As submitted to:

Neuromodulation

And later published:

Awake versus Asleep Placement of Spinal Cord Stimulators: A Cohort Analysis of Complications Associated with Placement

Volume 14, Issue 2, pages 130–135, March/April 2011

DOI: 10.1111/j.1525-1403.2010.00319.x

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Abstract:

Introduction: Patients will typically undergo awake surgery for permanent implantation of SCS in an attempt to optimize electrode placement using patient feedback about the distribution of stimulation-induced paresthesia. The present study compared efficacy of first-time electrode placement under awake conditions with that of neurophysiologically-guided placement under general anesthesia.

Methods: A retrospective review was performed of 387 SCS surgeries among 259 patients which included 167 new stimulator implantation to determine whether first time awake surgery for placement of spinal cord stimulators is preferable to non-awake placement.

Results: The incidence of device failure for patients implanted using neurophysiologically-guided placement under general anesthesia was one-half that for patients implanted awake (14.94% vs 29.7%).

Conclusion: Non-awake surgery is associated with fewer failure rates and therefore fewer re-operations, making it a viable alternative. Any benefits of awake implantation should carefully be considered in the future.

Introduction:

Spinal cord stimulation (SCS) is an adjustable, non-destructive, therapy which delivers doses of electrical current to the spinal cord for the management of neuropathic pain. The most common indications include post-laminectomy syndrome, complex regional pain syndrome (CRPS), ischemic limb pain, and angina. (**Reference 6**)

The success of the therapy relies on the ability to create an overlap between the pain areas and the device induced paresthesia. **(Reference 6)** Extensive work has been done

previously in describing the mapping of the spinal structure and the relationship between the spinal level of stimulation and the somatotopy of paresthesia. **(Reference 1)** A patient typically will undergo implantation of the device in an awake operation to permit testing of the distribution of the induced paresthesia and assessment of the discomfort thresholds. It is commonly believed that intra-operative testing in the awake patient is likely to optimize placement of the electrode, although this method has not been formally compared with other methods of guided placement.

Electrode implantation can be performed either under a version of profound anesthesia (local anesthetic and intravenous sedation) which allows for awake intraoperative testing of the implant or under general anesthesia which precludes patient interaction during surgery. The original practice at our institution was to perform the permanent implant under profound anesthesia. Observation and changes in the technique and evolution of the electrode technology allowed for a reassessment and a change in the implant technique. Over the last two years, the majority of the operations have shifted to general anesthesia.

The following study is designed to compare two implant techniques for a single surgeon by assessing differences in complications rates in the two cohort groups- awake versus non awake placement.

Methods:

An IRB approved retrospective review of 387 SCS surgeries with 167 first time internalization operations was undertaken to determine whether there are differences in the surgical complication rates between first time awake surgery for placement of spinal cord stimulators compared to non-awake placement. Patients implanted between 2002 - 2007 by a single surgeon at a single center were included in the review. All patients were implanted with either one or two dual column plate electrode(s). Patients included those requiring follow up despite having been implanted previously by a different surgeon; however, these patients were not included in the analysis of first time implantations. Failure revision surgery was also included for multiple operations or revisions on the same patient. All patients underwent spinal imaging via MRI as surgeon preference prior to implantation.

The most common post surgical events included repositioning of the battery, repositioning of the electrode, device failures, and infection. A device failure was defined as any re-operation secondary to a traumatic break in the SCS system, a device malfunction requiring re-exploration, or a device removal secondary to lack of efficacy. Infections were only included if they were associated with a draining wound which resulted in explantation of the entire system.

Description of the surgical procedures.

Awake Surgery:

The awake insertion has been previously described**. (Reference 6)** The key differences in the techniques used for the two cohorts (awake, non- awake) are described. In the awake group, all patients were positioned in the lateral decubitus position. The majority

of the dissection and laminotomy exposure was performed with a laryngeal mask airway under propofol for sedation (Diprivan, Stuart Pharmaceuticals, Wilmington, DE). Identification of the surgical level was confirmed with intra-operative X-ray. Once the electrode was positioned in the epidural space, anesthetics were decreased until the patient was lucid. The device was tested to assess distribution of the paresthesia and then re-positioned, as necessary. Closure was performed under additional sedation and local anesthetics.

Non-Awake Surgery:
General anesthesia was achieved utilizing a total intravenous anesthesia regimen (propofol, narcotics and benzodiazepines). The patient was intubated endotracheally and positioned on chest rolls in the prone position. The use of neuromuscular blocking agents was avoided following patient intubation. Sterile, 1.3cm, 27 gauge conventional subdermal needle electrode pairs (Sunspots Disposable Electrodes, Axon Systems, Hauppauge, New York) were placed into selected extremity muscle groups along the distributional path of the patient's pain. For T9-T10 thoracic stimulator electrode placements, monitoring electrodes were also placed in the periumbilical rectus abdominis muscles to achieve sensitivity in the T8-T12 spinal nerve root distributions. Symmetrical placement of the monitoring leads is critical since response amplitude comparisons are the basis for the neurophysiologic mapping of the dual strip electrode placement. All neuromonitoring was performed by a single group of board-certified professional surgical neurophysiologists capable of interpreting the data directly in the operating room.

Intra-operative fluoroscopy was utilized prior to making incision. The rostral-caudal level of the planned electrode insertion was determined based on the percutaneous trial experience and the active cathode position used at that time. Dissection was performed as previously described to allow exposure of the epidural space.

The electrode was connected to testing cables which were passed off the sterile field and connected to a portable stimulator. Intraoperative test stimulation was delivered between select pairs of electrodes at frequencies between 3-5Hz using a pulse-width (PW) between 100– 600 milliseconds (ms) and intensities up to 12 milliamperes (mA). Stimulation intensity was increased gradually from 0 mA until compound muscle action potentials (CMAPS) were elicited from one or more monitored myotomes. These stimulus-evoked electromyographic (EMG) responses were used together with surgeon perception of placement and fluoroscopyto determine the physiological midline, as well as laterality and orientation of the electrode.

Spinal cord and spinal nerve root function was monitored on all non-awake procedures to minimize the risk of iatrogenic injury during laminotomies and manipulation of epidural electrodes. This monitoring included somatosensory evoked potentials (SSEP), transcranial electric motor evoked potentials (tceMEP) and EMG. Additionally, electroencephalography (EEG) and train-of-four (TOF) testing was performed to aid in the assessment of depth of anesthesia and neuromuscular blockade clearing. Assessment

of these modalities assured the safety of the spinal cord and optimal testing conditions for placement of epidural stimulator electrodes.

Results:

During the period of the review 387 surgical procedures were performed of which 167 were first time internalization of a spinal cord stimulation paddle style electrode. This included 76 with the patient awake and 91 occurring under general anesthesia. . **FIGURE 1** shows a graph of the number of cases per year and change in methodology to non- awake surgery. The number of awake procedures peaked in 2004 and then declined as the number of procedures performed under general anesthesia increased.

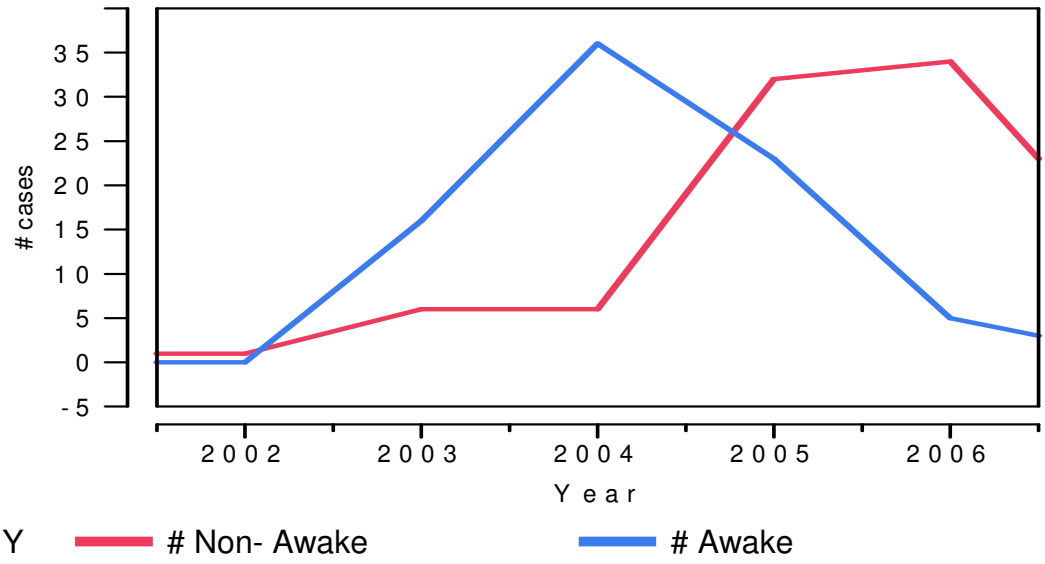
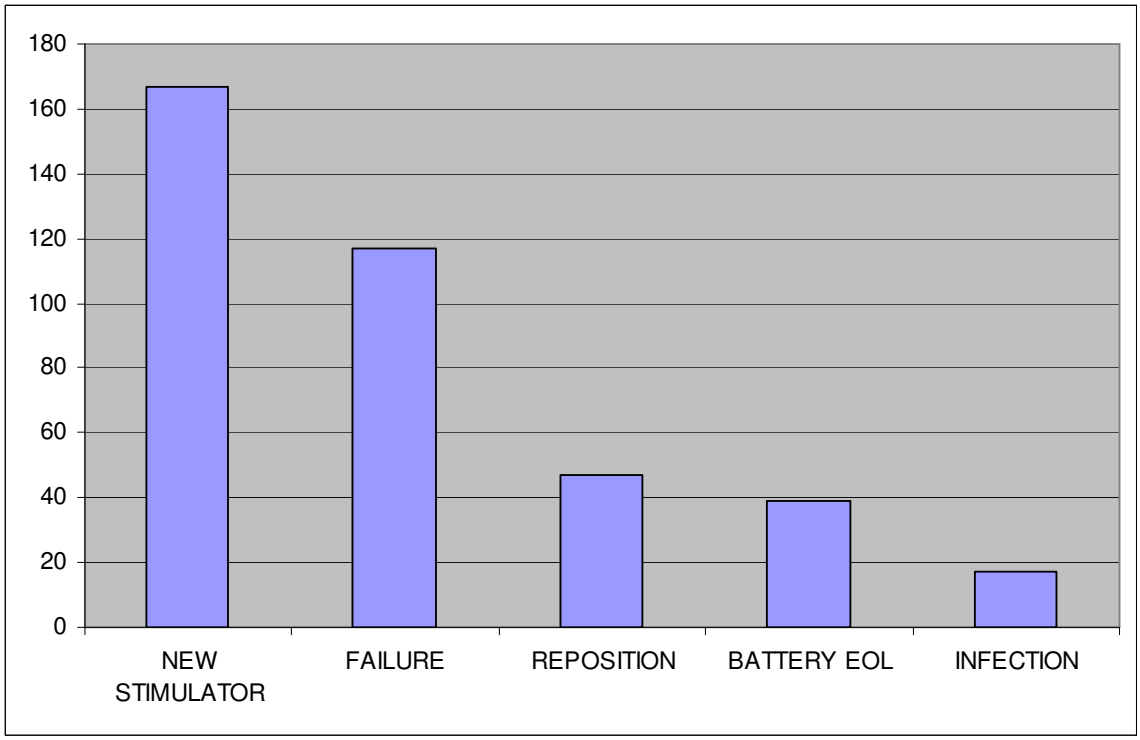


Figure 1: Number of cases per year performed awake versus number performed under general anesthesia

Figure 2 demonstrates the operations divided into five categories based on why the surgery was performed. The most common was for new implantation, or an additional implantation. Equipment failure was the second most common including multiple revisions on the same patient if needed. The least common indication for surgery was for infection requiring wound debridement or equipment removal.



Type	Count
NEW STIMULATOR	167
FAILURE	117
REPOSITION	47
BATTERY EOL	39
INFECTION	17
Total	387

Figure 2: Operations based on indication for surgery

A typical example of compound muscle action potentials recorded during neurophysiological mapping is shown for one patient in Figure 3. This patient presented preoperatively with a diagnosis of reflex sympathetic dystrophy and medically intractable pain in both legs. The stimulation electrode was positioned via a T9/10 laminotomy to trigger test responses from bilateral lower extremity myotomes whose distribution overlapped the somatotopic distribution of the patient's symptoms. Subsequent postoperative activation and programming of the stimulator was effective in facilitating management of the patient's pain in this distribution without disruptive motor side effects.

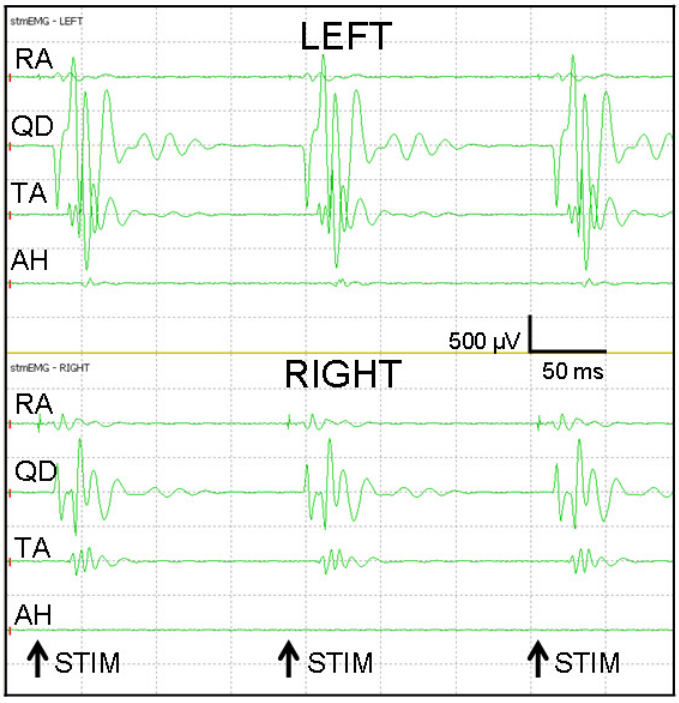


Figure 3: Example of EMG responses elicited intraoperatively from bilateral quadriceps and tibialis anterior muscles during test activation of a spinal cord stimulator implanted at the T9/10 spinal level. Position of the implanted electrode was adjusted until clear responses were recorded from both lower extremities, overlapping the distribution of the patient's preoperative pain. Arrows indicate test stimulus delivery times.
Muscle Abbreviations: RA- rectus abdominis, QD- quadriceps, TA- tibialis anterior, AH- abductor hallucis

Awake surgeries versus non awake surgeries were then divided into subcategories of failure versus non-failure within each. **Figure 4** demonstrates that using wakeup at first surgery is associated with a higher chance of seeing one or more failures. The incidence of device failure for patients implanted under general anesthesia was one-half that for patients implanted awake (14.94% vs 29.7%, p<.03). This failure rate included those patients requiring multiple surgeries and was over a greater than 5 year follow up period. The overall failure rate for new stimulator implants placed by the primary surgeon was 16%.

The rate of infection was analyzed. There was not a statistically significant difference when comparing awake (4.48%) to non- awake (5.7%) placement for rate of infection

and therefore the occurrence of infection is not explained by whether wakeup was used at the first surgery. (**Figure 4)**

Additionally, the rate of electrode repositioning for patients originally implanted under general anesthesia was 14.9%, and 17.9% for patients implanted awake. This difference did not reach statistical significance (**Figure 4),** therefore demonstrating no difference between these two groups.

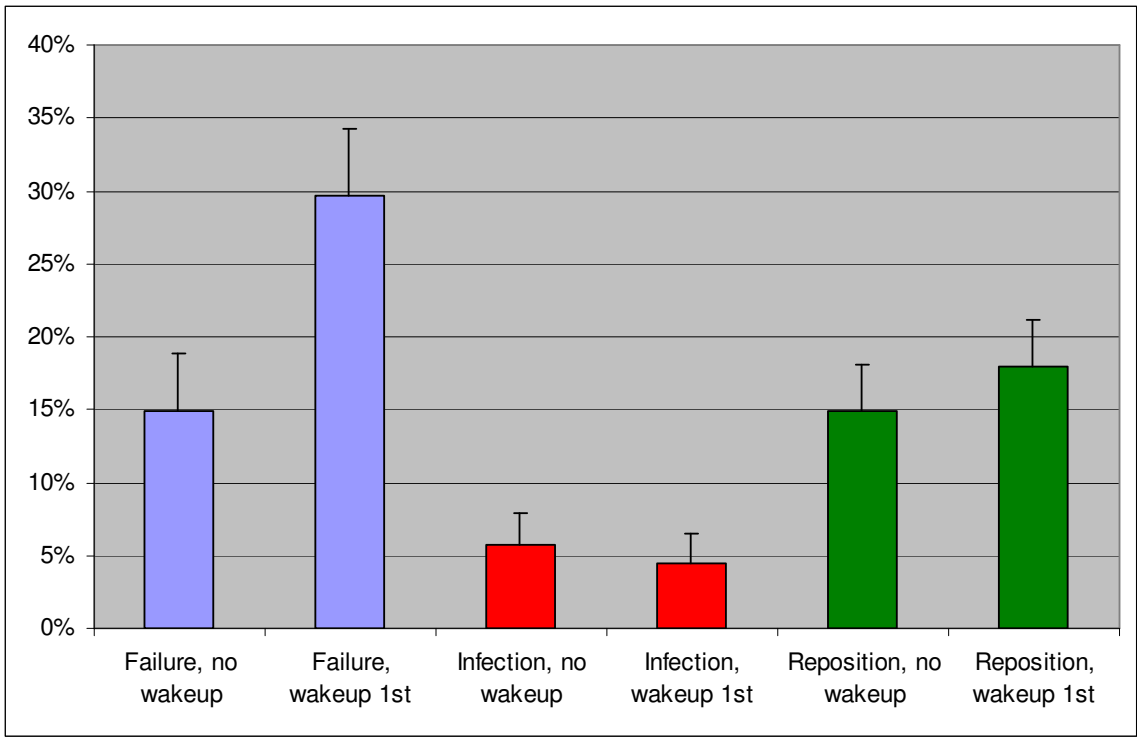


Figure 4: Comparison between Awake and Non- Awake placement of SCS

Discussion:

In the present series, the incidence of device failure following spinal cord implantation performed under general anesthesia using neurophysiologically guided electrode placement was significantly lower than that following implantation in the awake patient. This may be due in part to greater control of the patient under general anesthesia and an associated reduction in spontaneous movements which might otherwise dislodge electrodes and their connections. **Surgeon experience and improved technology may also be factors in the observed reduction of device failures implanted under general anesthesia. Surgeon experience increased from 2 years of practice to 7 years of practice during the observed time period. Awake**

implantations predominated early in the series, while those performed under general anesthesia were phased in later in time. The incidence of other major complications, including infections and poorly placed electrodes that required repositioning in a second operation, did not differ significantly between the two cohorts. These latter results suggest that the neurophysiological mapping technique used to help guide electrode placement under general anesthesia was at least as effective as patient feedback during awake placement.

The limitation in the interpretation of the data lies in the lack of two comparable groups done simultaneously. The ideal way to compare these two cohorts would be to have the patients randomized to either Awake or non- awake placement and performed over a set period of time. Surgeon experience and improved technology would then be held constant. This study however is an observation of these two cohorts and the change in surgeon preference overtime.

The initial conception for use of EMG/SSEP during implantation was devised in 1998 allowing a stimulation lead to be positioned relative to a physiological midline and/or positioned along the dorsal column in a longitudinal direction (Reference 7). This has been followed up with descriptions and clinical application in placement of surgical leads via a laminotomy (reference 8) as well as by clinical evaluation of this monitoring (reference 9).

Throughout the study period patients were implanted with either single or dual column electrodes. The analysis did not account for potential differences between these two patient groups. Manufacturer of the product was not maintained consistent throughout the study period and can also be a confounding factor. Although this study points out a change between placement in awake and non- awake patients it is important to realize that the critical change may not have been appreciated. It is because of these factors that are not accounted for, which are inherent in any study of this type, that the hope is to demonstrate equal efficacy between these two surgical techniques.

Device failure requiring revision is a soft and difficult endpoint to characterize. In the analysis some patients may have required one surgery to revise both a device malfunction, as well as a traumatic break. This may have also overlapped with the need for repositioning. The need for the revision of a malfunctioned 4 contact electrode is not equal to that of a 16 contact electrode. Therefore breakdown in each group for a sub analysis is beyond the scope of our study, but opens interest for looking at specific device failure as a future endpoint to study.

Historically, spinal cord stimulator implantation has been performed in the awake patient because it provides immediate feedback to the surgeon regarding stimulation-induced paresthesia. Two options for implantation include percutaneous electrodes and laminectomy electrode placement. Lind et al. performed the implantation with a spinal anesthetic and examined whether stimulation-induced paresthesiae could still be evoked to guide the positioning of the electrode. In all patients, it was possible to evoke paresthesiae, the distribution of which could be reproduced postoperatively. The

paresthesia thresholds during surgery were only moderately higher than those recorded after implantation (**reference 5**). Garcia-Perez et al evaluated the safety and efficacy of laminectomy lead placement under epidural anesthesia concluding that it was a feasible alternative (**reference 2**).

Minimally invasive techniques have recently come into favor and are now used in the placement of spinal cord stimulators. Vangeneugden (2007) compared postoperative outcomes following electrode placement using the classical midline laminotomy technique with those following use of a minimally invasive unilateral technique in awake patients. He concluded that a minimally invasive unilateral technique has some advantages over midline laminotomy, based on reduced postoperative pain and length of hospital stay (**reference 3**). Beems at al. used a modified implantation technique to implant under awake surgery. Using a tubular retractor system, originally developed for minimally invasive degenerative disc surgery, they introduced the plate electrode with a small approach under local anesthesia both allowing trial stimulation and avoiding severe postoperative backache related to the approach in these patients (**reference 4**).

Despite the advantages inherent in the use of different minimally invasive techniques and various methods of focused anesthesia under awake placement, there remain a number of reasons why implantation under general anesthesia may be desirable. The awake operation is often performed while the patient is under local anesthesia, which is very stressful for the patient, and predisposes them to movement. This can lead to decreased patient satisfaction, equipment migration, undesired stimulation effects and treatment failure. **These factors lead to the implanting surgeon having a preference for non- awake placement.**

Additionally, personal experience for most implanting physician's reveals that intraoperative wake up is not always desirable. Some patients are severely disoriented, and others are agitated, which interferes with reliable communication with the surgeon. Further the pre- operative narcotic medication doses frequently required for these patients with chronic severe pain often makes pain control during the wake up very difficult even with generous local anesthetic. Finally, X-ray identification of the midline is often times not possible in the lateral decubitus position.

The results of the present study show that when the procedure is performed under general anesthesia, it is possible to rely on radiographic information about electrode position and on the results of neurophysiological mapping to assure proper electrode placement. In our experience, this combination has proved effective for reliable electrode placement after a percutaneous trial. A multi- array electrode can be placed at the same location as the trial electrode, and the orientation and laterality of the lead can be confirmed and adjusted based on neurophysiologic surveillance and guidance.

The availability of multiple channel arrays and implantable pulse generators that can function with multiple electrodes now allows for generous implantation of extra electrodes. This advance in technology permits greater flexibility in generating appropriate paresthesia coverage postoperatively via programming of the device. Previously, with 4 or 8 contact electrodes, much more extensive intraoperative testing of the awake patient was required for accurate placement of the electrode.

Conclusion:

The treatment of chronic pain remains challenging. Spinal cord stimulation has been performed for over 30 years, and slow but steady progress with this technology has been made. Experience in the technique and the equipment has made SCS a much more reliable and safe modality. Careful follow-up of the patients is necessary for successful long-term satisfaction. Equipment related problems can arise at any time after implantation, such as electrode(s) breakage or migration, infection, etc., and an open dialogue with the patients is vital for the continuing successful implementation of the modality.

In the present series, implantation under general anesthesia was associated with a lower device failure rate than awake implantation, did not compromise therapeutic efficacy or result in additional complications, therefore leading to fewer re-operations, making it a viable alternative. Any benefits of awake implantation should carefully be considered in the future.

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