

Cost Effectiveness of a Novel 10 kHz High-Frequency Spinal Cord Stimulation System in Patients with Failed Back Surgery Syndrome (FBSS)

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ABSTRACT: *Objectives:* Spinal cord stimulation (SCS) is an effective method of relieving chronic intractable pain, and one of its key indications is failed back surgery syndrome (FBSS). The objective of the current study was to evaluate the cost effectiveness of 10 kHz high-frequency SCS (HF10 SCS) compared to conventional medical management (CMM), reoperation, and traditional nonrechargeable (TNR-SCS) and rechargeable SCS (TR-SCS). *Methods:* A health economic model of SCS in the United Kingdom was reproduced in the perspective of the health care system to simulate costs and quality adjusted life years (QALYs) over 15 years. In the model, both a decision tree and the Markov model were used to describe the health outcomes of the evaluated therapies. *Results:* HF10 SCS therapy showed a favorable incremental cost-effectiveness ratio (ICER) of £3,153 per QALY gained as compared to CMM and established dominance (less costly, more QALYs) compared to TNR-SCS (£8,802 per QALY vs. CMM) and TR-SCS (£5,101 per QALY vs. CMM). *Conclusion:* This first analysis of the cost effectiveness of HF10 SCS suggests that it is more cost effective and provides a greater number of QALYs than both TNR-SCS and TR-SCS.

KEY WORDS: spinal cord stimulation, high-frequency stimulation, cost effectiveness, pain relief, failed back surgery syndrome

I. INTRODUCTION

Spinal cord stimulation (SCS) has been shown to be an effective method of pain relief in patients with refractory angina, complex regional pain syndrome (CRPS), and most commonly, failed back surgery syndrome (FBSS).^{1–4} In 2008, the National Institute of Health and Clinical Excellence (NICE) in the United Kingdom (UK) commissioned a health technology assessment (HTA) of traditional nonrechargeable SCS (TNR-SCS) whereby its cost effectiveness was compared with either conventional medical management (CMM) or reoperation in several patient types.⁵ This extensive HTA, later published by Simpson et al., concluded that SCS is cost effective in FBSS patients when compared to both CMM and reoperation.² Assuming device longevity of 4 years and device cost of £9,000, TNR-SCS in combination with CMM resulted in an incremental cost-effectiveness ratio (ICER) of £10,480 per quality adjusted life year (QALY) gained when compared to CMM alone and £9,219 per QALY gained when compared to repeat operation.

Taylor et al. extended the NICE analysis, comparing the cost effectiveness of TNR-SCS systems and more costly traditional rechargeable SCS (TR-SCS) systems with CMM.⁶ They concluded that the ICER of TNR-SCS compared with CMM or reoperation was £5,624 and £6,392 per QALY, respectively, and that the rechargeable systems are more cost effective than nonrechargeable systems, as long as the longevity of the latter is 4 years or less. This finding that the rechargeable SCS systems are economically more favorable was also observed in an earlier study by Hornberger et al. in the US.⁷

The device assessed in this article is a high-frequency (HF10™) SCS system (Senza™, Nevro Corp., Menlo Park, CA, USA) with the ability to use proprietary high-frequency wave forms (up to 10 kHz) to deliver pain relief, and unlike traditional SCS, without paresthesia. The system uses a rechargeable implantable pulse generator (IPG). The 10 kHz high-frequency SCS (HF10 SCS) therapy utilizes familiar surgical techniques almost identical to traditional SCS, but is more streamlined as it eliminates the often time-consuming step of intraoperative paresthesia mapping and programming to guide lead placement.

Six-month clinical results for the HF10 SCS therapy have been presented previously.⁸ The study enrolled 67 FBSS patients of which 1 did not complete the initial trial phase due to patient decision. Among the enrolled patients, 91% presented with predominant back pain. This cohort represents a challenging group since effective relief of predominant back pain has been elusive despite technological advances aimed at trying to improve unreliable low back paresthesia coverage.⁹ Despite this challenging baseline etiology, the HF10 SCS therapy resulted in a high trial success rate and high level of pain relief sustained after implant. Among the 66 FBSS patients, 57 (86.4%) passed the initial SCS trial phase and received a permanent implant. Of these, 74% achieved significant pain relief at 6 months [$\geq 50\%$ reduction in pain visual analog score (VAS) scores]. Although no direct comparison with any other SCS has been carried out to date, the observed responder rate ($\geq 50\%$ relief) is greater than that reported in previous studies of traditional SCS therapy in patients with FBSS.^{2,10} Kumar et al. reported 48% responder rate and North reported a

responder rate of 47%.^{4,11} A 24-month follow-up study of the FBSS patients treated with HF10 SCS showed they maintained significant long-term improvements in leg pain, back pain, functional capacity, and opioid use.¹² While previous studies have predominantly shown that SCS treatments provide significant results in leg pain scores, the HF10 SCS therapy was also successful in producing significant improvements in back pain, which is a major driver of health care costs and loss of productivity.^{3,13,14} HF10 SCS therapy outcomes from this study compare favorably to traditional SCS therapy in FBSS as examined in randomized controlled trials by Kumar et al. and North et al.^{3,15} Notably, the HF10 therapy's results were obtained in a patient cohort which had primary axial back pain, a population that was excluded from the aforementioned trials.^{4,11} Specifically, after 24 months of the HF10 SCS therapy, 60% of patients reported a significant reduction in back pain ($\geq 50\%$ reduction in pain VAS scores) and 71% of patients reported a significant reduction in leg pain. These findings were associated with a very high rate of participants reporting they would recommend this treatment to others (90%), a high satisfaction rate (80%), and a strong follow-up rate, with 90% of participants contributing to the 24-month follow-up.¹²

In the current healthcare environment, the need to allocate public money wisely has increased the interest in comparative effectiveness and cost-effectiveness research.¹⁶ Therefore, it is important in the development of new technologies to not only investigate their clinical effectiveness but also to estimate the potential cost effectiveness of such technologies. The objective of this study was to estimate the cost effectiveness of the HF10 SCS therapy in treating FBSS patients with chronic pain and to identify the drivers of this cost effectiveness.

II. METHODS

A. Decision Model

We reproduced the original NICE health economic model in MS Excel 2010.^{2,6} The model has a dual structure, with a decision tree reflecting the outcomes in the first 6 months (Fig. 1A). After the

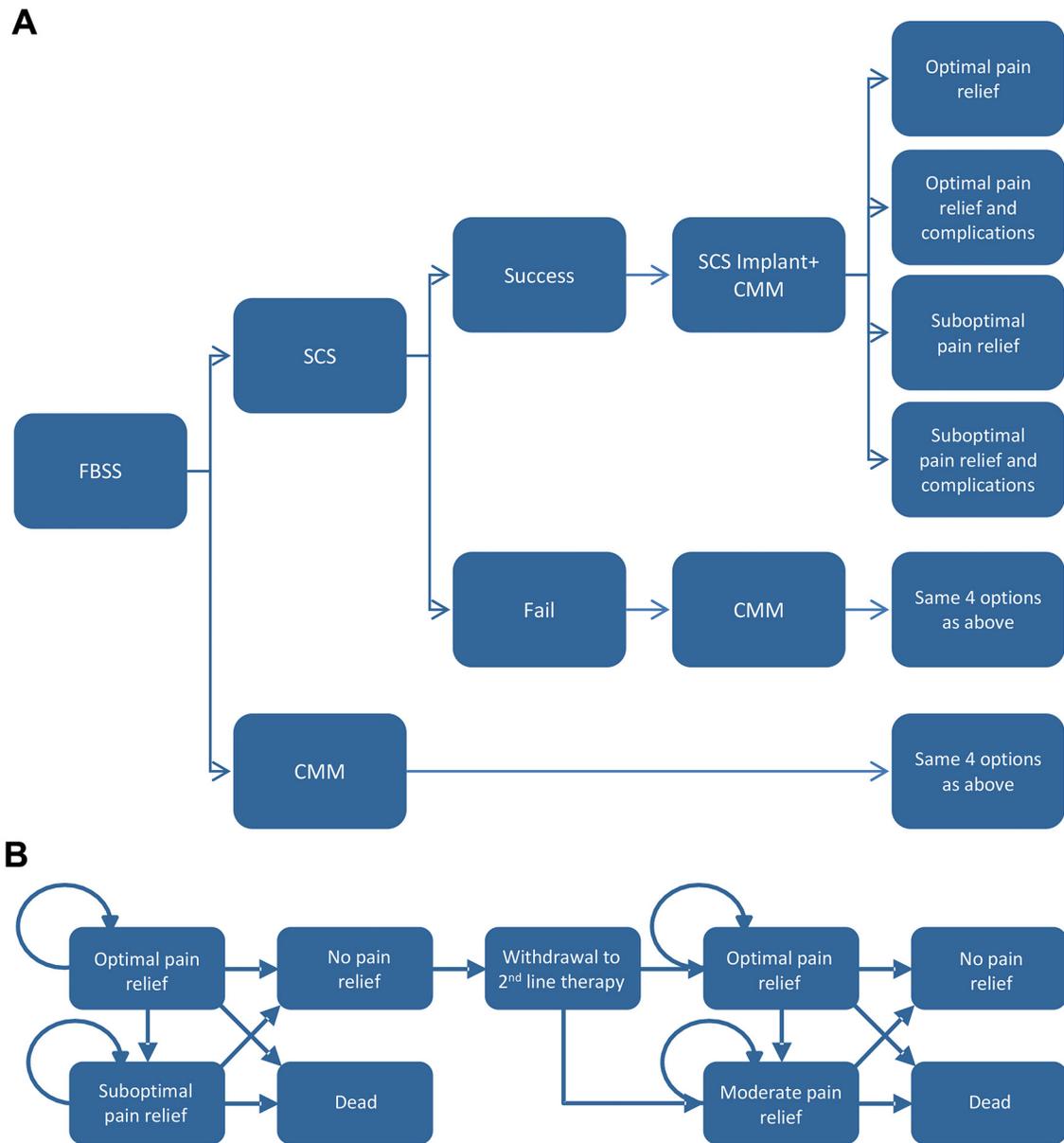


FIG. 1: Graphical presentation of the health economic model. (A) First 6 months (Decision tree). (B) Subsequent cycles of 3 months (Markov model). Note: Second line after withdrawal depends on initial arm: From SCS to CMM; from surgery to CMM; from CMM to surgery.

6-month period, a Markov “state transition” model was presented and predicted the further evolution of patients over a period of 15 years (Fig. 1B). A period of 15 years was used to ensure that there would be at least one replacement procedure for the HF10 SCS and TR-SCS treatments.

In the model, HF10 SCS is compared to conventional medical management (CMM), reoperation,

traditional nonrechargeable SCS (TNR-SCS), and traditional rechargeable SCS (TR-SCS).

At the start of the decision tree, patients in the SCS arms (HF10 SCS or traditional SCS) underwent a screening period to assess their pain relief. Patients who achieved satisfactory pain relief (as determined in studies used for model input) received an IPG implant whereas patients who failed the test

received CMM. After the IPG implantation, the model then took into account the initial 6-month response to treatment, whereby response (or optimal relief) was defined as a reduction of 50% or more of the baseline pain score. In the decision tree stage, the model incorporated the possibility for patients to have complications with the SCS systems, leading to withdrawal from therapy. The model assumed that no patient died within the first 6 months.

After 6 months, patients entered into the Markov part of the model and were assigned one of the following outcomes: optimal relief, moderate relief, no relief, or death. The Markov model was chosen as it is an accurate method of modeling prognosis for clinical problems with ongoing risk.¹⁷ The model provided a platform for which patients would always be in one of the 4 outcome states listed above. Following the first 6 months, cycles of 3 months were applied. The 3-month cycle allowed for ongoing, accurate monitoring of the transitions between states of each of the patients. At the end of each cycle, patients (a) stayed in the same state, (b) withdrew from SCS treatment if in the SCS arm (e.g., the device is removed either due to absence of pain relief or to complications), or (c) died. In the case that a device was removed in the SCS arm, patients were assumed to move to CMM. The same applied to surgical patients whose pain relief was no longer obtained during follow-up.

B. Clinical Data Input

Clinical data related to CMM, reoperation, and traditional SCS were obtained from the same sources as applied by Taylor et al.⁶ These main sources are Kumar et al. for the comparison with CMM and North et al. for the comparison with reoperation.^{3,4,13} To note, the results for SCS are different between these studies. Rather than attempting to calculate a pooled result, we generated, in line with Simpson et al. and Taylor et al., separate results in the respective comparisons with CMM and reoperation.^{2,6} Table 1 provides the key input data for the model.

The results of the HF10 SCS therapy were obtained from a series of 66 patients with FBSS.⁸ These patients are comparable in terms of age and

gender with those included in the Kumar et al. and North et al. trials, with mean age of 49.7 years and 45% male patients.^{3,4,13}

The mortality rate used in the Markov part of the model was reported by Simpson et al. and is assumed to be equal across all treatment options.² Similarly, complication and withdrawal rates are also assumed to be equal between all SCS systems because direct comparison across the studies is not possible due to different definitions of adverse events (AEs), serious AEs (SAEs), and complications.¹² We believe this assumption to be reasonable because (1) The surgical procedures for traditional SCS and the HF10 SCS are nearly identical. (2) HF10 SCS did not show evidence of additional neurological risk in a preclinical study and in clinical follow-ups.^{11,18,19} (3) The published clinical study on HF10 SCS reported 51 total AEs in 38 patients (46%) at 6 months, similar to the 43% reported in a systematic review of traditional SCS.^{8,20} The HF10 SCS study concluded that “the safety profile of this novel therapy is similar to the one of conventional SCS.” (4) The complication rates noted in prospective studies also helped to validate this approach. In regards to HF10 SCS, the percentage of patients with SAEs (adverse events that either resulted in in-patient hospitalization or extended hospitalization, or medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function) at 6 months was 16%.⁸ As for traditional SCS, Kumar et al. reported that 31.7% had “complications that required surgery” at 6 months.¹⁷ Van Buyten et al. reported 27% had surgical revisions at 12 months in a traditional rechargeable SCS study with mostly back and/or leg pain patients.²¹

C. Device Life

Consistent with Taylor et al. and Simpson et al., 4 years of device longevity was assumed for the nonrechargeable IPG in the FBSS model.^{2,6} The model uses 10 years of device longevity for traditional rechargeable IPG, which is similar to the assumption used in Taylor.⁶ Medtronic (Medtronic, Minneapolis, MN, USA) rechargeable IPGs have a 9-year end-of-life battery shutoff, and St. Jude Medical (St. Jude Medical, St. Paul, MN, USA)

TABLE 1: Clinical input data for first 6 months and per quarter from 6 months

Strategy	TNR-SCS	TNR-SCS	CMM	Reoperation	TR-SCS	HF10 SCS
Source	Kumar et al.	North	Kumar	North	Kumar and calculated ^f	See below ^g
First 6 months						
Initial success (%) ^a	82.7%	79.2%	NA	NA	82.7%	86.4%
Optimal pain relief (%) ^b	58.5%	52.9%	9.1%	11.5%	58.5%	73.7%
Complication rate	14.4%	14.4%	0.0%	0.0%	14.4%	14.4%
Markov model						
Complication rate (%/Quar)	4.8% ^c	4.8%	0.0%	0.0%	4.8%	4.8%
Withdrawal rate (%/Quar)	0.8% ^d	0.8%	1.2%	0.8%	0.8%	0.8%
Replacement rate (%/Quar)	7.25%	7.25%	NA	NA	3.94%	3.94%
Mortality rate (%/Quar)	0.2% ^e	0.2%	0.2%	0.2%	0.2%	0.2%

^aInitial success=trial phase success rate. ^bOptimal pain relief=percentage of patients with $\geq 50\%$ pain relief (response rate). ^cSource: Taylor: 18% compounded quarterly. ^dSource: Taylor: 3.2% annual rate after initial 6 months. ^eSource: Simpson. ^fSource: Kumar or calculated. ^gSource for initial success rate and optimal pain relief %: Van Buyten (2013).

rechargeable IPGs have a 10-year battery life claim.^{22,23} Similarly, Nevro has CE Mark labeling for 10-year battery life under typical HF10 SCS therapy settings.²⁴ Notably, the investigators observed that the more frequent charging required by HF10 SCS did not impact patient satisfaction and did not result in compliance issues.^{8,12}

D. Cost Data Input

A UK NHS perspective was used; therefore productivity lost through illness or costs incurred directly by patients are not included. Discount rates of 3.5% were applied to both future costs and health benefits, consistent with the current NICE guidelines.

Cost data for CMM, reoperation, and SCS were obtained from Taylor et al. and are reported in Table 2.⁶ The costs were assumed to be the same for TR-SCS and HF10 SCS, which would minimize the contribution of inflating costs when evaluating these two therapies. The acquisition cost for the HF10 SCS system was supplied by the manufacturer. Complication costs were in line with the per annum costs suggested by Taylor et al.⁶

We assumed the same average follow-up costs for all SCS systems, which is conservative

in regards to the HF10 SCS therapy since results with this therapy suggested a remarkably strong pain reduction compared to the data in the randomized trials. Based on Zucco et al. a VAS pain score improvement of 3 points equated to 50% reduction in follow-up costs.²⁵ Extrapolating these findings, one could estimate for the HF10 SCS therapy (with an average VAS pain score improvement of more than 5 points) a significant reduction of these follow-up costs compared to CMM. The latter was explored in a scenario analysis. Note that the reduction in follow-up costs assumed with traditional SCS was 50% which is in line with Zucco et al.²⁵

E. Utility Data

In order to calculate quality adjusted life years (QALYs), utility data were required. The QALY is a common measure of health improvement used in cost-effectiveness analyses. It combines mortality and quality of life gains by adjusting the number of years a person lives at the appropriate quality level (called utility) during those years. The maximum utility value is 1 and a value of 0 is assigned to death. As per the recommendations of NICE, and in

TABLE 2: Cost data applied in the model (Taylor et al., 2010) and data provided by Nevro (cost of the system)

	TNR-SCS	CMM	Reoperation	TR-SCS	HF10 SCS
SCS trial	£4,442	0	0	£4,442	£4,442
SCS implant	£9,762	0	0	£15,056	£15,056
Surgery	NA	0	£4,252	NA	NA
CMM first 6 months ^a	£1,720	£3,468	£3,468	£1,720	£1,720
CMM per 3 months, yr 1 ^a	£860	£1,734	£1,734	£860	£860
CMM per 3 months, yr 2+ ^a	£860	£1,734	£1,734	£860	£860
Complications ^b	£622	0	0	£622	£622
Cessation	£1,800	0	0	£1,800	£1,800

^aIncludes drug and non-drug pain therapy. ^bComplication costs were derived from Simpson et al. (2009).

line with Kumar et al. and Taylor et al., we applied a utility value of 0.598 in the case of optimal pain relief without complications, 0.528 in the case of optimal relief with complications, 0.258 in the case of suboptimal relief (both with or without complications), and 0.168 in the absence of any effect on pain.^{5,6,13} However, these utility values were based on studies with traditional SCS systems, for which back pain relief still remains undertreated. As such, the assumed utility value is conservative for the HF10 SCS therapy, given its notably high efficacy in both back and leg pain, even in predominantly back pain patients.

F. Model Validation

The model was validated using data recently reported by Al-Kaisy et al. on the 24-month follow-up of patients treated with HF10 SCS therapy.¹² The authors reported that after 24 months, 1.9% of patients had withdrawn from HF10 SCS therapy because of lack of efficacy. In our model, this figure is projected to be 1.5% at 24 months based on the 6-month data, i.e., a slight underestimation of withdrawal. The percentage of patients with optimal back pain relief in the follow-up study was 60% at 24 months, which is close to the approximation used in the model which projects 64% of patients with optimal pain relief at 24 months. Since the model does not entirely match the follow-up data, we performed a scenario analysis whereby the model was

calibrated to exactly match these follow-up data for HF10 SCS therapy (see below).

III. RESULTS

Table 3 shows the base case results of the analysis. The results for TNR-SCS and TR-SCS are in line with previously published studies (lower cost-effectiveness ratios as compared to the original NICE report but very similar to the later analysis from Taylor et al.).⁶ The HF10 SCS therapy shows an ICER of £3,153 and £2,666 per QALY vs. CMM and reoperation, respectively. Both HF10 SCS and TR-SCS are shown to be dominant over the TNR-SCS; however, comparing both rechargeable treatments, the HF10 SCS therapy is dominant, i.e., offering extra QALYs and lower cost. The savings are estimated to be £5,975 per patient over 15 years vs. TNR-SCS and about £1,023 per patient over 15 years vs. TR-SCS.

Sensitivity analyses confirmed that device longevity and device cost are the driving parameters in the model. The use of the observed 24 months data as alternative inputs in the model did not influence the results. This is shown in Fig. 2. Lastly, assuming an 86% trial phase success rate (which was seen in the HF10 SCS study's case series for FBSS patients), a threshold analysis revealed that the HF10 SCS therapy must show at least a 60% responder rate, as defined by percentage of patients with $\geq 50\%$ pain relief at 6 months, in order to

TABLE 3: Cost, QALYs, incremental cost, and incremental cost effectiveness ratios of different treatment options as compared to CMM or to reoperation in a simulated cohort of 1000 patients over 15 years

	Cost (£)	QALY	Incr cost	Incr QALY	ICER
Comparator=CMM					
CMM	80,605,788	3,308			
TNR-SCS	92,392,857	4,647	11,787,068	1,339	8,802
TR-SCS	87,440,887	4,648	6,835,098	1,340	5,101
HF10 SCS	86,417,656	5,151	5,811,868	1,843	3,153
Comparator=Reoperation					
Reoperation	82,187,498	3,565			
TNR-SCS	92,561,091	4,439	10,373,593	874	11,864
TR-SCS	87,440,887	4,648	5,253,389	1,083	4,849
HF10 SCS	86,417,656	5,151	4,230,158	1,587	2,666
Comparator=TNR-SCS PROCESS					
TNR-SCS	92,392,857	4,647			
TR-SCS	87,440,887	4,648	-4,951,970	1	Dominant ^a
HF10 SCS	86,417,656	5,151	-5,975,201	504	Dominant ^a
Comparator=TR-SCS					
TR-SCS	92,561,091	4,439			
TNR-SCS	87,440,887	4,648	-5,120,204	209	Dominant ^a
HF10 SCS	86,417,656	5,151	-1,023,231	712	Dominant ^a

^aDominant=lower costs and higher QALYs.³¹ ^bDominated=higher cost and lower QALYs.

remain dominant. Of note, the HF10 SCS therapy achieved a 71% responder rate at 24 months in a recent study.¹²

IV. DISCUSSION

The current model examined the cost effectiveness of the HF10 SCS treatment for patients with FBSS compared with other traditional SCS treatments, as well as with reoperation, and conservative modalities. This economic analysis found that when compared with CMM and reoperation, all three SCS treatments were shown to provide a cost-effective alternative treatment for patients with FBSS. HF10 SCS was the most cost effective

in comparison with CMM and reoperation with an ICER of £2,840 and £2,302 per QALY vs. CMM and reoperation, respectively. When compared against one another, HF10 SCS was shown to be less costly and to provide more QALYs than both the TNR-SCS and the TR-SCS treatments. Most importantly, the incremental cost-effectiveness ratio for HF10 SCS compared with all of these other treatments is much lower than the willingness-to-pay threshold of £20,000.⁶ Our findings are similar to those of 3 separate economic evaluations performed previously, which showed that SCS as a treatment is more cost effective than both CMM and reoperation.^{4,6,26} High-frequency stimulators were not examined in any of these trials; however,

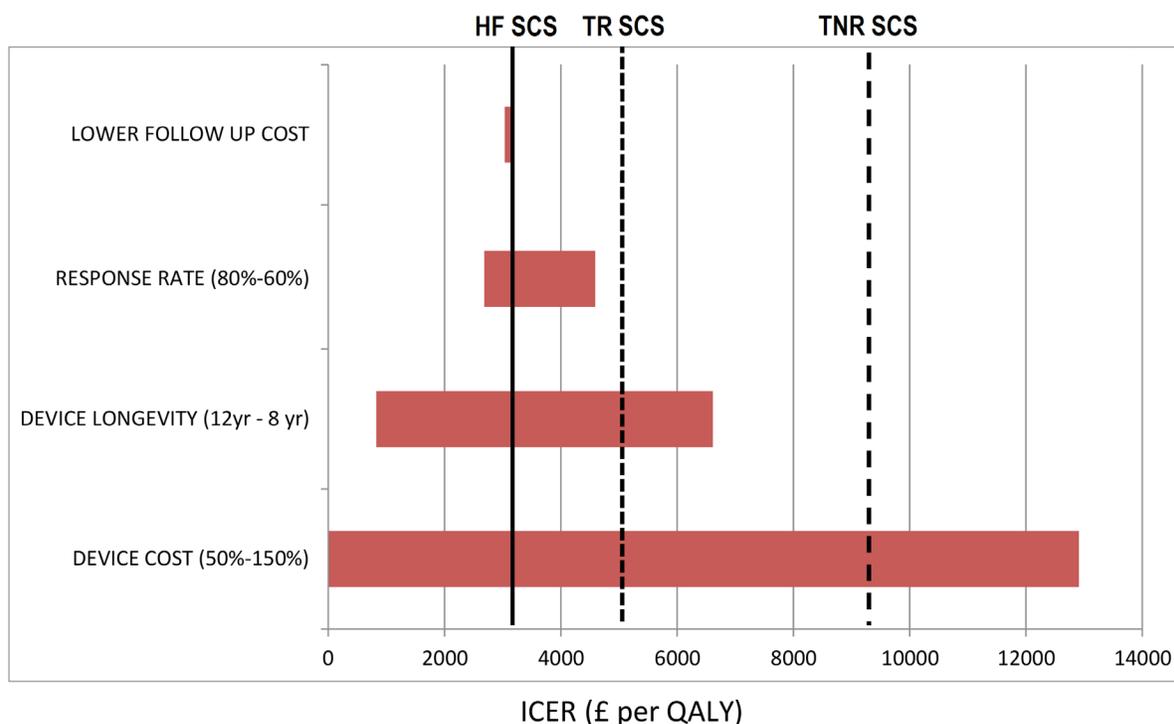


FIG. 2: Sensitivity analysis: The horizontal bars represent the range in the HF10 SCS therapy's ICER when changing the designated variable from the lower limit to the upper limit, while keeping the other input values constant. The solid line represents the ICER for the base case of the HF10 SCS therapy. The key inputs for the base case are described in Tables 1 and 2, and in the body of this article. The first dotted line represents the ICER for TR-SCS. The second dotted line represents the ICER for TNR-SCS.

traditional SCS systems were examined and were economically beneficial compared with reoperation and CMM.

Our current analysis has several strengths. The data that were used in this model were derived from two randomized controlled trials, and a 24-month multicenter prospective trial.^{3,4,11} The cost data were taken predominantly from Taylor et al., where all costs were based on a 6-month multinational trial that took place in Canada, Europe, Australia, and Israel.^{6,15} This study examined the pattern of healthcare use experienced by FBSS patients over a 6-month period and was extrapolated for the current data. The costs included took into consideration long-term costs and outcomes, including those of routine IPG replacement.⁶ The utility scores that were used in the current study were used in previous economic models and were based on EQ-5D utility scores reported by FBSS patients.^{2,5-7} Also, given the threshold analysis revealing that even a 60%

responder rate would make the HF10 SCS a more effective and less costly alternative than TR-SCS, the current results (based on the 71% responder rate observed in the 24-month HF10 SCS study) reach a strong level of robustness.

With all of the strengths provided by this economic model, there are also some limitations. First, due to the limited data available on the HF10 SCS, the key model input is based on noncomparative data and only one trial was available.¹⁶ The results from this prospective trial were compared with RCT studies. Although this comparison is not ideal, there is still great importance in comparing cost-effectiveness data of these different treatment modalities. This also applies to the clinical effectiveness, replacement rates, and complication rates. We applied the reported effectiveness rates from the respective studies and assumed that the complication rate for the different SCS systems was the same. The same logic was applied by Taylor et

al. based on the Kumar et al. and the North et al. publications.^{4,6,13} The replacement rates were estimates based on assumptions as well as previously published data. Confirmation of the results in a comparative study is required to verify the results. Nevertheless, the conclusions in this study are made on the most up-to-date clinical data available.

The current indirect comparison did not adjust for baseline characteristics. In the earlier traditional SCS trials, patients had predominantly leg pain, whereas in the HF10 SCS study patients had predominantly back pain. In principle, this selection bias should be to the disadvantage of the HF10 SCS therapy since patients with predominantly back pain are more difficult to manage.¹⁰ Additionally, the HF10 SCS treatment was the only treatment to show significant pain reduction in both leg and back pain.¹² As also noted in the PROCESS trial, only 24% of subjects had significant relief of low back pain.¹³

Baseline utilities were also derived from previously published data.^{5,6,13} There were a limited number of studies that reported on utility at baseline and at post-treatment with the multiple treatment options. While these utilities were taken from published EQ-5D data from FBSS patients, the accuracy of these numbers may be limited by the assumptions of the model itself.⁶ The model assumed that patients' status within a certain utility could change every 3 months; however, in the real world, changes can happen much more sporadically. The model simulated a cycle where patients have the same health utility status for at least 3 months, despite any complications that could occur within these time periods.

Another limitation that was encountered was that some uncertainties are contained in the existing models, for instance, in modeling the longevity of the devices. It was assumed that the nonrechargeable devices have an average life expectancy of 4 years, whereas the rechargeable devices have a life expectancy of 10 years. These assumptions are key to the calculated results as exhibited in the sensitivity analysis. The analysis shows that device longevity is one of the most important drivers in the cost effectiveness of the HF10 SCS, yet, the fact that the results for SCS in this study are in line with earlier publications contributes to the validity of the

study. It should also be noted that current clinical practice mandates that complex arrays with multiple contacts are used to capture paresthesia coverage of the low back in traditional SCS systems. These complex arrays may deplete a nonrechargeable system quickly, requiring reoperation as often as every 2 years in some cases.²¹

A further limitation of this study was that some of the total costs associated with each treatment option are estimated. Costs with associated with the TNR-SCS, CMM, and reoperation treatments were extracted from Taylor et al. and Simpson et al.; however, treatment costs were assumed to be the same for the TR-SCS and HF10 SCS treatments.^{2,6} The cost of the acquisition of the HF10 SCS was provided by the manufacturer, and this was standardized to the TR-SCS due to the similarity of the procedures performed. However, since the perspective of this analysis was the NHS, the study did not account for possible savings due to reduced procedure time and staffing requirements. Surgical procedures for SCS trial takes approximately 30 to 90 minutes and IPG implantation takes approximately 1 to 3 hours for traditional SCS, for a total of 1 ½ to 4 ½ hours.²⁷ This time can be far more consistent with the HF10 SCS therapy since intraoperative paresthesia mapping and programming are eliminated. Although this may be an economic advantage from a hospital perspective, the impact was not included in this model at this time.

The practice of economic models in the early development phase of technologies has existed for more than a decade, but has been largely applied only over the last few years.^{28–30} The idea is clear: based on anticipated or preliminary results from a new technology and its costs to the healthcare system, the potential cost effectiveness can be estimated, hence advising all stakeholders—manufacturers, policy makers, physicians, and patient advocacy groups—about what to expect from market access of the technology. Although HF10 SCS is compared to TNR-SCS and TR-SCS in terms of cost effectiveness, this paper does not compare TNR-SCS to TR-SCS and does not draw any conclusions between the two types of systems. In regards to this topic, Hornberger et al. and Taylor et al. have made clear conclusions that TR-SCS is more cost effective when compared to TNR-SCS.^{6,7}

V. CONCLUSION

In conclusion, the current analyses suggest favorable cost effectiveness of the HF10 SCS system in comparison to conventional medical management alone, reoperation, nonrechargeable SCS, and traditional rechargeable SCS.

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