

Threshold-based Monitoring of Compound Muscle Action Potentials for Percutaneous Pedicle Screw Placement in the Lumbosacral Spine: Can We Rely on Stimulation of the Uninsulated Screw to Provide a Valid Safety Warning?

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Abstract

Study Design: A prospective analysis.

Objective: To test if threshold-based monitoring of compound muscle action potentials (CMAPs) by stimulating the screw loaded to uninsulated extender sleeve provides a valid safety warning for percutaneous pedicle screw (PPS) placements in the lumbosacral spine.

Summary of Background Data: Utility of the CMAP monitoring to PPS procedures remains controversial.

Methods: A series of 202 patients underwent a total of 1664 lumbosacral PPS placements under CMAP monitoring without fluoroscopic guidance. The monitoring consisted of stimulating the PPS assembled to uninsulated extender sleeve and recording CMAPs from the vastus medialis, biceps femoris, tibialis anterior, and medial gastrocnemius. Automated steps of a threshold hunting algorithm using 0.2-ms duration pulses of increasing intensities delivered at 2/s allowed quick determination of a minimum stimulation current to evoke >100- μ V amplitude CMAPs.

Results: At L2 through S1 spines, postoperative CT scans identified 51 medial or inferior pedicle wall breaches of 1536 screws (3.3%) without neurologic complications. The ROC curve analysis determined the critical cut-off threshold value of 27 mA (74% sensitivity and 95% specificity) for predicting 35 breaches of 627 screws (5.6%) at L2 and L3, and

of 17 mA (100% sensitivity, 98% specificity) for 16 of 909 (1.8%) at L4 through S1.

While advancing the screw, 3 breaches (5.9%) showed a particularly low threshold of ≤ 6 -mA, allowing the surgeon to immediately redirect the screw and retest the new trajectory as safe.

Conclusion: Screw stimulation with threshold hunting algorithm has a distinct advantage over the time-consuming insulated pilot hole stimulation, allowing an uninterrupted flow of the surgery. The present findings have documented practical usefulness and reliability of CMAP monitoring using direct stimulation of the PPS assembled to uninsulated extender sleeve.

Key Words: Percutaneous pedicle screw, pedicle screw stimulation, CMAP monitoring, Lumboacral spine, Pedicle breach, Threshold hunting algorithm, ROC curve analysis, Sensitivity, Specificity, Critical cut-off current intensity, Uninsulated extender sleeve

Level of Evidence: 2

Key Points

- #. We tested if threshold-based monitoring of the lower limb CMAPs by stimulating the screw loaded to uninsulated extender sleeve provides a valid safety warning for lumbosacral PPS placements without fluoroscopic guidance.
- #. Automated steps of a threshold hunting algorithm with increasing stimulus current delivered to PPS allowed quick determination of a minimum current intensity to evoke >100- μ V amplitude CMAPs.
- #. At L2 through S1 spines, postoperative CT scans identified 51 medial or inferior pedicle wall breaches of 1536 screws (3.3%) without neurologic complications.
- #. The ROC curve analysis determined the critical cut-off threshold value of 27 mA (74% sensitivity and 95% specificity) for predicting 35 breaches of 627 screws (5.6%) at L2 and L3, and of 17 mA (100% sensitivity, 98% specificity) for 16 of 909 (1.8%) at L4 through S1.
- #. The present findings have documented practical usefulness and reliability of CMAP monitoring using direct stimulation of the PPS assembled to uninsulated extender sleeve.

Mini Abstract

We monitored threshold-based compound muscle action potentials during 1664 lumbar percutaneous pedicle screw (PPS) placements without fluoroscopic guidance. Direct stimulation of the PPS assembled to uninsulated extender sleeve provided a valid safety warning in predicting medial or inferior pedicle breaches, particularly at L4 through S1 level.

Percutaneous Pedicle Screw CMAP Monitoring

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65**1 Introduction**

2 The pedicle screw (PS) placements in the lumbosacral spine, intended to lie entirely
3 within the bone, may pass through the pedicle wall to irritate the nerve roots
4 postoperatively. As shown in previous studies¹⁻⁹ and reviews,^{10,11} which confirmed the
5 original work by Calancie et al. (1994),¹² the threshold-based monitoring of compound
6 muscle action potentials (CMAPs) provides valuable intraoperative safety measure
7 during conventional open PS placement. This strategy consists of electrically stimulating
8 either the pilot hole created in the pedicle for subsequent screwing or the screw itself and
9 recording CMAPs from the lower-limb muscles. The technique relies on the principle that
10 the pedicle presents an insulative barrier to low levels of current unless its wall breaches
11 medially or inferiorly. The current flow would then take the path of least resistance at the
12 insulation breakdown and excites the adjacent nerve roots evoking CMAPs with a low-
13 level stimulation.

14 Recent emphasis on minimal invasiveness in spinal stabilization surgery has
15 prompted spine surgeons to increasingly employ percutaneous pedicle screw (PPS)
16 placement. In this approach, unlike open PS placement, the surgeon can rely on neither
17 anatomic landmark nor tactile feedback when advancing the blunt-tipped probe into the
18 vertebral body. Instead, widely used PPS instrumentation systems utilize fluoroscopy-

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3 19 assisted guidewire insertion, followed by cannulated screw placements through minimal
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6 20 incisions. Threshold-based CMAP monitoring, therefore, should play a more important
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9 21 role for safe screw placement in PPS procedures than in the conventional open techniques.
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12 22 Only a limited number of PPS studies¹³⁻¹⁹ and reviews^{20,21} have, however, dealt with this
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16 23 type of neuromonitoring, probably for two reasons. First, percutaneous surgical
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19 24 techniques inevitably rely on fluoroscopy at the expense of radiation exposure. Second,
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22 25 minimal incisions call for the necessity of insulating the metallic instruments from the
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25 26 surrounding wet tissues to avoid the spread of current during stimulation.

27 We previously reported a lumbosacral PPS placement technique with a newly
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29 developed device named LICAP (Less Imaging Cannulated Awl and Probe) system,
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32 28 which requires neither fluoroscopy nor computer-aided navigations.^{22,23} This technique
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35 29 helps eliminate the potential cumulative risk of repeated, low-dose radiation exposure to
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38 30 surgical teams. To further improve the technical precision, we have introduced threshold-
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41 31 based CMAP monitoring into the LICAP-assisted PPS technique,²⁴ resulting in a better
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44 32 result with no PPS-related nerve root compromise. The present study attempts to
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47 33 determine the critical cut-off values of threshold stimulus intensity for predicting medially
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50 34 or inferiorly misplaced PPSs identified by postoperative CT scans.
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37 **Materials and Methods**

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39 1. Patients

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41 From August 2017 to August 2020, 202 patients (82 men), aged 44 to 89 (mean, 72)
42 years, underwent a total of 1664 lumbosacral LICAP-assisted PPS placements with
43 threshold-based CMAP monitoring at our institution. All agreed in writing to participate
44 in the study after reading an informed consent form approved by the IRB. The indications
45 for PPS instrumentation included spinal stenosis (106), spondylolisthesis (51), deformity
46 (38), pyogenic spondylitis (4) and metastatic spinal tumor (3). We employed the LICAP-
47 assisted PPS placement with CMAP monitoring even for spinal deformities unless they
48 required vertebral osteotomies with wider opening of the surgical field.

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50 2. Threshold-based CMAP monitoring

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52 *2.1. Surgical technique*

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54 As previously reported, we conducted lumbosacral PPS placements by using a set of

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3 55 newly developed devices without C-arm guidance or computer-aided navigation.^{22,23} In
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6 56 brief, our equipment consisted of a pedicle targeting tool designed to identify and escort
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9 57 the cannulated awl to the correct starting point for cortical bone perforation, a guidewire
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12 58 that served to maintain the optimal position throughout the subsequent surgical steps and
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15 59 a cannulated, blunt-tipped probe, an equivalent of the “gearshift” used in conventional
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19 60 open PS placements. The surgeon could then advance the blunt-tipped probe searching
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22 61 for the cancellous bone track within the pedicle using tactile feedback as experienced in
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25 62 open techniques (Fig. 1-A, B). Through the pilot hole thus created in the pedicle, we
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29 63 finally inserted the cannulated self-tapping screw, which was loaded to extender sleeve,
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32 64 over the guidewire. The neuromonitoring then began using the NVM5[®] system
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35 65 (NuVasive, Inc., San Diego, California, USA) while advancing the screw through the
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38 66 pedicle.

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51 70 A short-acting neuromuscular blockade, used only at induction of general anesthesia
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54 71 and not during surgery, usually left only a slight suppressive effect. Otherwise, we used a
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57 72 fast-acting reversal agent for immediate reversal of residual blockade effects. Prior to
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3 73 pedicle integrity testing, we delivered a train-of-four successive supramaximal
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6 74 stimulations to the fibular nerve at the knee and recorded CMAPs from the tibialis anterior
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9 75 muscle to confirm the muscle relaxation clearance.^{10,21}
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12 76 A clip (Reusable NV Clip) attached to the screwdriver served as the cathode with a pair
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16 77 of self-adhesive semicircular dual surface electrodes, each 32 mm in diameter, as anodes,
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19 78 mounted 2 cm apart (NVM5 Dual Gel Electrode) on the right or left buttock. Electrical
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22 79 stimulation consisted of a square wave, 0.2 ms in duration and up to 40 mA in intensity,
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25 80 delivered at a rate of 2/s. Over the course of rotating the handle on the screwdriver to
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28 81 advance the screw through the pedicle, the automated steps of a threshold hunting
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31 82 algorithm quickly found a threshold current intensity.
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38 84 *2.3. Recording*
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44 86 A pair of self-adhesive surface electrodes, placed bilaterally over the vastus medialis
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47 87 (L2, L3, L4), tibialis anterior (L4, L5), biceps femoris (L5, S1) and medial gastrocnemius
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51 88 (L5, S1, S2), allowed monitoring of L2 through S2 nerve roots with some overlap of
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54 89 myotomes.²⁵ An eight channel NVM5 system simultaneously registered evoked CMAPs
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57 90 from all sets of electrodes with oscilloscope settings for sensitivity at 100 μ V/div and for
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3 91 bandpass filters at 10 Hz to 10 KHz. Another dual surface electrode, 32 mm in diameter,
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6 92 served as the ground.
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12 94 *2.4. The multi-channel threshold hunting algorithm*²⁶
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19 96 We used a NVM5[®] software for a patented rapid threshold hunting algorithm, which
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22 97 controlled stimulation and recording to quickly find the minimum current intensity that
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25 98 evokes >100- μ V peak-to-peak amplitude CMAPs. It utilizes a combination of a
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28 99 bracketing method to find a range (bracket) and a bisection method to narrow the bracket.
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32 100 The process continued until the bracket width reached 0.1 mA. The display of the
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35 101 threshold current, thus determined, accompanied a color code; “red”, “yellow” and “green”
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38 102 to indicate unsafe (≤ 6 mA), intermediate (7-10 mA) and safe (≥ 11 mA) levels.
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44 104 3. Postoperative CT scan analysis
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51 106 Using the postoperative CT scans, we identified the location of the pedicle screw
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54 107 breach as medial, lateral, superior or inferior and related it to the presence or absence of
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57 108 clinical symptoms. The amount of breach was quantified with a simple classification
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109 modified from Zdichavsky's grading system²⁷ as follows: Grade 0, no breach; Grade 1,
110 breach less than half of screw diameter out of pedicle wall and Grade 2, breach more than
111 half of screw diameter out of pedicle wall.

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113 4. Receiver operating characteristic (ROC) curve analysis

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115 We used ROC curve analysis to determine the critical cut-off threshold value for
116 predicting medial or inferior pedicular breaches identified by postoperative CT scans. The
117 analysis was conducted separately for the upper (L2 and L3) and lower (L4 through S1)
118 spine groups of 627 and 909 screws. We excluded lateral and superior pedicular breaches
119 from this analysis because PS-related nerve root compromise primarily involved medial
120 or inferior pedicle wall with its proximity to the nerve root.²⁸ We also excluded the screws
121 placed at L1, which innervates none of the muscles used in the current study.

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123 5. Statistical analysis

124 We used t-test for comparing the threshold current intensities between correctly placed
125 and medially or inferiorly misplaced PPSs for the screws at L2 through S1 as a whole and,
126 for those in the subgroups of the upper and the lower spine groups, with $p < 0.05$

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127 considered significant. The values represent mean \pm standard error (SE) and
128 corresponding 95% confidence intervals (CIs). For various cut-off threshold values, the
129 graphical ROC curve was produced by plotting the calculated sensitivity (i.e., true
130 positive rate) on the y-axis against 1-specificity (i.e., false positive rate) on the x-axis.
131 We computed the area under the ROC curve (AUC) as a measure of an overall accuracy
132 of the test and chose the point nearest to the upper left corner of the curves as a critical
133 cut-off value. For all these analyses, we used SAS JMP software (SAS Institute Inc, Cary,
134 NC, USA).

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136 **Results**

137 Postoperative CT scans revealed the evidence of pedicle wall breaches for 120 of 1664
138 screws (7.2%) as shown in Table 1: 61 located medially, 53 laterally, 5 superiorly and one
139 inferiorly. Postoperatively, all these patients remained clinically asymptomatic, despite
140 identified breaches, with no signs of nerve root irritation or sensory/motor deficits, thus
141 requiring no revision surgery for the misplaced screws.

142 The upper (L2 and L3) and lower (L4 through S1) spines combined, 51 of 1536 screws
143 (3.3%) breached medially (50) or inferiorly (1) with 38 classified as grade 1 and 13 as
144 grade 2. The incidence of PPS misplacement varied depending on the spinal level (Table

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145 2). Analyzing all 1536 screws, the threshold current intensities showed significantly ($p <$
146 0.001) smaller values (mean \pm SE) of 19.2 ± 0.9 mA for 51 displaced compared to $36.8 \pm$
147 0.2 mA for 1485 correctly placed screws. The corresponding scores in the upper spine
148 group consisted of 22.2 ± 0.9 mA for 35 displaced and 38.5 ± 0.2 mA for 592 correctly
149 placed screws ($p < 0.001$) (Fig. 2-A and Table 3), and in the lower spine group, 12.6 ± 1.7
150 mA for 16 displaced and 35.7 ± 0.2 mA for 893 correctly placed screws ($p < 0.001$) (Fig.
151 2-B and Table 3). Figures 1-A and B show distribution of the threshold current intensities
152 for individual screws, combining those with 40 mA and any scores higher together, as
153 shown on top of the scatterplots, in calculating mean thresholds.

154 Of the 51 displaced screws, 3 (5.9%) in 3 patients triggered a “red” color warning with
155 particularly low threshold values, 3.5 mA, 5.0 mA and 5.0 mA, when advancing the screw
156 at L3, L5 and L5. This alarm prompted the surgeon to withdraw both the screw and the
157 guidewire and redirect the blunt-tipped probe to reposition the screw in a more lateral
158 orientation. Stimulating the realigned screw yielded a higher threshold value of 40 mA,
159 40 mA and 31mA, indicating the pedicle integrity by color “green” in all 3 cases.
160 Postoperative CT scans showed the correctly placed screws with the trajectory traces left
161 by prior medial misplacement (Fig. 3), consistent with grade 1 breach for 2 and grade 2
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163 The ROC curve analysis determined the critical cut-off for the threshold current
164 intensity of 27 mA (74% sensitivity, 95% specificity and 0.855 AUC) for the upper spines
165 (Fig. 4-A) and of 17 mA (100% sensitivity, 98% specificity and 0.995 AUC) for the lower
166 spines (Fig. 4-B).

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168 **Discussion**

169 Accumulated evidence indicates that the threshold-based CMAP monitoring helps
170 quickly verify correct PS placement during traditional open surgery.¹⁻¹² Some surgeons,
171 however, still question its true clinical value as the test yields few false positive but
172 many false negative results or high specificity with low sensitivity²⁹⁻³⁶ based on a recent
173 meta-analysis of up to 22% of misplaced screws.¹¹ When applying this technique to PPS
174 procedures, one of the main methodological concerns relates to an unintended current
175 leakage to the surrounding wet tissues through the metallic instruments. The stimulus
176 current, if delivered with a monopolar arrangement using the uninsulated PPS as the
177 cathode and a needle or surface electrode as the anode placed nearby or remotely, would
178 take multiple parallel pathways from one electrode to the other. To minimize this spread
179 of current, some investigators use either a plastic tube or apply a surface insulative
180 treatment on the pedicle access probe.¹³⁻²⁰ They then test the pilot hole by continuously

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181 stimulating a moving focal probe before PPS placement. Screw stimulation, as a final
182 test, however, must employ the uninsulated metallic instruments because insulating the
183 screw/extender sleeve assembly poses a practical difficulty. Such exhaustive preparation
184 improves the accuracy of monitoring at the expense of an additional operative time, a
185 major drawback not widely accepted by spine surgeons. We, therefore, conducted the
186 CMAP monitoring only when advancing the screw through the pedicle, which may have
187 possibly increased the threshold readings by a leakage of the stimulus current through
188 uninsulated extender sleeve.

189 The present study has demonstrated that PPS stimulation even with a widely-used set
190 of uninsulated metallic instruments serves well for monitoring purposes particularly for
191 the L4, L5, and S1 roots. At these lower spine levels, categorical scatterplots for the
192 breach (-) and breach (+) groups showed clearly different distributions without any
193 outlier points (Fig. 2-B). Based on the ROC curve analysis for predicting postoperative
194 medial or inferior pedicle breach at these levels (Fig. 4-B), we identified the critical cut-
195 off for the current intensity of 17 mA (100% sensitivity, 98% specificity, and 0.995 AUC).
196 This higher cut-off value than the specific searching intensities of 4 to 11 mA used in
197 most previous studies^{1-5,12,32} probably resulted from the leakage of the PS stimulus current
198 towards surrounding tissues before reaching the site of pedicle wall breach. Others

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9 201 thresholds than pilot hole stimulation with various insulated pedicle access probes.^{12,18}
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16 203 should show unpredictable values. In practice, however, it remained nearly constant in
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19 204 the same intraoperative settings, resulting in only a small threshold variability in detecting
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22 205 pedicle breaches. The use of relatively large surface anodes located remotely from the
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25 206 surgical wound may account for this observation. With such a distant surface anode,
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28 207 unlike a needle inserted nearby, the stimulating current spreads more widely to render its
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31 208 effective fraction reaching the nerve root under study relatively constant irrespective of
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35 209 anodal position, which varies slightly from one patient to another.
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38 210 In contrast to the lower spine group, the upper group showed a much greater threshold
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41 211 variability for pedicle breaches, making the monitoring less effective (Fig. 2-A). The
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44 212 ROC curve analysis (Fig. 4-A) revealed a reduced sensitivity of 74% for the critical cut-
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47 213 off of 27 mA, possibly reflecting the use of the vastus lateralis (L2 and L3) as the sole
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51 214 target muscle. Additional CMAP assessments from proximal lower-limb muscles such as
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54 215 the obturator-innervated adductor longus (L2, L3 and L4) and adductor magnus (L2, L3,
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57 216 L4 and L5) might have increased the test accuracy.
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217 In the present series, we experienced a particularly low threshold of ≤ 6 mA breaches
218 in 3 patients, necessitating prompt removal and repositioning of the screw in a more
219 lateral orientation (Fig. 3). The automated system used in this study provided the surgical
220 team with real-time identification of the low threshold intensity both visually and audibly.
221 This nearly instantaneous feedback allowed the surgeon to immediately redirect the screw
222 and retest the new trajectory as safe, avoiding nerve root compromise in all cases.

223 Threshold-based CMAP monitoring with PS stimulation plays a particularly important
224 role in our LICAP-assisted PPS procedure, which relies on fluoroscopy only when pen
225 marking the lateral border of each pedicle on the skin after positioning the patients prone
226 with general anesthesia. Without further use of fluoroscopy, our threshold monitoring
227 provides a useful addition to the surgeon's tactile feedback in avoiding nerve root
228 irritation. The present data have indicated that the warning criterion of 17 mA will provide
229 reliable safety feedback for PPS placements in the lower lumbosacral spines in preventing
230 not only neurologic complications but also asymptomatic medial or inferior pedicle wall
231 breaches. Screw stimulation with rapid threshold hunting algorithm has a distinct
232 advantage over the time-consuming insulated pilot hole stimulation, allowing an
233 uninterrupted flow of the surgery.

234 In PPS procedures without CMAP monitoring, lateral pedicle wall breach tends to

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235 occur more frequently than medial breach, as previously reported.^{37,38} The pattern
236 reversed to a medial breach preponderance by using the CMAP monitoring as experienced
237 in this study. This interesting change in orientation may reflect the surgeons' mental effort
238 to place the PPS more obliquely for better stability, if guided by this type of monitoring.
239 The present findings have documented practical usefulness and reliability of CMAP
240 monitoring using direct stimulation of the PPS assembled to uninsulated extender sleeve.

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Table1. Distribution of pedicle breaches of all directions for PPSs placed at L1 through S1 spines

Vertebral level	No of screws	Breach(+)	%
L1	128	23	18
L2	289	43	15
L3	338	24	7
L4	372	17	5
L5	381	12	3
S1	156	1	1
Total	1664	120	7.2

PPS, percutaneous pedicle screw

Table2. Distribution of medial or inferior pedicle breaches for PPSs placed at L2 through S1 spines

Vertebral level	No of screws	Breach(+)	%
L2	289	21	7
L3	338	14	4
L4	372	9	2
L5	381	7	2
S1	156	0	0
Total	1536	51	3.3

PPS, percutaneous pedicle screw

Table3. Comparison of threshold current intensities between PPS stimulation with and without medial or inferior pedicle breach

	All screws (L2 through S1)			Upper spines (L2 and L3)			Lower spines (L4 through S1)		
	Breach(+)	Breach(-)	p-value*	Breach(+)	Breach(-)	p-value*	Breach(+)	Breach(-)	p-value*
Number of screws	51	1485	NA	35	592	NA	16	893	NA
Threshold current intensity (mA)									
Mean \pm SE	19.2 \pm 0.9	36.8 \pm 0.2	<0.001	22.2 \pm 0.9	38.5 \pm 0.2	<0.001	12.6 \pm 1.7	35.7 \pm 0.2	<0.001
[95% CI]	[17.5 - 20.9]	[36.5 - 37.1]		[20.5 - 23.9]	[38.0 - 38.9]		[9.3 - 15.8]	[35.3 - 36.1]	

*Calculated according to t-test

NA, not applicable; PPS, percutaneous pedicle screw; CI, confidence interval

Figure 1-A

Blunt finger dissection to locate the transverse process (TP) and the facet (left), followed by PTT insertion so that its bifid hook grips and straddles the base of the TP (right).

Figure 1-B

Cannulate awl with stylet escorted by the PTT perforates cortical bone (left). Then, blunt-tipped probe was advanced within the pedicle over a guidewire (right).

Figure 2-A

Threshold current for 592 correctly placed and 35 misplaced PPSs at L2 and L3. As we used “40” for thresholds of ≥ 40 mA, the dots line up together on top of the scatterplots.

Figure 2-B

The same arrangement as in Fig. 1-A for 893 correctly placed and 16 misplaced screws at L4 through S1. Note the dots lined up together at 40 mA for the same reason as in the Fig. 1-A.

Figure 3

A postoperative CT at L5 in a 57-year-old patient shows the correctly repositioned PPS with a trajectory trace of grade 2 breach (arrows) left by the medially misplaced prior PPS.

Figure 4-A

An ROC curve drawn by plotting the true positive rate of medial or inferior pedicle wall breaches as a function of the false positive rate for different cut-off values at L2 and L3.

Figure 4-B

An ROC curve computed in the same way as Fig. 3-A for L4 through S1 spines, showing “0.995” AUC and the critical cut-off value of 17 mA with 100% sensitivity and 98% specificity.

Figure 1-A

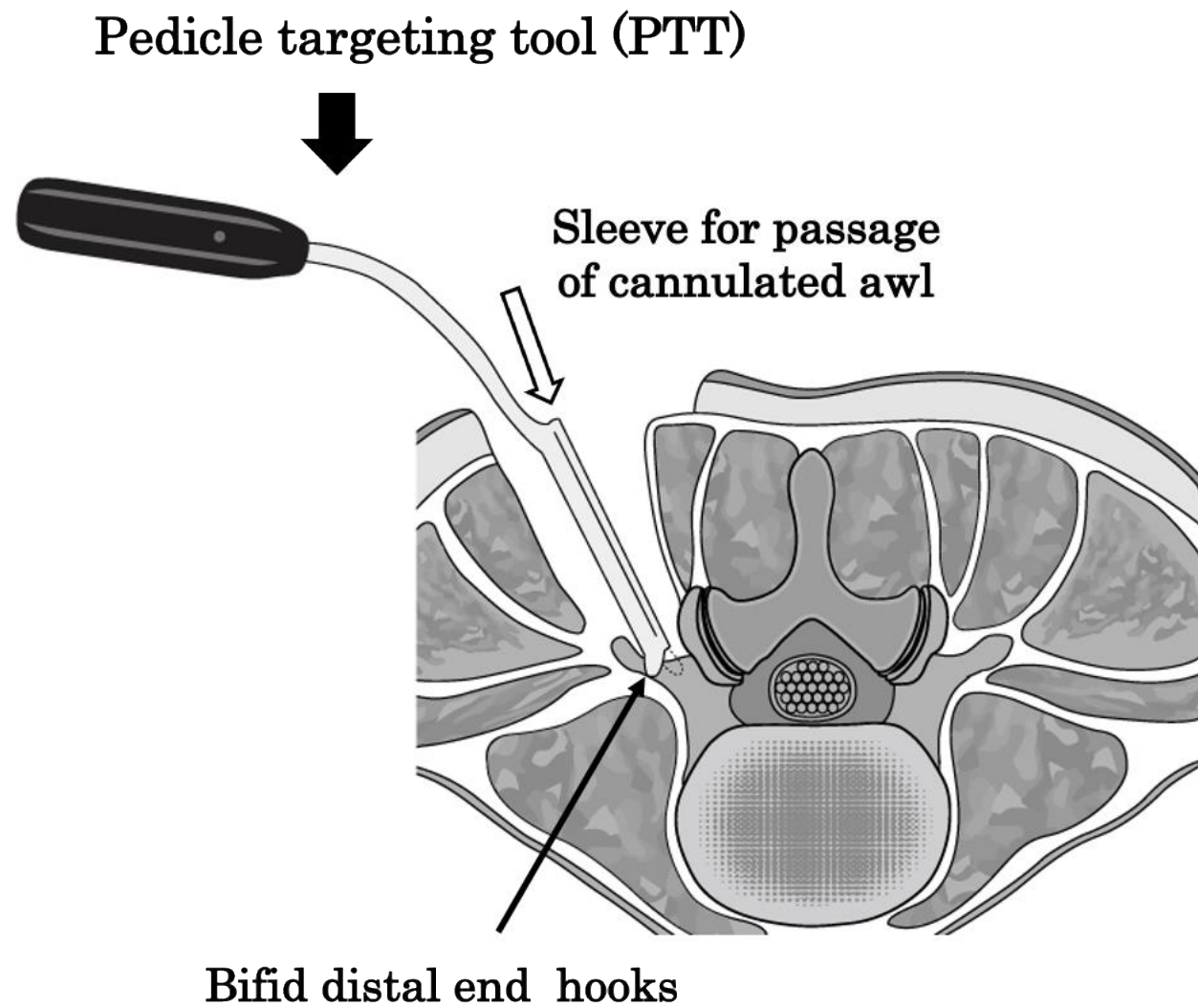
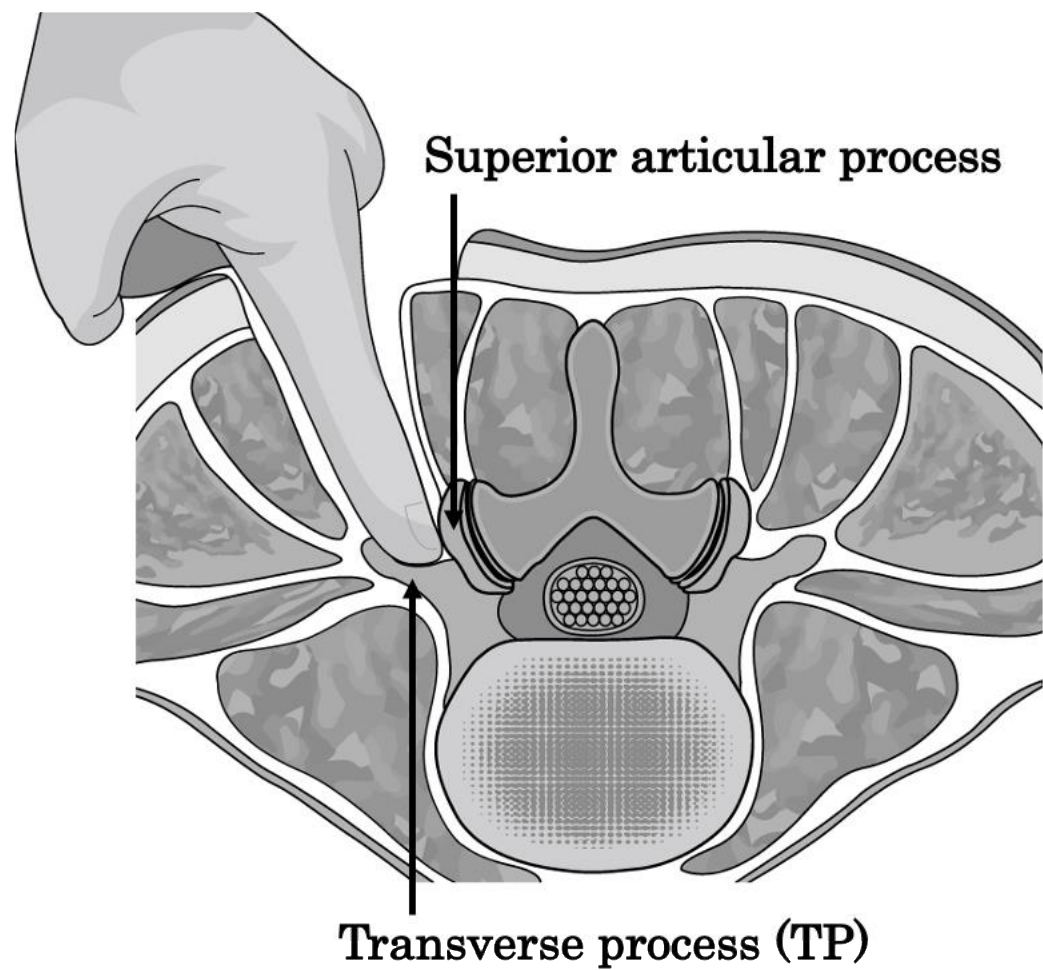


Figure 1-B

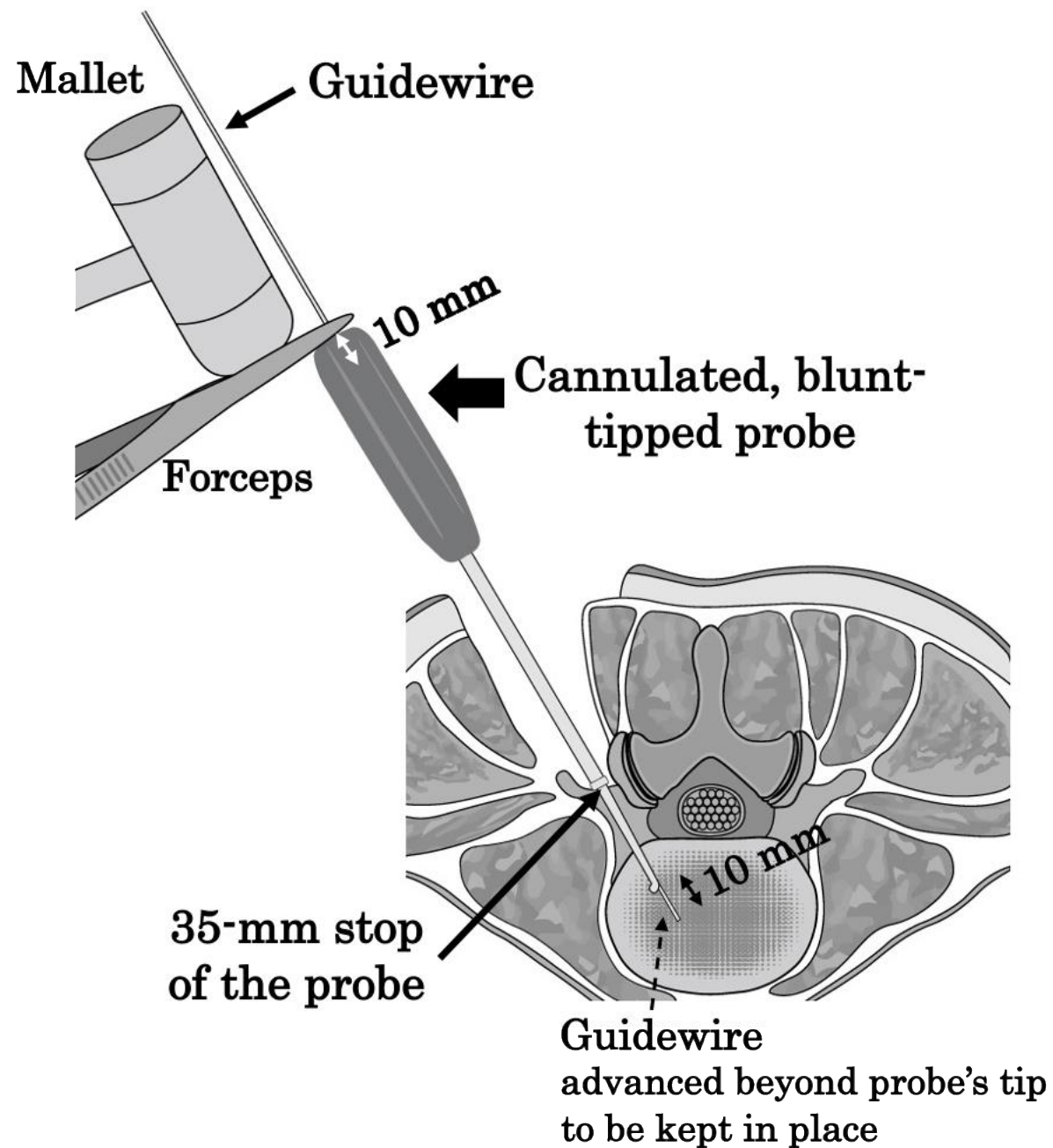
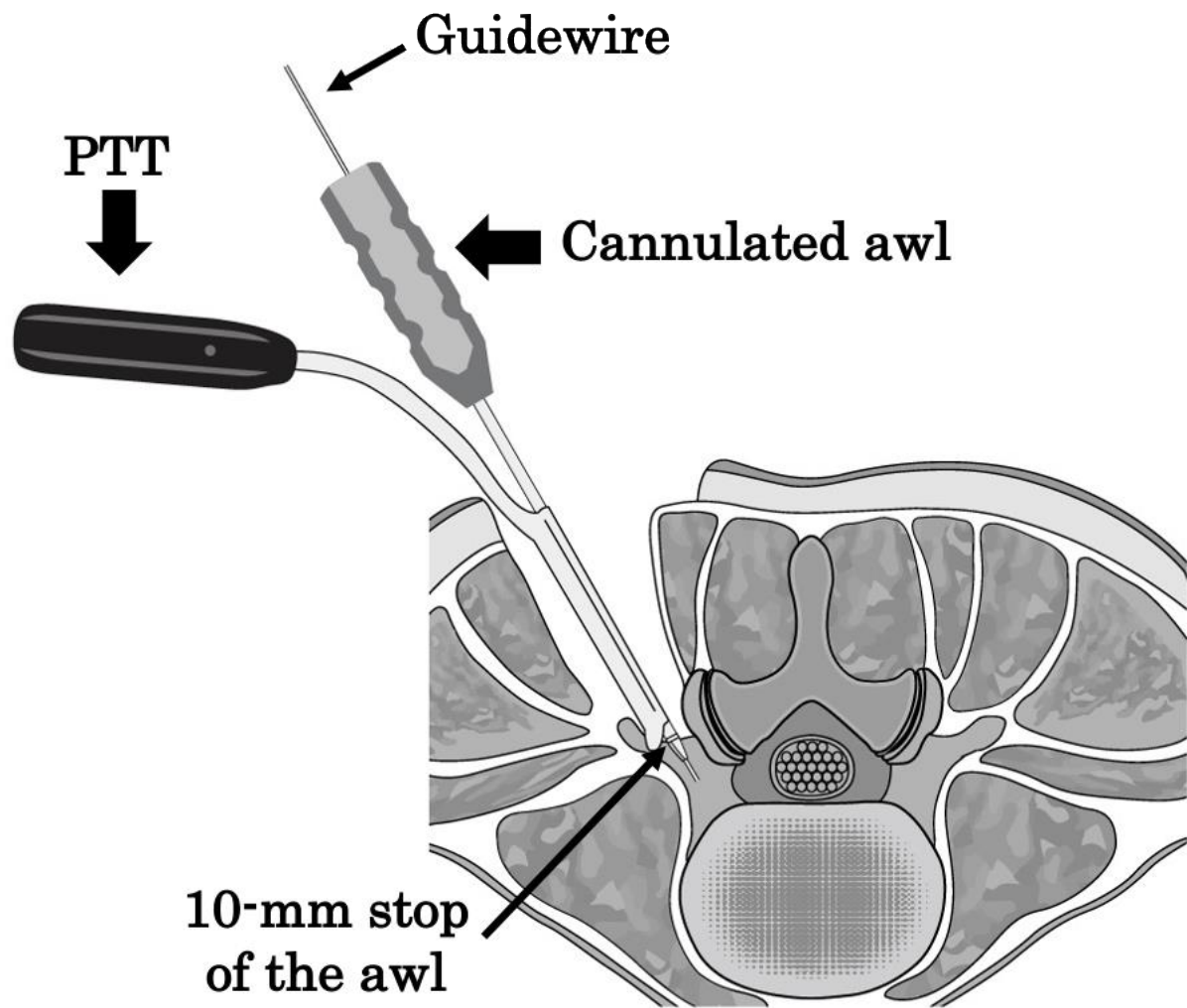


Figure 2-B

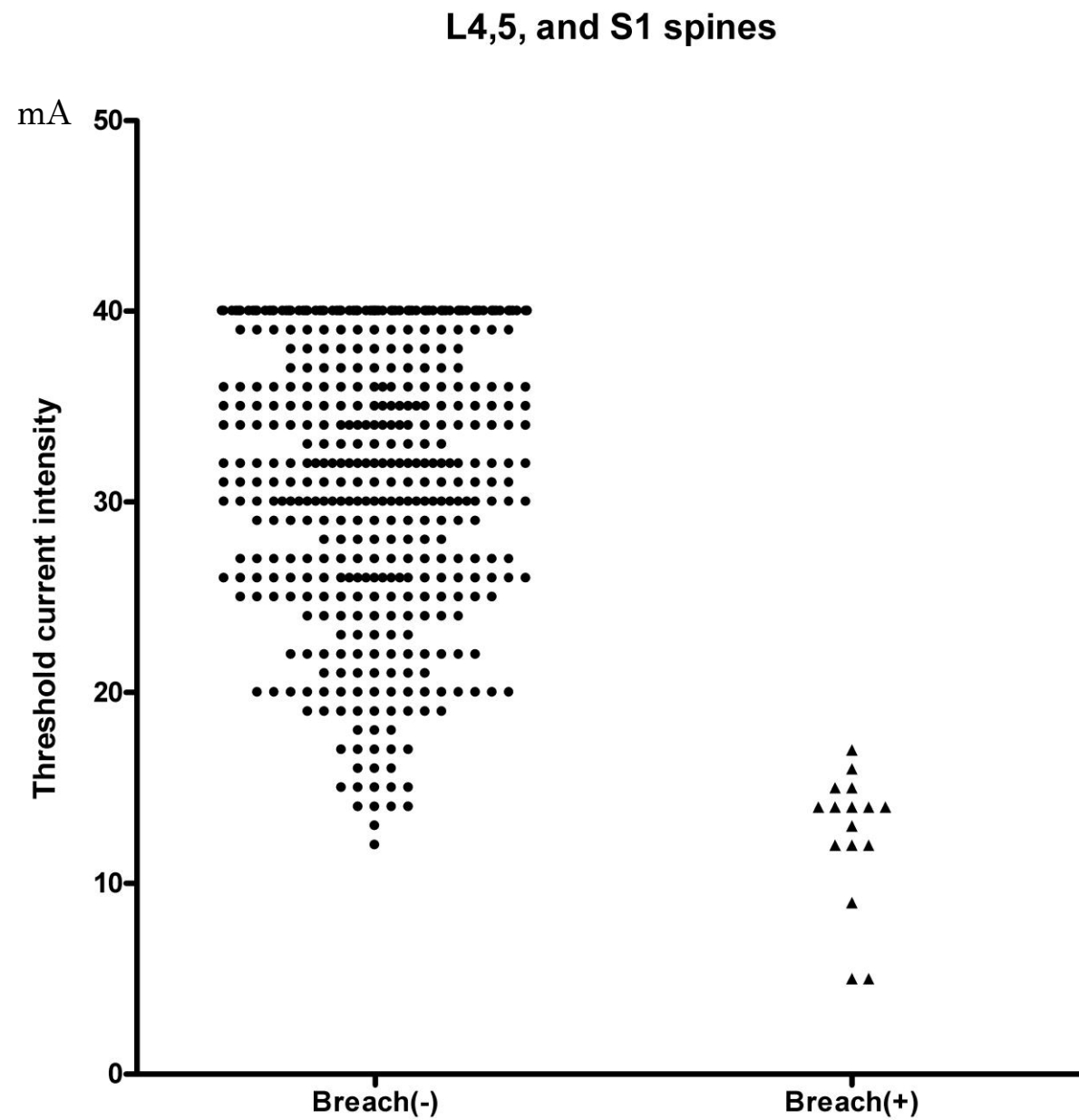


Figure 3.

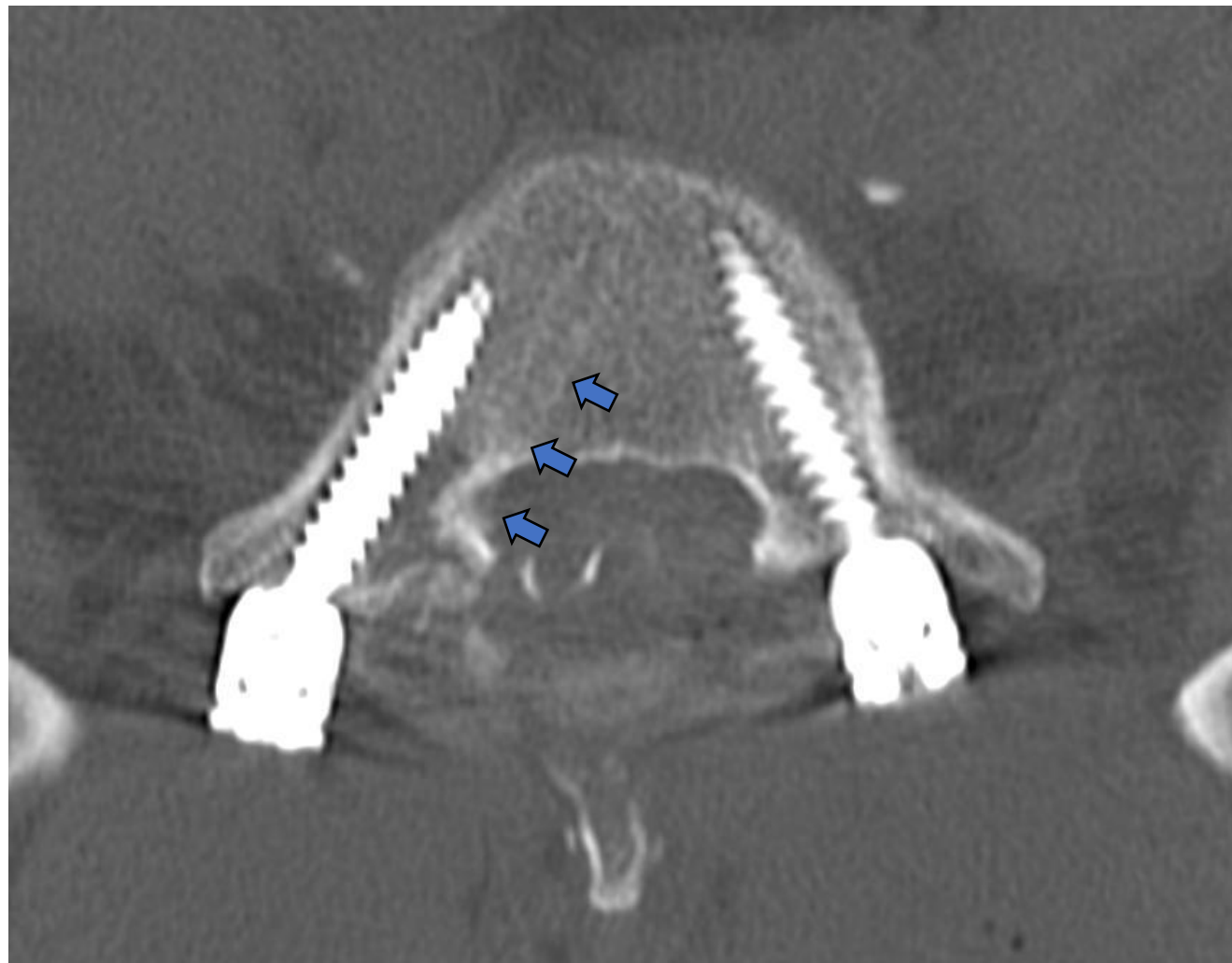


Figure 4-A

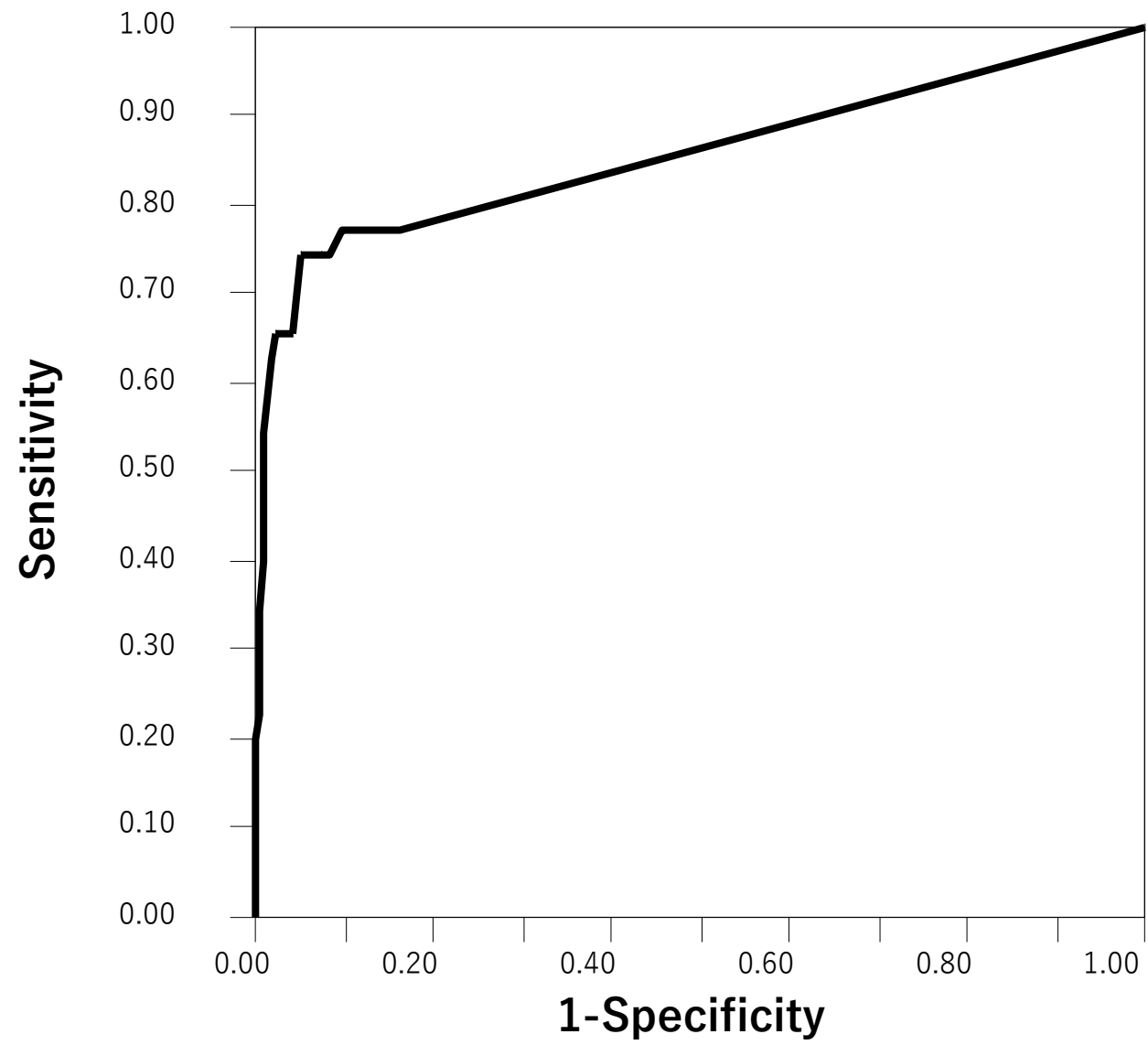


Figure 4-B

