

**Title:** Interim Results from the Partnership for Advancement In Neuromodulation (PAIN) Registry

**Running Title:** PAIN Registry Interim Results

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**Conflict of Interest Statement:**

Drs. Deer, Skaribas, McJunkin and Gomezese are paid consultants of St. Jude Medical. Donald Daudt is a former employee of St. Jude Medical. Stephanie Washburn is a current employee of St. Jude Medical.

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**Abstract**

## **Title**

Interim Results from the Partnership for Advancement In Neuromodulation (PAIN) Registry

## **Objectives**

Present results from a multicenter registry designed to obtain longitudinal clinical outcome data for patients implanted with a neuromodulation system for the management of chronic pain of the trunk and/or limbs.

## **Materials and Methods**

Interim data from 579 patients across 40 study sites was analyzed from a prospective, observational, non-interventional registry. Institutional Review Board approval was obtained prior to enrollment. The following were recorded at baseline and at 3, 6 and 12 months post-implant: patient reported pain relief, categorical ratings of pain relief, Pain Disability Index (PDI) scores, , quality of life, medication usage, patient satisfaction. Pain relief among (tobacco) smokers was also assessed. Descriptive statistics were compiled for all patient outcome measurements and data is reported as mean ( $\pm$  standard deviation). All statistical analysis was conducted using one-sided *t*-tests with a significance level of  $\alpha=0.05$ . Device related adverse events were captured and are reported.

## **Results**

Patient reported pain relief was 58.0% ( $\pm 26.2\%$ ) at 3 months, 58.1% ( $\pm 28.7\%$ ) at 6 months, and 57.0% ( $\pm 29.4\%$ ) at 12 months. Mean PDI scores were reduced from 47.7 points at baseline to 33.3, 32.4, and 31.9 points, respectively ( $p \leq 0.001$ ). The majority of patients categorized their pain relief as “excellent” or “good” and reported their overall quality of life as “greatly improved” or “improved” at all time-points. In addition, greater than 79% of patients were “satisfied” or “very satisfied” with the therapy at all timepoints assessed and 47.1% of

patients “stopped” or “decreased” use of narcotics/opioids. Pain relief was significantly attenuated by smoking ( $p=0.042$ ). The most common adverse event was lead migration which accounted for 18.9% of all events in 3.6% of all patients.

### **Conclusions**

These results provide evidence to further support the safety, efficacy and sustainability of neuromodulation in clinical practice.

### **Keywords:**

Chronic pain, failed back surgery syndrome, medication use, registry, neuromodulation, neurostimulation, spinal cord stimulation.

## **Introduction:**

Chronic pain is pain that persists or recurs for greater than 3 months or persists greater than one month after resolution of an acute tissue injury, or accompanies a non-healing lesion (Turk, 2001). Chronic pain is estimated to affect 1% of the United States population, with up to 15% of patients estimated to be refractory to standard medical therapy.<sup>1</sup> According to data extrapolated from the 2005 National Health Interview Survey, approximately 120 million people in the US suffer from various forms of chronic pain including low back pain (52 million), chronic migraine (30 million), head-neck pain (28 million) and jaw pain (9.5 million).<sup>2</sup> The annual fiscal burden on the United States is a growing problem. For example, in 1998, direct medical treatment cost and lost productivity were estimated at \$100 billion annually<sup>3</sup> and in 2012, the estimated costs were between \$560 and \$635 in the United States.<sup>4</sup> The most common categories of chronic pain include low back pain (52 million), chronic migraine (30 million), head-neck pain (28 million) and jaw pain (9.5 million).<sup>2</sup>

The evidence to support the safety and effectiveness of neurostimulation for the management of chronic pain syndromes is currently limited to a few randomized, controlled trials (RCTs) with few patients and very specific diagnoses and is largely based on numerous open label, uncontrolled studies and case series/case reports. For example, spinal cord stimulation (SCS) was shown to be statistically better than comprehensive medical management when treating patients with failed back surgery syndrome (FBSS) in the PROCESS study.<sup>5</sup> North and colleagues evaluated reoperation versus SCS in patients with a history of an initial failed back surgery. In that study, the end point of crossover at 12 weeks favored SCS over reoperation.<sup>6</sup> Kemler and colleagues evaluated SCS and physical therapy versus physical therapy alone in patients who met strict inclusion criteria for complex regional pain syndrome–Type I

(CRPS-I). In this study, the SCS group achieved greater pain relief at both the 6 month<sup>7</sup> and 24 month<sup>8</sup> follow-up. Although the results from these studies are important in demonstrating the safety and efficacy of neurostimulation, the nature of the inclusion criteria, randomization, and end points make the results difficult to generalize to every day clinical practice where neurostimulation is used to treat a variety of pain syndromes. In order to overcome these shortcomings, registries have been employed to assess patient outcomes and to compile a comprehensive database of “real-world” information that provides valuable insight on the effectiveness of neuromodulation devices without influencing healthcare provider decisions regarding proper treatment and care of chronic pain patients in the course of normal clinical practice. These non-controlled evaluations of therapy allow the observer to determine the value of a therapy in the clinical setting that most closely represents physician patient care

Several international registries evaluating the effectiveness of neurostimulation for the management of chronic pain have been conducted over the last two decades. Results from the first registry were published in 2002 and include data collected in patients between the years 1988 and 1999.<sup>9</sup> In this registry, 463 patients with chronic “vascular” or neuropathic pain were administered questionnaires to assess satisfaction, medication use, quality of life and complications. Overall, results were favorable among the 333 patients who completed the questionnaire with 81% percent reporting being satisfied with the therapy, 71% reporting reduced medication use, and 63% reporting an improvement in quality of life. Results from a registry designed to evaluate outcomes in patients diagnosed with spinal stenosis treated with spinal cord stimulation have been published more recently.<sup>10</sup> Results from this assessment of 69 patients between the years 1997 and 2005 were again favorable with clinically significant reductions on the visual analog scale, medication use and improvement in functional status at a

mean follow-up of 27 months. Plans for collection of patient data through additional registries seem inevitable as physicians at Aarhus University Hospital in Aarhus, Denmark have recently created a neuromodulation database designed to capture an exhaustive list of outcomes including pain intensity and quality, pain-related disability, function, quality of life, medical use.<sup>11</sup> “Real world” results from large multicenter registries like these are especially important as the algorithm for pain management evolves with the advent of evidence based medicine. The evaluation of a patient therapy can be characterized by the standard of the SAFE algorithm.<sup>12</sup> This algorithm suggests that a value of a treatment can be determined by the evidence that shows it is safe, appropriate, fiscally neutral, and effective. Since its approval by the FDA in 1989, neurostimulation techniques, including SCS, have traditionally been recommended as a last resort therapy for the management of chronic pain of the trunk and limbs. However, recent data showing both efficacy and cost effectiveness of this modality have led to a recommendation by many leaders in the field for an advancement of neurostimulation to an earlier position in the treatment continuum.<sup>6, 13-14</sup>

We recently completed enrollment in a large, multicenter, international registry developed to evaluate the safety and effectiveness of neurostimulation for the management of chronic pain conditions. We present data from an interim analysis of 579 patients across 40 investigational sites to supplement the amount of “real world” registry data available to physicians for consideration of use of this therapy.

## **Methods:**

### **Study Design and Participants**

Institutional Review Board (IRB) or Ethics Committee (EC) approval was obtained for all 40 sites (35 in the United States, 4 in Australia, and 1 in Colombia) prior to patient

enrollment. All patients enrolled in this registry signed and received a copy of the IRB/EC-approved informed consent form, had received permanent implant of a St. Jude Medical neuromodulation system within 30 days of enrollment, were 18 years of age or older and were not currently participating in another clinical study.

### **Effectiveness Measures:**

Patient assessments regarding baseline pain and functional levels prior to implant were collected retrospectively based on recall. Subsequent follow-up evaluations were collected during physician routine care visits at 3 months ( $\pm 30$  days), 6 months ( $\pm 30$  days), and 12 months ( $\pm 30$  days) post-implant. Pain relief was assessed by direct patient report of pain relief (percentage) and categorical ratings of pain relief. Patients were also assessed using the Pain Disability Index (PDI). Quality of life, patient satisfaction, medication use, and pain relief among (tobacco) smokers are also reported.

### **Statistical analysis:**

No artificial weighting or other adjustments were made to the data. Unless otherwise stated, descriptive statistics were compiled for all patient outcome measurements and data is reported as mean ( $\pm$  standard deviation). All statistical tests were one-sided t-tests with a significance level of  $\alpha=0.05$ , unless otherwise specified. Data regarding patient smoking is reported as mean ( $\pm$  standard error). Statistical analysis was performed using SPSS version 19 (IBM, Armonk, New York). All figures were generated using GraphPad Prism 6 (GraphPad, La Jolla, CA).

### **Safety analysis:**

Only device/procedure-related adverse events were collected. All event data were reviewed and classified into defined categories. The following categories were used: hardware-

related events, biological events, and stimulation-related events. Events were classified as “hardware-related” in cases of lead/IPG migration or if there was a malfunction of an implanted device. Events were classified as “biological” in cases where there was a biological reaction (hematoma, pain, etc.). Events were classified as “stimulation-related” if the event was known to be caused by stimulation. “Stimulation-related” events that resolved when the device was reprogrammed were not collected. Occurrence rates were calculated as the total number of adverse events in each category divided by the total number of adverse events.

## **Results:**

### **Patient Enrollment:**

Patient demographics and adverse events were available for 579 patients who received a neuromodulation system across 40 investigational sites. Follow-up data was obtained for 418 patients who completed the 3-month visit, 351 patients who completed the 6-month visit, and 252 patients who completed the 12-month visit. One hundred seventy-four (174) patients have currently withdrawn from the study. Among these patients, 63 patients were withdrawn by the investigator, 40 patients were lost to follow-up, 28 exited the study due to device related issues, 24 patients chose to withdraw consent, 9 patients exited due to adverse events, and 10 patients withdrew for “other” reasons.

### **Patient Demographics:**

Patient demographics are shown in Table 1. The mean ( $\pm$ SD) age of the patient was 54.0 ( $\pm$ 13.6) and 57.2% of patients were female. The majority (85.8%) of the patients were Caucasian. The primary diagnosis for the majority of enrolled patients was failed back surgery syndrome (n=269 or 46.5%), followed by radiculopathies (n=115 or 19.9%), Complex Regional Pain Syndrome types I and II (n=51 or 8.8%), chronic pain syndrome (n=32 or 5.5%),



degenerative disc disorder (n=29 or 5.0%), occipital neuralgia (n=10 or 1.7%), peripheral neuropathy (n=8 or 1.4%), neuralgia (n=8 or 1.4%), ischemic pain (n=6 or 1%), and migraine (n=6 or 1%). Additional diagnoses classified as “other” (n=41; 7.1%) included patients with neuropathies (n=8 or 1.4%), arachnoiditis (n=2 or 0.3%), and spinal stenosis (n=3 or 0.5%) —all remaining conditions classified as “other” at a rate of 1% or less. See Table 2 for additional information. The mean length of time since pain diagnosis was 9 years. At baseline, 70.1% of patients reported chronic pain in the lumbar spine, 43.7% reported bilateral leg pain, 27.3% reported unilateral leg pain, and 17.1% reported bilateral foot pain. Additional pain regions were recorded (Table 1). Forty-two percent (42.2%) of patients had private insurance.

#### **Device Information:**

The majority of patients (92.9%) were implanted with a rechargeable implantable pulse generator (IPG). Only 6.8% of patients received a conventional IPG. Over half the patients (406 or 70.1%) were implanted with single, dual or three percutaneous lead configurations consisting of 8-contact or 4-contact leads. In the remaining patients, 147 (25.4%) were implanted with a paddle lead (single or dual configurations), 18 (3.1%) received a percutaneous/paddle lead combination and the type of lead configuration was unknown in 8 (1.4%) of patients. Lead configuration and IPG type was determined by the physician for each patient.

#### **Patient Reported Pain Relief:**

Patients reported the percentage of pain relief (0% represents no relief; 100% represents complete relief) that the implant provided over the past week. Three months post-implant (Figure 1A), patients (n=411) reported 58.0% ( $\pm 26.2\%$ ) pain relief. Six months post-implant, patients (n=348) reported 58.2% ( $\pm 28.7\%$ ) pain relief. Twelve months post-implant, patients (n=249) reported 57.0% ( $\pm 29.4\%$ ) pain relief. Seventy-three percent (73.0%) of patients experienced

≥50% pain relief at three months (Figure 1B). At 6 and 12 months, 72.7% and 70.7% of patients, respectively, experienced ≥50% pain relief.

Pain relief among smokers and non-smokers is shown in Figure 2. Non-smokers reported a mean pain relief of 59.2% ( $\pm 3.3$ ); whereas, patients that currently smoked reported a significantly ( $p=0.04$ ) lower mean pain relief of 54.2% ( $\pm 2.4$ ).

### **Categorical Ratings of Pain Relief:**

Patients were asked to categorize their pain relief using the following categories: excellent, good, fair, or poor. Results are presented in Figure 3. At 3 months ( $n=414$ ), 69.1% of patients categorized their pain relief as excellent or good, 20.8% of patients reported their pain relief as fair, 5.6% reported pain relief as poor, and 4.6% were unable to decide. At 6 months ( $n=350$ ), 65.4% of patients categorized their pain relief as excellent or good, 20.1% reported their pain relief as fair, 10.0% reported pain relief as poor, and 4.3% were unable to decide. At 12 months ( $n=251$ ), 67.3% of patients categorized their pain relief as excellent or good, 18.3% reported their pain relief as fair, 8.4% reported their pain relief as poor, and 6.0% were unable to decide.

### **Pain Disability Index:**

The Pain Disability Index (PDI) measures the extent to which pain interferes with a patient's ability to function across seven categories: family/home responsibilities, recreation, social activity, occupation, sexual behavior, self care and life-support activities. Ratings are based on a scale from 0 (no disability) to 10 (total disability). At baseline, patients ( $n=565$ ) reported a mean PDI score of 47.1 ( $\pm 13.6$ ). Mean PDI scores were significantly reduced at 3 ( $n=407$ ), 6 ( $n=345$ ), and 12 months ( $n=242$ ) post-implant, to scores of 32.8 ( $\pm 17.1$ ), 31.4 ( $\pm 17.0$ ), and 31.5 ( $\pm 16.7$ ), respectively ( $p<0.0001$ ). PDI scores are displayed in Figure 4.

### **Quality of Life:**

Patients were asked if their quality of life had greatly improved, improved, neither improved nor deteriorated, deteriorated, or greatly deteriorated across 5 categories: general health, ability to sleep, ability to walk, general mood, and overall quality of life (Table 3). For general health, 78.5%, 73.2% and 66.7% of patients reported that compared to before the implant, their general health was improved or greatly improved at 3, 6, and 12 months post-implant, respectively. For sleep, 59.1%, 55.3% and 50.8% of patients reported that compared to before the implant, their ability to sleep was improved or greatly improved at 3, 6, and 12 months post-implant, respectively. Compared to before the implant, 70.8%, 65.3% and 64.7% of patients reported that their walking ability had improved or greatly improved at 3, 6, and 12 months post-implant, respectively. For mood, 68.2%, 59.0% and 59.5% of patients reported that compared to before the implant, their general mood had improved or greatly improved at 3, 6, and 12 months post-implant, respectively. Furthermore, 77.8%, 66.9% and 67.1% of patients reported that compared to before the implant, their overall quality of life was improved or greatly improved at 3, 6, and 12 months post-implant, respectively.

### **Medication Use:**

Medication use was evaluated at 3 months post-implant. Patients reported their medication usage over the last month (4 weeks) as one of five categories: increased, started, stayed about the same, decreased, or stopped. Six medication classes were examined: non-steroidal anti-inflammatory drugs (NSAIDs), narcotics/opioids, muscle relaxants, anti-convulsants, analgesics, or anti-depressant/psychotic (Figure 5). The percentage of patients who reported taking NSAIDs and either stopped or decreased their use of NSAIDs was 38.3%. The

percentage that stopped or decreased use of narcotics/opioids was 45.9%. Over a third of patients (36.6%) who were taking muscle relaxers reported that they stopped or decreased use of muscle relaxants. Of the patients taking anti-convulsants, 30.5% reported that they stopped or decreased use of anti-convulsants. For analgesics, 38.8% of patients reported that they stopped or decreased use, and 14.9% of patients reported that they stopped or decreased use of anti-depressants/psychotics.

### **Patient Satisfaction:**

Patients were asked to rate their satisfaction with SCS therapy as very satisfied, satisfied, neither satisfied nor dissatisfied, unsatisfied, or very unsatisfied. At 3 months post-implant, 84.4% of patients indicated that they were very satisfied or satisfied with the therapy. This rate of satisfaction was sustained throughout 6 and 12 months with 81.8% and 79.0% of patients respectively reporting being very satisfied or satisfied. Patients were also asked whether they would undergo the procedure again and whether they would recommend the procedure to someone else. Similar results were noted for these assessments of satisfaction with 75% or more of patients indicating that they would undergo the procedure again at all follow-up visits and greater than 83% of patients indicating that they would recommend the procedure to someone else (Figure 6).

### **Adverse Events:**

Ninety-two (92) patients experienced 111 adverse events (n=579). The most common event was lead migration (n=21), which accounted for 18.9% (21/111) of all reported events in 3.6% (21/579) of all patients. Persistent pain and/or numbness at IPG/lead site (n=18) accounted for 16.2% of all reported events in 3.1% of patients. Diminished or loss of therapy (n=15) occurred in 2.6% of patients and accounted for 13.5% of all reported events and infection (n=14)

accounted for 12.6% of all reported events in 2.4% of the patients. Table 4 outlines all device/procedure-related adverse events by category and action taken.

### **Discussion:**

This interim analysis reported on “real-world” clinical outcome data from a longitudinal clinical registry created to examine the effectiveness of SCS for the management of chronic pain of the trunk and/or limbs. Data was collected for 579 patients. Patient reported pain relief was **57% or greater** and the majority of patients categorized their pain relief as excellent or good at all **time-points** assessed. **More than 70%** of patients reported significant pain relief, defined as  $\geq 50\%$  pain relief. Interestingly, pain relief was significantly attenuated by smoking ( $p=0.042$ ). Mean PDI scores were significantly reduced from baseline at 3, 6 and 12 months post-implant and based on this reduction in scores it appears that SCS significantly reduced the impact that pain had on patient’s daily life. Most patients reported their overall quality of life as greatly improved or improved at all time-points and almost half of the patients (**45.9%**) stopped or decreased use of narcotics/opioids at 3 months. This reduction of narcotics/opioids in almost half of the patients is an impressive finding that has a direct relation with medical treatment cost reduction and increase of productivity. In addition, the majority of patients were satisfied or very satisfied with the therapy, indicated that they would undergo the procedure again and would recommend the procedure to someone else. These results suggests that almost 8 out of 10 patients are satisfied with SCS, almost 9 out of 10 patients are so satisfied from the overall benefits of SCS that are willing to undergo this procedure again, and impressively almost all of the patients would recommend SCS for pain treatment. The most common event was lead migration, which accounted for 18.9% of all reported events, which correlated to an incidence rate of 3.6% (21 events out of 579 implants) for all patients. This migration rate is favorable compared to

previously reported rates within the industry. For example, a systematic review which included incidence rates of adverse events reported in the literature noted a lead migration rate of 13.2% (261 events out of 2753 implants).<sup>15</sup>

The findings from this interim analysis are comparable to those observed in other registries designed to evaluate SCS for the management of chronic pain. For example, improvement in quality of life was shown for 63% of patients in a large Italian registry of SCS patients with vascular and neuropathic pain. In addition, 94% of patients were satisfied with the therapy and 87% would undergo the procedure again.<sup>9</sup> In a registry of patients implanted with an SCS system for the management of chronic pain from spinal stenosis, the mean overall pain reduction was 63% at 24 months and a significant reduction in consumption of opioid medications was noted.<sup>10</sup> The slight difference (6%) in pain reduction between our registry and the registry which included spinal stenosis patients may partially be explained by differences in the number and patient population in the registries. Our registry included data from approximately 250 patients whereas the other registry only contained 69 patients. Our registry also contained a very diverse patient population whereas the smaller registry only included patients with a specific diagnosis. These differences in design are likely contributors to the disparity.

An important and clinically interesting finding in this interim analysis was that smoking significantly attenuated pain relief. This finding is in line with other studies which have shown a negative impact of smoking on patient outcomes. Slover and colleagues demonstrated that change in Oswestry Disability Index scores following lumbar spine surgery was negatively impacted by smoking.<sup>16</sup> Behrend et al. also showed that compared with patients who had continued to smoke, those who had quit smoking during the course of treatment for axial or

radicular pain reported significantly greater improvement in VAS scores.<sup>17</sup> In addition, pain intensity is thought to be increased in smokers with back pain. Many smokers relate smoking to "coping" with the pain and as an anxiolytic, but the literature does not support that thought. Given this, it is not surprising that the response to SCS is not as good in this group, and suggests that smoking cessation should be considered in all patients considering this therapy.

Results from 2 sub-groups within the registry may provide interesting insight into recent hot topics within the field of neuromodulation. These sub-groups include patients implanted with a combination system comprised of a SCS system and a peripheral nerve field stimulation system for the management of chronic back pain and patients implanted with a peripheral nerve stimulation system for the management of headache disorders. At 3 months post-implant, results were available for 14 patients and at 6 months results were available for 13 patients implanted with a combination system. Overall, these patients reported greater pain relief (greater than 60% and 77% or more reported good or excellent pain relief at both time points) and more patients reported their quality of life as improved or greatly improved (greater than 76%) and being satisfied or very satisfied with the system (greater than 92%) than the general population. Among patients implanted with a peripheral nerve stimulation system for headache, 6 patients were diagnosed with chronic migraine and 9 patients were diagnosed with occipital neuralgia. Data was available for 5 chronic migraine patients at 3 months, 4 patients at 6 months and 5 patients at 12 months. Patient-reported pain relief again exceeded that seen among the general population with patients reporting 68% greater relief and 75% or more patients reporting excellent or good pain relief at all 3 time points. In addition all patients reported greatly improved or improved quality of life and being satisfied or very satisfied with the neurostimulation system. Pain relief, quality of life improvement and satisfaction were also high among patients diagnosed with

occipital neuralgia. Data from this patient cohort was available for 7 patients at 3 months and 5 patients at 6 months. The average patient reported percentage of pain relief was 65% or greater in these patients and 60% or greater of patients reported excellent or good pain relief at 3 and 6 months. Eighty percent or greater of patients reported greatly improved or improved quality of life and greater than 85% reported being very satisfied or satisfied with the therapy.

The results of this registry help further understanding of the overall impact of neurostimulation in a diverse patient population and complements data collected from randomized controlled trials regarding treatment patterns and patient reported outcomes. Compared to controlled studies such as the PROCESS multi-center analysis, the registry has equivalent results despite a heterogeneous population and variable diagnosis, symptoms and concomitant treatment options. This is encouraging when considering SCS therapies in the general population.

Patient reported pain relief was similar across all three time points, which is substantial when considering treatment durability. The Food and Drug Administration often requires 3 month effectiveness data and 6 month durability data. The ability of SCS to result in sustained pain relief, satisfaction, and quality of life suggests that SCS is a valuable therapeutic option in real life clinical practice.

### **Conclusion:**

The use of a patient registry is an emerging evaluation tool for the study of clinical use of neurostimulation to treat patients with chronic pain. The data shows an important and relevant treatment for a difficult patient population. The study suggests that neurostimulation is safe and effective with an acceptable complication rate, appropriate based on good patient response, and efficacious with an impressive number of patients experiencing good to excellent pain relief. In



addition, a significant number of patients reduced or eliminated their narcotic usage, which likely has implications for drug cost savings. The effectiveness is a substantial finding when considering the failure of most other alternatives prior to reaching entry into the registry. Based on these points we conclude that neurostimulation is an important and valuable treatment in chronic pain and the outcomes raise the strong possibility that earlier deployment of the therapy may reduce significant years of suffering as well as earlier restoration of functional capacity and quality of life improvement. Therefore, it should be considered much more often in patient care and earlier in the treatment algorithm.

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## Figure Legend

**Table 1.** Patient Demographics

**Table 2.** Patient Diagnoses.

**Table 3.** Quality of Life.

**Table 4.** Adverse events by Action Taken.

**Figure 1.** Patient Reported Pain Relief. (A) The mean Patient Reported Pain Relief from SCS was 58.0% ( $\pm 26.2\%$ ) at 3 months, 58.1% ( $\pm 28.7\%$ ) at 6 months, and 57.0% ( $\pm 29.4\%$ ) at 12 months. (B) 73.0%, 72.6%, and 70% of patients reported  $\geq 50\%$  pain relief at 3, 6, and 12 months, respectively.

**Figure 2.** Pain Relief Among Smokers and Non-Smokers. (A) Smoking (tobacco) significantly ( $p=0.042$ ) reduced pain relief by 8.4% [ $(59.2\% - 54.2\%)/59.2\%$ ]. (B) Non-smoking patients ( $n=295$ ) reported a mean pain relief of 59.2% ( $\pm 3.3$ ) and patients that smoke ( $n=112$ ) reported a mean pain relief of 54.2 ( $\pm 2.4$ ) at 3 months post-implant.

**Figure 3.** Categorical Ratings of Pain Relief. Patients reported categorical ratings of pain relief at 3, 6, and 12 months post-implant.

**Figure 4.** Pain Disability Index (PDI) Scores. At baseline, the mean PDI score was 47.7 ( $\pm 13.2$ ). At 3, 6, and 12 months the mean PDI scores significantly reduced to 33.3 ( $\pm 17.2$ ), 32.4 ( $\pm 17.0$ ), and 31.9 ( $\pm 16.9$ ), respectively.

**Figure 5.** Medication Use at 3 months post implant.

**Figure 6.** Patient Satisfaction. (A) Greater than 79% of patients reported that they were satisfied or very satisfied with the therapy at all timepoints assessed. (B) Greater than 75% of patients reported that they would undergo the procedure again. (C) Greater than 85% of patients reported that they would recommend the modality to others.