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Needle Placement and Position of Electrical Stimulation Inside Sacral Foramen Determines Pelvic Floor Electromyographic Response—Implications for Sacral Neuromodulation

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Background: Lead placement within the sacral foramen in sacral neuromodulation patients is guided by visual assessment of the contraction of the pelvic floor musculature (PFM) and/or verbal assessment of the sensation and location of sensation upon stimulation. Generally, lead placement is proceeded by needle probing. This study evaluates which location inside a single sacral foramen would be most ideal for the release of the permanent electrode lead, by measuring electromyographic (EMG) motor responses of the PFM upon stimulation of a peripheral nerve evaluation (PNE) needle.

Materials and Methods: In eight patients, four standard PNE needles, and in one patient, two PNE needles, were introduced into the same foramen, parallel to the midline and parallel to each other. Position was verified by X-ray. Needles were stimulated (square pulsed waves, 210 μsec, 14 Hz) at increasing amplitudes (1-2-3-5-7-10 mA). PFM EMG was measured using the Multiple Array Probe (MAPLe) placed intravaginally or intrarectally, with 24 derivations. For this study, the mean (normalized) EMG was taken of all electrodes and different positions within the foramen were compared using the Wilcoxon signed rank test.

Results: A total of 202 PFM EMG measurements were recorded upon stimulation. EMG motor responses of the PFM for current stimulation = <2 mA showed statistically significant higher mean (normalized) EMG values for needles positioned cranial, medial, and cranial-medial, in comparison to needles positioned caudal, lateral, and caudal-lateral ($p = 0.004$; $p = 0.021$; $p = 0.002$).

Conclusions: Our data suggest stronger PFM contractions are elicit in cranial- and medial-placed PNE needles upon stimulation with clinically relevant current amplitudes (≤ 2 mA). Placement of the lead should aim for this spot in the foramen.

Keywords: Electromyography, new instrumentation, overactive bladder, pelvic floor, pelvic organ dysfunction, prospective study, sacral neuromodulation, sacral neurostimulation, urinary incontinence neuromodulation, urinary retention

Conflict of Interests: Donald Vaganée receives a grant from Medtronic. Jeroen Voorham has a management and significant financial relationship at the company which manufactures and sells a device used in this contribution (MAPLe). This company owns patents related to this work. Petra Voorham-van der Zalm has no conflicts of interest to disclose. Stefan De Wachter does consultancy work for Medtronic and receives a grant from Medtronic.

INTRODUCTION

Sacral neuromodulation (SNM) is a well-accepted, minimally invasive treatment for patients with overactive bladder dry (OABD) or overactive bladder wet (OABW), non-obstructive urinary retention (NOUR) and fecal incontinence, refractory to conservative treatments (1).

Although its exact mechanism of action is not known, it relies on stimulation of the third or fourth sacral spinal nerve by a tined lead with four stimulation electrodes (2). Before the lead is placed, generally a peripheral nerve evaluation (PNE) needle is placed inside the sacral foramen, and its position is evaluated by the current amplitude needed to induce a sensation and the location of the sensation (sensory response) and/or by the current amplitude needed to induce a pelvic floor muscle (PFM) contraction and the clinical aspect of an inward movement of the PFM (motor response). The position within the foramen eliciting the best

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[1]Both authors contributed equally to this work (shared first authorship)

sensory and/or motor response upon stimulation of the needle is chosen where after the trajectory is dilated, the stimulation lead inserted and released from that point to follow the path of least resistance (3,4).

The clinical aspect of the PFM contraction is in general assessed by visual observation. A more objective measurement of the PFM contraction can be achieved by using electromyography (EMG). EMG of the PFM can quantify PFM contraction and therefore objectively differentiate PFM contraction between different sites within one patient (5).

The aim of this study is to evaluate which location inside the sacral foramen would be the most ideal for the release of the stimulation lead, by measuring EMG responses of the PFM upon stimulation of a PNE needle in four different quadrants of a single sacral foramen.

MATERIALS AND METHODS

Between August 2015 and November 2017, patients who met the criteria for SNM and were willing to participate were screened for inclusion in this experimental study. Patients with OABD and OABW, refractory to at least two different antimuscarinics were eligible, as were patients with NOUR who were on clean intermittent catheterization. Patients with known neurological diseases or low back surgery were excluded.

This study was approved by the local medical ethics research committee (14/50/526).

Procedure

The PNE needle stimulation and tined lead placement was performed by an experienced SNM implanter using the standardized tined lead placement technique (6).

The patients were generally anesthetized and positioned prone. No muscle relaxants were given. A Multiple Array Probe (MAPLe®), was placed intravaginally in female and intrarectally in male study subjects. The MAPLe is a probe with a matrix of 24 electrodes enabling valid and reliable EMG measurement from different sides and layers of the PFM (7). Fixation of the probe was ensured by taping the outer part against the perineum.

X-ray was guided by anteroposterior (AP) view, the skin was vertically marked at the level of the medial edges of the foramina where after a horizontal line was drawn through the lower edges of the sacroiliac joint. The intersection points of the lines mark the upper medial part of the third sacral foramen at the bony level. This was the starting position for the PNE needle introduction in the third sacral foramen. X-ray was switched to lateral view. In total, four needles were placed in the sacral foramen as shown in Figure 1. A standard PNE needle was inserted parallel to the midline with 60° inclination in the cranio-caudal direction, advancing the needle tip to the anterior border of the sacral bone (upper medial needle). A second needle was placed parallel and lateral of the first needle at the same level and inclination (upper lateral needle). X-ray in AP and lateral view confirmed the parallel position. A third needle was placed just below the first, parallel to the midline and parallel with the same inclination of the first needle (lower medial needle), and finally the fourth needle parallel to the second and third needle (lower lateral needle). All needle tips were advanced up to the anterior border of the sacral bone.

Thereafter, the PNE needles were randomly electrically stimulated with square wave pulses (210 µsec—14 Hz) at increasing amplitudes (1-2-3-5-7-10 mA). EMG of PFM, derived from the MAPLe, was recorded continuously. The implanter was blinded for the EMG recordings.

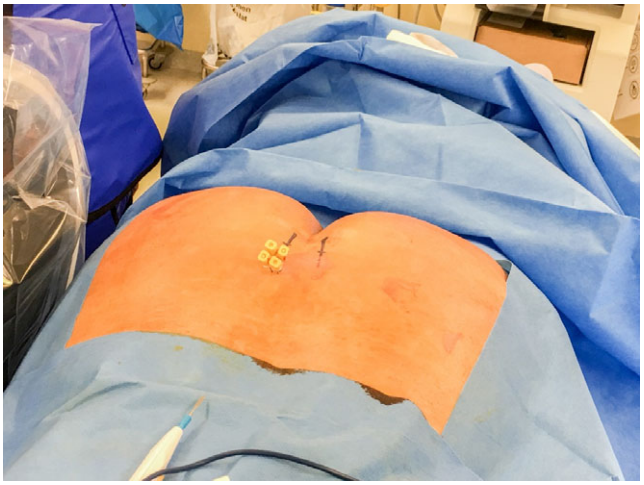

Figure 1. The placement of the 4 PNE needles within each quadrant (upper medial; upper lateral; lower medial; lower lateral) of one sacral foramen from a cranial oblique view. All were inserted parallel to the midline and each other with 60° inclination in the cranio-caudal direction and the needle tip at the anterior border of the sacral bone. Placement and position of the needles within the foramen and in respect to each other was verified by AP and lateral X-rays. [Color figure can be viewed at wileyonlinelibrary.com]

The presence of a visual clinical response was assessed by the implanter, distinguishing movement dorsal from the anus from clear inward movement of the PFM. The current amplitude at which a visual clinical response of the pelvic floor was seen was noted.

The location of the permanent lead electrode was determined based upon the PNE needle, which showed the strongest visual response of the PFM at the lowest stimulation amplitude.

Data Collection and Processing

The EMG recordings consisted out of unipolar raw EMG signals, which were acquired with the MAPLe system at a sample rate of 1000 Hz. For each electrode, the signals were prefiltered with a third order high-pass Butterworth filter with a 9–11 Hz cut-off frequency. EMG signals were analyzed using dedicated software (Signal analyser™).

For individual signal analysis, the trace of each of the 24 electrodes of the MAPLe was examined. The stimulation amplitude needed to achieve a significant EMG signal was noted and visualized by a color. An example for one patient can be found in Figure 2. Thereafter, the largest EMG response amplitude in a stimulation train (using a time window of 70 ms due to the stimulation frequency of 14 Hz) was taken for each of the stimulation amplitudes for every needle.

For statistical analysis, the EMG response of all 24 electrodes were combined by calculating the mean. Furthermore, the EMG responses within one individual were normalized by dividing each EMG response by the maximum recorded EMG response of that patient. Therefore, the normalized EMG response is a relative measure (in percentage), reflecting the activation of the pelvic floor compared to its maximal potential.

Response amplitudes were compared between different positions within the sacral foramen (cranial vs. caudal, medial

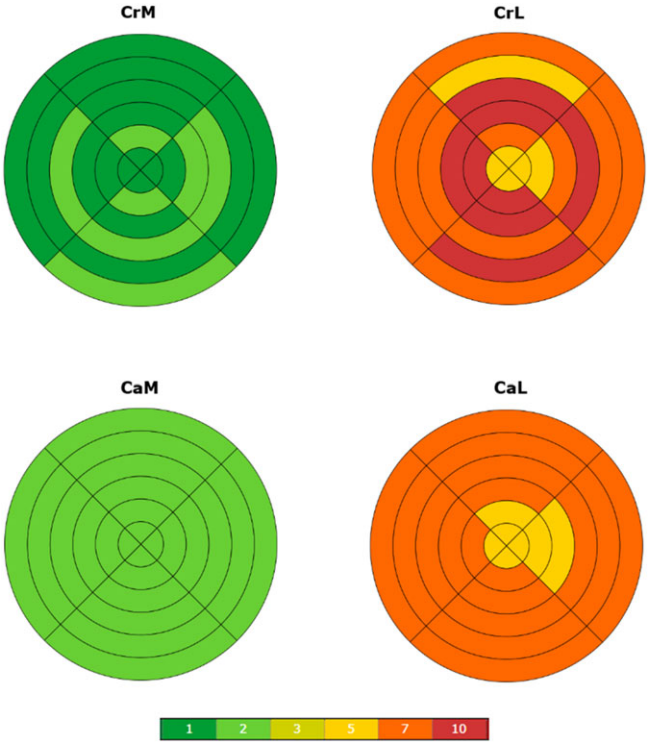

Figure 2. Overview of the PFM EMG measurements by the MAPLe. The four target grids represent the four locations in the sacral foramen (CrM, cranial-medial; CrL, cranial-lateral; CaM, caudal-medial; CaL, caudal-lateral) in which a PNE needle was placed and stimulated with stimulation amplitude 1-2-3-5-7-10 mA. Each target grit consists out of 24 areas, representing the 24 electrodes of the MAPLe. The four diagonal lines split the target grit in four quadrants corresponding with the different sides the pelvic floor (clockwise starting at 12 o'clock: anterior, left, posterior, right). Each side is divided in six crescent-shaped fields corresponding with the different depths (where the outer fields are caudal and the inner fields more cranial). In this example of one patient (p_245730706_tlp), a summary of the presence of the PFM EMG is shown. For each of the 24 electrodes, the stimulation amplitude needed to achieve a significant EMG signal is noted and visualized by a color. In this patient for example, when the needle is placed cranial-medially, most of the PFM are activated at stimulation amplitude 1 mA, denoted by the color dark green. In contrast, when the PNE needle is placed cranial-laterally, most of the PFM are activated at stimulation amplitude 7 mA, denoted by the color orange. For this study, the PFM EMG signals were further quantified and the mean was calculated. [Color figure can be viewed at wileyonlinelibrary.com]

vs. lateral, cranial-medial vs. cranial-lateral vs. caudal-medal vs. caudal-lateral) using the Wilcoxon signed rank test.

Furthermore, the presence and type of clinical response are described in this manuscript.

All analyses were done using IBM SPSS Statistics 23®.

All statistical tests were two-tailed and were conducted with type I error probability of 0.05.

RESULTS

A total of nine consecutive patients referred for SNM were included in this study. Mean age was 56.3 +/− 14.2 (range 36–82) years. Gender distribution was 88.9% (8/9) females and 11.1% (1/9) males. Indications were OAB: 88.9% (8/9), NOUR: 11.1% (1/9). Lead location: S3: 66.7% (6/9) [S3L: 4; S3R: 2], S4: 33.3% (3/9) [S4L: 2; S4R: 1].

In eight patients, the PNE needle could be placed in all four quadrants of one sacral foramen. In one patient, the sacral

Table 1. Mean EMG Activity of the Pelvic Floor Musculature (EMG) as Well as the Mean Normalized EMG Activity of the Pelvic Floor (nEMG) is Presented for Each Quadrant Within the Sacral Foramen (columns) and According to Each Current Amplitude (rows).

	Cranial-medial		Cranial-lateral		Caudal-medial		Caudal-lateral	
Current amplitude (mA)	EMG (μV)	nEMG (%)	EMG (μV)	nEMG (%)	EMG (μV)	nEMG (%)	EMG (μV)	nEMG (%)
1	90.1 +/− 116.5*	29.7 +/− 33.1*	34.9 +/− 55.7	15.5 +/− 26.1	42.3 +/− 73.0	15.1 +/− 25.0	10.0 +/− 13.7*	3.7 +/− 5.2*
2	150.9 +/− 122.7*,†	47.1 +/− 33.2*,†	97.3 +/− 101.0	31.2 +/− 29.9	80.4 +/− 99.1*	24.7 +/− 29.0*	64.2 +/− 99.0†	20.5 +/− 28.5†
3	191.5 +/− 125.3	61.0 +/− 28.7	99.6 +/− 97.7	33.6 +/−29.3	145.6 +/− 51.4	42.2 +/− 32.0	100.0 +/− 88.8	31.9 +/− 24.2
5	233.0 +/− 116.8*,†	77.1 +/− 19.4*,†	167.3 +/− 95.5	60.0 +/− 25.9	174.3 +/− 145.3*	51.9 +/− 37.3*	166.5 +/− 125.7†	52.4 +/− 33.8†
7	247.7 +/− 104.5*	84.0 +/− 15.1	215.8 +/− 105.7	77.4 +/− 27.7	212.8 +/− 138.2	64.0 +/− 33.9	170.8 +/− 112.7*	53.6 +/− 30.4
10	252.4 +/− 111.1	86.7 +/− 21.7*	241.9 +/− 76.9	84.6 +/− 13.1	257.9 +/− 113.7	82.8 +/− 14.2	236.0 +/− 134.3	74.6 +/− 23.7**
all	194.3 +/− 125.5*,†	64.3 /− 32.4*,†	142.8 +/− 112.9¶	50.4 +/− 35.6¶	148.6 +/− 134.3*	45.6 +/− 36.1*	124.6 +/− 123.7†,¶	39.5 +/− 34.1†,¶

The quadrants showing a statistically significant difference ($p < 0.05$) are denoted with *, † or ¶. It is important to notice the statistical results for EMG and nEMG are the same as statistical analysis is performed by Wilcoxon signed rank test. This test is based on the rank of each value, which remains the same for mean and mean normalized EMG activity of the pelvic floor.

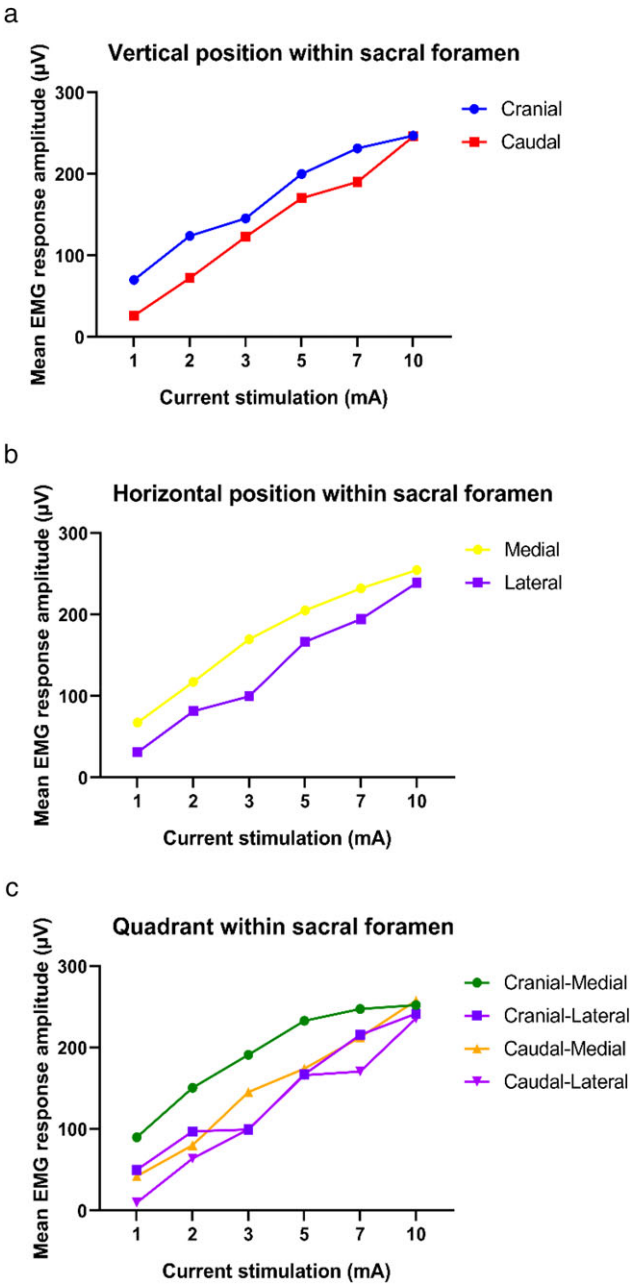

Figure 3. The mean EMG activity of the pelvic floor muscles for different current stimulations (1-2-3-5-7-10 mA) is shown for different positions within the sacral foramen: cranial vs caudal (a), medial vs lateral (b), cranial-medial vs cranial-lateral vs caudal-medial vs caudal lateral (c). [Color figure can be viewed at wileyonlinelibrary.com]

foramen was narrow leading to needle placement at only two locations, making only a distinction possible between a medial- vs. lateral-positioned needle. In another patient, two EMG recordings were missing (position within sacral foramen: caudal-medial; current stimulation: 7 and 10 mA). In total 202 stimulations were given to the patients.

Mean (Normalized) EMG Activity of the PFM

Large differences were noted when comparing mean (normalized) EMG activity of all recordings between a cranial and caudal position and a medial and lateral position, with higher values for cranial and medial positions ($p < 0.001$ and $p = 0.005$). When comparing the mean (normalized) EMG activity of all recordings between the four quadrants within the sacral foramen, a statistically significant difference was withheld between a cranial-medial position vs. a caudal-medial position ($p < 0.001$), a cranial-medial position vs. a caudal-lateral position ($p < 0.001$), and a cranial-lateral vs. caudal-lateral position ($p = 0.044$), with higher values for a cranial-medial and cranial-lateral position.

When looking into more detail, similar differences in EMG of the PFM between the different positions within the sacral foramen were also present at each current stimulations (1-2-3-5-7-10 mA). Cranially positioned PNE needles showed statistically significant higher mean (normalized) EMG activity vs. caudal-positioned PNE needles at 2 mA ($p = 0.010$) and 5 mA ($p = 0.030$). Medially positioned PNE needles showed statistically significant higher

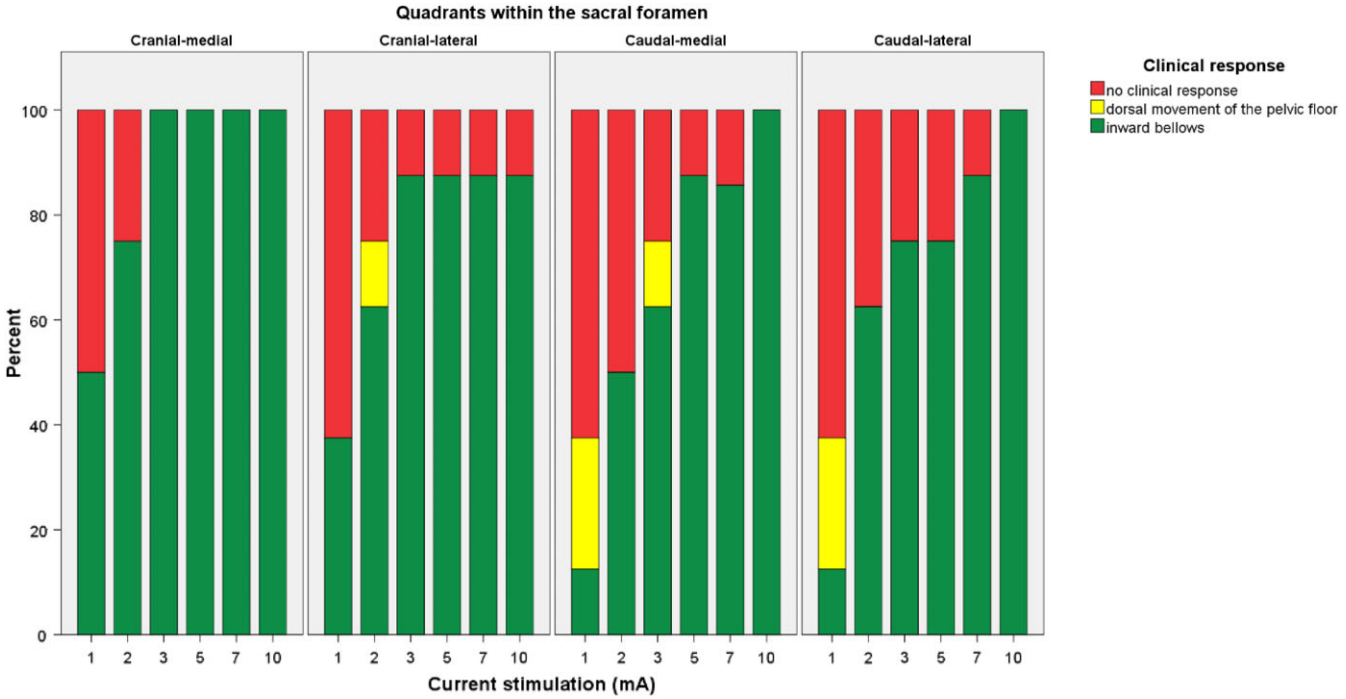

Figure 4. The presence and type of clinical response for each quadrant within the sacral foramen according to each current stimulation is depicted by a bar chart. "Red" represents the absence of a clinical response, "yellow" was noted when movement of the pelvic floor was only seen dorsally from the anus, and "green" represents a bilateral inward movement of the whole area around the anus (bellows movement). [Color figure can be viewed at wileyonlinelibrary.com]

mean (normalized) EMG activity vs. laterally positioned PNE needles at 3 mA (p = 0.044). When comparing the mean (normalized) EMG activity between all quadrants, a statistically significant difference was seen between a cranial-medial position vs. a caudal-lateral position at 1 mA (p = 0.036), 2 mA (p = 0.017), 5 mA (p = 0.036), and 10 mA (p = 0.017) and between a cranial-medial vs. a caudal-medial position at 2 mA (p = 0.012) and 5 mA (p = 0.017), with higher values for cranial-medial position.

The EMG responses for current stimulation = <2 mA showed a statistically significant difference between a cranial vs. caudal position (p = 0.004), a medial vs. lateral position (p = 0.021) and between a cranial-medial vs. caudal-lateral position (p = 0.002) cranial-medial vs. caudal-medial position (p = 0.005) within the foramen with higher values, respectively, for cranial, medial, and cranial-medial position. In Table 1, a detailed overview of the values of the mean (normalized) EMG activity for each quadrant within the sacral foramen is presented. In Figure 3, the mean EMG activity for each quadrant within the sacral foramen is visually shown.

Clinical Responses

Comparing the visual clinical responses upon stimulation of the PNE needle, a strong bilateral inward movement of the PFM at 1 mA was seen in 50.0% (4/8) of patients at the cranial-medial position. For a cranial-lateral, caudal-medial, and caudal-lateral position, a strong bilateral inward movement of the PFM at 1 mA was seen in, respectively, 37.5% (3/8), 12.5% (1/8), and 12.5% (1/8). At 2 mA, the prevalence of a strong bilateral inward movement of the PFM was, respectively, 75.0% (6/8), 62.5% (5/8), 50% (4/8), and 75% (6/8) for the different positions within the sacral foramen.

The presence of a bilateral inward movement of the PFM in all patients was seen at 3 mA for a cranial-medial position, at 5 mA for a cranial-lateral position, and at 10 mA for a caudal-medial and caudal-lateral position.

Interestingly, when increasing the current amplitude, rotation of the leg was more frequently seen, especially in the lateral placed PNE needles. For example, at 10 mA, rotation of the leg was seen in 25.0% (2/8) of patients when the PNE needle was positioned cranial-laterally or caudal-laterally. Rotation of the leg was seen in 12.5% (1/8) patient when the needle was placed cranial-medially and 0.0% (0/8) of the patients showed rotation of the leg when the needle was positioned caudal-medially.

In Figure 4, a clear representation of the visual clinical responses is shown.

Location of Permanent Lead Electrode

The PNE needle eventually used for the placement of the directional guide and lead electrode was positioned cranial-medially in 66.7% (6/9), cranial-laterally in 22.2% (2/9), caudal-medially in 11.1% (1/9), and caudal-laterally in 0.0% (0/9).

DISCUSSION

Generally, tined lead placement starts with needle probing within the sacral foramen, aiming for the best possible motor and/or sensory response. Motor response is currently assessed by visual inspection. In this study, the motor response was objectively examined using EMG of the PFM. Consequently, the ideal location inside the sacral foramen for release of the permanent lead electrode was determined based upon EMG of the PFM.

Our data show that stimulation of a PNE needle, at the clinically relevant current stimulations (1 and 2 mA), placed cranial and medial, in comparison to, respectively, a caudal- and lateral-

positioned needle leads to a stronger contraction of the PFM, objectively measured by EMG. Therefore, we can assume cranial- and medial-placed PNE needles require lower stimulation amplitudes for stronger PFM contraction at low-current stimulations.

The literature on sacral anatomy shows evidence that the sacral spinal nerves exit from the superior and medial portion of the anterior foramen where after they run caudal-laterally in the pelvis (8,9). Therefore, it seems justifiable that stimulation of a cranial-medially positioned PNE needle needs lower stimulation to elicit a strong PFM contraction in comparison to other positions within the sacral foramen, as the PNE needle is in closest proximity to the nerve at this location.

This was statistically shown using EMG of the PFM. Similar findings were found upon visual observation by the surgeon (an experienced SNM implanter). A bilateral inward movement of the PFM was seen in more patients at lower current amplitudes when the PNE needle was placed cranial and medial, in comparison to caudal and lateral.

Another important advantage of placing the PNE needle as medial to the medial border of the foramen is to avoid undesirable stimulation, for stimulation felt in the leg is often seen with laterally placed PNE needles/leads (10). The sensation of stimulation in the leg is due by (partly) stimulation of S2 fibers. The motor response, which corresponds with (partly) stimulation of S2 fibers, is rotation of the leg (10,11). Interestingly, this was also seen in our study where rotation of the leg was most commonly seen with lateral-placed PNE needles, indicating placement of the lead at this location could lead to undesirable stimulation in the leg.

It's important to mention PNE was initially—and still can be—performed without the aid of X-ray (12). If no X-ray is used, our results would recommend that if no satisfactory response is achieved after insertion of the PNE needle, one could try to place another PNE needle more cranial and medial of the latter, as this could elicit a stronger contraction of the PFM.

The largest limitation of this study is the low sample size due to the time-consuming nature of the study protocol and the need to perform this during surgery. Furthermore, placing four needles in a parallel fashion inside one foramen appeared to be very challenging. This is the reason why statistical significance, when comparing the PFM contraction between different locations within the sacral foramen, is not achieved for each current stimulation separately. In addition, we noticed large variations between study subjects and a decreasing difference in PFM activity with increasing current stimulation. However, in clinical practice, it is preferred to see an adequate clinical response upon stimulation at or below 2 mA, because this indicates proximity of the lead to the sacral spinal nerve, reducing unwanted stimulation of other surrounding nerves and leading to prolonged battery life during SNM treatment. At the lowest voltages, the advantage of a cranial- and medial-positioned needle over a caudal- and lateral-positioned needle was the clearest. Lastly, this study protocol assesses motor response during placement of the PNE needle and did not include clinical efficacy. Although motor response is currently considered as the best available predictor for successful therapy (13), it is unknown, if the distribution of motor nerves activated directly by neurostimulation is similar to the distribution of the rootlets stimulated for the indirect neuromodulation effect (14).

In conclusion, our data suggest that cranial- and medial-placed needles require lower stimulation amplitudes for stronger PFM contraction. Placement of the lead should aim for this spot in the foramen.

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Authorship Statement

Prof. Stefan De Wachter and Jeroen Voorham designed the study. Prof Dr. Stefan De Wachter and Dr. Donald Vaganée conducted the study, including patient recruitment, data collection, and data analysis. Dr. Donald Vaganée prepared the manuscript draft with important intellectual input from Prof. Stefan De Wachter, Jeroen Voorham and Prof. Petra Voorham. All authors approved the final manuscript.

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