

A Practical Method for Real-Time Detection of Pedicle Wall Breaching During Funneling

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Abstract

Background: A reliable, real-time method for the detection of pedicle wall breaching during funnelling in spine deformity surgery could be accessible to any surgeon assisted with neuromonitoring.

Methods: Fifty-six consecutive patients (1066 pedicles), who were submitted to spinal deformity surgery from December 2013 to July 2015 were included in the study group. A control group of 13 consecutive patients (226 pedicles) with spinal deformity surgery were operated on from January to December 2013 and were excluded from finder stimulation. In the study cohort, continuous stimulation during funnelling was delivered via a finder and subsequently a compound muscle action potential (CMAP) threshold was determined. Following funnelling, manual inspection of the pedicular internal walls was performed. The CMAP thresholds were compared with the results of palpation to determine the sensitivity and specificity of the technique for detecting pedicular breaching. In order to cover common ranges of damage, the medial and lateral breaches were compared and the concave-apical breaches compared to the non-apical or convex-apical breaches. In addition, a pedicle screw test was estimated for all patients.

Results: ROC analysis showed 9 mA cut-off to have a sensitivity of 88.0% and a specificity of 89.5% for predicting pedicular breaching, with an area under the curve of 0.92 (95% confidence interval, 0.90-0.94; $P < .001$). Using 9 mA threshold as an alert criterion, funnelling at the concave-apical pedicles showed significantly more true and false positive alerts and fewer true negative alerts when compared with the non-apical and convex-apical pedicles ($P < .001$). Medial breaches had significantly lower stimulation thresholds than lateral breaches ($P < .001$). Thresholds of screw-testing were significantly higher for study- than for control-patients ($P = .002$).

Conclusions: Finder stimulation has a considerably higher sensitivity and specificity for prediction of pedicular breaching, most prominent for medial breaches. Screw-testing displayed significantly better results in patients undergoing the finder stimulation technique, as compared with the control group. The main advantages of our method are its high safety level and low cost, which may be critical in less affluent countries.

Level of evidence III.

Introduction

Spine deformity surgeries are associated with neurological complications due to spinal cord and peripheral nerve injuries [1, 2]. Reports to this effect have been published since the days of the Harrington rod. Later on, they were found to occur with other spinal implants, such as sub-laminar wires [3]. Pedicle hooks pose three times more severe neurologic injury risk than the Harrington system [4]. The introduction of pedicle screws into the operative theater has increased the risk of recurring injury due to potential canal penetration during funnelling or screw insertion [1, 2, 5].

In an attempt to limit the incidence of neurological complications, neurophysiological monitoring has become a standard-of-care in deformity surgery [6–8]. Along with monitoring spinal functions by means of motor and somatosensory evoked potentials (MEP and SSEP, respectively), pedicle screw testing is routinely done to detect mal-positioning of screws [9–11]. During a screw test, an electrical stimulus is applied to the top of a screw. The threshold of the electrical stimulation which triggers a compound muscle action potential (CMAP) of the corresponding myotome is assessed. If the stimulation threshold in the screw test is low, a high risk of pedicle breaching is expected [9–12]. Unfortunately, since screw testing is done after screw insertion, the technique fails to prevent canal penetration while funnelling or tapping, and neurological complications are likely to occur. Of note, however, pedicle screws are employed very commonly in corrective surgery and although their benefits are evident, a few potential reinjuries are bound to occur with their use. These include spinal canal violation, pedicle fracture, nerve root compression and vascular lesions. Although not frequent, their clinical consequence might be devastating, but the method described here may help prevent these complications.

The study is aimed at describing and developing a method for real-time assessment of pedicle integrity during funnelling. This investigation is based on the following hypotheses, mostly sustained by relevant literature:

1. CMAP evoked by a low finder stimulus indicates cortex violation [10, 11].
2. Neurophysiological testing of the apical pedicles will result in higher rates of true positive and false positive alerts compared to other pedicles [13].
3. Medial wall breaching will evoke CMAPs at lower finder stimulation thresholds when compared with lateral breaches [14].
4. Thresholds of screw testing will be higher for patients in which a finder stimulation test was carried out compared with patients with no finder stimulation test.

Methods

The study group included 56 consecutive patients who underwent spinal deformity surgery from December 2013 to July 2015. Inclusion criteria were: (a) patients that underwent corrective surgery for scoliosis or kyphosis deformations, (b) who had effective MEP recordings at pre-incisions baseline, which indicates, for this purpose, the proper functioning of the lower motor neuron, the neuromuscular junction, and of the muscle. Exclusion criterion was a diagnosis of lower motor neuron or muscular disorder. A total of 1134 pedicles were funnelled in these 56 patients. Valid neurophysiological testing was performed during funnelling in 1073 pedicles, excluding cases of indeterminate results ($n = 3$) and missing data ($n = 58$) for statistical analysis. Of the valid neurophysiological results, indication of a breach was present in 368 pedicles and absent in 705 pedicles. In three pedicles with positive and four pedicles with negative results, manual palpation assessment showed indeterminate results, and were thus excluded from statistical analysis (see flowchart diagram in Fig. 4). A control group included 13 consecutive patients (226 pedicles) with spinal deformity surgery operated on between January and December 2013. In all cases, thoracic spine was an integral part of the planned arthrodesis with T3 as the most cephalic vertebra neurophysiologically tested. All surgical procedures involved posterior spinal instrumentation and were performed at one of two major tertiary referral medical centres. The funnelling process and screw insertion in both the study and control subsets were done by five experienced spine and pediatric-orthopaedic surgeons.

The Institutional Review Board approved of the study and of the employment of retrospective data used in the study and control groups.

Since the testing procedure described in this retrospective study was an integral part of the clinical procedure, and not of an experimental endeavour, no informed consent was required from the study subjects.

Neurophysiological assessment

The intraoperative neuromonitoring protocol included cord function monitoring via MEP and SSEP, spinal root monitoring by electromyography (EMG) recording, and electroencephalography (EEG) monitoring to assess the depth of anaesthesia [15].

In order to detect breaches in the pedicle wall, CMAPs were recorded in response to stimulation that was applied through the finder. This was done while funnelling (see Figs. 1 and 2) and subsequently, in response to screw stimulation.

The stimuli were of 200 μ sec duration continuous constant current pulses presented at a rate of 3.1 Hz [10]. Monopolar stimuli were delivered through a sterile alligator electrode (SpesMedica Inc., Genova, Italy; manufactured all electrodes) attached to the standard pedicle finder (Medtronic Legacy, Medtronic Inc., Minneapolis, MN.), and Depuy Expedium (DePuy Spine Inc., Raynham, MA) with the anode return 13-mm long monopolar needle electrode placed in the adjacent paraspinal muscles. EMG activity and CMAP were recorded from corresponding intercostal muscles for T3-T5 pedicles; from the abdominal musculature for T6-T12 pedicles; from iliopsoas and quadriceps femoris for L1-L4 pedicles; from tibialis anterior for L4-S1 pedicles; and from abductor hallucis and anal sphincter when sacral pedicles were involved. 13-mm dual subdermal needle recording electrodes were placed by the neurophysiologist following induction of general anaesthesia. Neuromonitoring was performed using an NIM Eclipse system (Medtronic Inc., Minneapolis, MN).

Neurophysiological assessment during funnelling was performed in the study group as follows: (a) Current intensity was set to 10mA at the beginning of each pedicle funnelling in accordance to the recommended threshold for screw testing [12, 16, 17]; (b) if CMAPs were triggered with 10mA stimulus, the surgeon was alerted, and; (c) stimulus intensity was gradually reduced to determine threshold (the minimal stimulation required to evoke CMAP; Fig. 3); (d) the surgeon performed a careful and detailed

inspection of the pedicle, using a delicate bold tip feeler (Medtronic Inc., Minneapolis, MN) to check for a cortical defect. In case a breach was detected, a new tract was funnelled. If no breach was palpated, the funnel was finalized; the cavity was closed, manually re-checked, and double-checked with fluoroscopy.

Following the insertion of all screws, the screw test was performed in both the study and control groups as follows: (a) Current intensity was set on 0mA at the beginning of each screw test; (b) the surgeon touched the centre of the screw head with a handheld probe and a return electrode similar to the funnelling test; (c) current intensity was increased until CMAPs were triggered (to a maximum of 30mA), determining the screw threshold.

We have used a straightforward anatomical approach to identify the starting point of the thoracic pedicles. Making sure to be aligned with the mid-point of the superior facet and never being medial to it, we used a sharp-tipped awl to open the cortex at a starting point. Next, a 2mm curved blunt tip finder, connected to the neuro-monitoring system, was introduced into the pedicle, carefully advanced deep inside while the neurophysiologist reverberates the CMAPs. In the event of a reduction, the funnelling process was immediately stopped and a 1mm ball tip feeler was introduced to palpate the inner walls of the funnel. The feeler was slightly curved so the surgeon could sense the tip touching the edge of the funnel. In case of penetration of the spinal canal by the tip, a medial breach was declared. If the tip was protruding towards the muscles, a lateral breach was diagnosed. A similar process was carried out cephalad and caudad. Once a breach was identified, the surgeon notified the neurophysiologist to mark it in his timeline records. Fluoroscopy was used twice: after placement of pedicular markers and following correction, at the end of surgery. Plain radiography was not used.

Anaesthetic management

Patients were first anesthetized by total intravenous anaesthesia target control infusion following induction. General anaesthesia was maintained by propofol plasma concentration of 4–8 $\mu\text{g mL}^{-1}$ (March model) and remifentanyl effect-site concentration of 4–10 ng mL^{-1} (Minto model) [18, 19].

Statistical analysis

To determine the optimal cut-off for stimulus intensity, a receiver operating characteristic (ROC) curve was created and sensitivity and specificity at optimal cut-off values calculated (Fig. 3 for diagram). The Mann–Whitney U test was performed to compare thresholds of lateral and medial breaches for data demonstrating a non-parametric distribution (Shapiro-Wilk $F(1066) = 0.701$, $P < .001$; Skewness= -1.113, Kurtosis= -0.275). Pearson chi-square analysis was performed to assess differences in the rates of true and false – positive and negative results in non-apical, apical concave, and apical convex pedicles. T-test was performed to assess group differences in the screw test thresholds between the study and control groups. Data analysis was performed using SPSS (Version 19 for Windows).

Results

The demographics and clinical diagnoses of the participants are displayed in Tables 1 and 2, respectively. There were no significant differences in mean age, sex, and diagnosis distributions between study and control groups.

Sensitivity and specificity of finder stimulus for identification of cortex violation.

Of the 1066 pedicles included in the analysis, manual inspection demonstrated 326 breaches (see Fig. 4 for flowchart diagram). We performed ROC analysis in order to identify the stimulus cut-off threshold that optimally predicts pedicle breaching during funnelling. Figure 5 shows the resulting ROC curve defining the cut-off for finder stimulation during pedicular funnelling, as depicted by SPSS. The ROC curve presented an "inverted L" shape, with a sharp angle around stimulation threshold of 9 mA (Table 3). The 9 mA cut-off revealed a sensitivity of 88.0% and a specificity of 89.5% for predicting pedicular breaching, with an area under the ROC curve (AUC) of 0.92 (95% confidence interval (CI), 0.90-0.94; $P < .001$). A lumbosacral ROC model (L1-S2 pedicles; $n=251$) showed an angle at stimulation threshold of 10 mA, demonstrating a sensitivity of 88.1% and a specificity of 96.6% for predicting pedicular breaching, and an AUC of 0.94 (95% CI, 0.87-0.99; $P < .001$). A thoracic ROC model (T3-T12 pedicles; $n=815$) showed an angle at stimulation threshold of 9mA, demonstrated a sensitivity of 89.1% and a specificity of 86.5% for predicting pedicular breaching, and an AUC of 0.91 (95% CI, 0.89-0.94; $P < .001$).

Effects of the scoliotic curve on finder stimulation testing.

Hypothesizing that neurophysiological testing of pedicles at the apical aspect of the scoliosis will result in a higher rate of true positive and false positive alerts, compared to non-apical pedicles, we compared the rates of true negative, true positive, false negative, and false positive alerts between three groups of pedicles in our scoliosis patients (omitting kyphosis cases from this analysis): non-apical (n=587), apical concave (n=188) and apical convex (n=187) pedicles. Using the 9 mA threshold, determined by the ROC curve to be the optimal cut-off for alerting the staff of pedicular breaching, Pearson chi-square analysis showed significant group differences ($\chi^2=30.9$, $P<.001$; Table 4). Post-hoc Pearson chi-square tests showed both higher rates of true positive and false positive alerts and lower rates of true negative alerts in apical concave than in non-apical ($\chi^2=22.9$, $P<.001$) and apical convex ($\chi^2=20.3$, $P<.001$) pedicles, but no significant differences between non-apical and apical convex pedicles ($\chi^2=4.1$, $P=.25$).

Effects of the breaching laterality on the finder stimulation testing.

We performed a Mann–Whitney U test to probe for threshold differences between medial and lateral breaches for all breaches where a medial or lateral violation was identified (n= 273).

Medial breaches (median±SE= 4.0±0.2 mA; n=144) had significantly lower stimulation thresholds than lateral breaches (median±SE= 7.0±0.2 mA; n=129) (Mann–Whitney U = 4659.0, $P<.001$).

Effects of the finder stimulation test thresholds.

Hypothesizing that the thresholds of screw testing will be higher for patients on whom finder stimulation test was carried out, compared with patients in which finder stimulation test was not performed, we compared the screw thresholds of the study and control groups. Since neurophysiological screw testing was employed in both groups after the insertion of all screws, achieving better screw placement in the finder stimulation group would result in higher screw thresholds. Results demonstrated a significantly higher mean threshold for the study vs. control group ($t(1228)=3.135$, $P=.002$). The study group, in which finder stimulation testing was applied during funnelling, previous to the screw test, had a mean screw threshold of 21.0±8.4 mA. The control group, in which finder stimulation testing was not used, had a mean screw threshold of 19.1±8.3 mA. The finder and the screw thresholds in the study group were positively correlated (Spearman's rho=0.377, $P<.001$). Clinical and cord neuromonitoring results showed MEP and SSEP monitoring to be stable during hole funnelling and screw insertion in all patients. There were no adverse events from performing the finder stimulation or the manual palpation. One patient developed a cord injury due to an iatrogenic cord contusion during an open canal deformity correction. No failures of the fixation were reported after an average of 5 years of follow-up.

Discussion

This report investigates the use of continuous CMAP monitoring via finder stimulation for early detection of pedicle violations during funnelling. Previous investigations reported the use of CMAP via hand-held probe stimulation to detect pedicle hole and screw violations [9–11, 20]. While these techniques have been reliable in detecting screw malposition, they had been performed after hole funnelling or, in the case of the screw test, after screw insertion [16, 20]. Thus, they do not provide the surgeon with a real-time indication of pedicle wall penetration and they will not prevent neurological harm. When performed continuously while funnelling, the current test may alert the spine surgeon about a possible breach occurrence to the spinal or root canal.

In the present study, pedicular wall breaching was successfully detected by manual palpation in 30.6% of the holes. Manual palpation has not been regarded as the gold standard for demonstrating a pedicular breach. The rate of pedicle violations in our series is higher than that reported in most studies [21]. The differences between breaching detected in the present study, as opposed to those described previously, may be explained by two means. First, while most previous investigations determined pedicle breaching of screws, the present study reports pedicle breaching in pedicle holes. Moreover, prior investigations displayed breaches on a post-operative CT scan, highly sensitive for > 2 mm violations, while our goal was to use an intraoperative, ongoing technique. For this purpose, our team considered an intraoperative manual palpation, although generally considered suboptimal, as a reference test. Since the breaches in our patients were generally not bigger than 2 mm (the finder tip was

withdrawn once an alert was displayed), manual palpation was established as the most appropriate method to determine pedicle integrity. In order to demonstrate pedicle integrity while funnelling, the CT scan is of similarly restricted sensitivity in identifying small breaches (1–2 mm). Moreover, in order to be relevant here, a CT scan should have been performed after each funnelling, and not at the end of the surgical procedure. Therefore, our young patients avoided exposure to unacceptable levels of radiation.

ROC analysis results show an AUC of 0.92, suggesting continuous finder stimulation to be a highly effective method to detect pedicle breaching. We found that a cut-off of 9 mA for alerting the surgeon of a suspected breach provides the optimal sensitivity-specificity trade off (sensitivity rate-88.0% and specificity rate 89.5%). Of note, while the lumbosacral and thoracic ROC models showed similar sensitivity at the recommended cut-offs (88.1% vs. 89.1%), the lumbosacral ROC had markedly higher specificity than the thoracic model (96.6% vs. 86.5%, respectively). These results may be due to less salient CMAP responses and higher stimulus artefacts, typical for the rectus abdomini and intercostal muscles [14, 22].

In agreement with previous findings [22], our results suggest that low stimulation thresholds are associated with high reliability of the alert, and may also indicate a medial breach which is of higher risk for neurological complications.

The finding of 7.3% false positive results may have three possible causes: (a) vertebrae typical to the concave apical region have small pedicles and a short pedicle–spinal cord distance or may have a low bony mass [23]; (b) leakage of finder electrical stimulation to soft tissues from outside the pedicle; and (c) cases of minimal breaches or a very thin pedicle wall are not detected by manual inspection [10, 16]. False negative results were only found in 3.7% of the cases, perhaps due to a suboptimal stimulation threshold. Higher stimulation may be required at levels below the conus medullaris compared to those in the thoracic region.

We have found that the thresholds of screw testing were significantly higher for patients for whom finder stimulation test was carried out. This finding implies that with the finder stimulation technique, a well-positioned screw is highly suggestive of a better hold and a lower risk for neurological injury. The association of the finder and the screw thresholds in the study group may suggest that correcting hole malposition during funnelling can result in a well-positioned, high-threshold screw. This finding emphasizes that the finder and screw tests may be complimentary, but not alternative, techniques.

Our study presents several limitations. First, pedicle integrity was assessed by manual inspection, the sensitivity of which is highly dependent on a surgeon's skill and experience [24, 25]. Caution is also advised when interpreting the results of successive attempts at funnelling with occurrence of a pedicle breach. In such instances, the stimulation current is expected to leak through the breached hole, resulting in low thresholds, despite proper correction of the hole orientation. Further prospective studies are needed to support the results of the current retrospective investigation. This study introduces an easy to use and sensitive technique which may assist in achieving a safe trajectory during a free-hand funnelling, even without the support of the CT scan. Moreover, our technique, when compared with the PediGard instrument, significantly reduces the price of the procedure. The PediGuard is a single-use hand-held tool for drilling pilot holes in order to place pedicle screws. The PediGuard has an NHS acquisition cost of £500 per single-use unit and its positive predictive value is described as 87.1%. The main differences between this instrument and our technique are: (1) the PediGard uses impedance changes of the tissues to infer funnelling integrity, while our method measures thresholds of muscle response to current nerve stimulation as an indicator of breaching of the pedicle. (2) In contrast with the PediGard, our technique does not present an additional cost for a similar sensitivity.

The study aimed to develop a method for real-time assessment of pedicle integrity. Our results suggest that continuous finder stimulation may provide the surgeon with an effective tool to confirm orientation and to avoid canal penetration once breaching occurs.

This method can be performed safely. In addition, the statistical analysis allows the determination of thresholds that have high sensitivity and specificity, while warning of the possible presence of a breach.

Finder stimulation is highly sensitive and specific in predicting pedicular breaching (especially medial breaching). When compared with the control group, screw-testing revealed better results, following the use of finder stimulation technique. However, the major advantages of the method described here are its high safety and low cost, which may prompt a differential choice in countries of lower affluence.

The burden of proof regarding our conclusions, that continuous finder stimulation is an effective tool, rely on the fact that not a single patient had neurologic injury, nor requested a revision surgery, in the context of a long follow up.

Level of evidence III.

Declarations

All the authors declare that they have no conflict of interest.

Funding: There is no funding source.

Ethical approval: This article does not contain any study with human participants or animals performed by any of the authors.

Informed consent: Since the testing procedure described in this retrospective study was an integral part of the clinical course, and not a scientific experimental endeavor, no informed consent was required from the work subjects.

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Tables

Table 1. Demographics

Group	Study	Control	Statistics
N	56	13	
Sex (M/F)	8/48	3/10	Pearson $\chi^2=0.61$, P=.44
Age (years \pm SD)	16.9 \pm 8.8	20.6 \pm 15.5	Independent Samples t=-0.78, P=.45

Table 2. Clinical diagnoses

Group	Study	Control	Statistics
Adolescent idiopathic scoliosis	46 (82.1%)	10 (76.9%)	Pearson $\chi^2 = 1.55$, P=.67
Neuromuscular scoliosis	1 (1.8%)	1 (7.7%)	
Connective tissue disorders scoliosis	1 (1.8%)	0 (0.0%)	
Kyphosis	8 (14.3%)	2 (15.4%)	

Table 3. Coordinates of the receiver operating characteristics (ROC) curve

Positive if stimulus is less than or equal to	Sensitivity (%)	Specificity (%)
1 mA	0.9%	100.0%
2 mA	5.8%	100.0%
3 mA	17.5%	99.7%
4 mA	31.9%	97.7%
5 mA	48.5%	96.2%
6 mA	64.1%	94.6%
7 mA	74.5%	93.1%
8 mA	84.0%	91.1%
9 mA	88.0%	89.5%
10 mA	92.3%	85.7%

Table 4. Cross tabulation of alert rates by funnelling location in 48 study-patients with scoliosis

Pedicle	True negative	True positive	False positive	False negative
Non-apex (n=587)	61.5%	26.9%	6.6%	4.9%
Apex convex (n=187)	67.9%	24.1%	5.9%	2.1%
Apex concave (n=188)	45.2%	41.5%	11.2%	2.1%

Figures



Figure 1

Photograph, A picture of the funnelling setup. To detect breaches in the pedicle, CMAPs were recorded in response to finder stimulation during funnelling. Monopolar stimuli were delivered through a sterile electrode (in black) attached to the standard pedicle finder, with the anode return 13-mm long monopolar needle electrode placed in the adjacent paraspinal muscles (in white).

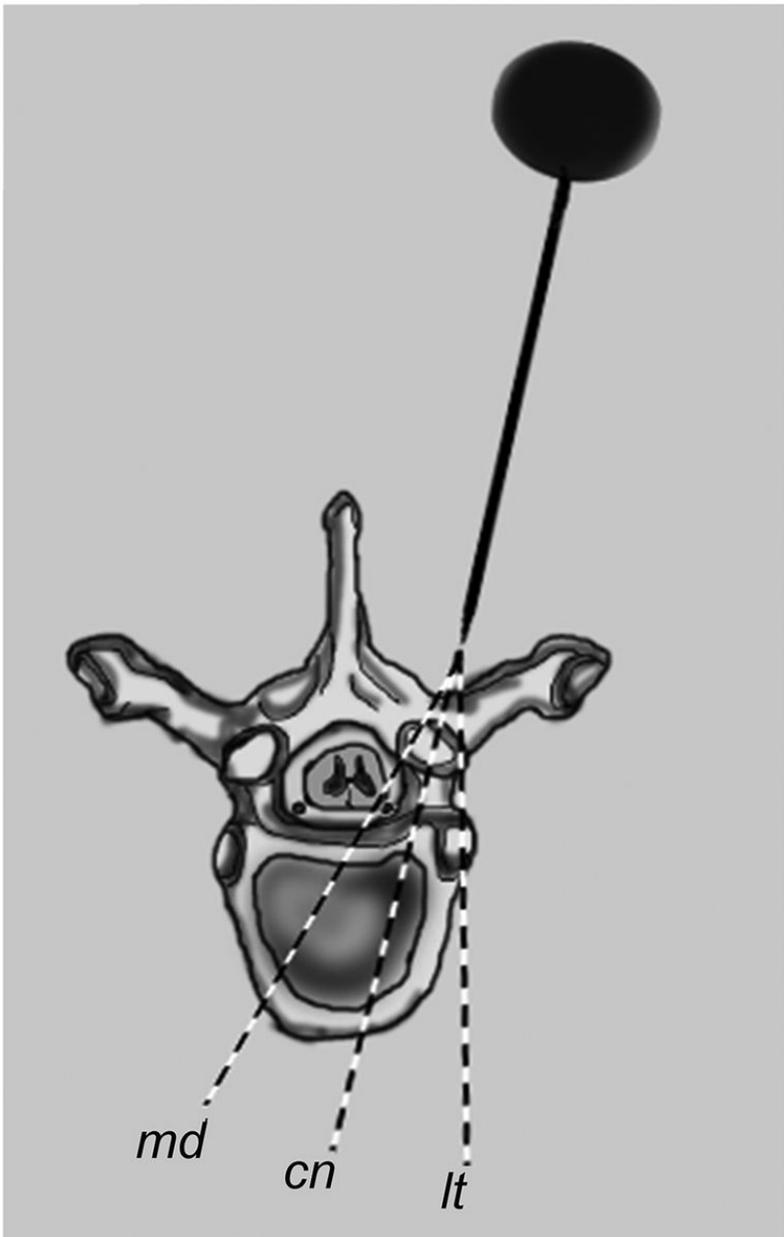


Figure 2

Illustration, Schematic illustration of pedicular hole funnelling prior to screw placement The hole is being funnelled in a central orientation [cn] within the pedicle; in a lateral orientation [lt], breaching the lateral aspect of the pedicle; or in a medial orientation [md], breaching the medial wall of the pedicle and protruding into the spinal cord canal.

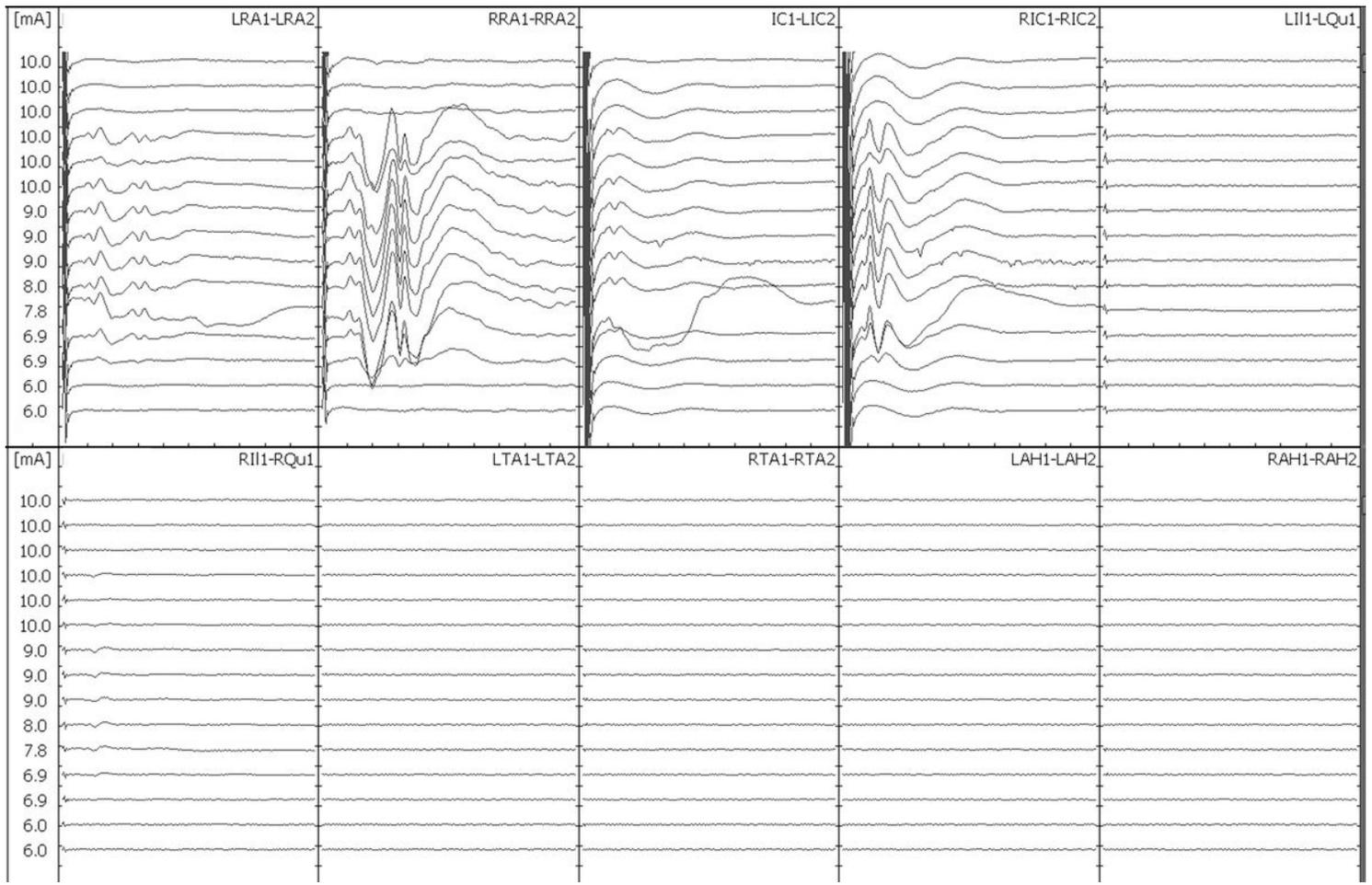


Figure 3

Graph, CMAP response during hole funnelling CMAP response evoked from right rectus abdominal and intercostal channels during a hole funnelling in the right T6 pedicle. Finder stimulation was reduced until the response disappeared to determine threshold (7 mA). In this case lateral breach was detected during manual inspection.

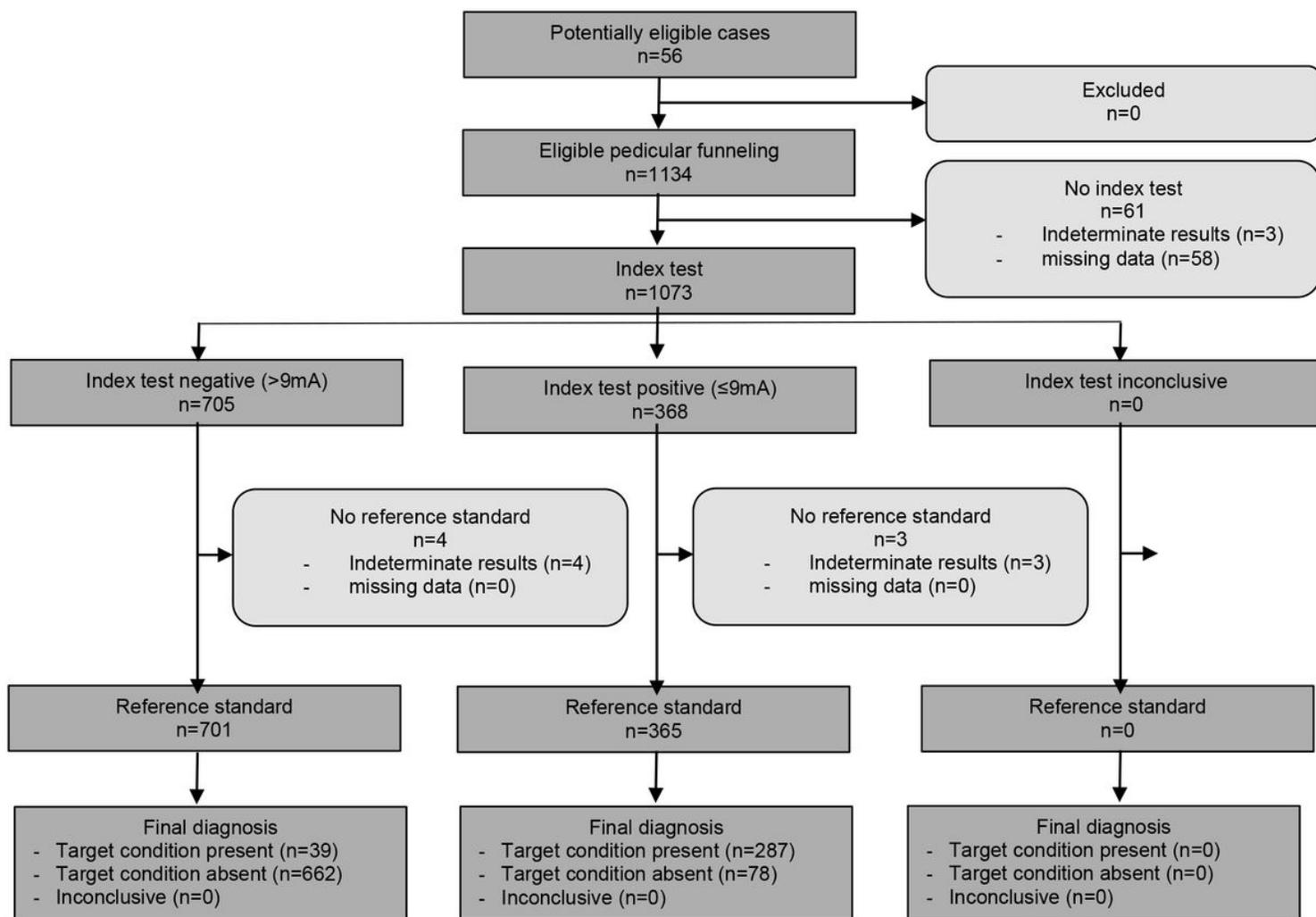


Figure 4

Flowchart, Patients flow through out the study 1134 pedicles were funnelled in 56 consecutive patients undergoing deformity correction and posterior spinal fusion procedures. Valid neurophysiological testing was performed during funnelling in 1073 pedicles, excluding cases of indeterminate results (n=3) and missing data (n=58) from statistical analysis. Of the valid neurophysiological results, indication for breach was present in 368 pedicles and absent in 705 pedicles. In 3 pedicles with positive and 4 pedicles with negative neurophysiological results manual palpation assessment had indeterminate results, thus excluded from statistical analysis. Manual palpation revealed pedicular breach in 287 of the 365 cases in which neurophysiological testing was positive, and in 39 of the 701 cases in which neurophysiological testing was negative.

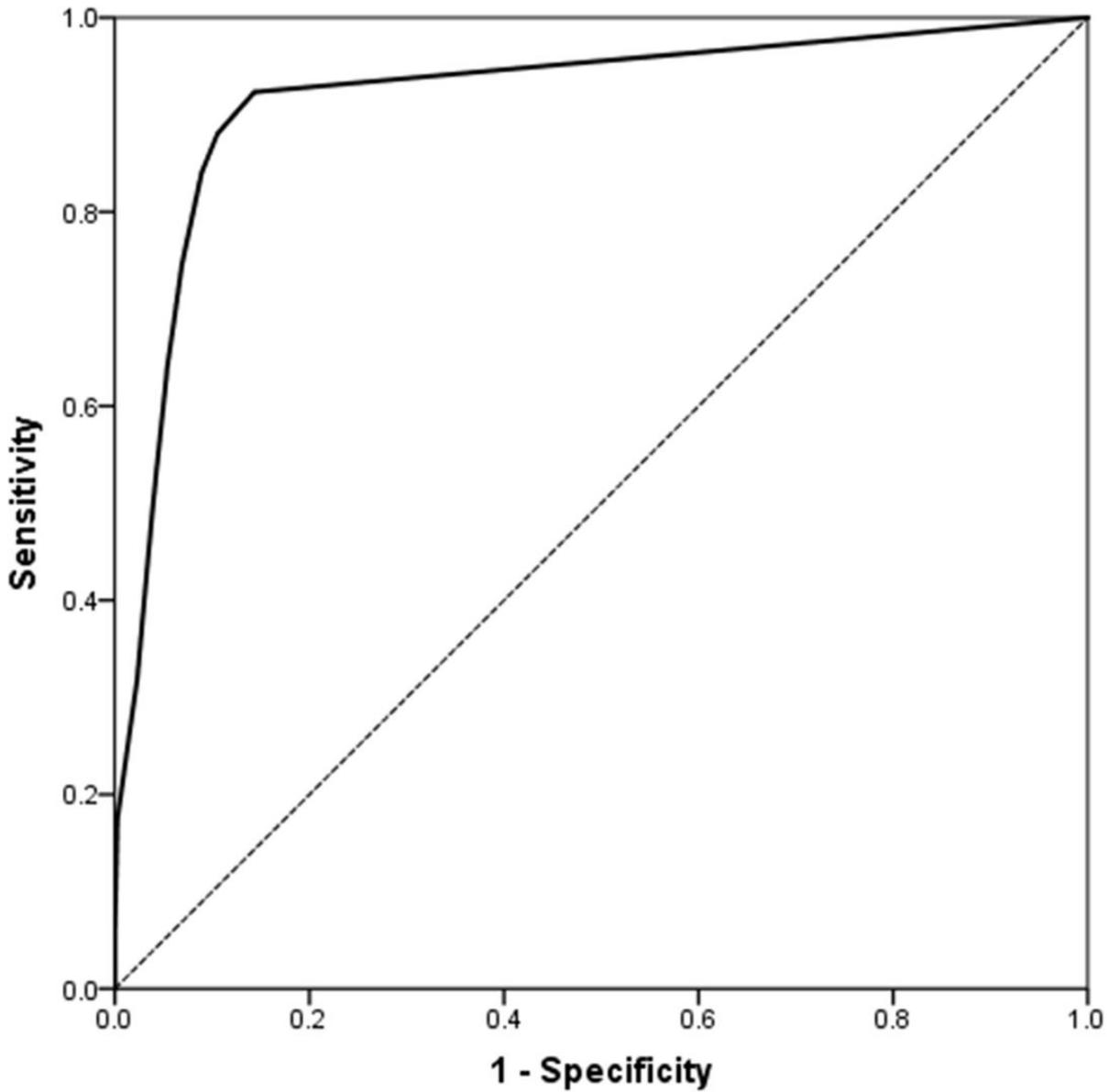


Figure 5

Graph, Receiver operating characteristic curve for cut-off finder stimulation intensity during pedicular funnelling Receiver operating characteristic curves to determine the cut-off finder stimulation intensity at pedicular funnelling (of both lumbar and thoracic pedicles). A 9 mA cut-off revealed sensitivity of 88.0% and specificity of 89.5% for predicting pedicular breaching, and an area under the ROC curve of 0.92(95% confidence interval, 0.90-0.94; $P < .001$).