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ORIGINAL ARTICLE

Optimizing electrode implantation in sacral nerve stimulation—an anatomical cadaver study controlled by a laparoscopic camera

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Abstract
Background and aim Sacral nerve stimulation is the therapy of choice in patients with neurogenic faecal and urine incontinence, constipation and some pelvic pain syndromes. The aim of this study is to determine the best insertion angles of the electrode under laparoscopic visualization of the sacral nerves.
Materials and methods Five fresh cadaver pelvises were dissected through an anterior approach of the presacral space, exposing the ventral sacral roots. Needles and electrodes were inserted into the S3 foramen. Both right and left sides were used, with the traditional percutaneous procedure. The validation was done by a laparoscopic camera controlling the position of the needle and electrode on the nerve. The angles were assessed with a goniometer and were confirmed in two living patients.
Results The mean angle of insertion in the sagittal plane was 62.9±3° (range, 59–70). In the axial plane, the mean angle for the left side was 91.7±13.5° (range, 80–110) and 83.2±7.7° for the right side (range, 75–95). These angles resulted in the optimal placement of the leads along the S3 sacral root, in all these cases.
Conclusions This study allows direct visualization during the placement of the needle and electrode, thus permitting accurate calculations of the best angle of approach during the surgical procedure in sacral nerve stimulation. These objective findings attempt to standardize this technique, which is often performed with the aid of intra-operative fluoroscopy but still leaving a lot to chance. These insertion angles should help to find more consistent and reproducible results and thus improved outcome in patients.

Keywords Sacral nerve stimulation · Neuromodulation · Faecal incontinence · Urinary incontinence · Constipation · Laparoscope

Buchs and Dembe have contributed equally to this work.

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Introduction

Sacral nerve stimulation is a relatively new, promising mode of treatment for selected urinary and bowel dysfunctions [1–3].

Faecal incontinence is a pathology very often minimized by both patients and physicians, although the incidence in the general population is 2.2% and greater than 50% in the institutionalized geriatric population [4–8]. The factors of risk are multiple: diabetes, multiple sclerosis, cerebral stroke, Parkinson's disease, medullary attacks, obstetric trauma and post-surgical lesions (sphincter lesions, low anterior rectal resections) [5, 6, 8–11].

In cases of a morphologically intact sphincter, sacral nerve stimulation offers good clinical results [3, 11–28]. The basis of this treatment is to stimulate the sacral nerve which has influence over the pelvic organs involved, for example bladder and rectum in incontinence patients. The ideal nerve to stimulate is sacral nerve S3, as it supplies the pelvic organs involved with minimal influence over the legs. This does not exclude the use of the other sacral nerves; however, S3 usually provides the most desired effects with minimal adverse reactions. The effect of sacral neurostimulation is not yet completely elucidated. Actions on the efferent nerves, stimulating the sphincter and related fibers, and on afferent nerves, modulating the reflexes (improving rectal sensitivity and motility), seem to play a role [14, 29]. Centrally, corticoanal excitability seems to be reduced with sacral nerve stimulation [2].

Many operators implant the electrode by using palpation of anatomical landmarks only. Nevertheless, the results can be quite variable, even in the same patient undergoing a repeat test. To our knowledge, no study has shown the correct in situ positioning of the electrode by means of a ventral view with a laparoscopic camera.

Optimal stimulation depends on the adequate detection of the S3 or S4 (less common) sacral nerve foramen and on the correct angle of introduction of the needle and electrode. The ideal electrode position is with as many electrode contact points parallel to the nerve as possible. When the electrode is well positioned, the patient will experience the maximal benefit in stimulation and thus a much greater chance for amelioration of symptoms. This treatment has good results, but they are not always reproducible due to several factors, largely surgeon's experience and technique.

The aim of this study is to evaluate the angles offering the best position of the electrode. By a new laparoscopic validation method, we can avoid any artifacts and electrode displacements resulting from posterior dissection. By determining and standardizing the optimal angles of insertion, we hope to contribute to improve the reproducibility of this procedure and thus improve patient outcome consistently.

Materials and methods

Five fresh cadaver pelvises (two men and three women, median age 71 years, range 50–85) were used. An accurate and non-traumatic dissection permitted the dissection of the retrorectal space. With anterior traction of the rectum, the mesorectum and its surrounding fascia were cleaved out from the presacral fascia. The cleavage was carried forward posterior to the fascia propria, down to the ano-rectal junction.

The presacral fascia was then partially dissected, exposing the ventral sacral nerves without changing their position, until their emergence from the anterior sacral foramina S1, S2 and S3.

The pelvis was then placed in the prone position used in the operative setting for normal electrode implantation.

In this study, we used the same anatomic external landmarks as in the actual operative procedure. These are: midway between the S1 process and the tip of the coccyx and one finger breadth lateral to the midline (Fig. 1).

The same surgeon performed the traditional percutaneous technique, described previously [17], and inserted 14 needles (Medtronic Interstim model 3093, Minneapolis, MN, USA) in the S3 foramen, on both sides.

A laparoscopic camera was positioned in the pelvic cavity, visualizing at the same time the insertion of the needles. When the position was deemed to be ideal, an electrode was inserted using the standard operative technique. Thus, the surgeon was able to see and assess the best position of the electrode along the sacral root.

Our criteria of success were a position lateral and parallel to the sacral root, contact with the nerve and no nerve penetration. This puts the electrode in contact with the nerve allowing as many possible contact points against the length of the nerve.

Then the angles of penetration of the needles were assessed with a goniometer in the axial and sagittal planes, according to the real correct position, confirmed by the laparoscopic camera.

Possible anatomic injuries were controlled by laparoscopic visualization during the entire procedure. And after the procedure, we dissected the pelvic cavity, looking for any vascular or nervous lesion.

To confirm and compare our experimental results on cadavers, we performed the traditional technique of sacral nerve stimulation in two living patients (two women). After correct positioning of the electrodes, confirmed by a good motor response, we assessed the angles of introduction with a goniometer and fluoroscopy.

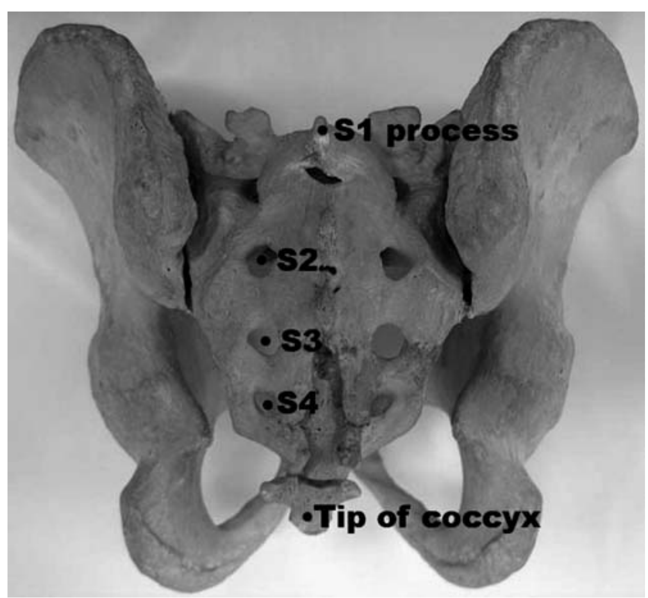

Fig. 1 Bony external landmarks in the pelvis

Table 1 Angles of needle entry into sacral foramen S3 in cadaver

	Mean angles of needle entry±SD (range)		
	Overall	Men	Women
Sagittal plane	62.9±3.0 (59–70)	62.6±4.6 (59–70)	63.2±3.6 (60–68)
Left side	63.2±4 (60–70)	64.7±5 (60–70)	61.7±2.9 (60–65)
Right side	62.6±4.1 (59–68)	59.5±0.7 (59–60)	64.7±4.2 (60–68)
Axial plane			
Left side	91.7±13.5 (80–110)	80.3±0.6 (80–81)	103±8.2 (94–110)
Right side	83.2±7.7 (75–95)	87.5±10.6 (80–95)	80.3±5.5 (75–86)

Results

Our experimental results are summarized in Table 1.

Of the 14 needle insertions, we excluded three due to suboptimal placement. Two of these were placed medial to the target position, and one penetrated the nerve root. These three cases all happened to be on the left side. Respectively, the angle of insertion was 50° and 60° in the sagittal plane, 80° and 105° in the axial plane for the two medial insertions. Concerning the nerve root penetration, the angle of insertion was 52° in the sagittal plane and 93° in the axial plane.

In the well-positioned electrodes, the mean angle in the sagittal plane was 62.9° (±3°).

In the axial plane, the insertion followed a slightly lateral direction in the optimal position (mean angle for the left side: 91.7±13.5° and 83.2±7.7° for the right side; Fig. 2a).

In the axial plane, the angle needed for men was different on the left side, requiring a more medial direction, rather than a lateral one as seen on the right (Fig. 2b). The angles are more apparent in the women, with a lateral angulation required for both the left and right sides (Fig. 2c). We did not find any difference between men and women concerning the insertion angle in the sagittal plane.

These angles allowed for optimal electrode placement along the sacral root S3, in all these cases (Fig. 3).

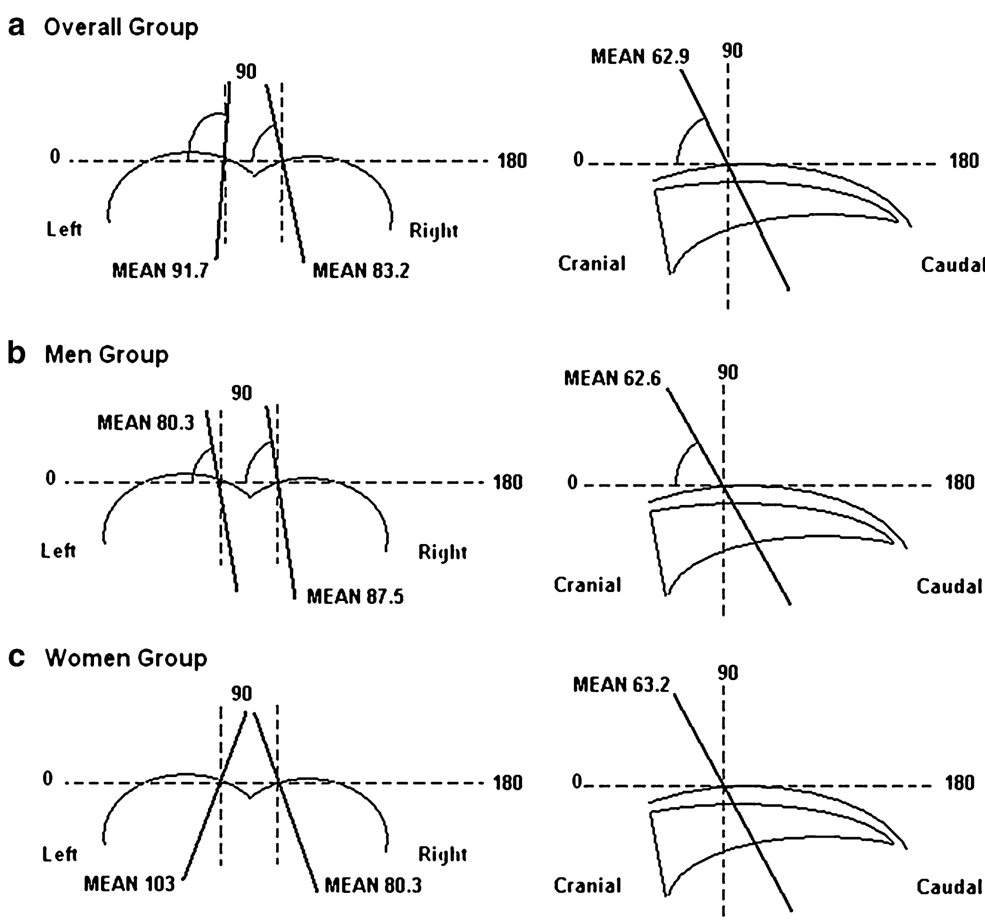

Fig. 2 **a** Mean angles (in degrees) of insertion for the overall group. **b** Mean angles of insertion for men. **c** Mean angles of insertion for women

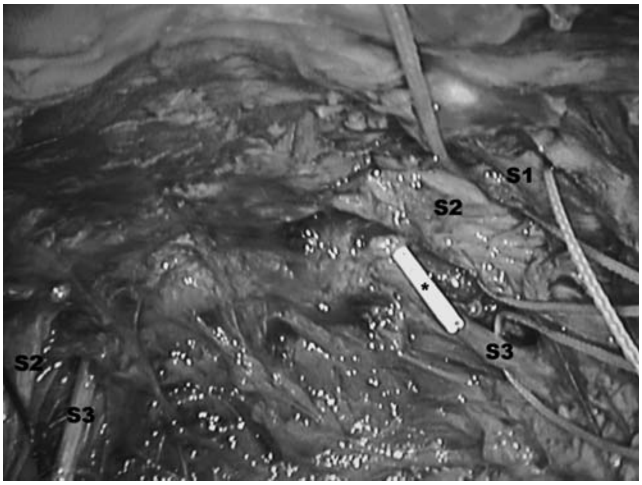

Fig. 3 View in situ of the needle's insertion (*asterisk*) on the left side

Furthermore, we did not notice any rectal injury or vascular lesion after the dissection.

Our results in living patients are summarized in Table 2.

We found similar introduction angles in living patients, with a good clinical response. In the sagittal plane (Fig. 4), we reported a mean introduction angle of 63.25°, with no real difference between the left and the right sides.

For the axial plane (Fig. 5), we found a mean introduction angle of 100.5° for the left side and 73.5° for the right side.

These results are confirmed by fluoroscopy (Fig. 6).

Discussion

Neuromodulation consists of a three-stage procedure:

1. The initial phase is the implant of the insulated needle where an acute muscular contraction of the anal sphincter and the perineum is the goal.
2. Once this is achieved, an electrode is implanted in place of the needle, and the external stimulation is continued for a period between 2 and 4 weeks, depending on patient response. This temporary test phase allows accurate assessment of the symptomatic response and integrity of nerves.
3. If this test period is successful, then implantation of a permanent pulse generator is performed, with a connection to the electrode lead [2, 20, 30].

The correct insertion of the electrode depends on adequate detection of the S3 or the S4 foramen.

The sacral plexus (L4-S4) gives off the pudendal nerve, a mixed nerved, which is formed from the anterior rami of S2, S3 and S4 [31, 32].

Patients with a thick layer of subcutaneous tissue, or sacral anomalies, can pose problems in electrode placement [1]. The most common complications associated with sacral nerve stimulation are: infections in 1–9% of cases and pain in 4–24% of cases. A good part of the complications is related to electrode placement itself, such as poor positioning of the electrode (2–7%) and migration of the electrode (1–20%) [1, 26, 33].

Moreover, the studies proposing the classical anatomical models [30, 34–36] have the disadvantage of creating anatomical artifacts and causing electrode displacement during the posterior dissection.

The sacrum can vary widely in shape and structure between different individuals and genders. Some individuals have five sacral foramina if the dorsal laminae of the fifth vertebra fuse completely; in others, the sacral canal is open for the entire lower half of the bone [37].

We decided to choose the S3 foramen [1, 27, 38] because the S3 nerve root contains sensory fibers from the genitals and perineum and afferent and efferent fibers from the anterior part of the levator ani. This is normally the nerve used as first choice in this procedure. Stimulation of S2 causes too much leg rotation and primarily, a contraction of the superficial pelvic floor. S4 projects more on the posterior part of the levator ani with sensation around the anus [27, 38].

Sacral nerve stimulation has been advocated as a novel form of treatment for faecal and urine incontinence, constipation and some forms of pelvic pain [1–3].

To our knowledge, this is the first validation with a laparoscopic camera of the electrode insertion for sacral nerve stimulation. Previous studies have determined the electrode's position by plain X-ray, computed tomography [39] and posterior anatomic dissection [30, 34–36]. Neither plain X-ray nor computed tomography is as reliable as real in situ visualization due to the lack of sensitivity of these two previous methods to visualize nerve roots. Perhaps magnetic resonance imaging could give more accurate information, but the metallic lead could pose problems for such an imaging modality. Furthermore, with the laparoscopic view of the presacral space, there is no alteration of the anatomy as seen in posterior dissection.

Some authors recommend the use of fluoroscopy to guide the needle insertion [1, 17, 33], especially in obese patients [37]. Moreover, Chai and Mamo [33] have shown that a fluoroscopic localization is necessary for the insertion

Table 2 Angles of needle entry with good clinical response in living patients

	Mean angles of needle entry±SD (range)
Sagittal plane	63.25±4.8 (56–66)
Left side	60.5±6.3 (56–65)
Right side	66±0
Axial plane	
Left side	100.5±14.8 (90–111)
Right side	73.5±3.5 (71–76)

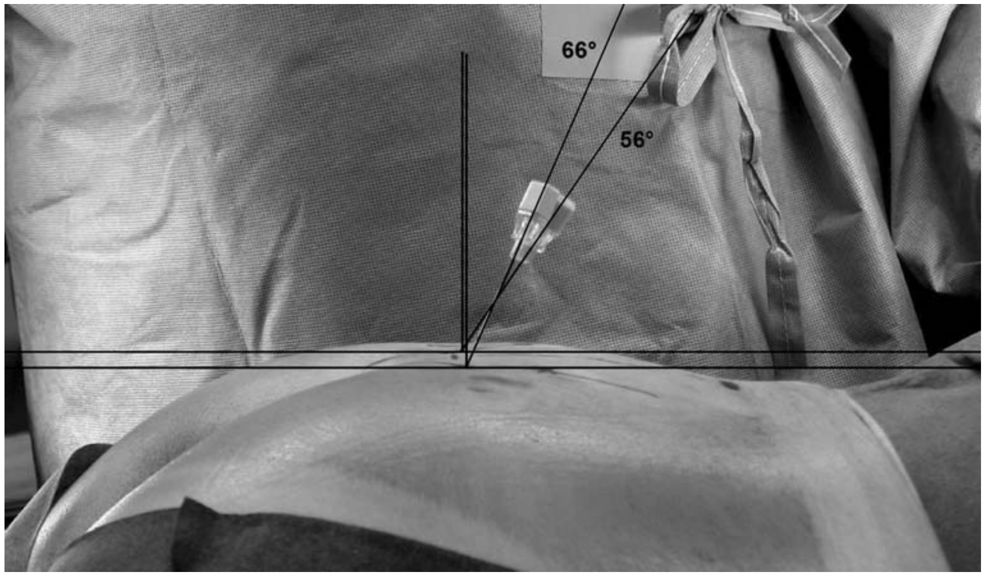

Fig. 4 Angles of insertion in the sagittal plane, in a living patient

of the electrode in the S3 foramen. This is widely accepted and used as intra-operative aid in the placement of sacral nerve electrodes. There are various bony landmarks such as the sciatic notch, midline sacral spinous processes, posterior iliac crest, sacral hiatus and the tip of the coccyx [38]. These landmarks can be helpful but do not always represent constant references [30]. The sciatic notch is not a discretely palpable landmark, and it is surrounded by abundant soft tissue [33]. Indeed, the amount of fat found on either side of the superficial fascia varies greatly [37]. However, with the anatomical reference points (midway between the tip of the coccyx and the S1 process, one fingerbreadth lateral to midline), we did not need fluoroscopy to find the S3 foramen in this cadaver study. We did not experience any significant difficulty in identifying the S3 foramen in either sex. But fluoroscopy is still a useful intra-operative aid during electrode placement in patients.

Direct laparoscopic visualization allows us to determine the best angle of insertion and to assess the position of the electrode in relation to the nerve, something which fluoroscopy cannot offer. Although the cadavers are not able to be stimulated to confirm the proper S3 responses (sensation in the rectum and vagina or pelvic bellows and plantar flexion of the great toe) [33, 38], the view with a laparoscopic camera gave sufficient details to validate the correct position of the electrode. Furthermore, we can confirm these experimental results with our trials on living patients. Indeed, we found similar angles of insertion between cadavers and living patients, allowing a good clinical response.

Schmidt et al. [38] reported an angle of insertion of about 60° in the sagittal plane. In another study, Hasan et al. [30] reported an angle of needle entry into the S3 foramen of 69° (range 45–90) in the sagittal plane. For them, there was no difference between men and women. Similar findings were shown in our study. The range of values in the study of Hasan et al. [30] is wider than ours. This is probably likely due to their dissection modalities, which can displace the electrodes.

However, Hasan et al. [30] found an angle of 103° for men and 106° for women in the axial plane. Although we agree with the findings for the women, our results differ for

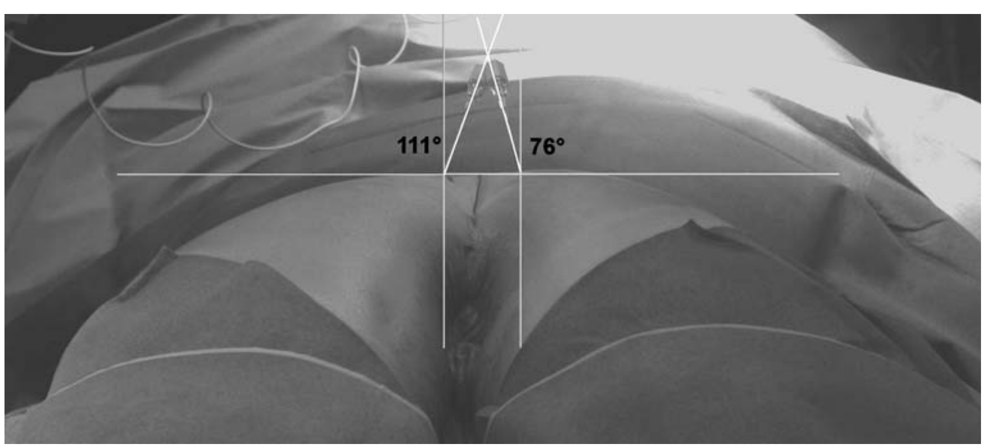

Fig. 5 Angles of insertion in the axial plane, in a living patient

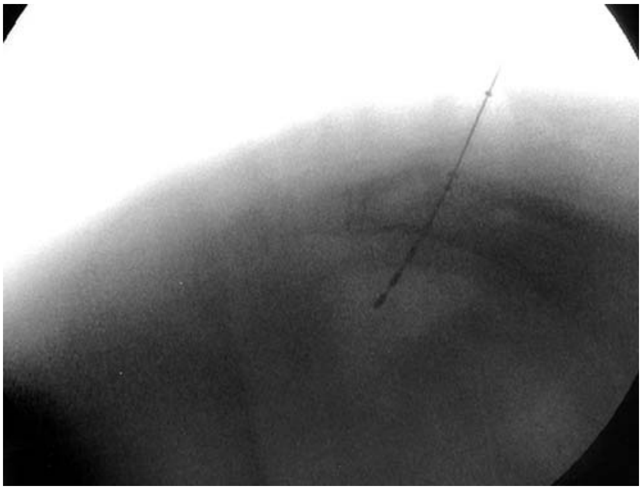

Fig. 6 Fluoroscopy showing the correct position of the electrode in the sacral foramen in a living patient

men. Because of the smaller, open android pelvis in the men [37], the angles were more medial than in the women. However, with our small sample, it is difficult to generalize to the overall population.

Xu et al. [36] reported that the S3 anterior foramen and nerve grooves extended an average of 2.5 mm superior, 11.5 mm lateral, 6.1 mm inferior and 1.3 mm medial to the nearest corresponding border of the posterior foramen. Some authors also found that the sacral nerve roots exit from the superior and medial portion of the anterior foramen [36, 38]. These results confirm the slightly lateral direction necessary to position the lead correctly, parallel and lateral to the nerve root. Furthermore, Hasan et al. [30] reported a higher incidence of nerve root penetration with an increasing angle of needle entry in the vertical plane. In the transverse plane, the incidence of nerve root penetration was significantly higher with the medial approach as compared with the lateral one. Indeed, the S3 and S4 nerve roots are surrounded by adipose tissue which fills their respective foramina, providing protection by allowing the nerve root to be pushed during procedures [30, 36]. We could not verify these findings with just one nerve root penetration in our study. During the actual surgical procedure, the incidence of sacral nerve penetration is probably higher than imagined. Complications such as pain could possibly be explained by these nerve injuries.

Liguro et al. [34] reported the risk of injuring the foraminal branch, of the lateral sacral artery in each foramen. This foraminal artery enters the inferior lateral quadrant of the foramen, occupied by the nerve root medially and the sacral bone edge laterally. However, Schimdt et al. [38] reported that it is common for blood to seep back through the needle from the puncture of veins traveling with the nerve in the foramen. However, in our series, we did notice any vascular injuries with the dissection after the procedure.

By dissecting the presacral space, we could confirm that no rectal perforation occurred. With laparoscopic visualization, we had proof that there was no potential risk of injuring the rectum using these angles, applied with a correct technique. Similar findings were reported previously [30, 38].

Complications which can be encountered are: infection, pain, lead migration and failure to ameliorate symptoms [1, 26, 33]. These complications could arise from the electrode implantation itself, and better lead insertion techniques could diminish them.

In conclusion, although our collectif is small and it is difficult to draw a solid conclusion, our study suggests a standardization of the technique for implantation of the electrode used in sacral nerve stimulation. In particular, determining standard angles used in electrode placement could optimize the electrode position lateral and parallel to the sacral nerve. This would result in consistently reproducible results and improvement in the accuracy of patient programming. This would minimize the risks of any structural damage and complications and maximize the chances for symptom amelioration. The results of this standardized technique require ongoing clinical evaluation to validate these anatomic findings.

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