

# Rechargeable Spinal Cord Stimulation Versus Nonrechargeable System for Patients With Failed Back Surgery Syndrome: A Cost-Consequences Analysis

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**Objectives:** Spinal cord stimulation (SCS) has been used for almost 40 years to treat refractory neuropathic pain after failed back surgery. Fully implantable nonrechargeable pulse generators have a battery life of between 2 and 5 years. A new SCS system with a rechargeable power source may last 10 to 25 years, or longer. The potential economic implications of longer battery life with a new SCS system has yet to be assessed. The study objective is to estimate the average difference in lifetime costs between rechargeable and nonrechargeable pulse generators used in treatment with SCS for failed back surgery syndrome.

**Methods:** A generalized state-transition probability framework was used to model costs. Input parameters for the base case analysis were obtained from several data sources including published literature, Medicare fee schedules, Medicare claims data, and expert opinion.

**Results:** A rechargeable SCS system is projected to require from 2.6 to 4.2 fewer battery generator replacements for battery depletion than a nonrechargeable SCS system. The total lifetime savings of a rechargeable system range from \$104,000 to \$168,833. In all of the one-way sensitivity analyses conducted, a rechargeable system saves money. Among all of the assumptions underlying the analysis, the annual cost after device removal contributes the most uncertainty.

**Conclusions:** A rechargeable SCS system is projected to save up to \$100,000 over a patient's lifetime. Fewer pulse generator replacements will also decrease patient discomfort and morbidity from procedural complications.

**Key Words:** chronic benign pain, spinal cord, stimulation therapy, rechargeable pulse generator, costs and cost analysis, computer modeling

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Neuropathic pain stems from injury to the nervous system, either as a direct result of trauma to a nerve or as sequelae to other medical conditions, such as postherpetic neuralgia, diabetes, critical limb ischemia, and refractory angina. Failed back surgery syndrome (FBSS) is a major source of neuropathic pain, and to some extent mixed pain, with components of both neuropathic and nociceptive pain.<sup>1–3</sup> The syndrome is characterized as persistent, severe pain in the low back and/or legs after spinal surgery. As it is generally accepted that leg pain is mostly neuropathic, the term neuropathic pain is predominantly used throughout this manuscript. FBSS affects approximately 30% of spinal surgery patients.<sup>4</sup>

Typically, neuropathic pain is chronic, lasting 6 months or more. Treatments for chronic neuropathic pain include pain medications, physical therapy, surgery, chiropractic manipulation, and nerve block injections.<sup>5,6</sup> Spinal cord stimulation (SCS) is another option for patients who fail to obtain sufficient pain relief on conventional medical management (CMM).<sup>7–10</sup> Patients eligible for SCS undergo a trial period of stimulation, the duration of which is variable from center to center. In most institutions, this may last for 1 week.<sup>11,12</sup> For this purpose, a device containing either a trial lead or a permanent lead, which could be internalized in case of successful trial, may be used. The leads are connected to an external trial stimulator and programmed for optimal pain relief. At the end of the temporary trial period, the extent of pain relief is assessed by the physician. One traditionally used criterion for determining a successful outcome, and subsequent permanent implantation, has been 50% or greater relief in the primary pain complaint.<sup>8,11,13–16</sup> The decision ultimately involves discussion between the physician and patient, also taking into consideration physical functioning, mood, and medication use. About 80% of patients undergoing the SCS trial have a permanent implantation.<sup>12,17</sup>

The technology has evolved gradually, resulting in the development of fully implantable pulse generators (IPGs) powered by nonrechargeable primary cell batteries. These devices are programmed to have stimulation parameters specific to each patient to ensure that the

stimulation-induced paresthesia covers at least 80% of the pain area required to provide relief. Limitations of such a nonrechargeable SCS system have included (1) the need for repeat surgical procedures in 2 to 5 years to replace the IPG owing to battery depletion,<sup>17-19</sup> (2) to prolong battery life, patients who require continuous or high-power stimulation may need to spend a portion of the day with the SCS system turned off, use a cycling mode, or on lower power settings, leading to reduced pain relief, and (3) the discomfort associated with the relatively large size of the devices for patients with a small physique.

The first fully implantable pulse generator (IPG) with a rechargeable battery was approved by the US Food and Drug Administration in 2004 (Precision SCS System, Boston Scientific Neuromodulation, Valencia, CA).<sup>20</sup> Manufacturer bench testing and battery life modeling using real-world clinical parameters suggest that these newer batteries may last 10 to 25 years or longer. The longer battery life will lead to fewer replacements and thereby, less morbidity associated with a surgical procedure and potential cost savings. The study objective was to project the economic implications of this new rechargeable SCS system compared with a non-rechargeable system over the lifetime of a representative patient with FBSS.

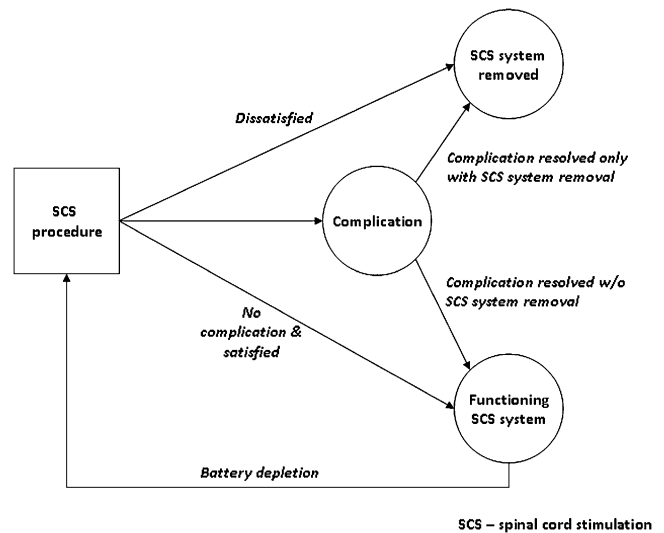
**METHODS AND DATA**

A generalized transition-state probability framework was adopted to compare the lifetime costs associated with the 2 SCS systems (rechargeable and nonrechargeable) for a representative patient with FBSS. The analysis was conducted from a US societal perspective for the lifetime of the patient, with a particular emphasis on the perspective of the Centers for Medicare and Medicaid Services (CMS). Indirect costs, such as lost wages and productivity, and time spent by unpaid caregivers were omitted. There is general consensus that while the devices are functioning, there will be little difference in lost work in use of indirect caregivers.

A comprehensive review and analysis of the literature was performed to obtain relevant input parameters and data to construct the base case model structure. The search was conducted electronically using PubMed (National Center for Biotechnology Information, Bethesda, MD) and OVID and produced several recent systematic reviews of the effectiveness and safety of SCS procedures. After careful data gathering, the final numbers were validated with clinical experts who have contributed to the literature and have conducted large numbers of procedures in the past 2 decades. Sensitivity analyses were performed to evaluate the importance of differences in data found in the literature.

**Model Structure**

Figure 1 summarizes the model’s framework. Patients eligible for SCS for chronic pain owing to FBSS may either have an IPG that has a nonrechargeable or rechargeable battery. All patients undergo an initial SCS



**FIGURE 1.** Flow diagram.

implant during the first cycle (year). After implantation, a patient may (1) have no complication, (2) be dissatisfied and have the device permanently removed, or (3) experience a complication. Complications include infection, lead failure and migration, generator failure (other than battery), and other minor complications that can be resolved without surgery. The model also accounts for the possibility of age-related mortality at each cycle from any state.

For each cycle thereafter, a patient with a functioning device may undergo a repeat operation to replace a depleted battery. Patients in the model who choose to have their implant removed do so permanently. The model cycle length is annual and all costs and benefits are discounted at a fixed annual rate of 3%.<sup>21</sup> The maximum number of SCS procedures (initial SCS and those owing to battery depletion) over a patient’s lifetime is limited to 6.

**Model Parameters**

Input parameters for the base case analysis were obtained from several data sources, including published literature, Medicare fee schedules, Medicare claims data, and expert opinion. Three review papers provided the basis of the probability estimates that formed the core of the model.<sup>14,22,23</sup> Studies in the review articles report slightly different numbers based on updates and changing technology over the years. The quality of the evidence was graded based on study design, internal validity, and external validity using the system proposed by Braithwaite et al.<sup>24</sup>

A study by Mekhail et al<sup>23</sup> provided appropriate baseline patient characteristics (Table 1), as it included extensive information on 196 patients receiving SCS or peripheral nerve stimulation for chronic pain at the Cleveland Clinic Pain Management Department between 1990 and 1998.<sup>23</sup> Procedural complication rates were

**TABLE 1.** Baseline Patient Characteristics, Event Probabilities, and Costs

Parameter	Base Case Estimate		Data Source	Strength of Evidence		
				Study Design	Internal Validity	External Validity
Patient demographics						
Mean age at first implantation, years	46		Observational; Mekhail et al <sup>23</sup>	2-2	Good	High
Proportion female	69%		Observational; Mekhail et al <sup>23</sup>	2-2	Good	High
Probabilities						
Procedural complication	0.343		Observational; Turner et al <sup>2</sup>	2-2	Good	High
Infection	0.045		Observational; Turner et al <sup>2</sup> ; Cameron <sup>14</sup> ; Bell et al <sup>22</sup>	2-2	Good	High
Device removal or replacement	0.110		Observational; Turner et al <sup>2</sup>	2-2	Good	High
Lead repositioning	0.140		Observational; Bell et al <sup>22</sup>	2-2	Good	High
Lead replacement	0.073		Observational; Bell et al <sup>22</sup>	2-2	Good	High
Device removal, given device failure (other than battery depletion)	0.012		Observational; Mekhail et al <sup>23</sup>	2-2	Good	High
Reimplanting device after battery depletion	1.00		Expert opinion	3	Fair	High
Battery life						
Nonrechargeable	4.1 y		Observational; Van Buyten <sup>4</sup>	2-2	Good	High
Rechargeable	17.5 y (range; 10-25 y)		Advanced; Bionics report	2-3	Fair	Low
Costs						
	Nonrechargeable	Rechargeable				
Initial procedure	\$26,005	\$35,109	Observational; CMS 2006	2-2	Good	High
Replace lead	—\$7338—	—	Observational; CMS 2006	2-2	Good	High
Reposition lead	—\$3421—	—	Observational; CMS 2006	2-2	Good	High
Infection	\$27,378	\$36,482	Observational; CMS 2006	2-2	Good	High
Remove IPG without replacement	—\$8286—	—	Observational; CMS 2006	2-2	Good	High
Replace IPG	\$11,932	\$21,036	Observational; CMS 2006	2-2	Good	High
Minor complications	—\$350—	—	Expert opinion	3	Poor	Low
Annual cost with functioning SCS (maintenance)	—\$5989—	—	Observational; CMS 2006; Bell et al <sup>22</sup> ; Mekhail et al <sup>23</sup>	2-2	Good	High
Annual cost after permanent SCS removal	—\$34,366—	—	Observational; CMS 2006; Bell et al <sup>22</sup> ; Mekhail et al <sup>23</sup>	2-2	Good	High

Grading the quality of evidence. Study design. Level 1: evidence obtained from at least 1 properly designed randomized controlled trials. Level 2-1: evidence obtained from well-designed controlled trials without randomization. Level 2-2: evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than 1 center or research group. Level 2-3: evidence obtained from multiple time series with or without the intervention. Level 3: opinions of respected authorities, based on clinical experience, descriptive studies and case reports, or reports of expert committees. Internal validity. Good, fair, poor. External validity. High or low.

obtained from the review articles,<sup>2,14</sup> key economic articles,<sup>22,23,25</sup> and expert opinion.

The average life of a nonrechargeable battery was derived based on a systematic review of the literature. Kumar et al<sup>17</sup> reported a mean battery life of 48 months. Van Buyten<sup>4</sup> report that of 61 patients with at least 5 years of follow-up, 32 patients had the battery replaced, resulting in a mean battery life of 28 months. The remaining 29 patients had battery life of 72 months. The mean for the entire cohort would be approximately 50 months. Budd<sup>26</sup> studied 20 patients, of which 8 patients had an IPG using internal batteries. Five of these patients had their IPG replaced between 12 and 18 months. Taylor et al<sup>27</sup> report a battery life similar to that reported by Kumar et al.<sup>17</sup> The mean battery life of a nonrechargeable system is set to 49 months (4.1 y) with a conservative range between 3 and 6 years.

Battery longevity of the Precision rechargeable generator was calculated by Boston Scientific based on engineering testing. The analysis parameters were derived from real time battery use cycled over 3 years, storage test results reported in quality tests, and accelerated cycling reported from engineering tests for low, medium, and high stimulation parameters as seen in the Precision IDE clinical study.<sup>20</sup> The functional battery life was defined as the projected number of years that the recharge interval remained longer than either 1 day, or 50% of the recharge interval at the beginning of battery service life, whichever was less. Parameter estimates were based on worst-case conditions for battery capacity loss rates.

The battery longevity estimation results indicate that the typical functional life of the rechargeable battery for the majority of clinical parameters is over 25 years. Under worst-case analysis parameters, the functional life of the battery is more than 10 years of continual service for low, medium, and high use cases. Owing to the design of the rechargeable SCS system, battery longevity does not depend on the recharging schedule used by the patient. The current drain can be changed at any time and the capacity fade profile will continue from the previous capacity. Therefore, the following analyses use the battery life range of a rechargeable system from 10 to 25 years, with the base case set to the median of the range, 17.5 years.

The incidence of events, such as battery replacement and adverse events, associated with each battery type was included in the model. Complete device removal, rather than replacement, after battery depletion occurs in approximately 1.2% of all SCS implantations; this probability was derived from data in the paper by Mekhail et al.<sup>23</sup> The probability of SCS removal (21/193 = 10.9%) was multiplied by the probability of removal owing to battery depletion (11.1%).

Costs for the model were computed using 2006 Medicare fee schedules for physicians and facilities. Costs (in the form of Medicare fee schedule amounts) associated with implanting the initial rechargeable or nonrechargeable SCS system included physician and facility costs for the SCS trial, the permanent implant, and analysis and programming are shown in Table 2. In 2006, Medicare

determined that rechargeable SCS generators represent a "substantial clinical improvement" over nonrechargeable SCS and began making additional payments to facilities to cover the full cost of these new devices. The incremental Medicare payment for rechargeable generators in 2006 was approximately \$10,000 (total cost of implantation of rechargeable IPG being \$20,858). Costs associated with lead replacement, repositioning, generator removal or replacement, were based on the corresponding Medicare rates for these procedures and so were the rates for analysis and programming. The cost of treating an infected implant includes the removal of the entire SCS system, a course of antibiotics, and subsequent reimplantation. Data from actual Medicare claims (Physician Supplier Procedure Summary Master File 2004) on the volumes of inpatient and outpatient procedures and percutaneous versus laminectomy lead placement were used to weight the Medicare fees (Table 2).

Annual follow-up costs after the initial SCS procedure were estimated by applying 2006 Medicare rates to averaged patient health resource use published in the literature.<sup>22,23</sup> These sources provided data on the number of physician and emergency room visits, hospitalizations, procedures, investigations such as computerized tomography/magnetic resonance imaging scan, medications, and rehabilitation services used by patients as a maintenance cost per year receiving their SCS implant and subsequently (Table 3). No data were found in the literature on health resource use for patients after permanent removal of SCS; hence, prior health resource utilization (cost of CMM) was used as a proxy. Because the health resource use reported in these 2 articles varies somewhat, the average units of each resource were used. The 2006 Medicare fee schedule amounts were multiplied by these averages and summed to derive total annual costs for a patient who continues with SCS therapy and for a patient who had the SCS system permanently removed or never implanted. Costs of minor complications were assumed to be \$350 (Table 3). No case report of a death arising from an SCS procedure has been reported in the literature, so mortality is assumed to approximate the age-adjusted rates of the US population at large.<sup>28</sup>

## RESULTS

### Base Case Analysis

Table 4 summarizes the base case results. The life expectancy of the average 46-year-old SCS patient was predicted to be 80.2 years; hence, a patient will use the device for an average of 80.2 minus 46 (= 34.2) years. A patient with a nonrechargeable system will likely need 5.9 replacement procedures whereas a patient with a rechargeable system will need 2.2 (range 1.7 to 3.3) replacement procedures over his or her lifetime. Thus a rechargeable SCS system will require 3.7 (range 2.6 to 4.2) fewer replacements for battery depletion, resulting in a savings in SCS procedure costs of \$49,344 (range \$25,710

**TABLE 2.** Calculation of Total Procedural Costs

Procedure	CPT Code(s)	Nonrechargeable*	Rechargeable*
Initial procedure cost			
SCS trial (percutaneous lead)	63650	\$6912	\$6912
Leads (weighted average.)	63650, 63655	\$7160	\$7160
Generator	63685	\$11,754	\$20,858
Analysis/programming	95971, 95972	\$178	\$178
Total		\$26,004	\$35,108
Explant and reimplant IPG			
Generator	63685	\$11,754	\$20,858
Analysis/programming	95971, 95972	\$178	\$178
Total		\$11,932	\$21,036
Lead replacement			
Leads (weighted avg.)	63650, 63655	\$7160	\$7160
Analysis/programming	95971, 95972	\$178	\$178
Total		\$7338	\$7338
Lead repositioning			
Revise/remove lead	63660	\$3243	\$3243
Analysis/programming	95971, 95972	\$178	\$178
Total		\$3421	\$3421
Manage infection			
Revise/remove lead	63660	\$3243	\$3243
Replace lead (different day)	63650, 63655	\$7160	\$7160
Revise/remove generator	63688	\$5043	\$5043
Replace generator (different day)	63685	\$11,754	\$20,858
Analysis/programming	95971, 95972	\$178	\$178
Total		\$27,378	\$36,482
Removing IPG w/o replacement			
Revise/remove generator	63688	\$5043	\$5043
Revise/remove electrode	63660	\$3242	\$3242
Total		\$8285	\$8285

On the basis of procedure volume data from the 2004 Physician/supplier procedure master file and 2006 Medicare cost data.

\*Costs include facility and physician costs.

CPT indicates current procedural terminology.

to \$59,283) in 2006 US dollars (net present value). Patients with rechargeable batteries are expected to have a functioning SCS longer, such that the follow-up costs with or without SCS are lower by \$96,161 (range \$74,807 to \$104,208). The expected total lifetime savings is \$150,297 (range \$104,000 to \$168,833) in 2006 US dollars (net present value) (Table 4).

Figure 2 shows the total cumulative costs of rechargeable and nonrechargeable SCS from the time

of first implantation. Although rechargeable SCS system are initially more expensive than nonrechargeable, these costs are offset at 4.1 years. By 10 years, the net savings associated with rechargeable SCS exceed \$104,000; by 20 years, net savings exceed \$158,000.

### Sensitivity Analysis

Figure 3 shows the results of one-way sensitivity analyses. The estimates are ordered such that the

**TABLE 3.** Mean Annual Costs for Patients With Chronic Pain

Type of Service	Cost Per Unit of Service	With SCS Implanted		After SCS Removed	
		Number of Service Units	Total Cost	Number of Service Units	Total Cost
MD office visit	\$51	9.1	\$462	24.3	\$1239
ED visit	\$192	0.4	\$67	1.6	\$307
Medical hospitalization	\$4248	0.7	\$2974	2.9	\$12,320
Nerve block injection	\$306	2.5	\$765	15.7	\$4805
Surgery	\$8689	0	\$0	1.3	\$11,296
Magnetic resonance imaging scan	\$472	0.1	\$47	1.7	\$779
Computed tomography scan	\$294	0.3	\$74	1	\$294
Medication			\$1250		\$2075
Rehabilitation			\$350		\$1250
Total mean annual cost			\$5989		\$34,365

Based on usage data from Mekhail et al<sup>23</sup> and Bell et al<sup>22</sup> (2006 Medicare rates).

ED indicates emergency department; MD, doctor of medicine.

TABLE 4. Base Case Results

	Nonrechargeable	Rechargeable		Difference*	
		Mean†	Range‡	Mean	Range
Life expectancy, yrs	34.2	34.2	NA	0	NA
Mean number of SCS procedures over lifetime	5.9	2.2	(3.3, 1.7)	-3.7	(-2.6, -4.2)
Mean costs (2006 US dollars)					
SCS implant costs	\$106,166	\$56,822	(\$80,447, \$46,883)	-\$49,344	(-\$25,710, -\$59,283)
Complication costs	\$7668	\$3040	(\$4304, \$2508)	-\$4628	(-\$3364, -\$5160)
Removal costs for dissatisfaction	\$271	\$107	(\$152, \$89)	-\$164	(-\$119, -\$182)
Costs of follow-up with or without functioning SCS	\$290,561	\$194,400	(\$215,755, \$186,353)	-\$96,161	(-\$74807, -\$104208)
Mean lifetime costs per patient	\$404,666	\$254,369	(\$300,658, \$235,833)	-\$150,297	(-\$104,000, -\$168833)

\*Rechargeable minus nonrechargeable.

†For battery life of 17.5y.

‡For range of battery life from 10y to 25y.

NA indicates not applicable because of no evidence that battery life affects overall survival.

parameters that most influence the cost difference are placed toward the top of the table and the parameters that least influences the cost difference are placed toward the bottom. In all scenarios, the rechargeable battery is cost saving. The earlier the nonrechargeable device is removed, the more the cost savings and vice versa; in other words, after removing the SCS, the cost of CMM is much higher than the maintenance cost of a functioning SCS (Table 3). The cost is varied from 25% to 200% of its baseline value, resulting in cost savings from \$272,369 to \$58,742; a difference of \$213,627. The figure also shows that net lifetime savings are expected to be lower on average for a younger patient (eg, 30y) than an older patient (eg, 70y). If a nonrechargeable battery were to last on average 6 years, then the net savings would decline to \$85,534. Most of the other cost inputs were modeled to approximate the impact on payers other than Medicare. As many payers pay providers based on a percentage of Medicare, the other cost inputs were varied from 85% to 200% of the Medicare rates, but exhibited minimal effect on the overall findings.

The parameters that most influence the findings include battery life for both nonrechargeable and rechargeable, annual discount rate, and time of analyses (age of first implantation and total time horizon). Longer nonrechargeable battery life, shorter RC battery life, higher discount rate, higher age, and shorter time horizon all reduce the projected cost savings. Many of the other parameters had relatively limited influence on projected costs savings. Most notably, the lack of literature-based evidence to estimate the cost of minor complications did not substantially affect the reliability of the model. Increasing the cost of minor complications to \$2000 had little impact on estimated cost savings.

## DISCUSSION

SCS has become an established treatment for patients with chronic pain secondary to FBSS. However, many payers consider SCS a treatment of last resort as the initial, up-front costs are high. The high initial

procedure costs associated with SCS have prompted several peer-reviewed economic evaluations and cost studies.<sup>6,12,22,23</sup> In 2004, Taylor et al<sup>27</sup> performed a comprehensive, systematic literature review on the cost-effectiveness of SCS for chronic pain. On the basis of 14 studies that met the search inclusion criteria, Taylor et al found that the costs associated with initial SCS implantation for a variety of indications are consistently offset by reductions in follow-up health resource use and costs. They also noted that the time period for recovering costs associated with the initial SCS implantation varied, and is associated with "relative efficacy of SCS, generator battery life, and the level of SCS usage by patients." Kumar et al<sup>25</sup> has shown that the initial high costs are recaptured after 2½ years, and after this point CMM becomes more costly. In 2002, Kemler and Furnée<sup>29</sup> published a full economic evaluation that included quality of life. They assessed both the costs and benefits of SCS plus physical therapy compared with physical therapy alone in patients with complex regional pain syndrome. This study calculated that the cost per quality-adjusted life year (QALY) gain was \$22,581 over 1 year, suggesting that the therapy is cost-effective. Taylor et al<sup>27</sup> examined the cost-effectiveness of SCS versus CMM in FBSS patients using decision-analytic modeling techniques. Their model used detailed costs from a study of FBSS patients in Canada.<sup>17</sup> The results show that SCS is both more effective and less costly than CMM over a patient's lifetime. They conclude that over the lifetime of patients, SCS is both cost saving to the healthcare system and more effective when compared to CMM, a finding that was robust across all sensitivity analysis.

All of these studies were conducted at a time when only older, nonrechargeable SCS technologies were available. Rechargeable SCS technology is rapidly being accepted as the standard of care for this therapy. This is the first study to model the economic impact of rechargeable IPG compared with nonrechargeable IPG used in a population of chronic benign pain patients. This analysis shows that over the lifetime of a typical patient (eg, age 46) undergoing implantation of a SCS,

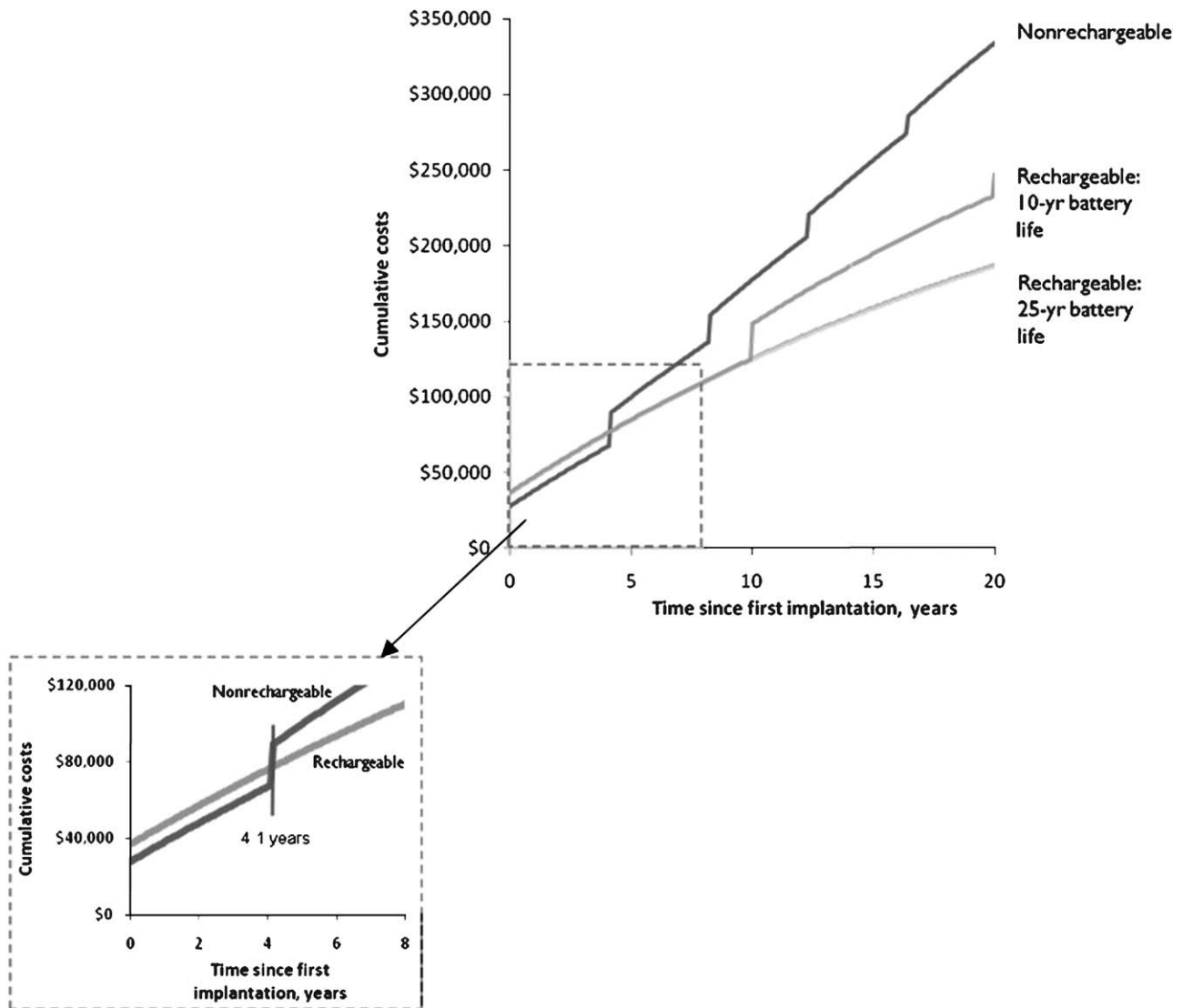


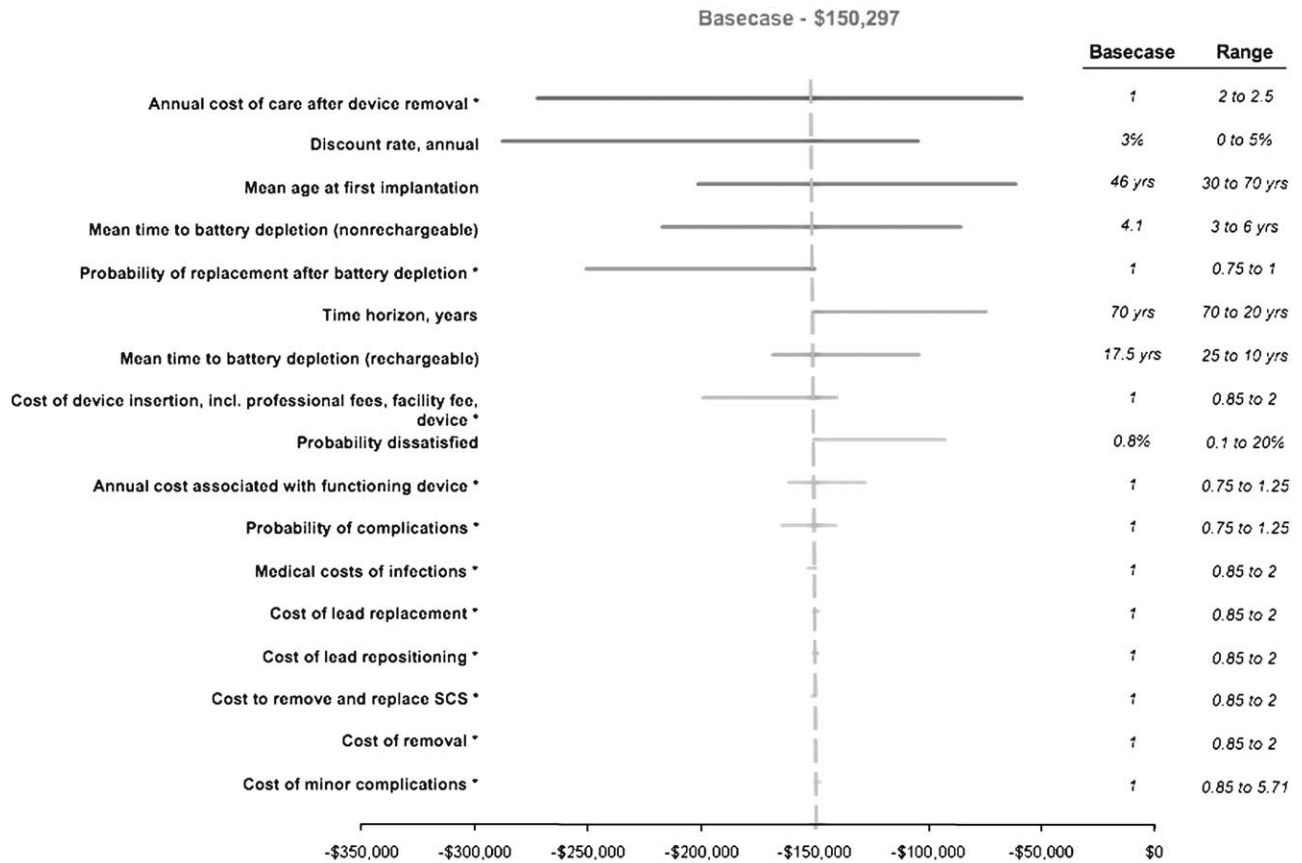
FIGURE 2. Cumulative costs of SCS system from time of first implantation, rechargeable versus nonrechargeable.

there should be 4.2 fewer reimplantations. No attempt is made to estimate the net health benefit of patients avoiding the discomfort and potential morbidity associated with IPG reimplantation. Not only are patients likely to undergo fewer reimplantations, but payers could realize a total patient lifetime net savings of approximately \$168,000 per patient.

The net savings may be higher or lower depending on a number of factors, which are addressed by performing sensitivity analyses. If the annual costs of maintenance after permanent removal of SCS are substantially lower—from \$34,366 to \$8500 per year—then the savings drop to \$69,000. Cost savings also are lower for older patients, who may succumb to other conditions and death before battery failure necessitating reimplantation. However, under a wide range of assumptions, in none of the one-way sensitivity analyses did a rechargeable, long-lived SCS battery fail to accrue cost savings.

### Limitations

Every study has potential uncertainties and limitations that may affect interpretation of the findings. Several caveats are important to mention here. First, future costs represent projections, such that the longer the time horizon of the analysis, the greater the uncertainty in the projections. It is impossible to anticipate all future price fluctuations in devices and other medical services, patterns of medical resource use, and potential new breakthroughs in management of patients with chronic pain. This analysis is based on historical trends over a 30-year history of SCS use. Second, the analysis reveals that the magnitude of cost savings is largely driven by the annual costs of CMM after SCS removal, which was one of the more uncertain parameters. All of the published literature has reported only health resource use and costs that occur before and after SCS procedures. Hence, although the estimate of an average net savings of \$168,000 is believed to be accurate,



\* Let *r* denote relative change from basecase value. When *r* is set equal to 1, the parameter is set to its basecase value. When *r* is less than 1, the parameter value is reduced by 1-*r* percent. When *r* is greater than 1, the parameter value increased by *r* - 1 percent.

FIGURE 3. Sensitivity analyses.

the savings could vary from approximately \$69,000 to \$301,000. Further precision on these estimates would require additional data collection.

Models simplify reality to facilitate comprehension of complicated processes. They rely on assumptions that can skew the validity of the outputs. Every attempt has been made to rely on well-substantiated and evidence-based inputs and sensitivity analyses were performed on all inputs to understand their effect on the study findings.

Additionally, indirect costs were not included although cost-effectiveness analysis protocols typically recommend including such data. In this case, not only are indirect costs difficult to quantify<sup>30</sup> with accuracy, omitting them actually makes the model more conservative. As more replacement procedures are required, the indirect costs associated with nonrechargeable batteries are necessarily higher than those associated with rechargeable batteries.

### CONCLUSIONS

Compared with current nonrechargeable technology, a rechargeable SCS system is anticipated to reduce

the number of IPG replacements owing to battery depletion, and that may contribute to patient discomfort and morbidity. Rechargeable SCS systems are projected to result in mean savings of approximately \$150,000 and within the range of \$104,000 to \$168,000 for a typical patient. The range is primarily as a consequence of the uncertainty at what stage in the cycle a permanent SCS removal that trigger the higher CMM costs once the SCS is removed. Because other economic studies of SCS using nonrechargeable technology have reported long-term cost savings versus other treatment modalities, it is likely that comparing rechargeable SCS systems to other treatments may have even greater cost-savings than those reported here. This study adds to the body of evidence that supports the cost-effectiveness of SCS therapy.

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