Health Services Research

Peripheral Nerve Stimulation for Intractable Chronic Pain: Real-World Clinical Outcomes, Utilization, and Economic Impact (PNS IMPACT Study)

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Background: Chronic pain imposes a substantial clinical and economic burden, as many patients undergo repeated procedures and high-risk opioids without durable relief, driving persistent health care costs and resource utilization.

Objectives: To evaluate whether established clinical outcomes can be replicated in real-world practice and to assess health care utilization and payer costs in a large cohort of patients treated with peripheral nerve stimulation (PNS).

Study Design: Hybrid single-center retrospective study (n = 175) combined with national claims analysis (n = 953). A site coordinator collected data independently of the treating physician.

Setting: Single US center supplemented by national claims data.

Methods: One hundred and seventy-five adults with chronic neuropathic pain underwent a PNS trial. Those achieving ≥ 50% pain relief were eligible for permanent implantation. Pain intensity was assessed with the Numeric Rating Scale (NRS-11) at baseline and up to 36 months post-implant. Health care utilization and payer costs were derived from CPT-coded encounters one year pre- to two years post-implant, supported by national claims data, with appropriate statistical testing applied.

Results: Of 175 patients, 163 (93%) achieved ≥ 50% pain relief during the trial, and 132 received permanent implants. Mean NRS-11 scores decreased from 7.2 ± 1.7 at baseline to approximately 1.7 ± 1.6 through 12 months, 1.4 ± 1.3 at 24 months, and 2.2 ± 1.8 at 36 months (all $P < 0.001$). No serious adverse events were reported. Pain center office visits decreased from 19.4 to 8.9 (54.1%) during months 0–12 (n = 103) and from 21.4 to 8.8 (58.9%) during months 13–24 (n = 50), with corresponding reductions in office-visit and pain management intervention costs (Wilcoxon $z \approx 2.8$–7.6; all $P < 0.001$). National claims analyses showed similar facility-use trends. Cost reductions totaled $10,271 over 2 years, with projected 3-year savings of $17,110–$18,586. Of 103 patients with 12-month data, 91% reported high pain scores at baseline despite use of opioids. Ninety percent subsequently discontinued, reduced, or maintained stable medication use.

Limitations: This analysis may be limited by coding variability, and differences between the EMR and claims datasets. Year-3 economic outcomes were projected from year-2 trends, though comparable patient characteristics support the relevance of the findings.

Conclusions: Permanent receiver-based PNS was associated with sustained pain reduction, no serious adverse events, and reduced health care utilization and costs in patients with chronic, intractable neuropathic pain of peripheral nerve origin. These findings support its clinical utility and potential economic value.

Key words: Health care utilization, peripheral nerve stimulation, neuropathic pain, safety, efficacy, opioids

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Chronic pain of peripheral nerve origin represents a significant and growing public health challenge, affecting millions of individuals in the United States, especially older adults, and contributing substantially to disability, health care utilization, and long-term economic burden (1). At the same time, the older adult population continues to increase, and national health expenditures continue to rise, underscoring the importance of evaluating therapies that may reduce downstream utilization and total cost of care. Patients suffering from intractable neuropathic pain often experience substantial functional impairment, diminished quality of life, and prolonged reliance on pharmacologic or procedural interventions (2,3). Despite a broad therapeutic armamentarium including oral analgesics, physical therapy, repeated trigger point injections, cryoneuroablation, radiofrequency ablation, alcohol or phenol neurolysis, hydrodissection, botulinum toxin, intrathecal opioids, spinal cord stimulation, and, in many cases open and more complex surgery, durable pain relief remains elusive for many patients, particularly those with longstanding or postsurgical neuropathic pain (4,5). As a result, these patients frequently cycle through care pathways characterized by repeated clinic visits, escalating costs, and variable clinical benefit (6). This cycle of suffering can persist for many years, as individuals pursue—often unsuccessfully—the right and effective therapy (7).

This study builds upon an extensive body of evidence, supporting peripheral nerve stimulation as an effective and safe therapy for chronic pain across a wide range of anatomical targets, including nerves of the upper extremity (e.g., suprascapular), lower extremity (e.g., infrapatellar saphenous, tibial), trunk (e.g., intercostal, superior cluneal), and craniofacial regions (e.g., trigeminal branches, occipital). The application of peripheral nerve stimulation (PNS) extends across multiple specialties, reflecting its multidisciplinary relevance, including interventional pain management, orthopedic and neurosurgery practice, where it is increasingly supported by evidence within multimodal chronic pain care. A randomized controlled trial (RCT) conducted under an FDA investigational device exemption by Hayek et al. studied complex craniofacial pain and supported the first PNS full body indication (8). The recently published study by Billet et al. (9) provides the highest clinical evidence through a multicenter, double-blinded RCT, reinforcing the evidence base by demonstrating significant pain reduction, functional improvements, and a confirmed safety profile. These findings are complemented by a robust body of prospective and retrospective clinical studies consistently showing durable efficacy, improved functionality, patient satisfaction, and opioid reduction (10-15). Fruh et al. evaluated PNS for chronic, refractory postsurgical knee pain, reporting a 75% pain reduction, significant improvements in quality of life, mood, sleep, and a notable 75% reduction in opioid usage (11). Orthopedic studies have demonstrated receiver-based PNS versatility, reporting consistent pain reduction with an average of 73%-87% across multiple peripheral nerves supporting broad applicability (14,15). This study extends the foundation by contributing real-world evidence from a large single-center cohort, further supplemented by national claims data, thereby enhancing the generalizability and external validity of prior findings.

Recent published health-economics work has also demonstrated that PNS was associated with lower health care resource utilization, reduced total medical costs, and decreased opioid use during the 12 months after implantation compared with the year before treatment (16). In that context, the present study extends the emerging literature by adding detailed EMR-derived clinical outcomes from a single multimodal pain practice, integrating supplemental all-cause national claims data, and exploring the potential persistence of economic effects through a scenario-based third-year analysis.

In addition to the strong body of evidence supporting its clinical effectiveness and utility, there is a clear opportunity to further characterize the longitudinal, real-world cost impact of PNS. The availability of long-term claims data enables evaluation of health care utilization trends over time among patients treated with this therapy. Notably, a longstanding National Coverage Determination (NCD 160.7) has supported receiver-based PNS for more than 30 years, ensuring sustained access for Medicare beneficiaries. Examining health care utilization trends to assess potential cost impact provides valuable insights for providers, payers, and policymakers on the broader economic and clinical value of PNS in managing chronic pain.

In practices that employ a true multimodal approach to pain management, clinicians are uniquely positioned to capture accurate real-world clinical and economic data across the full continuum of care. This environment allows for precise attribution of value when evaluating interventions such as PNS, given the extensive array of diagnostic blocks, therapeutic in-

jections, medication trials, and procedural strategies typically utilized before durable relief is achieved. The ability to quantify reductions in health care utilization is especially important in the current prescribing landscape, where opioid therapy carries substantial risks and contributes significantly to both societal and economic burden. Evidence has shown the increased risk for serious harms associated with long-term opioid therapy, including overdose, opioid abuse, fractures, myocardial infarction, and markers of sexual dysfunction (such as lowered testosterone and estrogen levels (17)); for some harms, the risk seems to be dose-dependent (18). Alternatives such as nonsteroidal anti-inflammatory agents (NSAIDs), acetaminophen (19), or anticonvulsants such as gabapentin, also have significant and potentially lethal side effects. Furthermore, drug class–specific adverse events include serious cardiovascular, gastrointestinal, and renal complications associated with NSAIDs, as well as sedation associated with anticonvulsant medications (20). Real-world evidence generated in multimodal settings can offer critical insights into how PNS can reduce costs, minimize reliance on high-risk pharmacologic strategies, and deliver sustainable long-term pain relief.

The broader health care landscape further underscores the need for rigorous real-world economic evaluations of therapies such as PNS. Rising health care costs, coupled with increasing pressure on insurers to limit coverage of certain treatments and procedures, have created a challenging environment for clinicians and patients seeking access to effective pain therapies. A modality that reliably reduces downstream utilization, minimizes procedure frequency, and decreases reliance on high-risk NSAIDs or potentially addictive opioids should be regarded as a strategically valuable intervention. Evidence demonstrating meaningful clinical effectiveness and long-term lowered cost impact would support the argument that receiver-based PNS is an effective treatment option that should be considered by insurance carriers and accessible for suitable chronic pain sufferers. Its combined clinical effectiveness and utility, as well as its economic advantages, position PNS as highly valuable modality for modern pain management.

To build on prior, favorable clinical effectiveness findings (8-15) and to fully understand the economic impact of PNS, we conducted a large retrospective analysis of pain relief, health care utilization and costs in patients treated with a receiver-based PNS system and followed these patients for 12 and 24 months. Drawing upon real-world data derived directly from electronic medical records; including pain relief, medical utilization, procedural and episode costs, this study provides a comprehensive assessment of both the therapeutic and economic value of PNS. In addition, medical resource consumption extramural to the study venue was obtained using national administrative claims data. These supplemental claims data were adjusted to reflect a population similar to that of the study site. The findings offer important insights for clinicians, payers, and health system leaders seeking effective, scalable, and economically sustainable solutions for intractable neuropathic pain.

Methods

This retrospective pre/post study was exempted from review by the WCG Institutional Review Board (IRB; #1-1769889-1).

Patient Selection

This retrospective analysis of real-world outcomes was conducted at a single private interventional pain practice that has provided multimodal chronic pain care for more than 10 years. The practice primarily delivers care reimbursed through insurance in a routine community setting rather than a concierge or cash-only model, which is relevant when considering external validity and generalizability. The study included 175 patients who received a PNS trial (at least 7 days) at various nerve targets to address chronic pain of peripheral nerve origin, and the subsequent 132 patients who noted $\geq$ 50% relief and went forward to receive a PNS system (Index Event). A retrospective study of the electronic medical records (EMR) was conducted to assess clinical baseline and follow-up parameters previously defined.

All patients were required to be at least 18 years old and to have a confirmed diagnosis of chronic pain of peripheral nerve origin based on initial physician examination and appropriate testing. Patients with any implanted neurostimulation devices in addition to the PNS system were excluded. Index Event cases were collected between October 2019 and March 2025. Data collection was performed independent of the practicing physician.

Supplementing the large single-site study cohort (primary dataset), claims from patients having a permanent PNS procedure for chronic pain in 2022 or 2023 and possessing a similar comorbidity burden to that of the single-site (secondary dataset) were included and derived from a multi-payer US claims database. The Age-adjusted

Charlson Comorbidity Index (ACCI) was selected to make this comparison. The ACCI is a weighted comorbidity score that sums 17 predefined chronic conditions, then each is assigned a weight according to its association with mortality or health care resource use in order to quantify overall comorbidity burden for risk adjustment and prognostic modeling in clinical and outcomes research (21).

Procedure Description (Index Event)

The PNS system used in this study (Freedom® Peripheral Nerve Stimulation System by Curonix LLC, Pompano Beach, FL) includes an implanted electrode array (with four or eight contacts), a separate implanted receiver, as well as a transmitter assembly and wearable accessory (Fig. 1). The transmitter uses HF-EMC (high-frequency electromagnetic coupling) technology to wirelessly transfer data and power to the 2-component implant that the physician connects and implants during the procedure. The physician is also required to create a separate, distinct pocket to permanently anchor the device. The procedure is typically performed in an outpatient setting. The Freedom PNS System is full body magnetic resonance imaging (MRI) conditional at both 1.5 and 3 tesla with the ability to scan over the implant (See full MR conditions in the Instructions for Use at curonix.com).

Demographic and Diagnostic Profiles - Single Operator

As noted above, all 175 included patients were diagnosed with chronic pain of peripheral nerve origin. Mean pain scores at pre-procedure baseline were recorded at 7.2 ± 1.7 with a verbally administered Numeric Rating Scale (NRS-11). Chronic knee pain was reported by 77 (44%) patients, 43 (25%) had lower back pain, 39 (22%) had pain in the foot/ankle, 7 (4%) had pain in the shoulder, 5 (3%) in the hip, and 4 (2%) in the wrist/hand. The mean age was 68.3 ± 12.8 years; 52 patients (30%) were men, and 123 (70%) were women (Table 1). All patients received a PNS trial lasting at least 7 days. One hundred and thirty-two patients proceeded to a permanent implant, 118 were followed for at least 3 months, 103 for 6 months, 103 for 12 months, 50 for 24 months and 17 for 36 months (Table 2). The study results are based on available clinical data for each patient; at the time the data was collected. The study does not report attrition, as most of these patients remain active within the practice. Each follow-up timepoint reports the patients and available data at the time of data collection. For example, the patients reported within the 12 months follow-up are those patients that have reached a 12 month follow-up within the practice at the time of the study data collection. In terms of patient comorbidity profiles, this EMR data was characterized by a mean ACCI score of 3.0, with no patients receiving a score of 7 or more (on a scale up to 19 points).

The national claims dataset was queried to identify permanent PNS recipients with diagnostic and comorbidity profiles similar to that of the single-operator's

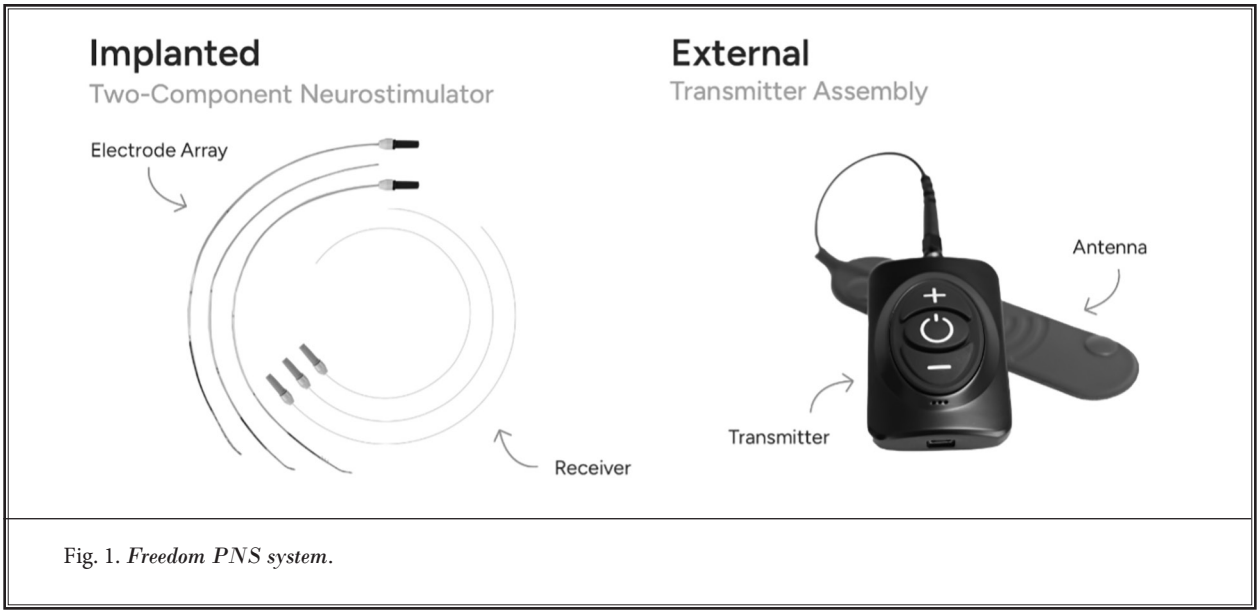


Fig. 1. *Freedom PNS system.*

cohort. Nine hundred and fifty-three patients met these criteria, with final data summary outputs focused on the utilization and cost of institutional (non-office) settings. Community office visit utilization was also captured to validate findings from the single center's EMR. Similar to the EMR dataset, this national claims-set yielded a mean ACCI score of 2.7 and any patient with a score of 7 or more was excluded (Tables 3a and 3b).

Data Analysis

The primary effectiveness analysis utilized the NRS-11, which is an 11-point scale that ranges from 0 (no pain) to 10 (worst pain imaginable), to assess pain reductions. Patients verbally reported the NRS-11 before treatment with the PNS system after a trial period and at various encounters. A 3-month, 6-month, 12-month, 24-month, and 36-month follow-up score was collected to assess the percentage of pain relief at the regular intervals.

Adverse events (AE; any undesirable experience associated with the use of a medical product in a patient) were reported descriptively and classified as serious AEs (SAE; the event is serious and reportable to the FDA when the patient outcome is death, hospitalization, disability or permanent damage, congenital anomaly or birth defect, required intervention to

Table 1. *Colorado Pain Care demographics.*

Demographic	n	%
Gender		
Male	52	30%
Female	123	70%
Age		
Mean	68.28	NA
Pain Location		
Knee	77	44%
Low Back	43	25%
Lower Extremities	39	22%
Shoulder	7	4%
Hip	5	3%
Upper Extremities	4	2%

Table 2. *Colorado Pain Care patient flow (PNS trial through 36 month follow-up).*

Stage of Study	n	% of Trialed (n = 175)
Trialed for Freedom PNS	175	100
Successful trial (≥ 50% pain relief)	163	93
Proceeded to permanent implant	132	75
With ≥ 3 month post implant follow up	118	67
With 6-month follow up	103	59
With 12-month follow up	103	59
With 24-month follow up	50	29
With 36-month follow-up	17	10

Table 3a. *Baseline patient characteristics: Colorado Pain Care vs national claims cohort (12 month cohort).*

Characteristic	Colorado Pain Care (n = 103)	National Claims Cohort (n = 953)	Z Score / χ^2	*P*-Value
Age (years)	66.8	65.4	1.04	0.299
Gender (% women)	72.8	66.9	1.05	0.292
Payer coverage (%)			χ^2 = 667.2	< 0.001
Commercial	33.0	13.2		
Medicare Advantage	22.3	52.9		
Medicare FFS	42.7	26.8		
Medicaid	0.0	5.60		
Other	2.0	1.8		
ACCI Score (mean/median)	3.0/3.0	2.7/3.0	1.56	0.120
ACCI Score Categories (%)			χ^2 = 3.63	0.304
0	9 (8.7)	86 (8.9)		
1-2	29 (28.1)	334 (34.6)		
3-4	46 (44.7)	423 (43.9)		
5-6	19 (18.5)	121 (12.6)		
Total	103 (100)	964(100)		

(a) Derived from Colorado Pain Care (n = 103), represents pain-related care only for Freedom PNS recipients
(b) Derived from National Claims Cohort (n = 953), represents all-cause care for any chronic pain permanent PNS treatment
Test statistics: Z scores from Wilcoxon rank sum tests (non-parametric comparisons of continuous variables); χ^2 values from Pearson chi-square tests for categorical variables.

Table 3b. *Baseline patient characteristics of Colorado Pain Care vs national claims (24 month cohort).*

Characteristic	Colorado Pain Care (n = 50)	National Claims Cohort (n = 406)	Z Score / χ^2	*P*-Value
Age (years)	67.7	65.1	Z = 1.17	0.243
Gender (% women)	80.0	68.7	Z = 1.53	0.127
Payer coverage (%)			χ^2 = 309.33	< 0.001
Commercial	26.0	15.0		
Medicare Advantage	22.0	47.5		
Medicare FFS	50.0	29.3		
Medicaid	0.0	6.1		
Other	2.0	1.9		
ACCI Score	3.1	3.0	2.470	0.013
ACCI Category (%)			χ^2 = 6.00	0.112
0	4 (8.0)	43 (10.5)		
1–2	12 (24.0)	152 (37.0)		
3–4	25 (50.0)	176 (42.9)		
5-6	9 (18.0)	39 (9.5)		
Total	50 (100)	410 (100)		

(a) Derived from Colorado Pain Center (n = 50), represents pain-related care only for Freedom PNS recipients
(b) Derived from National Claims Cohort (n = 406), represents all-cause care for any chronic pain permanent PNS treatment
Test statistics: Z-scores from Wilcoxon rank-sum tests (non-parametric comparisons of continuous variables); χ^2 values from Pearson chi-square tests for categorical.

prevent permanent impairment of damage, or other important medical event), nonserious AEs, and/or unrelated AEs.

A payer cost impact analysis included health care resource utilization and the associated costs through the collection of CPT codes aggregated at the encounter including visit (evaluation and management - E&M) and pain management intervention (PMI) codes from all patients as reported in the EMR one year before the permanent implant and compared to the CPT codes as reported 2 years after the permanent implants in all patients that had at least 2 years of follow-up. This single-site EMR data source provided the authors with community office visit and in-office PMI data (e.g., physical therapy, nerve blocks, injections) as well as opioid medication data.

In order to validate, strengthen and broaden the site findings, researchers utilized the AcuityMD (Boston, MA) national administrative claims database to identify and analyze patients that received a permanent peripheral nerve stimulator for chronic pain management. The administrative claims data were adjusted to reflect the patient comorbidity profile of the single-site's patient cohort (Tables 3a and 3b). These datasets provided community office visits to validate the site data referenced above and also offered institutional utilization at 3 places of service: Ambulatory Surgery Centers (ASC), Hospital Outpatient Department (HOPD), and Emergency Department (ED).

It is also important to note that the all-cause (all health care related encounters) national claims data was assessed to ensure that the vast majority of the reported care was pain related. After extensive procedure code reviews by coding and physician experts, we confirmed that over 90% of the ASC and HOPD care was pain related. We did not perform this study for ED for 2 reasons: ED did not contribute meaningful utilization or financial findings and the reasons for most of the ED visits were not readily available.

Statistical Analysis

All analyses were conducted on the analytic cohort of patients who underwent PNS implantation and had pre- and post-procedure data over the defined observation windows. Statistical significance was assessed using 2-sided tests with an α level of 0.05. All statistical analyses were performed using Stata/BE version 19.5 (StataCorp LLC, College Station, TX, USA).

For continuous and/or ordinal variables (e.g., age, ACCI, outcome measures), the mean and SD, and when it was informative, the median and interquartile range (IQR), were also reviewed (but not reported in all cases). For categorical variables (e.g., gender, payer, and ACCI categories such as 0, 1, 2, ≥ 3), counts and percentages

were reported. For the 3 primary outcome domains: (1) pain severity (NRS-11 scores), (2) health care utilization (i.e., number of PMI, ED, HOPD, ASC and office visits per patient in the pre- and post-PNS periods), and (3) analgesic use (e.g., morphine milligram equivalents, MME), pre- and post-PNS values were summarized using mean and median.

Because the same patients were observed before and after the PNS procedure (Index Event), all inferential comparisons of pre- and post-PNS values used paired tests. For each of the 3 outcome domains (clinical outcomes of NRS-11 pain scores; utilization rates for PMI, ED, HOPD, ASC and office visits; and MME values to estimate pain medication usage), the within-patient difference between the post-PNS and pre-PNS values was calculated.

Statistical distributions for cost, utilization, and opioid variables were evaluated using histograms, normal Q–Q plots, and skewness–kurtosis tests for normality (not shown). All variables showed marked departures from normality, with highly significant skewness and kurtosis (all joint skewness–kurtosis tests $P < 0.001$). Given these non-normal, right-skewed distributions, Wilcoxon signed-rank tests were used as the primary method for unadjusted pre–post comparisons. Because the Stata software reports the Wilcoxon statistic as a standardized normal deviate, we present the resulting z-statistics and associated *P*-values as the test outputs. These z-values reflect the normal approximation to the underlying Wilcoxon statistic rather than a separate parametric z-test.

Cost Outcomes Associated with Utilization and Opioid Drug Use

For each patient, costs associated with each utilization category (pain office visits, PMI, ED, HOPD, ASC) and with analgesic/opioid drugs for the pre-PNS and post-PNS periods (e.g., total cost per patient) were calculated or reported using payer allowed amounts. For the single-site EMR data, normative allowed amount data from CMS Medicare fee-for-service schedules (or 150% of Medicare for commercially insured patients) was applied to the CPT utilization. For the national claims data, payer allowed amounts were available within the final data extract.

For each cost component, pre- and post-PNS values were summarized using means and medians given the expected skewness of cost data. Paired comparisons of costs between the pre- and post-PNS periods were then performed. Given that distributions of cost differences were non-normal, the Wilcoxon signed rank test was used to assess statistical significance and the associated Z scores and *P*-values were reported for each pair.

Results

Patient Characteristics, and Comorbidity

Comorbidity burden, measured using the ACCI, was moderate to high in both the single-site cohort and the national claims-based cohorts. Among single-site patients (n = 103), the mean ACCI was 3.0 (SD 1.6), with a median of 3 (IQR 2–4) and scores ranging from 0 to 6; 63% of patients had ACCI ≥ 3, 28% had ACCI scores of 1–2, and 9% had no recorded comorbid conditions, indicating substantial medical complexity in the single-site cohort. In the national claims 12- and 24-month follow-up cohorts, ACCI distributions were similar (2.7), with most patients clustering in the 2–4 range and a comparable proportion exhibiting higher comorbidity burden. Across both follow-up periods, chi-square tests of ACCI category frequencies and Wilcoxon rank-sum tests of ordinal ACCI distributions showed no statistically significant differences at the 0.05 significance level between single-site and national claims cohorts, supporting comparability in comorbidity burden and justifying the use of national claims data to extend single-site findings (Tables 3a and 3b).

Our approach of using ACCI to demonstrate comparable comorbidity burden between patients receiving PNS in a single pain clinic and those identified in a national claims–based cohort aligns with prior work showing that ACCI functions as a robust summary measure in both medical record–based and administrative claims settings. Austin et al. (21) demonstrated that a claims-derived Charlson score had nearly identical discriminative performance to models using individual comorbidities in SEER–Medicare data and provided theoretical and simulation-based justification that comorbidity summary scores can be used in place of their individual components for prognosis and adjustment. This supports the use of ACCI derived from single-site medical records and from national claims data to generalize single-site findings to a broader treated population.

Clinical Effectiveness

Following careful patient selection and with the benefit of a mature practice and health care team experienced with PNS, 163/175 patients (93%) achieved a successful trial outcome, reporting at least 50% pain

relief at the end of the trial period. Patients (n = 175) reported an average pain reduction of 78% ($P < 0.001$) with post-trial implant mean pain scores of 1.6 ± 1.8, down from 7.2 ± 1.7 at baseline. At this point in time, 31 of the patients with a positive trial have not yet received a permanent implant for various reasons (e.g., insurance denial, awaiting implant procedure). One hundred and thirty-two patients with a positive trial moved forward to permanent implantation. One hundred and eighteen of these patients had a permanent implant for at least 3 months, with follow-up assessment at 6 months (n = 103), 12 months (n = 103), 24 months (n = 50), and 36 months (n = 17) post-permanent implant. Responder rates throughout follow-up were 110/118 (93%) at 3 months, 96/103 (93%) at 6 months, 90/103 (87%) at 12 months, 46/50 (92%) at 24 months and 13/17 (76%) at 36 months. The mean NRS-11 score decreased from baseline (7.2 ± 1.7) to 1.4 ± 1.6 (80%; $P < 0.001$) at 3 months, to 1.5 ± 1.5 (80%; $P < 0.001$) at 6 months, to 1.7 ± 1.6 (77%; $P < 0.001$) at 12 months, to 1.4 ± 1.3 (80%; $P < 0.001$) at 24 months and to 2.2 ± 1.8 (69%; $P < 0.001$) at 36 months (Fig. 2). These results demonstrate both clinical and statistically significant pain relief associated with PNS.

Among 103 patients in the single-center cohort 9/103 (9%) reported no opioid medication use at baseline or throughout follow-up while 94/103 (91%) were taking opioid medications at baseline yet continued to report high pain scores averaging greater than 7, indicating inadequate pain control and the need to pursue alternative treatment options. Overall, of the 94 patients taking opioid medication, 85/94 (90%) initially reporting opioid usage either discontinued, reduced, or maintained similar opioid use at 12 months. Among patients using opioid medication at baseline, 48/94 (51%) reduced (n = 40) or discontinued (n = 8) opioid medication, while 37/94 (39%) maintained the same opioid medication use without change from baseline. Out of fifty patients with 24-month follow-up data, 48/50 (96%) were taking opioid medications at baseline. Of those 48 patients 37/48 (77%) either discontinued, reduced, or maintained similar opioid use at 24 months. Of these, 28/48 (58%) reduced (n = 24) or discontinued (n = 4) opioid medication use, while 9/48 (19%) reported no change in medication use from baseline.

According to the Centers for Disease Control and Prevention 2022 Clinical Practice Guideline for Prescribing Opioids for Pain, opioid dosage is associated with varying levels of risk. The guideline reviewed multiple studies evaluating lower opioid dosages (< 50 MME/day), medium dosages (50-90 MME/day), and higher dosages (> 90 MME/day), along with the risks associated with each dosage category (22). In our study, we analyzed the patients that reduced opioids from baseline at 12 months 48/94 (51%) of which, 17 patients were receiving high-dose opioids (> 90 MME/day), 17 were receiving medium doses (50-90 MME/day), and 14 were receiving low doses (< 50 MME/day). At 12 months, the number of patients receiving high-dose opioids decreased from 17 to 7, while the number receiving medium doses decreased from 17 to 12 and 8 patients discontinued opioid medication (Fig. 3).

In the 24-month cohort, 28 of 48 patients (58%) demonstrated a reduction in opioid use from baseline to 24 months. Among these patients, 11 were receiving high-dose opioids (> 90 MME/day), 13 were receiving medium-dose opioids (50-90 MME/day), and 4 were receiving low-dose opioids (< 50 MME/day) at baseline. By 24 months, the number of patients receiving high-dose opioids decreased from 11 to 2, while the number receiving medium-dose opioids decreased from 13 to 11. Four patients discontinued opioid use altogether (Fig. 4).

Safety

Of the 175 patients trialed and 132 implanted no serious adverse events were reported throughout the follow-up period. Seven out of 175 (4%) patients reported a nonserious adverse event. Two patients reported erosions (one revised; one explanted), 2 noted superficial infections (one revised; one explanted), and 1 due to loss of therapy (explanted). One flare-up and one infection required no intervention. No other complications were reported.

Health Care Resource Utilization and Cost Comparisons

For these comparisons, mean values are reported in this section of the results for each outcome category while both mean and median values are reported in Tables 4 and 5. Median differences are used for the non-normal tests of significance (p-values).

Health Care Resource Utilization: 12-Month Follow-up

Inferential analysis using the Wilcoxon signed-ranked test revealed substantial reductions in pain-related office-visits, PMI utilization, HOPD services and ASC services from 12 months pre-index compared

to the 12-month follow-up period. Pain-related office visits declined by 10.5 (19.4 vs. 8.9, 54.1%; $P < 0.001$), PMI utilization declined by 4.3 (4.9 vs. 0.6, 87.8%; $P < 0.001$), MME usage decreased during the post-index 12-month timeframe by 17.7 (66.1 vs. 48.4, 26.8%; $P < 0.001$). HOPD services decreased by 0.6 (3.4 vs. 2.8, 17.6%; $P < 0.001$) and ASC services decreased by 0.6 (1.5 vs. 0.9, 40.0%; $P < 0.001$). Emergency room services were unchanged from pre-to-post 12 months (1.0 vs. 1.0, 0.0%; $P = 0.382$) (Table 4a).

Health Care Cost Comparison: 12-Month Follow-up

Average total costs decreased by $4,896 per patient (35.4%) during the 12 months post-index procedure compared to the 12 months pre-index. This decrease is attributed to significant payer cost savings for pain-related office visits of $1,531 ($2,779 vs. $1,248, 55.1%; $P < 0.001$), PMI utilization of $737 ($1,166 vs. $429, 63.2%; $P < 0.001$), MME utilization of $133 ($495 vs. $362, 26.9%; $P < 0.001$), HOPD services of $655 ($2,625 vs. $1,970, 25.0%; $P < 0.001$), and ASC services of $1,859 ($5,794 vs. $3,935, 32.1%; $P < 0.001$) (Table 4b).

Health Care Resource Utilization: 24-Month Follow-up

The subgroup analysis of patients that had 24 months of follow-up sustained reductions in pain-related office visits, PMI utilization, HOPD services, and ASC services from 12 months pre-index compared to the 24-month (months 13–24) follow-up period. Pain-related office visits declined by 12.6 (21.4 vs. 8.8, 58.9%; $P < 0.001$). PMI utilization declined by 5.4 (6.0 vs. 0.6, 90.0%; $P < 0.001$). MME usage decreased by 19 (67.0 vs. 48.0, 28.4%; $P = 0.002$). HOPD services decreased by 1.3 (3.7 vs. 2.4, 35.1%; $P < 0.001$). ASC services decreased by 1.0 (1.7 vs. 0.7, 58.8%; $P < 0.001$). Emergency room services were relatively unchanged, with a modest non-significant decline of 0.2 observed during months 13–24 (1.1 vs. 0.9, 18.2%; $P = 0.341$). For the 24-month subgroup analysis, the results are similar in both direction and magnitude when comparing health care resource utilization for the 12 months pre-index to post-index 12 months (Table 5a).

Health Care Cost Comparison: 24-Month Follow-up

Average total costs decreased by $10,271 per patient across the 24-month post-index timeframe

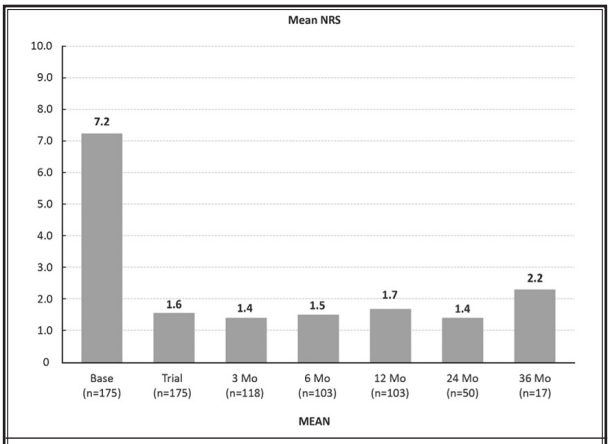


Fig. 2. *Mean NRS-11 scores.*

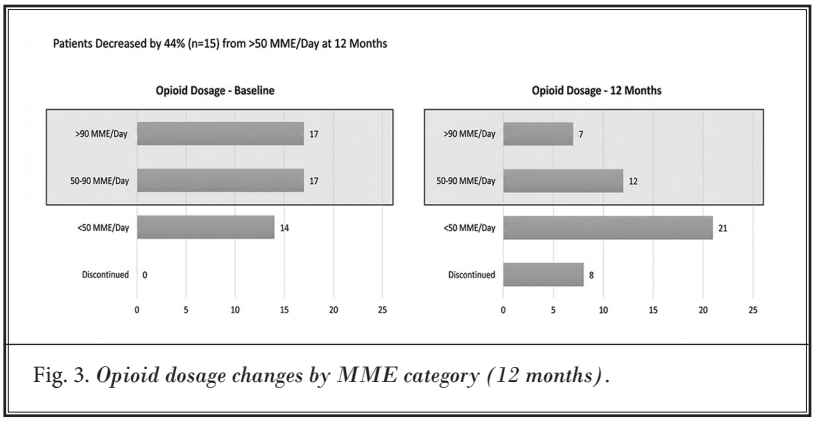


Fig. 3. *Opioid dosage changes by MME category (12 months).*

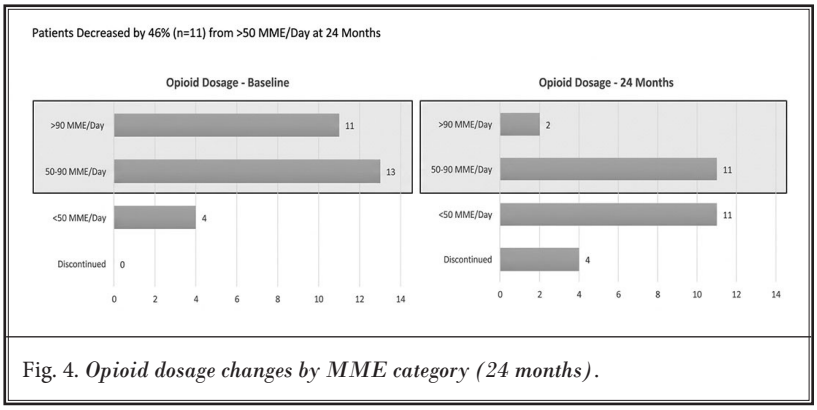


Fig. 4. *Opioid dosage changes by MME category (24 months).*

Table 4a. *Average health care resource utilization for recipients of PNS system (12 mos. pre-index and 12 mos. post-index).*

Health Care Resource	12 months pre-index procedure Mean (Median)[d]	12 months post-index procedure Mean (Median)	Mean Post/Pre difference	Mean Post/Pre percent difference	*P*-Value	Z-Score[e]	Effect Size[f]
Office Visits[a]	19.4 (18.0)	8.9 (8.0)	-10.5	-54.1%	< 0.001	-8.33	-0.83
Pain Management Interventions[a]	4.9 (3.0)	0.6 (0.0)	-4.3	-87.8%	< 0.001	-8.43	-0.89
Opioid Medication (MME)[a, b]	66.1 (45.0)	48.4 (40.0)	-17.7	-26.8%	< 0.001	-5.26	-0.52
Hospital Outpatient Department Services[c]	3.4 (2.0)	2.8 (1.0)	-0.6	-17.6%	< 0.001	-5.63	-0.22
Ambulatory Surgical Center Services[c]	1.5 (1.0)	0.9 (0.0)	-0.6	-40.0%	< 0.001	-10.37	-0.45
Emergency Room[c]	1.0 (0.0)	1.0 (0.0)	0.0	0.0%	0.382	-0.87	-0.04

(a) Derived from Colorado Pain Care (n = 103), represents pain-related care only for Freedom PNS recipients
(b) Derived from Colorado Prescription Drug Monitoring Program (PDMP) Database
(c) Derived from National Claims Cohort (n = 953), represents all-cause care for any chronic pain permanent PNS treatment
(d) PNS trial and permanent activity (CPTs 64555 & 64590) were removed from the pre period to ensure the pre and post periods were comparable.
(e) Standardized non-parametric Wilcoxon Signed-Rank test of post/pre median differences
(f) Cohen's r effect size, where negative values indicate reductions after PNS implantation and positive values indicate increases.

Table 4b. *Average reimbursement for recipients of PNS system (12 mos. pre-index and 12 mos. post-index).*

Health Care Resource	12 months pre-index procedure Mean (Median) [d]	12 months post-index procedure Mean (Median)	Mean Post/Pre difference	Mean Post/Pre percent difference	*P*-Value	Z-Score[e]	Effect Size[f]
Office Visits[a]	$2,779 ($2,719)	$1,248 ($1,112)	-$1,531	-55.1%	< 0.001	-8.43	-0.84
Pain Management Interventions[a]	$1,166 ($794)	$429 ($0)	-$737	-63.2%	< 0.001	-7.45	-0.79
Opioid Medication (MME)[a, b]	$495 ($337)	$362 ($300)	-$133	-26.9%	< 0.001	-5.26	-0.52
Hospital Outpatient Department Services[c]	$2,625 ($374)	$1,970 ($180)	-$655	-25.0%	< 0.001	-4.92	-0.18
Ambulatory Surgical Center Services[c]	$5,794 ($1,051)	$3,935 ($0)	-$1,859	-32.1%	< 0.001	-10.68	-0.42
Emergency Room[c]	$977 ($0)	$996 ($0)	$19	1.9%	0.5860	-0.54	-0.01
Total	$13,836	$8,940	-$4,896	-35.4%	NA[g]	NA[g]	NA[g]

(a) Derived from Colorado Pain Care (n = 103), represents pain-related care only for Freedom PNS recipients
(b) Derived from Colorado Prescription Drug Monitoring Program (PDMP) Database
(c) Derived from National Claims Cohort (n = 953), represents all-cause care for any chronic pain permanent PNS treatment
(d) PNS trial and permanent activity (CPTs 64555 & 64590) were removed from the pre period to ensure the pre and post periods were comparable.
(e) Standardized non-parametric Wilcoxon Signed-Rank test of post/pre median differences
(f) Cohen's r effect size, where negative values indicate reductions after PNS implantation and positive values indicate increases.
(g) Statistical testing of the total post/pre cost difference was not performed due to national claims data restrictions, precluding valid estimation of variance and confidence intervals for the total cost measure.

compared to the pre-index period. The majority of the cost reductions (67%) were recognized during months 13–24 ($6,839 savings) of the 24-month comparison, with savings observed for pain-related office visits of $1,718 ($2,945 vs. $1,227, 58.3%; $P < 0.001$), PMI utilization of $982 ($1,117 vs. $135, 87.9%; $P < 0.001$), MME utilization of $143 ($501 vs. $358, 28.5%; $P = 0.002$), HOPD services of $1,025 ($2,841 vs. $1,816, 36.1%; $P < 0.001$), and ASC services of $2,777 ($5,804 vs. $3,027, 47.8%; $P < 0.001$). For the 24-month subgroup analysis, the results for all but ASC are similar in both direction and magnitude when comparing health care costs for the 12 months pre-index to post-index 12 months (Table 5b). For ASC, the 13-24 month

Table 5a. *Average health care resource utilization for sub-group analysis of recipients of PNS system (12 mos. pre-index and 24 mos. post-index).*

Health Care Resource	12 months pre-index procedure Mean (Median)[d]	12 months post-index procedure Mean (Median)	Mean Post/Pre difference	Mean Post/ Pre percent difference	Months 13-24 post-index procedure Mean (Median)	Mean Post/ Pre 13-24 month difference	Mean Post/ Pre 13-24 month percent difference	*P*-Value	Z-Score[e]	Effect Size[f]
Office Visits[a]	21.4 (19.5)	10.8 (9.5)	-10.6	-49.5%	8.8 (9.0)	-12.6	-58.9%	< 0.001	-5.98	-0.85
Pain Management Interventions[a]	6.0 (4.0)	0.7 (0.0)	-5.3	-88.3%	0.6 (1.0)	-5.4	-90.0%	< 0.001	-3.65	-0.94
Opioid Medication (MME)[a, b]	67.0 (50.0)	49.0 (45.0)	-18.0	-26.9%	48 (50.0)	-19.0	-28.4%	0.002	-3.05	-0.43
Hospital Outpatient Department Services[c]	3.7 (2.0)	3.0 (1.0)	-0.7	-18.9%	2.4 (1.0)	-1.3	-35.1%	< 0.001	-6.42	-0.32
Ambulatory Surgical Center Services[c]	1.7 (1.0)	1.0 (0.0)	-0.7	-41.2%	0.7 (0.0)	-1.0	-58.8%	< 0.001	-7.08	-0.45
Emergency Room[c]	1.1 (0.0)	1.0 (0.0)	-0.1	-9.1%	0.9 (0.0)	-0.2	-18.2%	0.341	-0.95	-0.07

(a) Derived from Colorado Pain Care (n = 50), represents pain-related care only for Freedom PNS recipients
(b) Derived from Colorado Prescription Drug Monitoring Program (PDMP) Database
(c) Derived from National Claims Cohort (n = 406), represents all-cause care for any chronic pain permanent PNS treatment
(d) PNS trial and permanent activity (CPTs 64555 & 64590) were removed from the pre period to ensure the pre and post periods were comparable.
(e) Standardized non-parametric Wilcoxon Signed-Rank test of post/pre median differences
(f) Cohen's r effect size, where negative values indicate reductions after PNS implantation and positive values indicate increases.

(second year) cost reductions are notably higher than that of months 1-12.

Together, these findings substantiate that the intervention was associated with statistically significant, durable reductions in health care utilization, costs, and pain intensity, with meaningful clinical effects on prescribed opioid exposure over the follow-up period. These results are summarized in the following tables (Tables 4a, 4b, 5a, 5b). All costs are reported as payer allowed amounts. The post-index period includes costs associated with routine follow-up care and index-period treatment episodes captured within the analytic window. No inflation adjustment was applied because the primary objective was within-patient pre/post comparison rather than estimation of inflation-adjusted national spending.

Scenario Based 3 Year Cost Projections

To estimate economic impact over a longer horizon, we applied a conservative "second year carryover" approach that assumes the observed year 2 utilization patterns persist into year 3 (Table 6). Under this assumption framework, modeled resource use continues to decrease over time, consistent with the observed reductions in pain medication use. From an economic perspective, this conservative cost impact model estimated cumulative per patient savings of $10,271 by 2 years after PNS implantation and $17,110 by the end of year 3, relative to baseline care (Table 6).

Table 7 presents a scenario analysis in which modest incremental reductions are applied to year 2 utilization for office visits, pain medications, HOPD visits, and ASC procedures, while other categories (e.g., ED visits and pain management interventions) are held constant. Under this scenario, further reductions in these services yield an additional $1,476 in projected savings per patient by year 3, increasing the projected 3-year cumulative savings to $18,586 per patient.

Discussion

Published Level 1 PNS clinical studies such as the FDA IDE pathway RCT by Hayek et al. (8) and the double-blinded RCT by Billet et al. (9) provide a controlled environment to demonstrate long-term pain relief. Our findings reinforce prior studies of PNS as an effective therapy for patients with intractable neuropathic

Table 5b. *Average reimbursement for sub-group analysis of recipients for PNS system (12 mos. pre-index and 24 mos. post-index).*

Health Care Resource	12 months pre-index procedure Mean (Median)[d]	12 months post-index procedure Mean (Median)	Mean Post/Pre difference	Mean Post/ Pre percent difference	Months 13-24 post-index procedure Mean (Median)	Mean Post/Pre-difference	Mean Post/ Pre percent difference	Total Δ ($)	*P*-Value	Z-Score[e]	Effect Size[f]
Office Visits[a]	$2,945 ($2,812)	$1,452 ($1,329)	-$1,493	-50.7%	$1,227 ($1,112)	-$1,718	-58.3%	-$3,211	< 0.001	-5.92	-0.84
Pain Management Interventions[a]	$1,117 ($815)	$360 ($0)	-$757	-67.8%	$135 ($72)	-$982	-87.9%	-$1,739	< 0.001	-3.35	-0.87
Opioid Medication (MME)[a, b]	$501 ($375)	$369 ($337)	-$132	-26.3%	$358 ($375)	-$143	-28.5%	-$275	0.002	-3.08	-0.44
Hospital Outpatient Department Services[c]	$2,841 ($304)	$2,157 ($187)	-$684	-24.1%	$1,816 ($17)	-$1,025	-36.1%	-$1,709	< 0.001	-4.78	-0.28
Ambulatory Surgical Center Services[c]	$5,804 ($816)	$5,468 ($0)	-$336	-5.8%	$3,027 ($0)	-$2,777	-47.8%	-$3,113	< 0.001	-7.00	-0.42
Emergency Room[c]	$1,046 ($0)	$1,016 ($0)	-$30	-2.9%	$852 ($0)	-$194	-18.6%	-$224	0.3948	-0.85	-0.08
Total	$14,254	$10,822	-$3,432	-24.1%	$7,415	$6,839	-48.0%	-$10,271	NA[g]	NA[g]	NA[g]

(a) Derived from Colorado Pain Care (n=50), represents pain-related care only for Freedom PNS recipients
(b) Derived from Colorado Prescription Drug Monitoring Program (PDMP) Database
(c) Derived from National Claims Cohort (n=406), represents all-cause care for any chronic pain permanent PNS treatment
(d) PNS trial and permanent activity (CPTs 64555 & 64590) were removed from the pre period to ensure the pre and post periods were comparable.
(e) Standardized non-parametric Wilcoxon Signed-Rank test of post/pre median differences
(f) Cohen's r effect size, where negative values indicate reductions after PNS implantation and positive values indicate increases.
(g) Statistical testing of the total post/pre cost difference was not performed due to national claims data restrictions, precluding valid estimation of variance and confidence intervals for the total cost measure.

Table 6. *Three year projections of annual health utilization savings.*

Timeframe	Average Annual Savings	Difference ($)	% Savings
Pre 12 Months	$14,254		
Year 1	$10,822	-$3,432	-24%
Year 2	$7,415	-$6,839	-48%
Year 3 (Projected) [a]	$7,415	-$6,839	-48%
Years 1-3		-$17,110	-40%

[a]Year 2 savings carried over to year 3

pain (8-15) and confirm that the benefits observed in controlled and observational settings can be replicated into real-world clinical practice.

The robust statistical findings were supported by comprehensive assessment of distributional assumptions. Given the non-normal, right-skewed distributions typical of health care utilization and cost data, nonparametric methods (Wilcoxon signed-rank tests) provided appropriate inference while the descriptive statistics (means, medians, IQRs) offered clinically interpretable effect sizes.

Importantly, the observed clinical improvements were accompanied by measurable reductions in health care utilization. Patients required fewer health care resources after treatment, and these reductions were sustained into the second year of follow-up. This alignment between pain relief and reduced health care use highlights the dual clinical and economic value of PNS in real-world practice.

From a clinical and patient journey standpoint, routine follow-up care was most intensive during the first year after implantation, with health care utilization declining substantially in the second year as symptoms stabilized. To estimate economic impact into a third year (which corresponds with our pain relief findings showing a third year of meaningful pain relief), we ap-

plied a conservative "second year carryover" approach that assumes year 2 utilization patterns persist into year 3 plus some modest incremental improvements in key areas. Therefore, the per PNS patient cost profile begins at $14,254, followed by post PNS period costs of $10,822 in year one, $7,415 in year 2 and an estimated $7,415 in year 3. Cumulatively, this led to savings of $3,432 at one year, $10,271 at 2 years and an estimated $17,110 without incremental year 3 improvements and over $18,500 with modest incremental improvements in year 3.

While the 2-year data showed reductions in pain-related visits, PMI and HOPD/ASC utilization, the third-year projection was driven by additional pain visit and pain medication reductions in addition to further HOPD/ASC reductions. All the third-year assumptions are premised on a stable symptom profile leading to utilization profile characterized by pain control maintenance. Thus, the third-year assumptions include quarterly pain visits, less reliance on opioids as the weaning process becomes easier and fewer facility visits tied to pain-related procedures. When interpreted alongside the sustained clinical improvements and declining health care utilization reported in long-term PNS outcome studies, these projected savings suggest that PNS can provide meaningful long-term value for payers and health care systems.

Beyond near-term cost savings, PNS may also help avert the need for additional major and costly interventions over time. Avoidance of these downstream treatments represents an additional source of economic value that was not represented in the already significant cost savings presented in this study.

An important consideration not included in the analysis is the additional cost associated for systems requiring an implanted battery. These implantable pulse generators have a finite lifespan (often 3–7 years depending on rechargeability and usage) (23), necessitating replacement procedures that require repeat surgery. These repeat interventions can cumulatively add tens of thousands of dollars over a patient's lifetime. In contrast, PNS systems that do not rely on an implanted battery avoid costs associated with battery replacement surgery. Surgical costs for replacing a PNS system battery can run as high as $16,224 in an ASC and $19,820 in a HOPD; and patients undergoing SCS battery replacements can expect even higher costs estimated at $27,485 and $31,526 in an ASC and HOPD, respectively (24). By eliminating the need for battery replacement procedures, these systems reduce long-term economic burden and minimize patient risk associated with additional surgeries. Ongoing assessment of long-term outcomes may be warranted to quantify the total cost implications of battery replacement surgeries in PNS.

A further cost consideration is associated with the need to remove an implanted neurostimulator that cannot be scanned utilizing MRI for potential future diagnostic requirements. With over 40 million MRI scans performed annually in the United States (25), the likelihood of needing an MRI scan increases significantly with age, rising from approximately 47% at age 30 to around 69% at age 70 (26). The cost of having to explant a neurostimulation device can range from approximately $3,000 to more than $7,000. After imaging is completed, patients typically require an additional procedure to reimplant the device to maintain pain relief which can cost $19,000 to over $30,000 (24) (Table

Table 7. *Three-year projection of annual health utilization (estimated incremental improvements).*

Setting	Units	Year 2 Actual	Percent Reduction	Year 3 Estimated	Incremental Savings (Est.)
Office Visits	Visits	8.8	50%	4.4	$614
PMI	Procedures	0.6	0%	0.6	$0
Medications	MMEs	48	25%	36	$75
HOPD	Visits	2.4	20%	1.9	$363
ASC	Procedures	0.7	14%	0.6	$424
ER	Visits	0.9	0%	0.9	$0
Total 3-Year Estimated Incremental Improvements					$1,476

Table 8. *Additional cost considerations for PNS and SCS systems not MRI compatible.*

Potential Costs for Other PNS & SCS Systems [a]	CPT	ASC	HOPD
Cost of PNS Removal for Systems That Cannot MRI Scan Over Neurostimulator	64585 & 64595	$4,006	$7,144
Cost of PNS Replacement After MRI Scan	64555 & 64590	$21,999	$19,820
Cost of SCS Removal for Systems That Cannot MRI Scan Over Neurostimulator	63661 & 63688	$2,952	$5,567
Cost of SCS Replacement After MRI Scan	63650 & 63685	$32,517	$31,526

[a]Costs reflect 1 lead two-component systems using 2026 national average Medicare payment rates

8). Additional economic evaluations may be needed to quantify the total potential financial impact.

Opioid reductions observed in this study demonstrate a favorable downward trend, suggesting the potential for reduced long-term reliance on opioids. Opioid tolerance is the decreased pharmacologic response of the opioid receptor to the opioid agonist which fuels the need for dose escalation to continue to achieve the desired effects (27,28). Given the well-documented development of tolerance, opioids are unlikely to remain effective indefinitely, as patients often require escalating doses to achieve the same effect, with diminishing benefit over time (29). In addition to patients discontinuing or reducing opioids, 37/94 (39%) avoided dose escalation which is a meaningful outcome, especially as they reported statistically significant pain reduction. It is also important to note that 3 quarters of people with chronic pain have pain presenting in multiple anatomical sites, which may also explain the need for continued medication for those sites not treated by the implant (30).

The CDC guidelines recommend if opioids are continued, clinicians should carefully evaluate individual benefits and risks when considering increasing dosage and should avoid increasing dosage above levels likely to yield diminishing returns in benefits relative to risks to patients. Additional dosage increases beyond 50 MME/day are progressively more likely to yield diminishing returns in benefits for pain and function relative to risks to patients as dosage increases further. Many patients do not experience benefits in pain or function from increasing opioid dosages to > 50 MME/day but are exposed to increases in risk as dosage increases. Risks for serious harms related to opioid therapy, including opioid misuse, overdose, and death, increase at higher opioid dosage (31). Therapies that successfully reduce or maintain lower opioid dosages represent a crucial strategy for health care providers managing chronic pain.

Finally, this analysis was designed to reflect "usual practice." Accordingly, we focused on outpatient care and excluded inpatient utilization, as hospital admissions are rarely attributable solely to pain management. This approach enhances the specificity of our findings and strengthens the relevance of the results to routine clinical and payer decision-making. This study reflects outcomes from a mature, multimodal private practice that primarily delivers care reimbursed through insurance and therefore may better approximate usual community interventional pain practice than highly selective referral only or boutique settings. Collectively, these findings demonstrate that PNS delivers sustained clinical benefit, reduces health care utilization, and offers compelling long-term economic value.

Limitations

Retrospective studies like this one, using both EMR and claims datasets are susceptible to coding anomalies and missing values that should be recognized when reviewing these results. Moreover, the 2 datasets, while reasonably aligned by the researchers through various methodological approaches, differed along the following attributes: the collection timeframes were broader for the primary EMR dataset (2019-2025) than the claims dataset (2022-2025), the single-site captured "pain-related care" while the claims dataset reflected "all-cause care" and finally, the EMR data focused on the receiver-based PNS therapy while the claims data captured other permanent PNS systems for chronic pain. However, these differences are fully disclosed and do not undermine the results reported herein. The year-3 economic estimates were scenario-based extrapolations derived from observed year-2 modeled utilization patterns rather than directly measured outcomes. These year-3 estimates are useful for illustrating potential longer-term value but should not be interpreted as observed savings for year-3. Furthermore, health care costs may vary by site of care, geographic region, and insurance provider. This variation is reflective of real-world practice. Finally, although numeric ratings of pain relief were not directly available in the claims dataset, the patient characteristics closely mirrored those of the single-site cohort in which clinical outcomes were systematically captured, supporting the relevance of the economic findings to the broader population.

Conclusions

This large retrospective analysis, with data collection conducted independently of the treating physician, provides a comprehensive real-world evaluation of permanent PNS and demonstrates its safety and clinical effectiveness in the treatment of chronic, intractable neuropathic pain. The results confirm a robust existing body of evidence, showing significant, durable pain relief and improved patient outcomes without any serious adverse events. Additionally, PNS therapy is associated with significantly lower health care utilization, the key drivers of costs, highlighting its clinical value and its potential to deliver substantial economic benefits across the health care system.

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