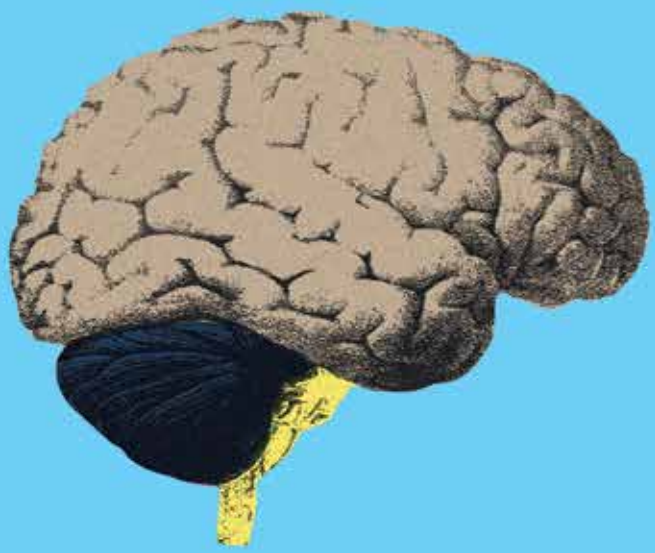
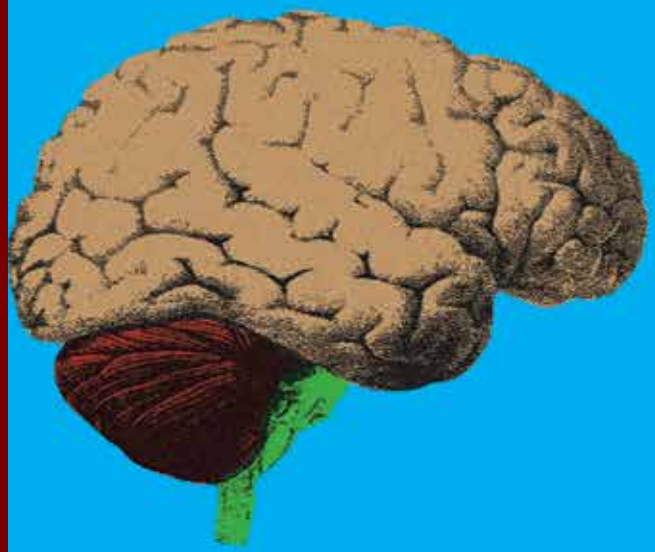
Rev Mex Neuroci ahora en CONACyT

Volumen 18, Enero, Año 2017

Revista Mexicana de Neurociencia

Publicación oficial de la Academia Mexicana de Neurología A.C.





Revista Mexicana de Neurociencia 2017; 18(1):54-64

www.revmexneuroci.com / ISSN 1665-5044

Órgano Oficial de Difusión de la AMN

Academia Mexicana de Neurología, A.C.

Contribución Original

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Propuesta de una nueva curva de aprendizaje para la fusión intersomática lumbar transforaminal mínimamente invasiva: ¿Realmente importa el entrenamiento?

Proposed novel learning curve pattern for minimally invasive transforaminal lumbar interbody fusion: does training really matter?

Resumen

Introducción: Algunos estudios han reportado la curva de aprendizaje en la técnica de fusión intersomática lumbar transforaminal mínimamente invasiva (FISLT-MI) basado en el tiempo quirúrgico, pérdida sanguínea estimada y alta tasa de complicaciones perioperatorias asociadas con la experiencia inicial en la realización de la técnica. En este estudio se propone un enfoque diferente a la curva de aprendizaje tradicional de esta técnica.

Objetivo: Evaluar la curva de aprendizaje en FISLT-MI por un único cirujano durante su formación en cirugía de columna mínimamente invasiva.

Métodos: Revisión retrospectiva de registros quirúrgicos. Se aplicó regresión por partes y análisis de suma acumulativa (CUSUM, por sus siglas en inglés) para evaluar la curva de aprendizaje de un solo cirujano para técnica FISLT-MI desde febrero de 2012 a marzo de 2015.

Resultados: Se revisaron registros quirúrgicos de 54 pacientes sometidos al procedimiento FISLT-MI. Se evaluaron habilidades relacionadas con la técnica obtenidas durante la formación de cirugía de columna mínimamente invasiva. El análisis del gráfico CUSUM sobre el tiempo quirúrgico demuestra una inflexión en el paciente 16. El tiempo quirúrgico promedio fue de 182.4±63.6 min, la media intraoperatoria de la pérdida de sangre fue de 43.8±34.1 mL y la duración promedio de la hospitalización fue de 3 días. Hubo diferencias significativas en los resultados clínicos y funcionales a los seis meses y en el seguimiento final. No se produjeron complicaciones perioperatorias. La evaluación de habilidades técnicas objetivas estructuradas fueron ≥ 25 en cada procedimiento. El gráfico CUSUM demostró un prolongado dominio quirúrgico después el paciente número 16.

Palabras clave

Columna Lumbar, Curva de aprendizaje, Cirugía mínimamente invasiva, Fusión Intersomática lumbar transforaminal, Cirugía de columna vertebral

Conclusiones: La curva de aprendizaje de la FISLT-MI requiere conocimientos y habilidades adquiridas a través de sesiones de entrenamiento anatómico, biomecánico y cadavérico, como estrategias de simulación y aprendizaje en sala de operaciones por tiempo prolongado. Finalmente, el dominio quirúrgico representa una virtud personal que no puede medirse fácilmente y que el cirujano debe llevar a cabo para obtener determinados objetivos quirúrgicos.

Abstract

Introduction: Several studies have reported the learning curve in minimally invasive transforaminal lumbar interbody fusion (MI-TLIF) technique based on surgical time, estimated blood loss, and high rate of perioperative complications associated with the initial experience in performing the technique. A different approach to the learning curve of this technique is proposed in this study.

Objective: To assess the learning curve in MI-TLIF by a single surgeon during his minimally invasive spine surgery fellowship training.

Methods: Retrospective review of surg
ical records. Piecewise regression and cumulative sum (CUSUM) analysis were applied to assess the learning curve of a single surgeon for MI-TLIF technique from February 2012 to March 2015.

Results: Surgical records of 54 patients who underwent MI-TLIF procedure were reviewed. Technique-related skills obtained during the minimally invasive spine surgery fellowship were evaluated. Piecewise regression analysis and CUSUM operative time chart evidenced an inflection at the 16th patient. The mean operative time was 182.4±63.6 min, mean intraoperative blood loss was 43.8±34.1 mL and median hospital length stay was 3 days. There were significant differences in clinical and functional outcomes at six months and at final follow-up. No perioperative complications occurred. The objective structured assessment of technical skills evaluations were ≥ 25 in every procedure. CUSUM chart demonstrated an extended period of surgical proficiency after the 16th patient.

Conclusions: MI-TLIF learning curve requires knowledge and skills acquired through anatomical, biomechanical and cadaveric training sessions, as well as simulation and learning strategies in operating room for a long time. Finally, surgical proficiency represents a personal gift that cannot be easily measured and the surgeon must perform in order to obtain particular surgical goals.

Keywords

Lumbar spine, Learning curve, Minimally invasive surgery, Transforaminal lumbar interbody fusion, Spinal surgery

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Introduction

Since the last two decades there is a growing interest for the treatment of the spinal disorders through minimally invasive surgical procedures.[1,2] Recently, several manuscripts reported successful outcomes associated with minimally invasive transforaminal lumbar interbody fusion *(MI-TLIF)*. Also several authors evidenced that MI-TLIF procedures provide benefits regarding estimated blood loss, postoperative pain intensity and length of hospital stay.[3-5] Some disadvantages about MI-TLIF are the difficulty of working through a narrow surgical corridor that limits visualization of important anatomical landmarks and its steep learning curve.[6,7] Several articles report the existence of a learning curve applied to MI-TLIF taking in account the operating time and other perioperative and postoperative data.[1,6-8] Furthermore, other studies refer that the rate of complications are the best indicators reflecting the experience of a spine surgeon and those studies recommend to be cautious during initial MI-TLIF procedures to avoid complications associated to the learning effect.[6,9] The process of learning MI-TLIF requires acquiring knowledge and surgical skills through a number of anatomical and biomechanical learning sessions, cadaveric practices and specific training with sophisticated simulation equipment without omitting the importance of learning acquired in the operating room. The main objective of this study was to assess the learning curve of one of the authors in MI-TLIF during his minimally invasive spine surgery fellowship training preceding his surgical autonomy.

Materials and methods

The approval of local ethics committee was obtained.

We retrospectively reviewed clinical records of all patients who underwent MI-TLIF during February 2012 to March 2015. Same surgical team performed all MI-TLIF procedures. Inclusion criteria were adult patients, both genders, with degenerative lumbar spine disease and without clinical improvement to conservative treatment for at least a six months period prior to MI-TLIF. In addition, we excluded patients in which revision surgery was performed. With these selection criteria we included fifty-four patients as a discretionary sampling. Of these patients, database of surgical activities performed by a single MISS-fellow *(index surgeon)* was reviewed.

Surgical technique

With the patient in prone position under general anesthesia and continuous neurophysiologic monitoring and fluoroscopic image guidance with C-arm, surgical approach was performed on the most symptomatic side. Progressive tubular retractors were used. Minimally invasive surgical procedure was performed through a 16 mm diameter working cannula. Complete lateral facetectomy and discectomy was performed; the endplates were prepared and bone graft was delivered in the lumbar intersomatic space. A rectangular bullet-nose cage was inserted. Cannulated transpedicular screws were placed afterwards. The exact details of the surgical procedure are described elsewhere.[10]

Parameters measured

Perioperative parameters included patient demographics, operative time, estimated blood loss, perioperative complications and length of hospital stay. VAS *(Visual Analogue Scale)* for back and leg pain, ODI *(Oswestry Disability Index)* and SF-36 *(The 36-Item Short Form Health Survey)* were preoperatively assessed and at 6 and 12 months postoperatively. MI-TLIF learning parameters included the amount of surgical tasks and the time it took to perform on each patient. Surgical skills were evaluated using The Objective Structured Assessment of Technical Skills *(OSATS)* global rating scale.[11] Evaluations were carried out by the surgeons who participated in the procedure.

Statistical analysis

Descriptive statistics was performed using SPSS version 17.0 statistical software. The clinical records were sequentially ordered according to date of surgery. Surgical time was properly adjusted on patients undergoing multilevel MI-TLIF.[12] The learning curve based on surgical time was calculated by piecewise regression analysis using the mathematical algorithm described by Muggeo,[13] *(SigmaPlot statistical software version 12.3)*. Additionally, cumulative sum *(CUSUM)* method was applied for the analysis of the learning curve using Statgraphics Centurion statistical software, Version 16.2.[14]

Results

Of 54 patients evaluated from February 2012 to March 2015, 30 patients *(55.5%)* were female and 24 patients *(44.4%)* were male. Mean *(±SD)* age of the patients was 68.91±7.18 years *(range 65-89 years)*. Two-level surgery was performed in 19 patients *(35.18%)* and 2 cases *(3.7%)* required a three-level fusion surgery. Mean *(±SD)* operative time was 182.4±63.6 min *(range 90-340 min)*, mean *(±SD)* estimated blood loss was 43.8±34.1 mL *(range 10-250 mL)*. The median hospital length stay was 3 days *(IQR 2-10 days)*. VAS back and leg pain, ODI were assessed preoperatively and at 6 and 12 months. SF-36 survey was evaluated preoperatively and at the final follow-up *(Table 1)*.

None of the cases required conversion to open surgery technique. No perioperative complications occurred.

Learning Curve

Piecewise regression analysis evidenced that according to operative time in MI-TLIF, there is a break point at the 16th patient *(Figure 1)*. CUSUM chart for operative time demonstrated a downward-trend pattern of surgical proficiency after the 16th patient *(Figure 2)*. The moving range chart demonstrated longer surgical time in patients 9, 26 and 36 despite the average operating time *(Figure 3)*.

MI-TLIF Learning Process

The regression analysis chart showed a different pattern in the learning curve when compared with operating time curve. This pattern represents the progressive acquisition of surgical skills until achieving the full execution of MI-TLIF procedure. The inflection identified at the 16th patient corresponds with surgical time proficiency; from the 32nd patient the surgeon *(MISS-fellow)* reached self-confidence and fluency in the execution of the MI-TLIF technique. *(Figure 4)* The latter is explained in *Table 2* that represents the surgical tasks performed by the index surgeon *(MISS-fellow)* during his learning process of MI-TLIF, more specifically at the first 18 months as MISS-fellow performing 237 tasks in 32 patients. To our knowledge, this is a novel learning curve pattern that has not been previously discussed in the literature. This curve demonstrates that while performing more tasks during the learning process, more experience

	Preoperative	6 months	12 months
VAS back pain	7.94±2.21	2.50±1.65	1.25±0.95
VAS leg pain	7.42±2.97	1.14±1.51	0.66±1.67
ODI	43.26±19.68	8.40±12.12	8.00±3.46
SF-36 physical function	29.62±23.49		63.65±25.91
SF-36 mental health	50.77±34.19		81.54±14.47

VAS: Visual analogue scale, SF-36: 36-Item Short Form Health Survey, ODI: Oswestry Disability Index, expressed as mean ± standard deviation.

Table 1. Summary of clinical outcomes in 54 patients using VAS, ODI and SF-36 scales.

the surgeon acquires. The CUSUM chart shows a negative slope due to less time for executing more surgical tasks in relation with an increase in surgical experience *(Figure 5)*. The evaluation of surgical skills with OSATS *(Objective Structured Assessment of Technical Skills)* global rating scale rated 27 points in the first 237 tasks and 30 points in the subsequent 220 tasks performed by index surgeon.

	N=32 (First 18 months)	N=22 (Subsequent 6 months)	Total of Surgical Tasks Performed
Patient placement	32	22	54
Fluoroscopic planning	32	22	54
Incision	32	22	54
Tubular retractor docking	25	22	47
Facetectomy with high-speed drill	22	22	44
Microdiscectomy	16	22	38
End plate preparation	8	22	30
Bone graft placement	30	22	52
Cage introduction	15	22	37
Pedicle screw placement	25	22	47
Total	237	220	457

Table 2. Surgical tasks performed by a MISS-fellow in his learning process of MI-TLIF during two years.

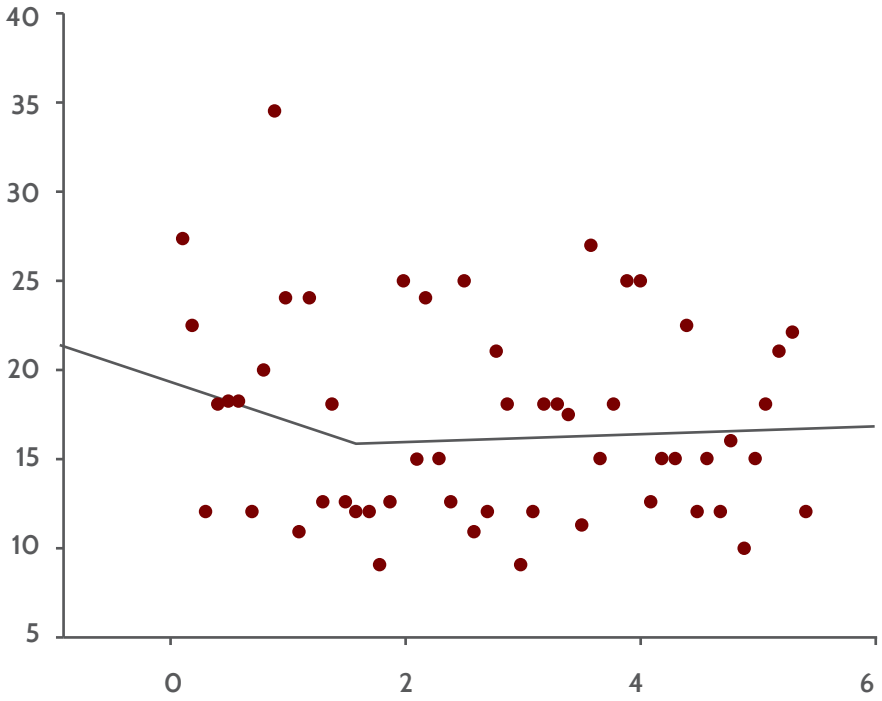

Figure 1.-MI-TLIF learning curve. The piecewise regression analysis estimates the break point at 16th patient.

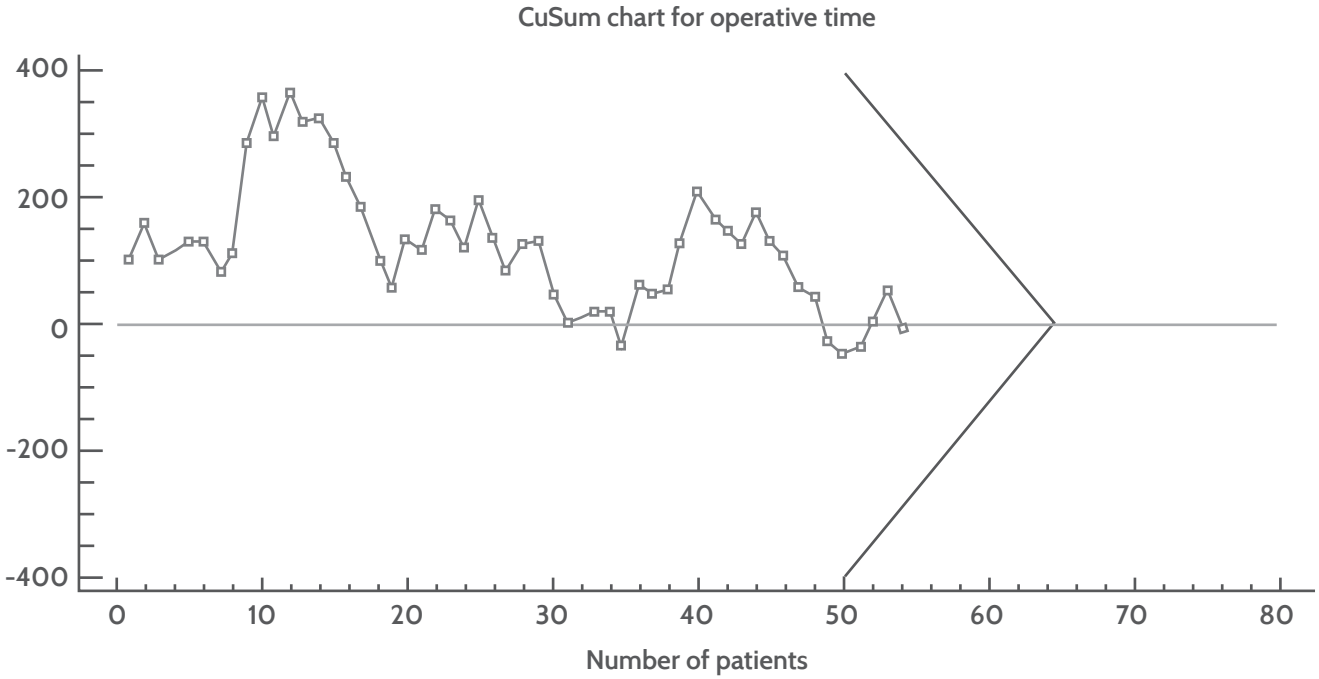

Figure 2.-CUSUM chart for operative time showing surgical proficiency at 17th patient.

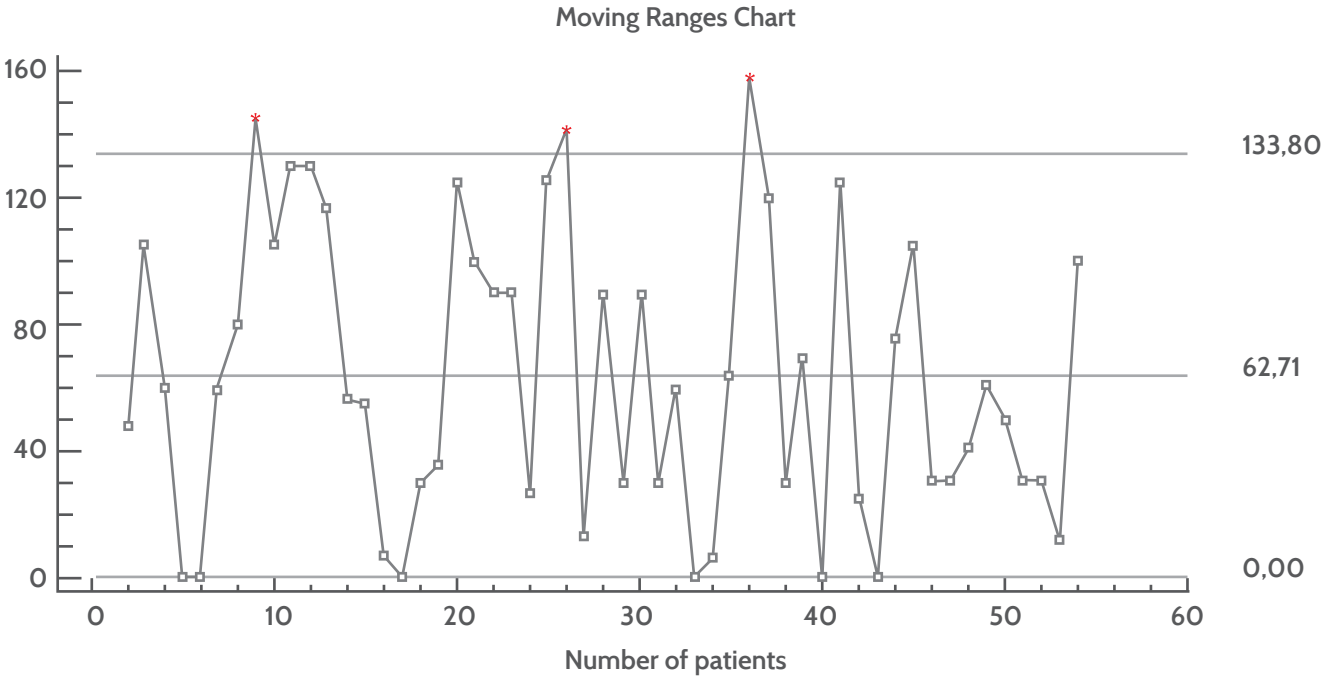

Figure 3.-The average moving range chart demonstrates longer surgical time in patients 9, 26 and 36 independently from expected operating time, explained by several factors non dependent on the surgeon in training. This reflects that surgical time should not be the primary parameter to be evaluated in a learning curve.

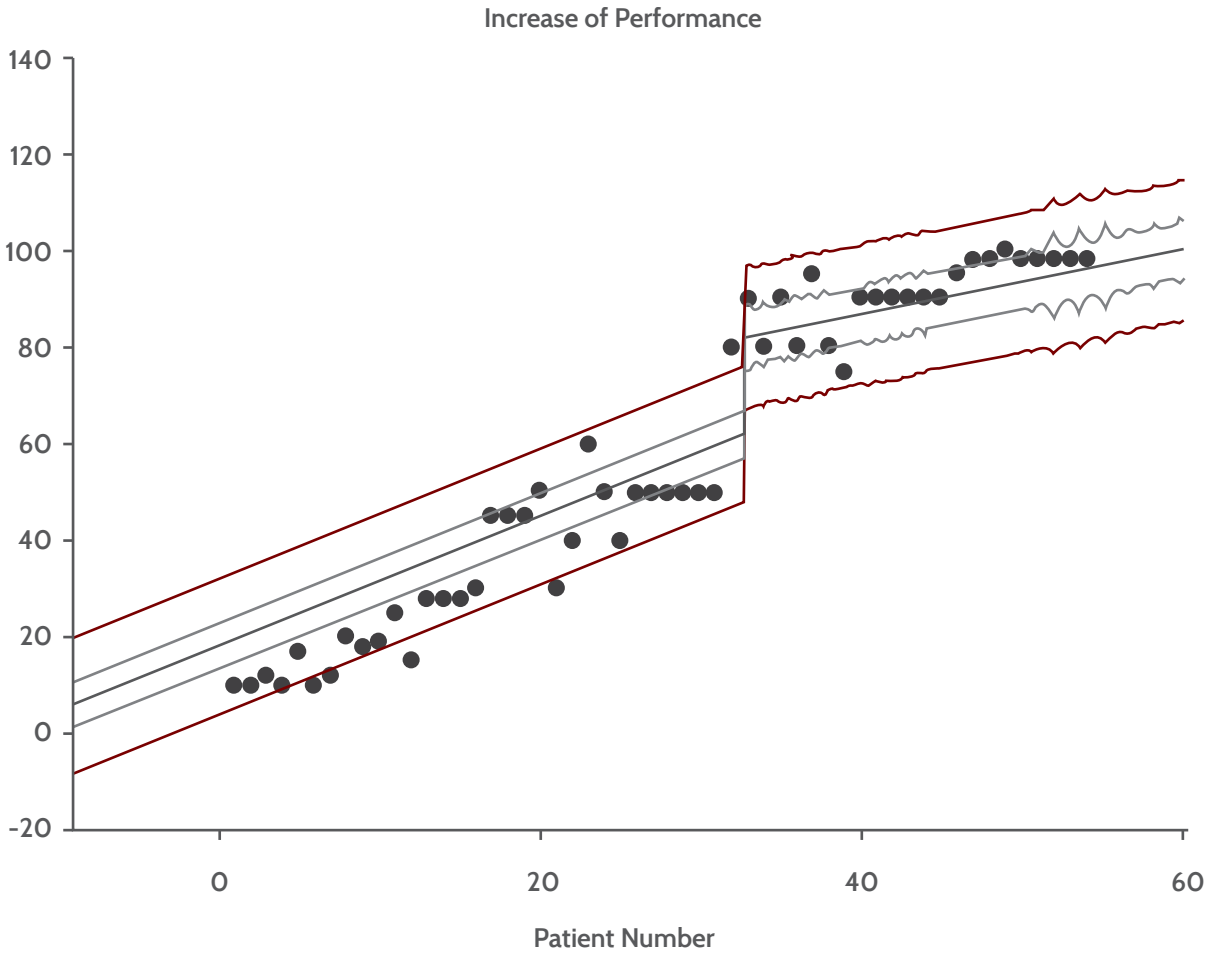

Figure 4.-Proposed learning curve for a spine surgeon in training.

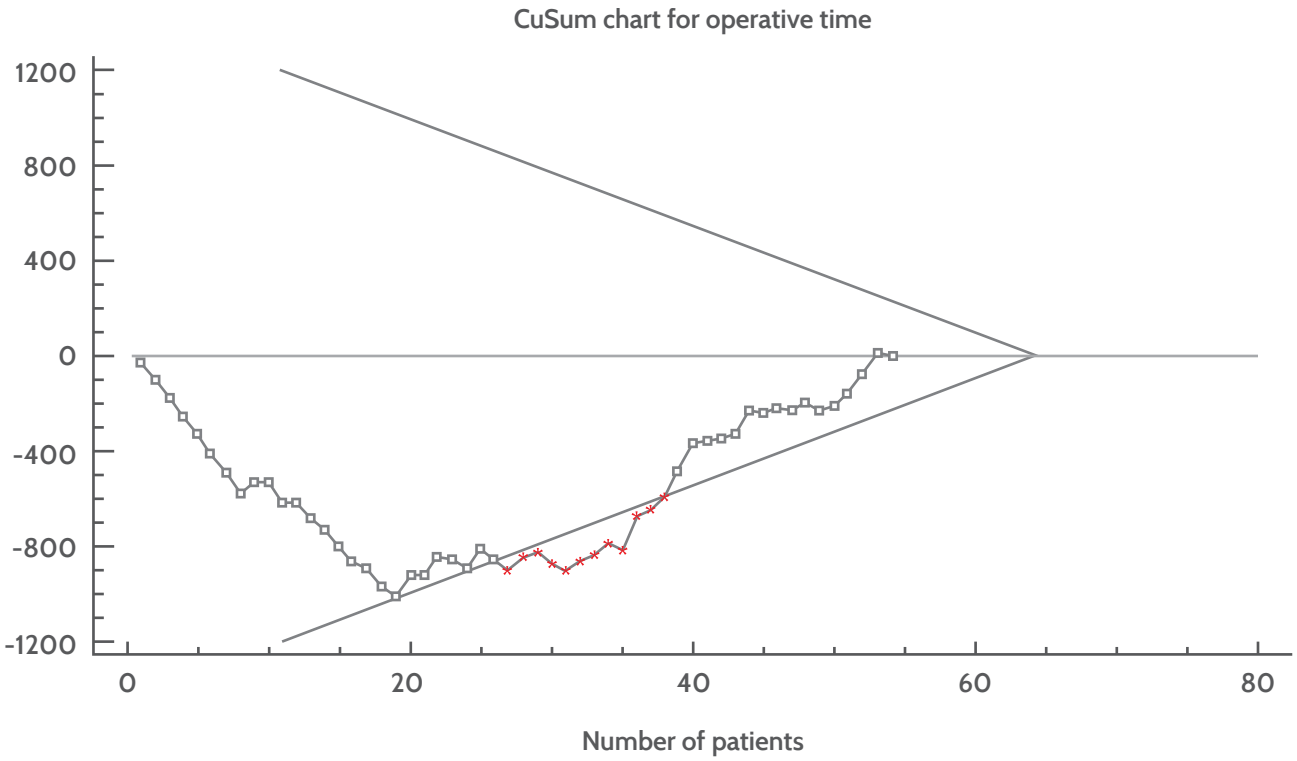

Figure 5.-CUSUM chart shows the number of tasks realized in relation to time. Asterisks (*) below the line represent how the surgeon can perform more tasks in less time, meaning surgical competence.

Discussion

The ability to treat conditions of the spine through minimally invasive surgical *(MIS)* techniques has gained interest from spine surgeons and their patients over the last two decades.[1,2] Web, et al[15] assessed the arguments emitted by eighty-seven spine surgeons about limitations and disadvantages of MIS techniques and they concluded lack of effectiveness, technical difficulty, radiation exposure and few opportunities to learn these types of technique, a fact that is more prominent in Latin America. Nevertheless, results of recent clinical studies and meta-analysis showed that MI-TLIF provides benefits regarding perioperative bleeding, postoperative pain, hospital length stay, infection rates and overall costs.[3-5] Several papers have reported the existence of a steep learning curve in MI-TLIF based on surgical time and estimated blood loss, which is associated with increasing incidence of perioperative complications during initial experience with MI-TLIF.[1,6-8] Furthermore, studies consider rate of complications like the best clinical indicator that reflects the spine surgeon´s experience and recommend to be cautious during initial procedures of MI-TLIF to avoid potential complications related to learning effect.[6,9] Nandyala, et al[16] referred perioperative outcomes in sixty-five procedures of MI-TLIF and demonstrated longer surgical time, more blood loss, and increased anesthetic time in the first thirty-three cases; in addition, the frequency of complications and hospital length stay were similar to those operated by conventional open surgery. Schizas, et al8 reported a learning curve in MI-TLIF that showed decreased surgical time after twelve patients operated consecutively, and also showed no increase in the frequency of complications associated to the learning effect. It is important to remember that the principle underlying the learning curve is well established: performing tasks in repetitive fashion, reduces the time to complete them and increase the quality of those tasks. Several authors emphasize that surgical time is not associated with the surgical competence, and is an unreliable measure due to the influence of other factors; therefore, they recommend assessing other parameters including outcomes-related and patient-centered criteria.[17-18] Therefore, learning curves must be interpreted according to each specific context. In this study a learning curve associated with surgical time was estimated in 54 patients who underwent MI-TLIF during twenty-four months.

The learning curve showed stabilization in surgical time after the 16th patient. However, the objective of this learning curve is to demonstrate the progressive acquisition of the surgical skills needed to perform a fluid MI-TLIF technique. Thirty-second patient in the piecewise regression analysis represents the acquisition of technical fluency and confidence to perform the technique; this can be explained by the amount of surgical tasks realized in the first 18 months of the fellowship training which represents key points for the knowledge of the technique *(Table 2)*. An educational program is crucial for the correct knowledge and future good clinical results applying the technique. In the past 6 months the surgeon performed a similar number of tasks compared with his first 18 months, demonstrated in the CUSUM chart *(Figure 5)* supporting the concept: repetitive tasks entail better results in less time.

Neal, et al[19] reported a learning curve associated with MI-TLIF operating time after 15 consecutive cases. They indicated that the decrease in surgical time is not necessarily associated with better clinical outcomes. They also noted that assessing mastery of the MI-TLIF should consider the frequency of complications, readmissions and long-term clinical outcomes. Several authors report a series of patients in whom MI-TLIF was performed to identify the number of cases that represent their initial experience in MI-TLIF according to their learning curve, they compared perioperative parameters and clinical follow-up in consecutive patients who underwent surgery. Lee, et al[20] reported a learning curve of MI-TLIF reached after 30 cases. They compared their first 30 cases with subsequent ones. These patients had less operating time, less estimated blood loss, and

less hospital length stay. However, at 1-year follow-up, both groups reported similar ODI and VAS back and leg pain scores.

The initial experience in MI-TLIF is acquired with the partial execution of numerous tasks of the surgical technique. Therefore, the pattern of the learning curve in this study showed a particular morphology completely different from the initial experience, representing the acquisition of surgical skills. The mastery of individual surgical tasks is verified by the fluency and ergonomics of movements, which leads to surgical proficiency of the whole procedure. The pattern of the learning curve in the initial experience in MI-TLIF has not been reported in the literature, this is the first study that acknowledge the learning curve of a spine surgeon in training.

Conclusions

We consider that the learning curve in MI-TLIF begins with sequential training and knowledge of every step that conforms the technique since the surgeon begins his training, also it is influenced by the number and repetition of surgical tasks performed in particular clinical scenarios (patient individual setting) and finally by the application of the whole technique in his surgical practice as a faculty surgeon. In addition, the whole process of experience is completed by academic labor of the surgeon.

The contribution of this study is the idea of taking in account the aforementioned parameters to develop a statistically-based learning curve applied to the surgical technique of MI-TLIF. To reach the asymptote in this learning curve a progressive complexity task designation method was necessary to obtain the proficiency of the technique and not just the outcome evaluation.

Declaración de conflictos de interés
Los autores declaran que en este estudio no existen conflictos de interés relevantes.

Fuentes de financiamiento
No existió una fuente de financiamiento particular para este informe científico

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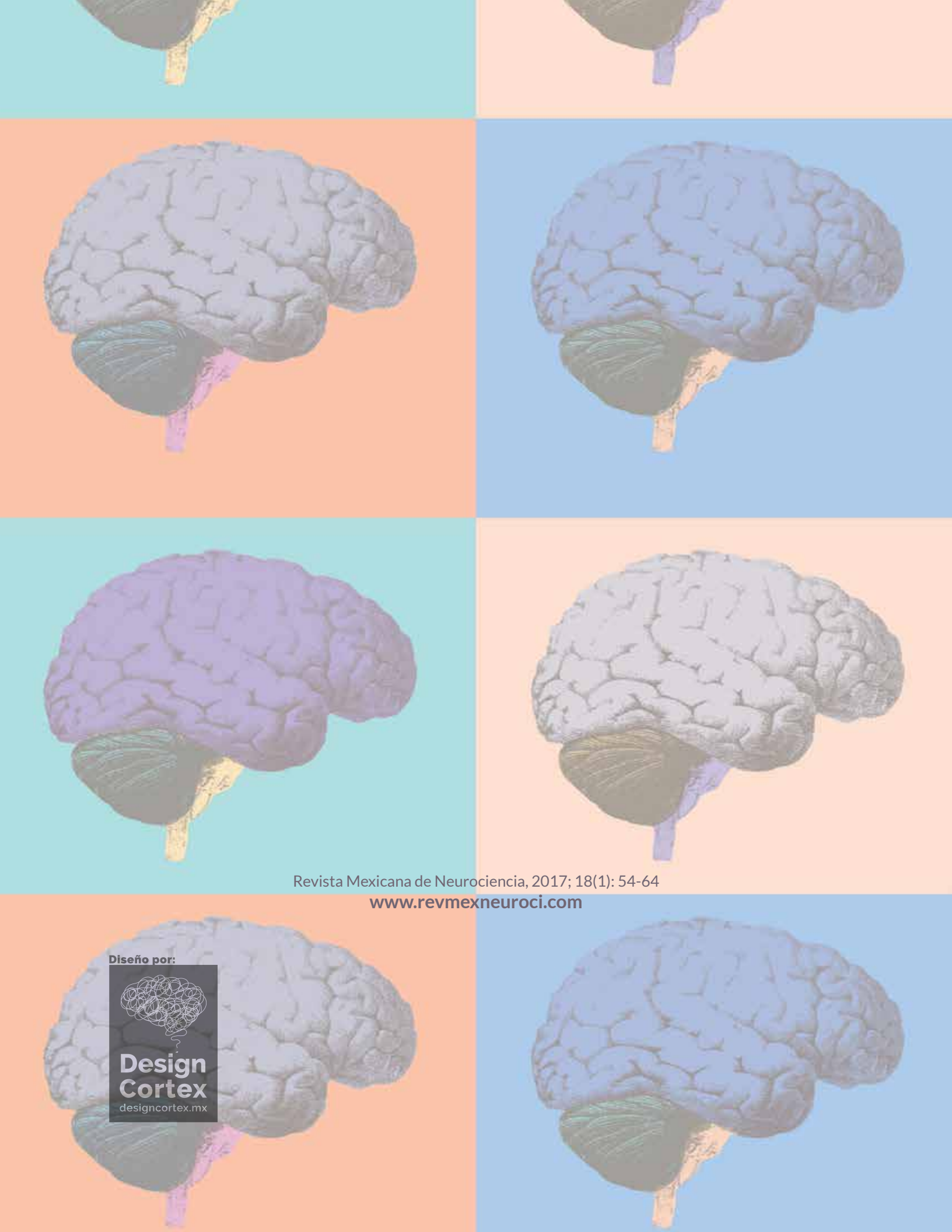

Revista Mexicana de Neurociencia, 2017; 18(1): 54-64
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