Retrospective Review

Open Paddle Lead Trial for Spinal Cord Stimulation: An Institutional Experience

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Background: Spinal cord stimulation (SCS) is an accepted treatment for certain chronic pain syndromes. It is imperative that patients undergo a stimulation screening trial. For trial stimulation, typically patients undergo a percutaneous lead placement. Due to technical considerations, there exists a subset of patients who are not candidates for a percutaneous trial.

Objective: We present our experience with open paddle trial for spinal cord stimulation and review the characteristics of this patient population as well as the technique and efficacy of an open paddle lead trial for spinal cord stimulation.

Study Design: Retrospective review.

Setting: University of Texas Southwestern Medical Center, Department of Neurosurgery.

Methods: We retrospectively identified 25 patients undergoing a paddle lead trial for spinal cord stimulation from September 2014 to September 2019.

Results: Twenty-five patients underwent a paddle lead trial for spinal cord stimulation. The average age was 61 with a range of 40 to 82 years; 19 were women and 6 were men. Twenty-two patients (88%) had failed back surgery syndrome (FBSS). Nine patients had attempted percutaneous trials that were unsuccessful, and 14 patients had extensive hardware and/or scar tissue, necessitating an open paddle trial. Twenty-three (92%) patients had a positive trial and went on to permanent implantation.

Limitations: The retrospective nature is a major limitation as well as loss to follow-up on several patients.

Conclusion: Patients, who have either failed or are deemed suboptimal for percutaneous trialing for spinal cord stimulation, should be considered for open paddle lead trialing. A multidisciplinary approach improves communication and helps to identify that subset of patients who otherwise may be left to pursue conservative measures only.

Key words: Paddle lead trial, spinal cord stimulator, failed back surgery syndrome

IRB compliance statement and ethical adherence: This study was written in compliance with our institutional ethical review board (IRB #STU-2020-0824.) Patient consent was not sought given the retrospective nature of the review and the deidentified nature of the data collected.

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Spinal cord stimulation (SCS) is an effective treatment for a number of chronic pain syndromes (1). Successful trial stimulation is imperative for patient selection and subsequent long-term implantation. Percutaneous trial stimulation is the preferred trialing technique and is performed with intraoperative fluoroscopy to confirm entry level and target placement site. A subset of patients,

typically those with prior spine surgery, have scarring, preventing threading of the percutaneous leads; extensive spinal hardware obscuring fluoroscopy; or interlaminar/interspinous bony fusion preventing access to the epidural space.

In many practices, the implant surgeon only performs the stage II procedure which is permanent placement of a spinal cord stimulator after successful trialing. Many times, patients who are unable to undergo percutaneous trial stimulation are treated via conservative measures only. At this institution, patients who have failed a percutaneous trial for technical and/or anatomical reasons, or are deemed unsuitable for a percutaneous trial after discussion in a multidisciplinary clinic, are offered an open surgery paddle lead trial for spinal cord stimulation. We review the characteristics of this subset of patients as well as outcomes.

Methods

This study was approved by the Hospital Institutional Review Board. We retrospectively identified all patients who had an open paddle lead trial for spinal cord stimulation from September 2014 to September 2019. Candidates for spinal cord stimulators were evaluated in a multidisciplinary spine clinic with an initial evaluation by physiatry. If the patient had significant scarring, hardware, and/or bony fusion making percutaneous trialing less favorable, a referral was made to an implant surgeon to counsel the patient on an open paddle trial. Another subset of patients referred to an implant surgeon included those who had failed percutaneous trials, either by those within the multidisciplinary clinic or other providers in the community.

Surgical Technique

Stage I: Open Placement of Paddle Lead for Trial Stimulation

Under general anesthesia, the patient is placed prone identical to a standard open laminectomy. Typical placement for patients with postlumbar laminectomy syndrome includes paddle coverage from T7 to T9 in order to treat back and leg symptoms. The T9-T10 interspace is identified to perform a partial T9 laminotomy. After accessing the epidural space at the T9 level, the paddle lead is passed, and fluoroscopy is used to confirm coverage of the appropriate levels.

Neuromonitoring is then used to capture electromyography bilaterally into the abdominal musculature and lower extremities. The extension wire is then tunneled from the surgical cavity in the thoracic region to the gluteal region via a stab incision. It is then connected to the original paddle lead. The extension wire is now ready to be connected to the trial battery/device for trial stimulation.

Stage II: Implantation of Battery and Connection to Existing Paddle Lead

After a week of trial stimulation and at least a 50% reduction in pain, permanent implantation is then performed. The previous surgical incision is re-opened, and the extension wire is disconnected from the paddle lead. The extension wire is then removed in an inside-out method so that the wire goes from the cavity to outside the skin. This ensures that unsterile wiring does not contaminate the surgical cavity.

A new incision is made near the gluteal region in which a subcutaneous pocket is created for the battery. The original lead is then tunneled to the subcutaneous pocket and connected to the battery. The original lead is anchored within the original surgical cavity. The surgical cavities are irrigated with an antibiotic solution containing saline and vancomycin powder is applied to the cavity.

Illustrative Case:

Figure 1 illustrates a patient with juvenile idiopathic scoliosis who underwent multiple spinal surgeries in adolescence that involved deformity correction with a Harrington rod and lateral thoracolumbar fusion. A year prior to visiting our clinic, the patient had a T10 to pelvis fusion with partial removal of the Harrington rod. The patient then presented with bilateral lower extremity pain and back pain which had failed conservative treatment. The plain radiographs (Figs. 1A,B) show the extensive rod instrumented fusion throughout the spine and specifically at the T12-L1 level where a percutaneous SCS would be targeted.

Spinal cord stimulation was offered to the patient as a possible treatment option for continued pain symptoms. A computed tomography (CT) myelogram of the lumbar spine was obtained during the prior workup for any areas of significant stenosis; it was negative for spinal stenosis. However, the CT lumbar spine coronal view (Fig. 1C) showed extensive bony fusion that obscured normal landmarks and prevented entry into the epidural space using a Tuohy needle at the T12-L1 level, which is used for percutaneous SCS trials. The patient underwent an open paddle lead trial. Intraoperative fluoroscopy (Fig. 1D) shows removal of

a section of the Harrington rod in order to gain access to the T9 lamina as well as placement of the paddle lead. The trial was positive and subsequently followed by permanent implantation.

Results

The basic demographics including the age, gender, etiology of pain syndrome, distribution of pain, vendor, as well as trial outcomes are included in Table 1. Twenty-five patients underwent a paddle lead trial for spinal cord stimulation. The average age was 61 +/- 13 years, with a range of 40 to 82 years. There were 19 women and 6 men. Twenty-four patients (96%) had prior spine surgery. Twenty-two patients had a diagnosis of failed back surgery syndrome (FBSS) (88%). Two patients had complex pain regional syndrome (CRPS) type I, and one patient had CRPS type II. Three patients had idiopathic juvenile scoliosis with previous spinal fusion earlier in life. One patient had a prior myxopapillary ependymoma resection. One patient, with no history of spine surgery, had a failed percutaneous trial secondary to hyperlordosis of the lumbar spine.

Nineteen patients (76%) had back pain with either unilateral or bilateral leg pain. Four patients (16%) had primarily lower extremity pain. One patient had bilateral upper extremity pain and underwent a successful cervical paddle trial followed by permanent implantation.

Nine patients (36%) had failed percutaneous trials. Fourteen patients (56%) had extensive hardware and/or scar tissue. One patient had significant lower thoracic stenosis. and was referred for an open paddle trial. One patient had lead migration of a questionably effective, percutaneously placed SCS, and underwent a successful open paddle trial followed by implantation. Eleven patients (44%) did not have an attempted percutaneous trial but went straight to open paddle trial after review in our multidisciplinary spine clinic. All 11 of these patients had at least a 4-level lumbar fusion, with most fusion segments extending into the lower thoracic region.

Three implant surgeons at the University of Texas Southwestern Medical Center, Department of Neurosurgery performed the open paddle trials with a majority (n = 19, 76%) performed by M.A. The average duration of the trial procedure was 96 minutes and the average blood loss was 28 cm^3.

All patients returned for the second stage procedure. Twenty-three patients (92%) had a successful trial, with over a 50% reduction in pain symptoms and went on to permanent implantation. Two patients (10%) had negative trials with less than a 25% reduction in symptoms and had a subsequent removal of the paddle lead. Eighteen patients had at least one year follow-up with the number of months included in Table 2. Three patients were lost to follow-up. Of the 23 patients who had a positive trial and implantation, 17 (74%) had continued good coverage (≥ 50% pain reduction) at the last follow-up, which was gathered by clinic notes or phone calls made at the time of this writing. After

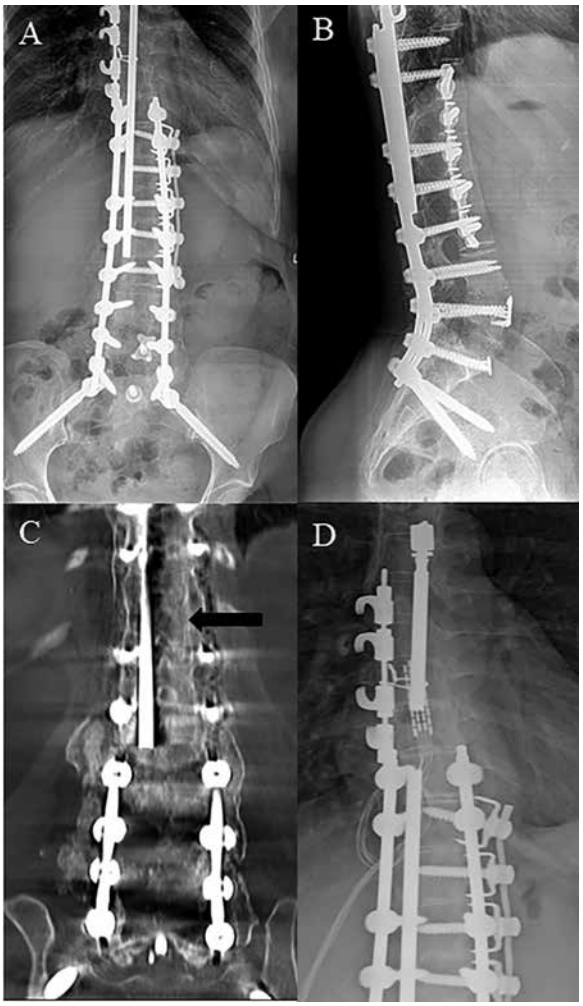

Fig. 1. A) *Anteroposterior plain film radiograph displays a thoracic to pelvic fusion with a Harrington rod.* B) *Lateral plain film radiograph shows significant hardware obscuring the normal entry point for a percutaneous SCS trial.* C) *CT myelogram lumbar spine coronal view showing complete bony fusion across the intralaminar space and interspinous space at the T12 - L1 level as marked by the black arrow.* D) *Intraoperative films during paddle lead trial shows removal of part of the Harrington rod as well as laminectomy to place the paddle lead.*

Table 1. *Summary of patient demographics.*

Pt	Age	Gender	Etiology	Distribution	Vendor	Pass/Fail	% pain reduction at trial
1	56	F	CPRS-I	legs	St. Jude	Positive	> 50% reduction
2	82	F	FBSS	back & legs	Medtronic	Positive	> 60% reduction
3	46	F	CRPS-II	arms	Medtronic	Positive	> 50% reduction
4	64	F	FBSS	back	Medtronic	Positive	> 50% reduction
5	55	F	FBSS	back & R leg	Medtronic	Positive	> 50% reduction
6	65	M	FBSS	back & L leg	Medtronic	Positive	> 80% reduction
7	60	F	FBSS	back and L leg	Boston Scientific	Negative	< 25% reduction
8	57	F	FBSS	legs	St. Jude	Positive	> 60% reduction
9	80	M	FBSS	R leg	Nevro	Negative	< 20% reduction
10	69	F	FBSS	back & legs	St. Jude	Positive	> 70% reduction
11	44	F	FBSS	back & legs	Boston Scientific	Positive	> 70% reduction
12	53	M	CRPS-I	back & legs	Nevro	Positive	> 75% reduction
13	57	M	FBSS	back	St. Jude	Positive	> 80% reduction
14	70	F	FBSS	back & R leg	St. Jude	Positive	> 65% reduction
15	40	F	FBSS	back & legs	St. Jude	Positive	> 65% reduction
16	48	F	FBSS	back & L leg	Boston Scientific	Positive	> 70% reduction
17	60	F	FBSS	back & legs	Boston Scientific	Positive	> 80% reduction
18	66	F	FBSS	back & L leg	Boston Scientific	Positive	> 50% reduction
19	83	M	FBSS	R leg	Nevro	Positive	> 80% reduction
20	67	F	FBSS	back & legs	Boston Scientific	Positive	> 60% reduction
21	72	F	FBSS	back & legs	St. Jude	Positive	> 80% reduction
22	39	M	FBSS	back & legs	Boston Scientific	Positive	> 60% reduction
23	80	F	FBSS	back & L leg	Boston Scientific	Positive	> 70% reduction
24	65	F	FBSS	back & L leg	Medtronic	Positive	> 60% reduction
25	49	F	FBSS	back & legs	Boston Scientific	Positive	> 60% reduction

St. Jude Medical, 6300 Bee Cave Road, Building Two Suite 100, Austin, TX 78746
Medtronic, 710 Medtronic Parkway, Minneapolis, MN, 55432
Boston Scientific, 300 Boston Scientific Way, Marlborough, MA, 01752
Nevro, 1800 Bridge Parkway, Redwood City, CA, 94065

a positive trial and implantation, 2 patients had their systems removed for decreasing efficacy at 7 years and 1.5 years postimplantation. There were no infections requiring wound washout or removal of the implant.

Discussion

Spinal cord stimulation has become an accepted treatment for patients with chronic pain syndromes (1). A stimulation trial is performed in order to identify those that will most benefit from an implanted SCS. A percutaneous trial of spinal cord stimulation is the least invasive technique and current best practice for initial trialing. However, there does exist a subset of patients in whom a percutaneous trial is unachievable or unfavorable. Numerous factors can prohibit a successful percutaneous trial from being performed. In our review, this includes excessive scar tissue that prohibits the provider from threading the lead into the epidural space; excessive hardware obscuring the visualization of the lead placement; and/or significant bony fusion prohibiting a Tuohy needle from reaching the epidural space. Patients most at risk are those who have had previous spine surgery and typically carry a diagnosis of FBSS. As such, most of our patients in this series 24 (96%) had a prior spine surgery and 22 (88%) had a diagnosis of FBSS.

Indications for Open Paddle Trial:

Little literature exists on an algorithm for open paddle lead trials for SCS. Weinand et al (2) reported on prolonged screening for spinal cord stimulation with 39% (n = 21) of patients requiring open placement

of a paddle lead; however, no details as to the indications for open versus percutaneous trialing was listed. Similarly, Son et al (3) reported on SCS for patients with FBSS with 50% undergoing an open paddle lead stimulation trial. In the discussion, it appeared to be institutional practice to trial with a surgically placed paddle lead for those patients with FBSS who had bilateral leg pain or back and leg pain symptoms, but no description was given on those patients who failed percutaneous trialing or the technical considerations for open paddle trialing. Similarly, Nissen et al (4) reported on 224 patients with FBSS who received an open paddle lead trial with 175 patients (78%) undergoing permanent implantation. Their institutional practice utilizes open paddle lead trialing as the initial trialing method for that cohort of patients with FBSS with no discussion on prior failure or evaluation of percutaneous trialing.

Pahapill et al (5) reported on 22 patients who underwent open paddle placement for trialing of spinal cord stimulation after a percutaneous trial could not be completed. Indication for open paddle trial was significant scarring or hardware in 62% (n = 13), migration of percutaneous leads in 18% (n = 4), warfarin usage in 14% (n = 3), and scoliosis in 5% (n = 1). This finding is consistent with our study in which a majority of patients had significant hardware and/or scarring from previous spine surgeries. Lee et al (6) reported on 12 patients who underwent open paddle placement for stage I spinal cord stimulation trialing. All 12 patients had FBSS which is consistent with our patient population. The indication for open paddle trial was extensive hardware in 10 patients and failed percutaneous trialing in 2 patients.

The authors of the present study agree that percutaneous trialing should remain the initial trialing procedure of choice. Those that fail percutaneous trialing due to technical considerations should be considered for an open paddle lead trial. A number of patients with FBSS with extensive hardware and suspected scar tissue may go straight to an open paddle trial as an initial treatment option. The criteria for those patients will vary from institution to institution and specifically on the trialing provider's level of comfort with percutaneous trialing in that subset of patients. A multidisciplinary approach will aid in identifying those patients who have failed percutaneous trialing in which an open paddle trial may be beneficial as well as limiting the number of patients undergoing an open trial unnecessarily when a percutaneous trial may have been feasible.

Table 2. *Summary of Outcomes at Last Follow-Up*

Pt	Age	Gender	Etiology	# months at last follow-up	Follow-up status
1	56	F	CPRS-I	72	50% reduction
2	82	F	FBSS	72	SCS removed
3	46	F	CRPS-II	NA	NA
4	64	F	FBSS	33	50% reduction
5	55	F	FBSS	NA	NA
6	65	M	FBSS	12	50% reduction
7	60	F	FBSS	Failed Stage I: never implanted	
8	57	F	FBSS	28	60% reduction
9	80	M	FBSS	Failed Stage I: never implanted	
10	69	F	FBSS	NA	NA
11	44	F	FBSS	24	50% reduction
12	53	M	CRPS-I	17	50% reduction
13	57	M	FBSS	27	70% reduction
14	70	F	FBSS	25	70% reduction
15	40	F	FBSS	24	20% reduction
16	48	F	FBSS	22	50% reduction
17	60	F	FBSS	19	50% reduction
18	66	F	FBSS	18	50% reduction
19	83	M	FBSS	18	SCS removed
20	67	F	FBSS	2	50% reduction
21	72	F	FBSS	20	70% reduction
22	39	M	FBSS	21	70% reduction
23	80	F	FBSS	9	50% reduction
24	65	F	FBSS	12	50% reduction
25	49	F	FBSS	12	70% reduction

Outcomes in Open Paddle Trial:

The success rate in percutaneous trialing has been reported anywhere from 64% to 80% (5,7,8). The few studies that exist report a success rate for open paddle lead trialing anywhere from 73% to 100% (3,5,6). Lee et al (6) reported a 100% success rate, which is most likely biased by its small sample size. In our cohort, there was a 90% success rate in open paddle lead trials for spinal cord stimulation consistent with the higher than average success rate of open paddle trials. This higher success rate of paddle lead trials could be secondary to better coverage afforded by the paddle electrode (9,10).

The failure rate of percutaneous trialing secondary to technical causes has been reported anywhere from 2.3% to 7%, but the true incidence is suspected to be

higher and warrants further investigation especially in patients with FBSS (5,7).

Conclusion

There does exist a patient population, typically those with FBSS, who have either failed or are deemed suboptimal for percutaneous trialing for spinal cord stimulation. Those patients should be considered for an open paddle lead trialing which is a safe and effective stage I procedure for SCS. A multidisciplinary approach improves communication and helps to identify that subset of patients who otherwise may be left to pursue conservative measures.

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