All findings were summarized qualitatively without statistical pooling or performing meta-analysis. Statistical findings from relevant studies are listed individually (Table 1).

Results

Decompression Procedures

Results from 528 decompression procedures (428 prospective, 100 retrospective) were included from six publications [6, 12, 15, 16, 18, 23] (Table 1). Five studies had Level IV evidence [6, 12, 15, 16, 23] and one had Level III evidence [18]. There were 195 microendoscopic discectomy cases, 282 tubular microdiscectomy cases, and 51 percutaneous endoscopic lumbar discectomy cases included in this review [6, 12, 15, 16, 18, 23].

All cases of durotomy, neurologic injury, and conversion to open procedures in these publications occurred within the initial 30 cases. When adverse events were recorded relative to sequential case number, there were combined complication rates of 11% (31 of 283) during the initial 30 decompression cases performed and 0% (0 of 117) after the 30th consecutive case by the learning surgeon. An overall complication rate of 6% (37 of 580) was reported in this collection of studies. The most frequently reported complications were durotomy (n = 25), nerve root compromise (n = 3), and incorrect level operation (n = 2). There was a combined reoperation rate of 3% (19 of 580) and a rate of conversion to open technique of 2% (five of 247).

Procedure length was also reported as a function of chronologic case number in four publications [15, 16, 18, 23]. The operative time was observed to decrease throughout these case series and approached an asymptote between the 15th and 30th procedure.

Percutaneous Pedicle Screw Insertion

A single percutaneous pedicle screw insertion learning curve study (Level IV evidence) met the inclusion criteria [3] (Table 1). That prospective study reported data on 52 successive percutaneous pedicle screw insertions in 12 patients. The authors of that study discovered loosening of the fixation construct after the first chronologic case that required revision surgery. There were no subsequent complications in that study.

MIS TLIF

Results from 99 MIS TLIF procedures (60 prospective, 39 retrospective) were included from five publications [1, 8, 11, 19, 25] (Table 1). The evidence was classified as Level II in two of these studies [19, 25] and as Level III in three studies [1, 8, 11].

For these studies, there was an overall complication rate of 20% (20 of 99), which included instrumentation malposition/migration (n = 6), perioperative infection (n = 4), nonunions (n = 5), durotomy (n = 1), and postoperative contralateral stenosis (n = 1). There were no reported conversions from MIS to open TLIF procedures. There was a cumulative complication rate of 33% (10 of 30) in three separate studies that evaluated complication rate relative to chronologic case number within the initial 10 cases performed by the learning surgeon [1, 11, 25].

There were two MIS TLIF studies that reported procedure time as a function of chronologic case number and

Table 1. Characteristics of included studies	luded studies				
Study	Intervention	Study design	Sample size	Level of evidence	Learning curve findings
Nowitzke [16] (2005)	Microendoscopic discectomy	Prospective	35	IV	Procedure time: asymptote reached at Case 30
Jhala and Mistry [6] (2010)	Microendoscopic discectomy	Retrospective	100	IV	Complications: all occurred in initial 10 cases (n = 4): nerve root injury with conversion (Case 1), discitis (Case 4), unintended removal of facet joint (Case 5), dural tear (Case 7)
Rong et al. [23] (2008)	Microendoscopic discectomy	Prospective	60	IV	Conversion to open: 1 in the initial 10 procedures; none thereafter
					Complications: all occurred in the initial 20 procedures $(n = 5)$
					Procedure time: asymptote reached at Case 20 FBI: asymptote reached at Case 20
					Reoperations: none
McLoughlin and Fourney [15] (2008)	Tubular microdiscectomy	Prospective	52	IV	Complications: all occurred in the initial 30 procedures $(n = 3)$; dural tears (Cases 2, 8, 26)
					Procedure time: asymptote reached at Case 15
Parikh et al. [18] (2008)	Microdiscectomy and MIS laminectomy	Prospective	230	III	Procedure time: 55% decrease in procedure time from initial case to Case 230
Lee and Lee [12] (2008)	Pecutaneous endoscopic lumbar discectomy	Prospective	51	IV	Complications: all occurred in the initial 25 procedures $(n = 2)$
					Procedure time: asymptote reached at Case 35
					Clinical outcome: trend toward better clinical outcome with more experience
Foley and Gupta [3] (2002)	Percutaneous pedicle screw	Prospective	52 (screws)	IV	Complications: single reoperation for hardware loosening (Case 1)
					Procedure time: decreased chronologically
Lau et al. [11] (2011)	MIS TLIF	Retrospective	10	Ħ	Complications: in initial 10 cases (n = 4); cardiopulmonary event and deep wound infection (n = 1), superficial wound infection (n = 1), pseudarthrosis (n = 1), instrumentation malposition requiring reoperation (n = 1)
Park and Ha [19] (2007)	MIS TLIF	Prospective	32	П	Complications: 13% rate in the initial 32 cases $(n = 4)$; screw malposition $(n = 1)$, spacer migration $(n = 1)$, deep wound infection $(n = 1)$, nonunion $(n = 1)$

Table 1. continued					
Study	Intervention	Study design	Sample size	Level of evidence	Learning curve findings
Schizas et al. [25] (2009)	MIS TLIF	Prospective	18	Π	Complications: no pattern of increased complications during initial MIS cases compared to open group Procedure time: asymptote reached at Case 15 (30% decrease from initial case) EBL: lower EBL in initial series of MIS group
Dhall et al. [1] (2008)	MIS TLIF	Retrospective	21	Π	compared to open group Complications: 14% rate in the initial 20 cases ($n = 3$); spacer migration ($n = 1$), malpositioned screw ($n = 1$), pseudarthrosis ($n = 1$) Procedure time: asymptote reached at Case 20 (50%)
					decrease from initial case) EBL: lower EBL in initial series of MIS patients compared to open patients
Kim et al. [8] (2008)	MIS TLIF-imaging technology	Prospective/ retrospective	10/8	Ш	Complications: none in initial series Procedure time: navigation reduces fluoroscopy time and radiation exposure without increasing overall
Regan et al. [21] (1999)	Laparoscopic ALIF	Prospective	240	IV	operative time Procedure time: 23% decrease in operative time for all learning surgeons (first five cases vs last five cases)
Tan et al. [27] (2008)	Endoscopic anterior cervical discectomy	Prospective	36	IV	Procedure time: asymptote reached at Case 20 Conversion to open: none reported Fusion rate: 100% fusion rate
Scheufler and Kirsch [24] (2007)	Percutaneous posterior cervical decompression	Prospective	Ξ	IV	Procedure time: decreased 41% over initial series
MIS = minimally invasive surg	MIS = minimally invasive surgery; TLIF = transforaminal lumbar interbody fusion; ALIF = anterior lumbar interbody fusion; EBL = estimated blood loss.	oar interbody fusion; ALIF =	anterior lumbar interl	ody fusion; EBL =	= estimated blood loss.

they demonstrated mean decreases in operative time of 33% (360 minutes to 240 minutes) and 50% (250 minutes) to 125 minutes) over the initial 20 MIS TLIF cases [1, 25]. These results suggest that the MIS TLIF learning curve in terms of operative time is approximately 20 cases.

ALIF

A single prospective collection of 240 laparoscopic ALIF procedures (Level IV evidence) met inclusion criteria and was included in the review [21] (Table 1). A total of 19 surgeons participated in this study. Collectively, there was a rate of intraoperative conversion to a traditional ALIF of 10% (25 of 240) and a reoperation rate of 5% (10 of 215). Complication rate was not assessed relative to chronologic procedure number. There was a mean decrease in operative time of 23% (215 minutes to 165 minutes) between the first five and last five procedures performed by each participating surgeon.

MIS Cervical Procedures

The search strategy captured prospectively collected data for 36 endoscopic anterior cervical decompression [27] and 11 percutaneous posterior cervical decompression procedures [24] (Table 1). The evidence in both studies was categorized as Level IV.

There was a complication rate of 3% (one of 36) (wound dehiscence) reported in the endoscopic anterior cervical decompression learning curve study [27] and no perioperative complications reported in a series of 11 percutaneous posterior cervical decompression and fusion procedures [24]. All cases were successfully completed without conversion to open techniques.

Operative time decreased 41% (243 minutes to 143 minutes) over the initial 10 cases of the posterior cervical decompression and fusion series [24]. Similarly, procedure length decreased 50% (140 minutes to 70 minutes) as the endoscopic anterior cervical decompression learning curve was overcome and an operative time asymptote was approached by the 20th procedure [27].

Discussion

There is an inherently difficult learning curve associated with MIS approaches to spinal decompression and fusion procedures. Since the association between important surgical parameters such as complication rate and operative time and the learning curve remains unclear, we conducted a review to characterize complication rate and operative time as a function of surgeon experience with MIS techniques for the spine. All studies that met the inclusion criteria of this review presented complication rate or operative time in terms of chronologic case number for the learning surgeon. The learning curve was overcome for both parameters after 30 chronologic cases in this collection of studies representing several MIS techniques.

This systematic review had a number of limitations. First, the learning surgeon may preferentially choose straightforward cases early in their experience with a new MIS technique, which could result in misleading complication rate and procedure time data. This selection bias would be reduced in an unselected series or properly designed randomized controlled study. Second, procedure time and complication rate were measured inconsistently in the included studies. In many cases, the operating surgeon was responsible for detecting these end points, which could greatly affect the frequency and severity of reported adverse events. Given these limitations, data presented in this review should be interpreted as merely an estimation of surgeon progression through the MIS learning curve.

Perhaps the most clinically relevant parameter used to assess surgeon progression through the procedural learning curve is complication rate. All complications, adverse events, and conversions to open techniques occurred within the initial 30 procedures when these parameters were reported as a function of chronologic case number. The lack of clear anatomic landmarks appears to be a significant limitation in the MIS approach to the spine. Jhala and Mistry [14] attributed complications during the microendoscopic discectomy learning curve period to unfamiliarity with endoscopic image orientation and suboptimal approach to the surgical target. This resulted in injury to neurologic structures, multiple durotomies, wrong-level procedures, and unintended removal of facet joint structures in the initial series of patients. Multiple authors argue the key step in overcoming the MIS learning curve is an ideal entry point and trajectory during the surgical approach [1, 19, 23]. Dhall et al. [1] and Park and Ha [19] both assert that a correct initial placement of the tubular dilator during the MIS TLIF approach prevents intraoperative readjustments, which can lead to a high rate of neurologic injury and inadequate decompression.

Procedure time is a frequently used parameter to assess surgeon progression through the learning curve. Several studies plotted operative time as a function of chronologic case number and correlated surgeon comfort and technical efficiency to a decrease in procedure length [1, 12, 15, 16, 21, 23–25, 27]. These studies demonstrated procedure time rapidly decreased 23% to 58% during the initial series of cases and approached an asymptote between the 10th and 30th case [1, 15, 16, 21, 23–25, 27].

In summary, we found that studies evaluated the learning curve very inconsistently. Most studies utilized procedure time versus chronologic case number as the main parameter to assess competence. Complication rate as a function of chronologic case number, a key parameter, was not always discussed. Standardization of studies on this important topic would allow better assessment of strategies to decrease learning curve problems, such as the use of advanced intraoperative imaging technologies or specialized training programs. Future studies should standardize learning curve assessment to include both procedure time and complication rate as a function of case number. Additional parameters such as health-related quality-of-life outcomes, estimated blood loss, reoperation rate, and conversion to open techniques should also be evaluated in relation to sequential procedure performed within the learning curve period.

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