

Retrospective Study of Nerve Injury and Pedicle Screw Breach after Pedicle Screw Fixation with Intraoperative Triggered Electromyography Monitoring

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Abstract:

Objective: To evaluate the incidence of nerve injury and pedicle breach after pedicle screw fixation (PSF) with intraoperative triggered electromyography (tEMG) monitoring.

Material and Methods: All patients who underwent PSF with intraoperative tEMG at Vajira Hospital between October 2018 and March 2020 were included. Patients with dysmorphic pedicle features, preoperative infection, or incomplete follow-up data were excluded. PSF was done with intraoperative tEMG. The stimulation threshold was recorded. Stimulation threshold <7 mA was not allowed to proceed with the procedure and required reposition of pedicle screw immediately. Post-operative nerve injury was evaluated by physical examination and computer tomography of the spine was done to detect any pedicle breaches. The sensitivity and specificity of intraoperative tEMG to detect pedicle breach were calculated. The risk factors associated with pedicle breach were analyzed.

Results: The records of thirty-six patients with 278 pedicle screws were analyzed. No post-operative nerve injuries were found. The incidence of pedicle breach was 2.2%. The sensitivity and specificity were 83.0% and 91.0%, respectively. The risk factors associated with pedicle breach were degenerative disease and tumor(s) (odds ratio (OR) 3.05, 95% confidence interval (CI) 1.11–8.41, p-value=0.030) and stimulation threshold 7–10 mA (OR 0.02, 95% CI 0.00–0.19, p-value< 0.001).

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Conclusion: PSF with intraoperative tEMG was safe for neural integrity. Intraoperative tEMG had the ability to detect pedicle breaches with fair sensitivity and high specificity. Patients with degenerative disease, tumors, or stimulation threshold less than 11 mA had a higher risk of pedicle breach.

Keywords: pedicle breach, pedicle screws, triggered electromyography monitoring

Introduction

The fixation of pedicle screws is commonly used to treat spinal pathologies such as trauma, degenerative disease, scoliosis, and tumors. The advantages of pedicle screw fixation (PSF) are stability, correct alignment, and improved fusion rates. The accuracy of pedicle screw placement is very important as malposition of the screw and pedicle wall breach could lead to serious complications such as nerve root injury, spinal cord injury, vascular injury, dural laceration, visceral injury, pseudarthrosis, and/or instrument failure. Nerve injury is the most common complication that confronts the spine surgeon. In the literature, other common complication reported is malposition of the pedicle screw, with one study reported an incidence of 42.0%¹ and neurological deficit rates between 1.0–11.0%.² Pedicle breach rates ranged from 10.0–58.0%.³ Despite technical advances over the last few decades, PSF is still associated with risk of complications. A number of methods such as fluoroscope and intraoperative navigation–assisted PSF to aid visualization/navigation of the pedicle or laminectomy for pedicle wall palpation to create space and allow for easier pedicle screw placement have become accepted tools to improve the procedure and reduce complications. Electromyography threshold testing is another intervention used to precisely place a PSF.

In 1992 Calencie et al.⁴ introduced intraoperative triggered electromyography (tEMG) by applied electrical stimulus through pedicle screws or instruments and subsequent measurement of muscle action potentials from myotomes innervated by nearby nerve roots, then reported

the result of an evoked electromyography (EMG) stimulation threshold. An irritated or damaged nerve root would cause a decrease in this threshold. Maguire et al.⁵ concluded that an EMG threshold of ≤ 6 mA was the optimal sensitivity cutoff for detecting a malpositioned screw. Initially tEMG was applied to assure correct placement of a lumbosacral PSF. Subsequently this technique has been applied to thoracic PSFs, cervical lateral mass screws and iliosacral screw fixation.

The purpose of this research was to study the efficacy of intraoperative tEMG during PSF to protect neural integrity and detect potential pedicle wall breaches during free–hand PSF technique.

Material and Methods

After approval by the Institution's Ethics Committee (027/63), patients aged 16–85 years who underwent PSF with intraoperative tEMG monitoring at Vajira Hospital between October 2018 and March 2020 were included. The indications for PSF were trauma, degenerative disease, scoliosis, and tumor(s). Patients with dysmorphic pedicle features such as congenital scoliosis, preoperative infection, or incomplete follow–up data were excluded.

Preoperative X–rays and magnetic resonance imaging spines were obtained for all patients. General anesthesia was done without a neuromuscular blocker or agents that affect neuromuscular monitoring. Intraoperative neuromuscular monitoring was done with an NVM5[®] machine (NUVASIVE, San Diego, USA) to evaluate somatosensory–evoked potentials, transcranial motor–evoked potentials,

and electromyography. A train of four twitches was done at the common peroneal nerve. A response rate $\geq 75.0\%$ was required before tEMG recording was begun.

All screws were placed by a single experienced spinal neurosurgeon using a free-hand technique. The entry point depended on the spinal level as follows:

Cervical spine: lateral mass screws inserted at 1mm below and 1 mm medial to the midpoint of the lateral mass directed to the upper outer quadrant of the lateral mass.

Thoracic spine: entry point made at 3 mm caudal to the junction of transverse process and superior articular facet.

Lumbosacral spine: entry point made at the junction of the pars interarticularis, mamillary process, midpoint of transverse process, on lateral border of facet joint.

After an entry point was identified, the pedicle probe was advanced into the vertebral bodies through the pedicles. A pedicle-sounding device was used to palpate the 5 bony borders (medial, lateral, proximal, distal and floor) of the pedicle hole. A tapper was used to tap pedicle

holes and pedicle-sounding device was palpated again. Stimuli were applied by attaching a dynamic stimulation clip to the instruments including a pedicle probe, tapper, and screw driver (Figure 1). The tEMG threshold was obtained in rectangular, monophasic pulse waveform, a constant current of pulse width 200 microseconds $\pm 2.0\%$ at a rate of 5 hertz (Hz). Stimulation occurred at 5 Hz at varying current intensities following a patented rapid hunting algorithm. Information from the tEMG was displayed both in waveform and pictorial color-coded mode on the system's monitor. The color coding for the response threshold current values was divided into 3 groups: green for responses greater than 10 mA, yellow for responses between 7 to 10 mA, and red for responses less than 7 mA (Figure 2).

Pedicule screws activating the red threshold (< 7 mA) were immediately repositioned and retested. Finally, pedicle screw placement was confirmed intraoperatively by direct visualization, tactile palpation of the pedicle walls and neural structures, and fluoroscopy after completing the operation. Stimulation thresholds through the instruments with the dynamic stimulation clip were recorded.

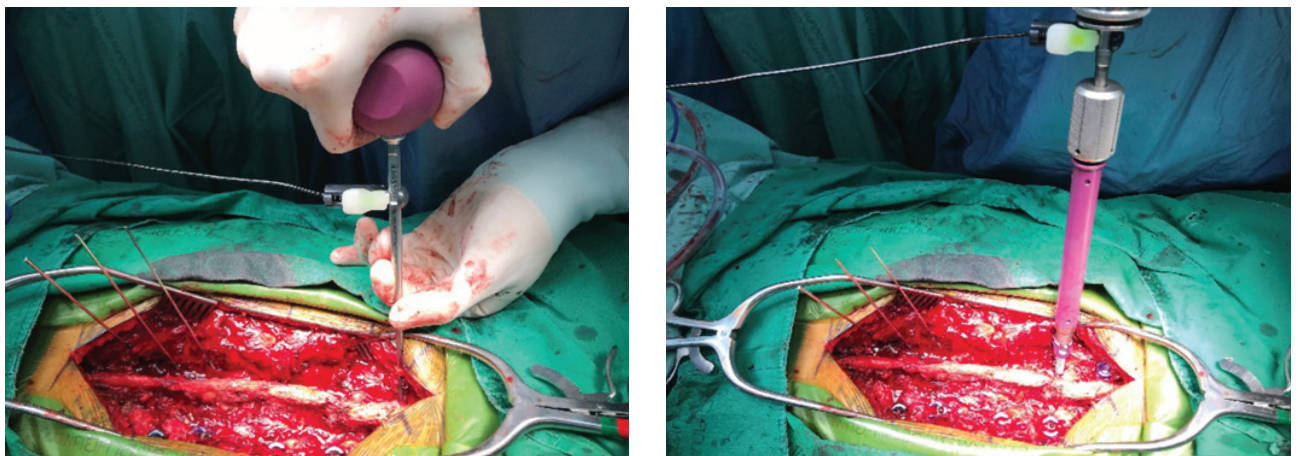


Figure 1 Intraoperative triggered electromyography (tEMG)

The stimulation triggered through a pedicle probe and pedicle screwdriver by dynamic stimulation clip.
(A) Pedicle probe with dynamic stimulation clip. (B) Pedicle screwdriver with dynamic stimulation clip.



Figure 2 Intraoperative triggered electromyography (tEMG) monitor shows color coding for the response threshold current values

Confounding factors for tEMG monitoring were controlled. Attempts were made to maintain a dry test surgical field, to prevent soft tissue contact with all instruments attached to the dynamic stimulation clip, keep temperature between 36–38 °C and mean arterial pressure between 65–85 mmHg.

All patients were evaluated by a physical examination and a computerized tomography (CT) scan at the level of the instrumented spine. The CT scans were reviewed by two neurosurgeons. The location of the pedicle screws was

assessed and rated according to the criteria of Gertzbein and Robbins⁶, who suggested that a margin of 4 mm. adjacent to the pedicle could be violated safely without impinging on the spinal cord or nerve root.

Statistical analysis was performed with the Statistical Package for Social Science program version 22 for Windows (SPSS Inc., Chicago, IL, USA). Univariate analysis and multivariate analysis were performed with logistic regression. A p-value of <0.050 was considered statistically significant. Sensitivity and specificity were calculated.

Results

Patients demographics and pedicle screw characteristic

Forty patients who met the inclusion criteria were identified, of whom four were then excluded (1 dysmorphic pedicle feature, 2 preoperative infections, 1 incomplete postoperative imaging). Thirty-six patients with 278 pedicle screws were analyzed. Patient demographic data are shown in Table 1. The mean age of the patients was 51.6±17.2 years, and mean body mass index (BMI) was 24.1±4.3 kg/m². The most common indications for PSF were trauma (36.1%) and degenerative disease (33.3%). 38.9% had no underlying disease. The characteristics of the pedicle screws are shown in Table 2. The most common screw location was the lumbosacral spine (51.8%). The stimulation threshold by using a dynamic stimulation clip attached to the instruments above 10 mA was achieved in 249 pedicle screws (89.6%).

Table 1 Patient demographic data

Characteristic	N=36
Age (years)	51.6±17.2
Sex	
Male	17 (42.2%)
Female	19 (52.8%)
Body mass index (kg/m ²)	24.1±4.3
Diagnosis	
Trauma	13 (36.1%)
Scoliosis	5 (13.9%)
Degenerative disease	12 (33.3%)
Tumors	6 (16.7%)
Underlying disease	
None	17 (38.9%)
Osteoporosis	7 (19.4%)
Type II diabetes	5 (13.9%)
Other	10 (27.8%)
Operation	
Pedicle screw fixation	26 (72.2%)
Lateral mass screw fixation	10 (27.8%)
Operation time, minutes	300 (120–650)
Blood loss (ml)	350 (10–2,500)
Blood transfusion (units)	0 (0–2)

Table 2 Characteristics of pedicle screw

Characteristic	N=278 (%)
Diagnosis	
Trauma	112 (40.3)
Scoliosis	42 (15.1)
Degenerative disease	66 (23.7)
Tumors	58 (20.9)
Underlying disease	
None	114 (41.0)
Osteoporosis	52 (18.7)
Type II diabetes	42 (15.1)
Others	70 (25.2)
Operation type	
Pedicle screw fixation	220 (79.1)
Lateral mass screw fixation	58 (20.9)
Vertebral level	
Cervical spine	58 (20.9)
Thoracic spine	76 (27.3)
Lumbosacral spine	144 (51.8)
Stimulation threshold (mA)	
7–10	29 (10.4)
>10	249 (89.6)

mA=milliampere(s)

Surgical complications and risk factors

No post-operative neurological deficits, infections, or hematomas were found in this cohort. One patient (2.8%) had post-operative cerebrospinal fluid leakage after revision surgery. The reoperation rate in this series was zero. Six pedicle breaches (2.2%) occurred (cervical spine 2, thoracic spine 2, lumbar spine 1, and sacrum 1). All were lateral breaches with a breach distance <4 mm. The potential risk factors were age, sex, BMI, diagnosis, underlying disease, operation type, vertebral level, and stimulation threshold (Table 3). Diagnosis (OR 3.05 [95% CI 1.11–8.41]; p-value =0.030) and stimulation threshold (OR 0.02 [95% CI 0.00–0.19]; p-value<0.001) were associated with pedicle breach. The multivariate analysis is shown in Table 4, in which both diagnosis and stimulation threshold maintained the association with pedicle breach (p-value<0.050 for both factors). Degenerative disease and tumors had higher risks

of pedicle breach, 4.6% and 5.2%, respectively. The lower stimulation threshold (7–10 mA) had a higher risk of pedicle breach (20.8% in 7–10 mA vs. 0.4% in >11 mA).

Stimulation threshold predicting pedicle breach

Five breached pedicles were in the lower stimulation threshold group (7–10 mA). One breached pedicle was in the higher stimulation threshold group (>10 mA). At the stimulation threshold ≥ 7 mA, the sensitivity and specificity

of intraoperative tEMG to detect a potential pedicle breach were 83.0% and 91.0%, respectively. The positive predictive value (PPV) was 17.0% and the negative predictive value (NPV) was 99.0% (Table 5). PPV refers to the likelihood of pedicle breach after PSF when the stimulation threshold was < 7 mA. NPV refers to the likelihood of the pedicle wall remaining intact after PSF when the stimulation threshold was ≥ 7 mA.

Table 3 Univariate analysis of potential factors associated with pedicle breach

Factor	Number (%)	OR (95%CI)	p-value
Age (years)		2.44 (0.48–12.36)	0.280
<60	3/196 (1.5)		
≥ 60	3/82 (3.7)		
Sex		1.40 (0.25–7.78)	0.700
Male	2/114 (1.8)		
Female	4/164 (2.4)		
Body mass index		0.31 (0.09–1.12)	0.070
<18.5	2/42 (4.8)		
18.5–24.9	4/148 (2.7)		
≥ 25	0/88 (0.0)		
Diagnosis		3.05 (1.11–8.41)	0.030
Trauma	0/112 (0.0)		
Scoliosis	0/42 (0.0)		
Degenerative disease	3/66 (4.6)		
Tumors	3/58 (5.2)		
Underlying disease		1.07 (0.65–1.74)	0.800
None	2/144 (1.4)		
Osteoporosis	0/52 (0.0)		
Type II diabetes	3/42 (7.1)		
Others	1/70 (1.4)		
Operation type		1.39 (0.59–3.29)	0.460
Pedicle screw fixation	4/220 (1.8)		
Lateral mass screw fixation	2/58 (3.5)		
Vertebral level		0.63 (0.24–1.65)	0.340
Cervical spine	2/58 (3.5)		
Thoracic spine	2/76 (2.6)		
Lumbar spine	1/126 (0.8)		
Sacral spine	1/18 (5.6)		
Stimulation threshold (mA)		0.02 (0.00–0.19)	<0.001*
7–10	5/24 (20.8)		
>10	1/248 (0.4)		

p-value calculated by logistic regression.

*p-value=0.000471

OR=Odds ratio, CI=confidence interval

Table 4 Multivariate analysis of potential factors associated with pedicle breach

Factors	Number (%)	OR (95%CI)	p-value
Diagnosis		2.85 (1.03–7.92)	<0.045
Trauma	0/112 (0.0)		
Scoliosis	0/42 (0.0)		
Degenerative disease	3/66 (4.6)		
Tumors	3/58 (5.2)		
Stimulation threshold (mA)		0.02 (0.00–0.20)	<0.001
7–10	5/24 (20.8)		
>10	1/248 (0.4)		

p-value calculated by logistic regression.
 mA=milliampere(s), OR=odds ratio, CI=confidence interval

Table 5 Sensitivity and specificity analysis

Threshold (mA)	Pedicle breach	Intact pedicle	Total PDS
7–10	5	24	29
>10	1	248	249
Sensitivity 83.0%	Specificity 91.0%	PPV 17.0%*	NPV 99.0%**

*PPV=positive predictive value, **NPV=negative predictive value, PDS=pedicle screw

Discussion

One study reported the neurological deficit rate after PSF was 1.0–11.0%.² Other studies have reported that using intraoperative tEMG, the neurological deficit was reduced to 0.0–2.2%.^{7–10} In this study, using intraoperative tEMG resulted in zero neurological deficits after PSF (0.0%), further supporting the hypothesis that PSF with intraoperative tEMG is safe for neural integrity.

A meta-analysis of intraoperative tEMG used for detecting misplaced pedicle screws showed fair sensitivity of 78.0% with high specificity of 94.0% from different instruments.¹¹ With fair sensitivity, intraoperative tEMG can be a helpful monitoring device for detecting potential neural structure injury due to pedicle breach. The sensitivity and specificity for detecting a potential pedicle breach with intraoperative tEMG in this study were 83.0% and 91.0%, respectively, comparable to previous report.¹¹ Many authors

recommended stimulation threshold ≥ 6 mA based on animal study.^{4,7} Prospective clinical series indicated pedicle screw was totally within pedicle with stimulation threshold ≥ 6 mA and lower stimulation threshold indicated potential pedicle breach.^{5,12,13} From this study, the negative predictive value was 99.0%, suggesting that a pedicle breach is highly unlikely when the stimulation threshold is ≥ 7 mA. The high specificity of our study indicated that a lower stimulation threshold (<7 mA) has a high chance of pedicle breach and requires screw repositioning. It is possible that the low positive predictive value (17.0%) in this study reflected the low incidence of pedicle breach (2.2%).

In exploratory analysis, this study found that diagnosis and stimulation threshold were associated with pedicle breach (Table 4). A high pedicle breach rate was found in patients with degenerative disease or tumors. This may have resulted from more deformed anatomical

landmarks of the spine in patients with degenerative disease or tumor than trauma or scoliosis, so the entry point for PSF was difficult to identify. Cordemans et al. used an intraoperative CT technique to detect pedicle breaches which they found in 11.7% of their cases (81/695).¹⁴ They also found that non-degenerative diseases including trauma, scoliosis, tumors and infection had higher pedicle breach rates. Both the Cordemans et al. study and this study found that disease was a risk factor for pedicle breach. However, non-degenerative disease had a higher risk in the Cordemans study while degenerative disease and tumors had higher risks in this study. This may result from the different techniques and/or surgeon experience. Seventy percent of their patients had degenerative disease versus 33.3% in this study. A high pedicle breach rate was also found in patients with relatively low stimulation thresholds (7–10 mA). This could be because electrical stimuli can pass through a pedicle screw, and muscles that are innervated by nearby nerve roots could produce action potentials with low thresholds. A nerve root irritated or damaged by a pedicle screw breach would cause a decrease in this threshold. For these reasons, we suggest using a stimulation threshold ≥ 11 mA as an optimal cut off to ensure a safe PSF as this level indicates an intact pedicle wall. Belmont et al. recommended the acceptable limits for preventing neurological deficit were 2 mm for medial wall breach and 6 mm for lateral wall breach.³ All breached pedicles (6 pedicles) in this study were lateral breach and all met the Belmont suggestion (distance < 4 mm). Further supported by the evidence that none of the patients with breach in this study had post-operative neurological deficit. However, one silent breached pedicle was detected from the post-operative CT scan without a previously alarm from the intraoperative tEMG, which was a false negative from the intraoperative tEMG. This may have been caused by attached the dynamic stimulation clip too quickly to the instruments. The tEMG monitor failure to detect the change

of stimulation threshold. To avoid this problem, we suggest gradually applying all instruments during the stimulation test and carefully examining the pedicle holes prior to pedicle screw placement.

The author recommends that PSF with intraoperative tEMG should be used in conjunction with intraoperative tactile palpation of the pedicle walls and neural structures after decompression and radiography, and using a stimulation threshold ≥ 11 mA to ensure optimal and safe PSF. The authors accept a lower stimulation threshold but not lower than 7 mA at the sacral area or osteoporosis patients because the quality of bone in these patients or areas permits more stimuli than normal bone.

This study had several limitations in this study. First, this was a retrospective study with a limited number of patients, thus we could not control for missing data and it was underpowered. Authors did not compare variations in the size of the pedicle screws or other material that may have affected the current threshold resulting in inaccurate predictions of the potential of pedicle breach, possibly also impacting the sensitivity and specificity of the predicting tool. Furthermore, we did not attempt to evaluate underlying diseases which may have affected the bone quality or chronically compressed nerve roots, factors which could affect the current threshold and should be studied in the future.

Conclusion

PSF with intraoperative tEMG was safe for neural integrity. Intraoperative tEMG had the ability to detect pedicle breaches with fair sensitivity and high specificity. Patients with degenerative disease, tumors, or stimulation threshold less than 11 mA had higher risk of pedicle breach.

Conflict of interest

None

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