ORIGINAL ARTICLE

# Multisystem Spinal Cord Stimulation Trialing: A Single Center, Retrospective, Observational Study

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■ **Abstract**

*Background:* Spinal cord stimulation is a well-established modality for the treatment of chronic intractable pain. The safety and efficacy of various stimulation therapy designs have been demonstrated in multiple randomized controlled studies, oftentimes comparing an investigational device to an existing commercial therapy. In the real-world setting, data are lacking regarding selection of spinal cord stimulation (SCS) therapy, as waveform, pulse trains, and programming are not interchangeable among the devices. The purpose of this study is to help dissect a methodology for a patient centric multisystem trialing.

*Methods:* We conducted a single center, retrospective, open label observational chart review. Between June 2017 and June 2019, 83 patients underwent SCS trials. Devices from four commercially available systems were trialed. Patients were given the opportunity to trial up to three systems. If the patient reported 50% or more pain relief/functional improvement with the trial, they were able to choose which system they liked best and proceed with implantation.

*Results:* There were 82% (68/83) of patients who proceeded to permanent implant, with 72 patients electing to trial more than one stimulation paradigm. Of those, 62 trialed 2 SCS systems, whereas 11 trialed 3. During the SCS trials, loss of efficacy due to lead migration was 1.2% (1/83) and no infections occurred. The average pain score measured on the numeric pain rating scale (NRS), improved from 6.8 at baseline to 2.9 after implantation.

*Conclusions:* Multisystem trialing is safe and effective in providing patients increased exposure to multiple commercially available SCS systems. ■

**Key Words:** device explant, epidural leads, infection rate, opioid dose, spinal cord stimulation, trial stimulation

## INTRODUCTION

Spinal cord stimulation (SCS) is a well-established modality for the treatment of chronic intractable neuropathic pain.[1] Its efficacy and safety have been demonstrated in several randomized controlled trials (RCTs),[2] oftentimes comparing an investigational device to itself (closed loop or an existing commercially available technology to an investigational device), investigating noninferiority. Further, all of these studies are industry sponsored (10-kHz high-frequency therapy [HF-10],[1] dorsal root ganglion [DRG],[3] Burst,[2] and Closed loop[4]). With a variety of stimulation therapies to choose from, it can be challenging to determine which therapy is optimal for each individual patient.

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Submitted: January 12, 2021; Revised March 30, 2021; Revision accepted: April 1, 2021
DOI. 10.1111/papr.13016

Despite the reported success, failures exist in patient selection and device failure. Pope et al.[5] investigated retrospectively the device failure as defined as explant, with most rechargeable systems removed, which were explanted prior to 15 months, demonstrating poor cost effectiveness and lack of efficacy as the most cited reason. Once patients are implanted, they are maintained with the stimulation strategy that the device supports: stimulation advancements are not shared between systems, and therefore the patient only experiences one device at a time, based on physician preference, and one treatment at a time. Patients are blinded to any other stimulation strategy, as they are serving as an "*n*" of one. The current stimulation trialing paradigm in the United States is lacking the ability for the patient to experience and compare one SCS strategy to another, and therefore SCS systems and the results suffer from selection bias from sampling restriction. The duration of SCS trials last 3 to 7 days typically, with most trials ending within 5 days. Interestingly, extending the trial with a single system trial did not improve the outcome.[6]

The importance of a cost-effective way to best select one trialed system for a patient was underscored by the recent US Food and Drug Administration (FDA) guidance of trialing before implant, the Office of Inspector General (OIG) letter to healthcare providers regarding an internal pulse generator survey, and the Center for Medicare/Medicaid Services (CMS) requiring pre-authorization. The theme is responsible for patient selection and device implementation.

The FDA and Center for Devices and Radiological Health (CDRH) place the utmost importance on patient preference information.[7] It is recommended that patients evaluate, contrast, and compare one treatment strategy from another, moving away from a complete single system approach. Whether physicians drive the system choice paternalistically, or patients drive the SCS system choice based on preconceived expectations, if trial failure (or success) occurs, no data are available to determine if the patient could have responded better (and potentially more enduring). However, there have been salvage reports looking into different therapies, such as 10-kHz high-frequency therapy (HF-10) and dorsal root ganglion (DRG). One study showed that out of 105 patients that failed traditional SCS, 81% achieved greater than 50% pain relief with HF-10, and almost all exhibited some clinical improvement.[8] Another case report showed sustained pain improves after 8 months when using DRG spinal stimulation in patients with complex regional pain syndrome (CRPS) that had failed traditional SCS.[9] The popularized trialing strategy should be more patient centric and this investigation serves as the foundational work.

Clearly, the conversion rates from trials that leads to permanent SCS systems have important implications for healthcare resource utilization (HCRU) and pain management. In a 2017 large multicenter real-world study, the trial-to-permanent ratio was 64.7%.[10] These results were similar to our center's single system trial-to-permanent ratio of 60% based on our internal analysis of over 300 trials. Higher trial-to-permanent ratios have been reported in other industry sponsored studies.[1] In the real-world setting, data are lacking regarding selection of SCS therapy, as waveform, pulse trains, and programming are not interchangeable among the devices. The purpose of this study is to help dissect a methodology for a patient centric, multisystem trialing strategy.

## MATERIALS AND METHODS

After institutional review board (IRB) exemption was obtained, we conducted a real-world, nonindustry sponsored, open label observational, retrospective review between June 2017 and June 2019. Several outcomes were measured, including numeric rating scale (NRS), morphine equivalents per day (MED), trial-to-permanent ratio, complications, explant rate, and the reason for explant. Congruent with the standard of care, all SCS trials were pre-authorized through currently available payers in the United States, requiring documentation of medical necessity and psychological screen. All trials were performed by four pain management physicians at Spanish Hills Interventional Pain Specialists (SHIPS) in Camarillo, CA. Patients were covered by multiple insurance payors, including Worker's Compensation.

Spinal cord stimulation companies that were commercially available at the time were trialed: Proclaim (Abbott Inc.), Intellis (Medtronic Inc.), Senza II (Nevro Corp.), and Spectra WaveWriter (Boston Scientific).

Once patients were selected as candidates for SCS therapy and pre-authorization was obtained, patients underwent a multisystem trial (Figure 1). Typically, the physician chose the order of the systems with approval from the patient with an emphasis to alternate the system order every trial. The patient would be assigned to a system and trial for 3 to 5 days, following an assessment and the option to continue with another

treatment paradigm or ending the trial. This sequence was followed for a maximum of 3 systems trialed over a maximum of 14 days. The patient had the choice at any point to end or prolong the SCS trial. Patients were encouraged to trial more than one system, even if they reported greater than 50% pain relief in order to accurately compare different therapies. The SCS leads were provided by the vendor who was selected first. One exception was that Medtronic leads were used if they were included in the trial, as they did not have adapters to connect to other system trial leads at that time. The leads were placed based on the standard of care for the first system chosen (re: anatomic vs. paresthesia mapped leads). The main level for anatomic placement is the T9-10 junction. The physicians took this into account to make sure at least one of the leads was in that junction. The subsequent SCS therapies that require anatomic placement were given images of the trial to correlate programming. If there was an issue with efficacy, the patient would be brought back to confirm lead placement.

The SCS leads were secured by Stayfix or sutures. An infection prevention protocol was established by a local infectious disease physician. All patients were given preoperative antibiotics, Hibiclens/chlorhexidine scrub prior to procedure, and Bactrim was prescribed postoperatively throughout the duration of the trial.

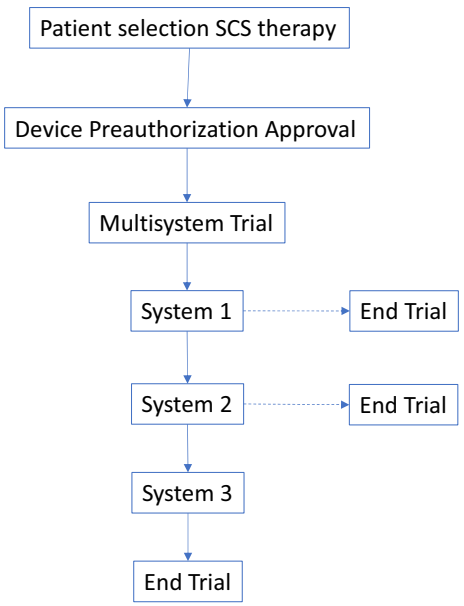


**FIGURE 1.** Patient recruitment strategy. SCS, spinal cord stimulation.

During the multisystem trials, after the external pulse generator (EPG) was programmed, the patient trialed the system for 5 days. Upon return to the clinic, an adapter was placed on the externalized leads and then connected to the second system to be trialed for 5 days. During each interval, patients were in contact with the respective SCS representatives for programming. Just as the standard of care for defining success and candidacy for SCS implantation, the patient must have reported at least 50% relief of their pain and improvement in their function during the trial. If the trial leads migrated, the patient had the option to stop the trial and proceed with implantation if the trial was successful or start a new trial with a different therapy.

## RESULTS

A total of 83 patients underwent a SCS trial from June 2017 to June 2019, where 82% (68/83) proceeded to permanent implant. The average (SD) patient age was 65 (15) years and 63% (52) were women. The most common diagnosis was post-laminectomy/failed back surgery syndrome (41%; Table 1). The average duration of follow-up was 12.5 months ranging from 4 to 20 months.

During the trial period, one patient (1.2%) experienced a loss of efficacy due to lead migration; a gross lead migration was discovered between the first and second system trials. No infections occurred during the trial period.

Of the 83 patients, 11 (13.3%) elected to proceed straight to permanent implant after the first exposure of a system in the multisystem trial. These patients reported 90% to 100% pain relief and were completely satisfied

**TABLE 1. Demographic information**

| Patients | *N* = 83 |
|---|---|
| Age (years) | |
| Mean | 65 |
| Range | 34–98 |
| Sex | |
| Male | 31 |
| Female | 52 |
| Diagnosis | |
| Lumbar radiculopathy | 34 |
| Lumbar post-laminectomy syndrome | 39 |
| Lumbar spinal stenosis | 4 |
| Cervical radiculopathy | 1 |
| Cervical post-laminectomy syndrome | 3 |
| CRPS | 1 |
| Post-herpetic neuralgia | 1 |

Abbreviation: CRPS, complex regional pain syndrome.

**TABLE 2. Multisystem trialing strategy**

| Trailing strategy | Trial ($n$ = 83) | Perm (%) |
|---|---|---|
| System 1 | 11 | 11 (100) |
| System 2 | 62 | 50 (81) |
| System 3 | 10 | 7 (70) |

Abbreviation: Perm, permanent.

with the initial SCS therapy. Therefore 72 patients elected to proceed to system 2 and, of these, 10 underwent a 3-system trial (Table 2). There were several factors for patients choosing to stop the SCS trial after the second system. The main factor was that patients reported greater than 50% relief and felt they had a good understanding of the differences between the 2 therapies to proceed to implantation. Some patients could not tolerate a longer duration trial. Some issues were due to not being able to shower or skin irritation to the wound dressing.

Of the multisystem trials, 81% of the patients went on to permanent implant, with 48% choosing the first vendor trialed. Of the 10 patients who underwent a 3-system trial, the implant rate was slightly lower at 70% with 57% choosing the first system trialed.

Post-SCS implant patients were followed up until June 2019 to evaluated NRS and MED scores. Explant and infection rates for all patients were evaluated in September 2019. The infection rate post-SCS implant was also 0% (0/68). The average pain score, as measured on the NRS, improved from 6.8 at baseline to 2.9 after implantation (Figure 2). Of the patients taking opioids prior to implant, 65.3% (32/49) reduced or tapered off of their opioid medications after implant. Within those same patients, 10 of 49 (20.4%) weaned off their opioid medications completely. The average MED was reduced from 53.1 to 37.9 (Figure 3). There was no significant difference in NRS scores or MED between patients that trialed one, two, or three systems. Over the same 2-year period, the explant rate was 2.9% (2/68). One explant was due to extreme pain at the SCS generator site. The other explant was due to loss of efficacy, and occurred in a patient who only underwent a single system trial.

## DISCUSSION

This investigation serves as the foundational pilot work to allow for multisystem trials in the real-world using an opt-in multisystem trial to improve informed decision on commercially available SCS therapies for patients. Patient exposure to multiple system options is critical in the trial. Appreciating this reduces repeated procedure risk when retrialing is performed in sequence, and system trialing after implant typically involves replacement of one battery for another, clearly inflating health care cost per life insured.

We believe multisystem SCS trialing provides a benefit to patient centered care. With the current healthcare insurance guidelines, which is one or two neurostimulation trials per body region, per lifetime may be all a patient can have access to, and with more systems, waveforms, and neural targets available, improving patient selection and patient preference with

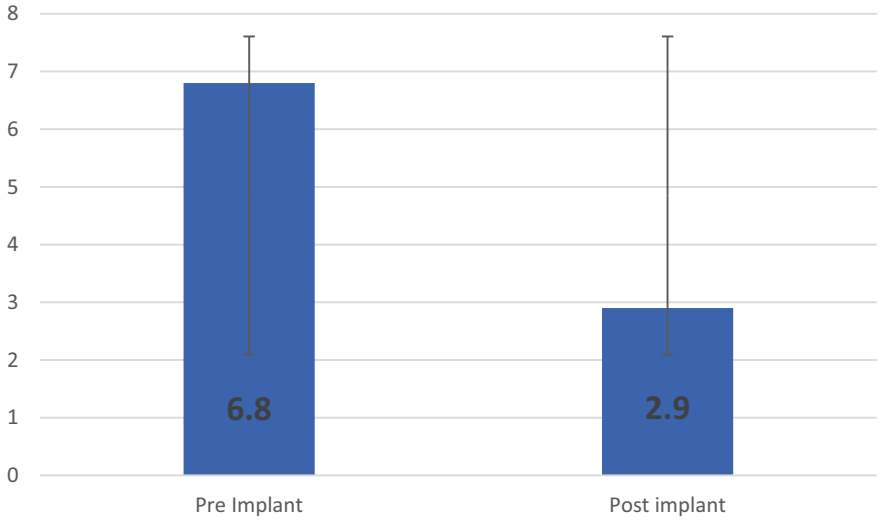


**FIGURE 2.** Numeric pain rating scores (NRS) pre and post-SCS implant. SCS, spinal cord stimulation.

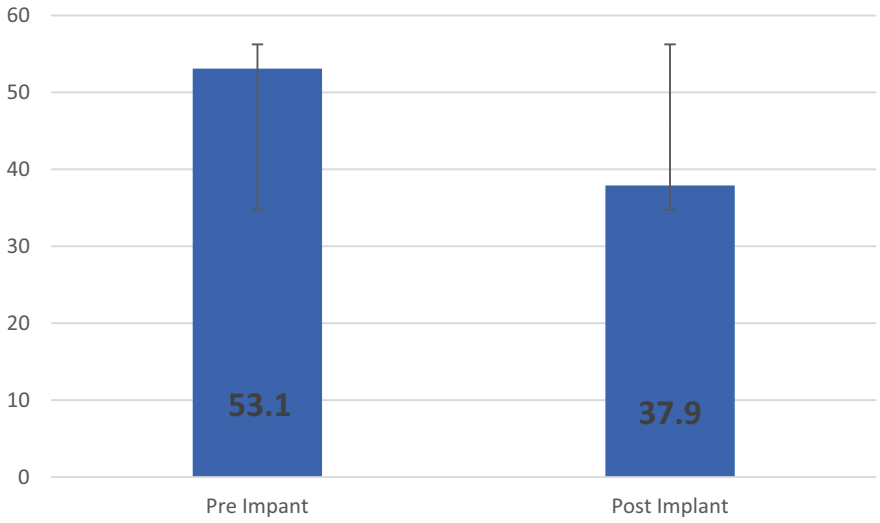


**FIGURE 3.** Total morphine equivalents per day (MED) pre and post-SCS implant. SCS, spinal cord stimulation.

exposure to multiple systems makes intuitive sense and is becoming increasingly necessary. When compared with the recently published large scale multicenter study trial conversion rate of 64.7%, and our own single system rate of 60%, implementing a multisystem trialing protocol substantially increases the trial conversion rate (82%; Figure 4). Some may observe that the multisystem SCS trial-to-permanent ratio is not as high as some of the industry sponsored SCS studies. Compared with other industry sponsored studies, there were no strict inclusion/exclusion criteria in this study. This study encompassed all insurance carriers in the real world, including Worker's Compensation, and a wide patient age range (34–98 years old). In this single center cohort over 2 years, this retrospective review of a multisystem trial strategy increased our practice's trial-to-permanent ratio by over 36%.

The significance of a noninvasive multisystem, opt in, trialing strategy is important for a sustainability of the therapy, but also cost effectiveness. Pope and colleagues reported on device failure at explant, and a key reason for explant was loss of efficacy, which often occurs within 15 months from implant.[5] In this retrospective review, after 2 years, the explant rate was significantly lower (2.9%) than the national average (9.2%).[11] The reasons for this are unclear. We hypothesize one consideration may be the psychology of the patient. By having exposure to multiple commercially available systems and treatment stimulation paradigms, and having an opportunity to select the therapy they prefer, yielding the best results, the patients may be more committed to having their SCS implant long term. For

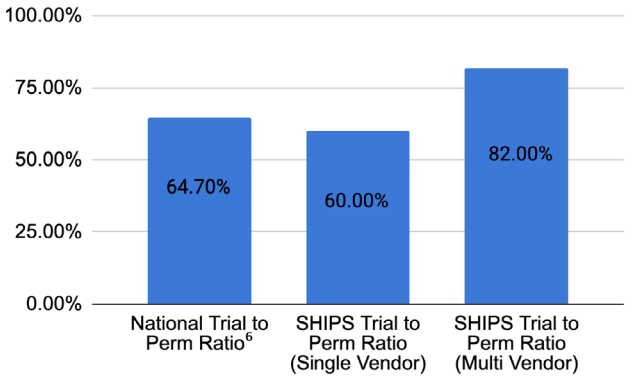


**FIGURE 4.** SCS trial-to-permanent ratio. SCS, spinal cord stimulation.

example, if a patient received 50% relief with one therapy and 90% relief with the other therapy, they may be more likely to keep their SCS despite habituation or reduced efficacy in the future.

Our main objective in this investigation was to introduce the concept of a multisystem, opt-in, stimulation trial strategy that can be operationalized. This allows for increased patient exposure to commercially available systems and is becoming increasingly necessary with the growing number of options for treatment, with no direct comparisons of one therapy to another. Having patients serve as their own control may solve this problem. There were several reasons for patients choosing to trial at least two systems. Some patients did not report greater than 50% with the first system. Most patients wanted to compare at least two systems to obtain the best efficacy possible and remove buyer's

remorse. Patients were encouraged by physicians to trial at least two systems. Patients chose the system they wanted to proceed to implantation using several factors: pain relief (most importantly), function, the feeling of each waveform, option to choose a rechargeable versus a nonrechargeable generator, and ease of using the programmer.

Further, as cost-effectiveness of these therapies are increasingly being evaluated, prudent management of patient selection by multisystem exposure may reduce the practice of "IPG swapping."

Infectious complications in surgery are always a concern. It has been published that extended SCS trials (3–15 days) was associated with a 7.5% infection rate.[12] Our multisystem SCS trialing strategy allowed patients to experience multiple stimulation therapies, while reducing the infection rate (0%) and loss of efficacy due to lead migration (1.2%). We believe that adhering to the Center for Disease Control (CDC) and local infectious disease guidelines allows for optimal infection control during a 10 to 14 day trial period. Use of extended oral antibiotics carry their own risk, such as the emergence of antibiotic resistance and toxicity. Physicians should consult with their local infectious disease specialists to create their own guidelines.

The limitations of this study include the retrospective nature of the investigation and single center design. The purpose of this investigation was not to advocate for one stimulation paradigm compared to another, but more specifically emphasize the importance of exposure to multiple strategies and waveform paradigms intra-trial. A prospective, randomized study with 2-year follow-up should be considered when optimizing patient selection and exposure to device differences. Limitations also include a lack of insight as to the best order of vendors to trial different systems. For example, if we knew 10 kHz should come first because of anatomic restrictions or paresthesia because of rapid onset, then we could further reduce trial duration and reduce infectious risks. The trial itself can become more challenging for the patient as time goes on because of physical restrictions and wearing adhesives on the back (e.g., itching). This study does suggest that the trial may be of more value to patients if more than one wave form is experienced by the patient.

## CONCLUSION

Multisystem trialing is safe and effective in providing patients increased exposure to multiple commercially available SCS systems. It can be implemented in practices to provide patients with exposure to several different forms of spinal cord stimulation therapy. This can change the approach to SCS trialing. It has increased the trial-to-permanent ratio in our practice from 60% to 82% (36.7% increase), while sustaining an extremely low explant rate compared to the national average (2.9% vs. 9.2%).

## CONFLICT OF INTEREST

Dr. Kiker is a consultant for Abbott. Dr. Buchanan is a consultant for Abbott, PainTeq and Aurora Spine. He is a principal investigator for Abbott and PainTeq. Dr. Pope is a consultant for Abbott, Medtronic, Flowonix, Ethos, PainTeq, Thermaquil, Vertos, Boston Scientific, Saluda, SpineThera, SPR Therapeutics, WISE, Stimgenics, and Aurora Spine. He has equity in Stimgenics, SPR Therapeutics, SpineThera, Thermaquil, Vertos, Neural Integrative Solutions, AGR, PainTeq, Aurora Spine, and Celeri Health, and his institution receives research grants from Painteq, Boston Scientific, Abbott, Medtronic, Saluda, Vertos, Ethos, Flowonix, and AIS.

## AUTHOR CONTRIBUTIONS

P.B. designed and conducted the study, interpreted and analyzed the data, collected data, and prepared manuscript. D.K. designed the study and was involved in patient recruitment and paper review. A.K. was involved in patient recruitment and paper review. F.K. was involved in patient recruitment and paper review. J.P. was involved with analyzing data and paper review.

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