A Retrospective Multi-Center Study Assessing the Safety of Using Insulated Access Needles in Conjunction with Intraoperative Neuromonitoring During Minimally Invasive Pedicle Screw Fixation

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Objective: The foremost concern of a surgeon during pedicle screw fixation is safety. Assistive modalities, especially intraoperative electromyographic monitoring (EMG) can function as an essential tool to recognize screw malposition that may compromise neural integrity, so that the screws can be repositioned immediately rather than later. We intend to study the efficacy of intraoperative EMG monitoring in conjunction with the ALARA neuro access needle kit manufactured by SurGenTec, LLC to detect potential pedicle breach and evaluate whether they provided a safer systematic approach for surgeons when inserting pedicle screws.

Method: A retrospective, post-market, open label clinical study of three sites and 75 patients, with 367 pedicle screws implanted. The primary study objective was to obtain clinical data from physicians using the SurGenTec neurostimulation clip with the ALARA neuro access needle kit. Surgeons would determine safe and reliable neuromonitoring value thresholds for spinal pedicles, thus avoiding nerve root irritation or damage.

Results: With the guidance and additional safety provided by the ALARA neuro access needle, 367 pedicle screws were placed in 185 spine levels. With the assistance of neuromonitoring in combination with the ALARA neuro access needle kit, 341 (93%) pedicle screws were accurately implanted. 26 (7%) screws were repositioned due to abnormal EMG readings and only one (0.3%) screw produced readings which indicated potential pedicle breach. All patients were examined post-operatively and there were no indications of neurological deficit. The baseline EMG reading used was 5 mA on the ALARA needle before proceeding with a tap or pedicle screw. **Conclusions:** The neuromonitoring reading of the ALARA needle provided accurate feedback of any nerve root proximity or irritation. As a result of this feedback, the surgeons were able to accurately place pedicle screws without any iatrogenic neurological injury. The ALARA needle allows for safe and reliable neuromonitoring when used at specific thresholds to facilitate accurate pedicle screw placement. Any reading of 5 mA and above using the ALARA needle correlate to a 10 mA or above with a tap or pedicle screw.

Key Words: minimally invasive surgery; pedicle; electromyography; nerve monitoring; trajectory

Introduction

Pedicle screw fixation is the gold standard for stabilization in spine surgery because it provides superb biomechanical stability. Pedicle screw instrumentation may be performed using either minimally invasive or open approaches. There are multiple new modalities that may be used to help identify landmarks prior to pedicle screw insertion including robotics, navigation, and augmented reality (AR). Although these technologies assist with safety and efficacy there may be downsides such as large capital investment, compatibility of implants to specific systems, increased surgical time, technology expiration due to the rapid advancement in technology and learning curves of physicians and OR staff. Minimally invasive pedicle screw placement is becoming a standard of care now that implants, instrumentation, and retractors have evolved. Surgeries are reproducible with less scarring, blood loss and faster recovery. In both open or MIS pedicle screw approaches the physician relies on using fluoroscopy to identify the pedicle targeting landmarks first established by Roy-Camile, Magerl and Weinstein.[1] The accuracy of placement of screws percutaneously relies in great part to the surgeon's knowledge of pedicular anatomy and experience. During minimally invasive surgical approaches a traditional non-insulated targeting needle is used to cannulate a pedicle in the correct trajectory. The instrument is used with fluoroscopic guidance to create a safe path for the pedicle screw with optimal purchase. Once this path is created a guidewire is placed down the lumen of the targeting needle and the needle is extracted. Then a pedicle screw is placed over the guidewire into the pedicle. This technique is tried-and-true but there is no safeguard to minimize the risk of misplacing a screw prior to insertion. If the screw is misplaced it must be removed and generally replaced with a screw with larger diameter due to loss of bone purchase. There may also be irritation, injury, or paralysis if the screw comes in close or direct contact with the nerve. In the past 2 decades interoperative neurophysiologic monitoring techniques have been introduced to supplement radiographic assessment by quickly alerting the surgeon of possible impingement of neural structures. Clinical studies have shown the value of measuring evoked potentials to determine the accuracy of pedicle screw placement.[2] Percutaneous approaches eliminate that ability for the surgeon to visualize and palpate the pedicle walls to confirm their integrity after screw insertion. Therefore, accurate neuromonitoring as an adjunct to fluoroscopy has been proven to be beneficial (Figure 1).

A study published in Spine by Glassman et al, evaluated the accuracy of interoperative electric stimulation for percutaneous lumbar pedicle insertion[3]. The study reviewed the confidence thresholds to indicate that the screw was within the pedicle. A stimulation threshold of more than 15 mA provided 98% confidence, while stimulation between 10 and 15 mA provided 87% confidence. A stimulation threshold of less than 10 mA was associated with cortical perforation and further clinical exploration was recommended. Proper use of neuromonitoring has been proven to provide a real-time assessment of spinal cord and nerve root function.[1,3,4]

The combination of the targeting needle with neuromonitoring provides a powerful and valuable resource to identify landmarks and create a safe trajectory prior to placing a tap or pedicle screw. The ALARA neuro access needle is an FDA cleared medical device for neurostimulation of pedicle screws. The adjustable rigid sheath provides a predetermined depth, so the needle advances to a desired depth. The insulated sheath allows for accurate reading using neuromonitoring MA values to determine safe thresholds. The needle threshold reading values are generally lower than that of a tap or pedicle screw. This study aims to set forth safe ALARA neuro access needle thresholds prior to pedicle screw insertion.

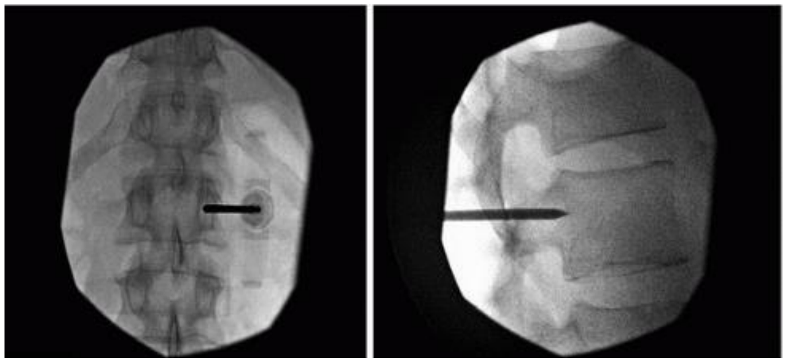

Figure 1:. A: Depiction of access needle being inserted into the pedicle on an AP (left image) and a lateral (right image). Fluoroscopy must be used in both views to help ensure proper trajectory is achieved

Clinical Material and Methods

Patient Population

Between 2020 and 2021, three spine surgeons at different institutions performed lumbar MIS pedicle screw implantation in 75 patients at 367 pedicles with a mean age of 56.3 years. MIS pedicle screw systems manufactued by different companies were used throughout the study. The patient demographic and treatment-related data are presented in Table 1 and Table2.

Surgeon	# of Patients	Pedicle Screws Inserted
Mo	25	132
Patel	25	121
Myers	25	114

Table 1: Patients per treated by each surgeon

Indications for Surgery	
Spondylolisthesis	17
Degenerative Disc Disease	22
Spinal Stenosis	22
Scoliosis	13
Neurogenic Claudication	1
Instability	6

Table 2: Indications for surgery

Neuromonitoring and Pedicle Screw Placement

An 11 guage ALARA bevel or diamond tip needle was chosen depending on surgeon preference. The ALARA needle sheath was set to the desired depth. Using AP and lateral flouroscopic guidance, the ALARA needle tip was placed onto the target pedicle (Figure 2). The needle was advanced into the pedicle using AP fluoroscopy to prevent excessive medial placement. When necessary, a lateral image was used to adjust trajectory in the sagittal plane. The radiopaque marker at the distal end of the sheath was used to confirm the sheath was flush against the pedicle. The surgeon proceeded to monitoring when satisfied with the trajectory and that the outer insultated sheath was against the pedicle. The SurGenTec neurostimulation clip was connected to the needle cannula within handle to deliever continuous stimulation.

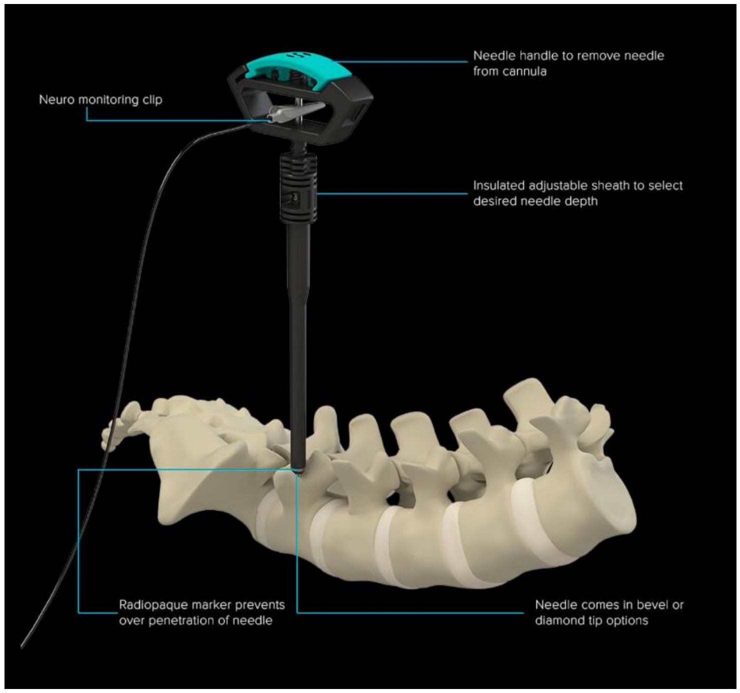

Figure 2: The ALARA needle

The neuromonitoring reading of the ALARA needle and stimulation clip provided feedback of any nerve root activity. An incorrect trajectory would result in EMG activation and indicate a pedicle breach. If activation occured, the trajectory was readjusted using fluoroscopic images, and the needle was advanced again. It was determined in this study that 5 mA was the minumum accepted threshold reading before proceding to a tap or screw. This correlated to a reading of 10 mA or higher when proceeded with a tap or screw. When a safe position was achieved, a guidewire was inserted through the needle cannula and the needle was removed. If desired, a tap was placed over the guidewire. Lastly, the cannulated pedicle screw was inserted over the guidewire. When the surgeons were not satisfied with EMG reading, the needle or screws were repositioned until higher readings were achieved (Table 4). There is a body of evidence in literature on the efficacy of neuromonitoring during percutaneous screw placement. There are often high screw repositioning rates when neuromonitoring is not used which may lead to longer surgery times, larger implants and increased potential for complication.One study showed that 76% of screws were repositioned due to inadequate EMG readings with a pedicle violation rate of 3%. [3,4,6]

Pedicle Screws Implanted	Spinal Levels Treated	# of Screws Repositioned	Potential Pedicle Violations
367	182	26	1

	Percentage	7%	0.3%

Table 3: Summary of pedicle screw placement

Spinal Level	Total per Level	Percent of Total	Total Implants
L1	1	1%	2
L2	11	6%	22
L3	20	11%	40
L4	56	30%	111
L5	61	33%	122
S1	35	19%	70

Table 4a: Summary of pedicle screws placed by level

Pedicle Screw Accuracy

An EMG reading above 15 mA represents a high probability that the implant is properly placed within the pedicle.[3] In this study, 367 pedicle screws were placed percutaneously, assisted by EMG guidance using the ALARA needle and clip. Of these, 26 screws had to be repositioned and one pedicle was possibly breached (Table 3).

Spine Level	EMG Value (mA)	Left Needle Value	Right Needle Value	Left Screw Value	Right Screw Value
L1	15 - 19	-	-	-	-
L1	>= 20	1	1	1	1
L2	15 - 19	5	4	3	1
L2	>= 20	1	3	3	9
L3	15 - 19	3	2	3	2
L3	>= 20	7	7	10	16
L4	15 -19	10	18	7	10
L4	>= 20	19	11	33	38
L5	15 - 19	16	13	6	10
L5	>= 20	20	25	41	49
S1	15 - 19	5	6	9	10
S1	>= 20	9	11	18	21

Table 4b: EMG values of needle and apparently properly placed screws

EMG Value (mA)	Left Needle Value	Right Needle Value	Left Tap Value	Right Tap Value	Left Screw Value	Right Screw Value
% <20	67%	64%	17%	25%	26%	24%

% >= 20	33%	34%	83%	75%	**72%**	**75%**

Table 5: Cumulative EMG readings

Discussion

Combined posterior lumbar spinal decompression and instrumentation placement has been associated with occasional complications, often due to malpositioned implants intraoperative EMG monitoring has been proven to be a useful adjunct.[1] The ALARA access needle (Figure 2) was used by the surgeons involved in this study to accurately place percuntaneous pedicle screws. Pedicle screws were placed at multiple levels in the lumbar and sacrum regions. The trajectory of pedicle screw placement varies at each level due to the normal curvature of the spine. Degenerative conditions or deformities may also affect the trajectory of the pedicle[1]. These factors augment the importance of intraoperative neuromonitoring and fluroscopy. A EMG stimulation threshold of 15 mA or greater is associated with a 98% probability that the screw is properly placed in the pedicle.[3] A summary of the data from the patients broken down by level treated is shown in the following pages.

Summary of L1

Two screws were placed at L1. The stimulation values of both the needle and screw remained above 20 mA (Table 6a).

Spine Level	EMG Value (mA)	# of Left Needle Readings	# of Right Needle Readings	# of Left Tap Readings	# of Right Tap Readings	# of Left Screw Readings	# of Right Screw Readings
L1	15 - 19	-	-	-	-	-	-
L1	>= 20	1	1	1	1	1	1

Table 6a: summary of EMG readings at L1

Summary of L2

L2 was operated in 11 pateints which represented 6% of treated levels. A total of 22 pedicle screws were placed into L2. There were no screws with readings less than 15 mA (Table 6b).

Spine Level	EMG Reading (mA)	# of Left Needle Readings	# of Right Needle Readings	# of Left Tap Readings	# of Right Tap Readings	# of Left Screw Readings	# of Right Screw Readings
L2	< 15	-	-	-	-	-	-
L2	15 - 19	5	4	1	-	3	1
L2	>= 20	1	3	2	4	3	9

Table 6b : summary of EMG readings at L2

Summary of L3

L3 was operated in 20 patients which represented 11% of treated levels. A total of 40 pedicle screws were placed into L3. There was one incidence of a reading below 15 mA, yet the left and right readings were recorded at values of 11 and 12 mA respectively (Table 6c).

Spine Level	EMG Reading (mA)	# of Left Needle Readings	# of Right Needle Readings	# of Left Tap Readings	# of Right Tap Readings	# of Left Screw Readings	# of Right Screw Readings
L3	<15	8	9	-	1	1	1
L3	15 - 19	3	2	1	-	3	2
L3	>= 20	7	7	5	5	10	16

Table 6c : summary of EMG readings at L3

Summary of L4

L4 was operated in 55 patients during this study, which represented 30% of treated levels. A total of 109 pedicle screws were placed into L4. There were four incidences of readings below 15 mA, with values of 11,12, and 14 mA. One pedicle screw recorded a reading of 9mA. When the needle readings were suboptimal, the needle was repositioned and higher readings were seen for the pedicle screws (Table 6d).

Spine Level	EMG Reading (mA)	# of Left Needle Readings	# of Right Needle Readings	# of Left Tap Readings	# of Right Tap Readings	# of Left Screw Readings	# of Right Screw Readings
L4	< 15	24	19	1	1	4	4
L4	15 -19	10	18	2	6	6	10
L4	>= 20	19	11	18	13	33	38

Table 6d : summary of EMG readings at L4

Summary of L5

L5 was operated in 60 patients during this study and represents 33% of treated levels. A total of 120 pedicle screws were placed into L5. There were six incidences of readings below 15 mA, with values of 12 (3 times), 13, and 14 mA. One pedicle screw recorded a reading of 9 mA. When the needle readings were suboptimal, the needle was repositioned and higher readings were seen for the pedicle screws (Table 6e).

Spine Level	EMG Reading (mA)	# of Left Needle Readings	# of Right Needle Readings	# of Left Tap Readings	# of Right Tap Readings	# of Left Screw Readings	# of Right Screw Readings
L5	< 15	23	23	1	-	4	2
L5	15 - 19	16	13	3	3	6	10
L5	>= 20	20	24	15	16	40	48

Table 6e: summary of EMG readings at L5

Summary of S1

S1 was operated in 34 patients during this study and represents 19% of treated levels. A total of 68 pedicle screws were placed into S1. There were four incidences of readings below 15 mA, with readings of 11, 12, 14 mA and 9 mA. When the needle readings were suboptimal, the needle was repositioned and higher readings were seen for the pedicle screws (Table 6f).

Spine Level	EMG Reading (mA)	# of Left Needle Readings	# of Right Needle Readings	# of Left Tap Readings	# of Right Tap Readings	# of Left Screw Readings	# of Right Screw Readings
S1	< 15	20	16	1	1	2	2
S1	15 - 19	5	5	-	2	9	10
S1	>= 20	9	11	7	3	17	20

Table 6f: summary of EMG readings at S1

Conclusions

Neuromonitoring has been an important tool to reduce iatrogenic complications associated with minimally invasive pedicle screw placement. A continuous stimulation of ALARA neuro access needle alerts the surgeon to incorrect medial trajectories and may lead to safer pedicle cannulation. A pedicle screw stimulation threshold above 5 mA or higher provides confidence that the screw is in the pedicle.[3]

In this review of 367 pedicle screws over 98% of the screws were properly placed. When the needle readings were less than optimal, the trajectory was adjusted. Each screw was tested after implantation to verify it's position. There was only one instance of a possible pedicle violation, a very low rate of 0.3%. This is lower than what is typically reported in literature. In a previous study, the ALARA access needle in conjunction with extension instrument was proven to be a simple and cost effective option to reduce short and long term radiation expsure during these procedures. This study proves the versatility of the ALARA access needle to be used to accurately neuromonitor and access the proper placement of percutaneous pedicle screws using multiple systems in a wide patient population.

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