Model-Based Battery Longevity Estimates for a Deep Brain Stimulation Pulse Generator

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Introduction

Battery longevity is a consideration for the use of non-rechargeable Deep Brain Stimulation (DBS) systems, as shorter battery life leads to increased replacement surgery in patients. Battery life, and thus energy use, is affected by DBS programming parameters, including impedance, amplitude, and pulse width. Use of directional leads could result in decreased battery life due to increased energy use from higher electrode impedances. The purpose of this study is to investigate the model-predicted battery longevity of a newly available DBS system under various programming conditions.

Methods

An energy use model was developed and validated by Boston Scientific (BSC) which predicts the energy use of a new Vercise PC implant. The model accounts for the energy in the stimulation output (given impedance), as well as internal energy use of the circuitry, which is not externally measurable. The model, as well as the programming software, reports energy use as an Energy Use Index (EUI), a parameter created by BSC to map energy use to battery longevity (fig. 4) [1]. Bench testing validated the model against IPG electronics, with an average difference of +1.14% (the model conservatively predicts a higher energy use/shorter battery life). In our study, EUI (battery life) was calculated for a combination of amplitudes and pulse widths, for impedances and fractionalizations which were lead-type specific (table 1). Common clinical ranges for these parameters were used, while rate was held constant at 130 Hz. Fractionalization refers to current steering by defining the fraction of current on each electrode. The nominal use case is defined here as 60 μs pulse width and 3 mA current. The set of impedances for the linear lead are 0.5, 1, and 2 kOhms, which represents the clinical range, and are multiplied by a factor of 2.3 for the directional lead due to decreased electrode surface area, which leads to increased electrode impedance. Our analysis characterizes the relationship between programming parameters and EUI for this stimulator.

Table 1: Variables tested	
Pulse width [μs]	30, 60, 90
Amplitude [mA]	1.5, 3, 6
Impedance [kΩ]	Linear: 0.5, 1, 2 Directional: 1.15, 2.3, 4.6
Rate [Hz]	130
Linear fractionalizations [%] (e1/e2)	100/0**, 50/50**
Directional fractionalizations [%] (e2/e3/e4)	100/0/0, 80/10/10, 50/25/25, 34/33/33**
**Ring Mode fractionalizations	

Figure 1: Vercise PC programming software.

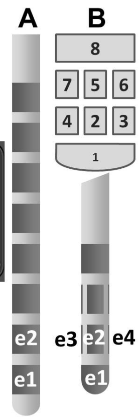

Figure 2: A) BSC linear lead. **B)** BSC directional lead.

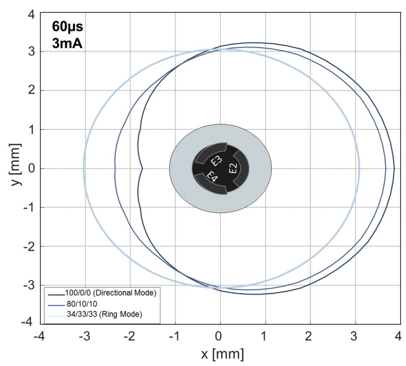

Figure 3: SFM contours of fractionalizations used in this study.

Results

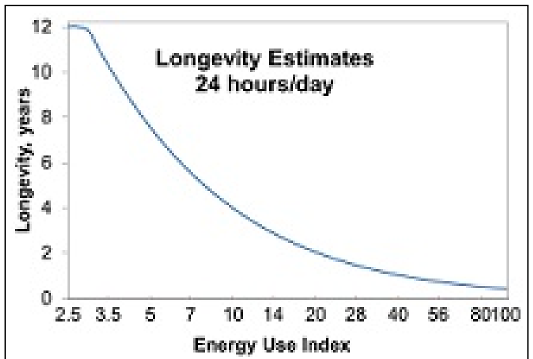

Figure 4: Battery longevity in years vs. EUI, based on a 24 hour/day DBS usage [1].

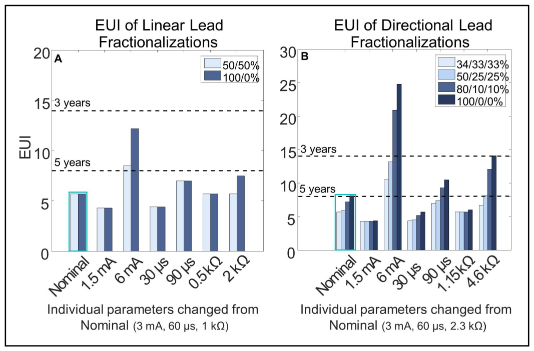

Figure 5: Comparisons of EUI changes from the nominal case (outlined) for **A)** linear lead and **B)** directional lead fractionalizations. Dashed horizontal lines note <5 years and <3 years of battery life as EUI increases.

- Few combinations of parameters changed from the nominal settings estimate a battery longevity of less than 3 years.
- The highest energy use occurs with single-electrode (100/0/0%) directional lead.
- Current steering towards Ring Mode (34/33/33%) lowers EUI, thus extending battery life, for high energy settings.
- Ring Mode on a directional lead has lower EUI than a single ring electrode (100/0%) on a linear lead.
- When energy use is low, current steering does not affect EUI (table 2).
- Amplitude changes cause the largest changes in EUI:
  - Doubling amplitude (from nominal to 6mA) causes a higher increase (~+306%) in EUI compared to changing pulse width (~+160%) and impedance (~+174%) for the directional lead Directional Mode case (100/0/0%).
  - For the linear lead Single-Electrode Mode case (100/0%), amplitude causes a +214% increase in EUI, while pulse width and impedance cause +155% and +164% increases, respectively.

Table 2: Best & Worst EUI Performance

Lead	Case	Stimulator Settings	Fractionalization	EUI
Linear	Best	30 μs, 1.5 mA, 0.5 kΩ	All	3.6
	Worst	90 μs, 6 mA, 2 kΩ	Single-Electrode Mode (100/0)	31.4
Directional	Best	30 μs, 1.5 mA, 1.15 kΩ	All	3.6
	Worst	90 μs, 6 mA, 4.3 kΩ	Directional Mode (100/0/0)	37.4

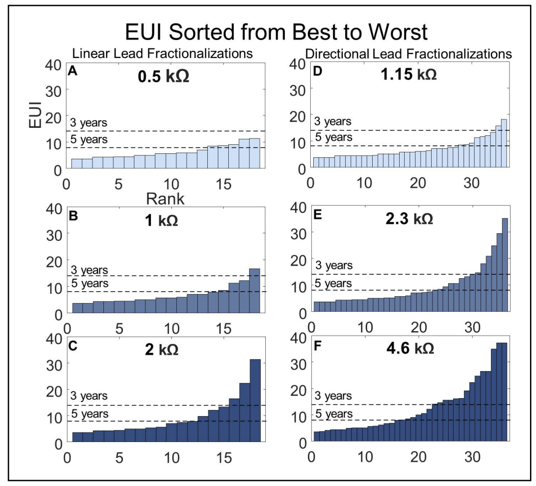

Figure 6: All EUI cases, sorted from best (lowest) to worst (highest) and plotted per impedance. Dashed horizontal lines note <5 years and <3 years of battery life as EUI increases. **A,B,C)** Linear lead EUI cases for 0.5, 1, and 2 kOhms, respectively. **D,E,F)** Directional lead EUI cases 1.15, 2.3, and 4.6 kOhms, respectively.

- With the increased impedance for the directional lead, EUI and therefore energy use increases, especially for higher impedances **(D,E,F)**.
- Few combinations of programming settings for the linear lead (4/60, ~6.7%) estimate a battery longevity below 3 years, but almost a quarter (~23%) of directional lead programming combinations do.

Conclusions

- Energy use estimates based on EUI should include the effects of the internal IPG circuitry.
- While higher impedances, amplitudes, and pulse widths increase energy use, there are few settings tested for the linear lead and only a quarter of the settings tested for the directional lead that estimate expected battery longevity of less than 3 years.
- Of the settings tested, amplitude has the strongest effect on EUI for either lead.
- Energy use and battery life can be improved by current steering to multiple electrodes in higher energy scenarios; towards Ring Mode in the case of the directional lead.
- The increased energy use of directional stimulation must be weighed against therapeutic benefit.

Reference

1. Vercise Navigator Programming Manual (91046489-01 REV A). Boston Scientific Neuromodulation.