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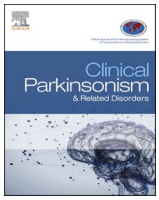

Movement disorder Deep brain stimulation Hybridization: Patient and caregiver outcomes

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A B S T R A C T

Background and Objectives: Deep brain stimulation (DBS) is a well-established surgical treatment for certain movement disorders and involves the implantation of brain electrodes connected to implantable pulse generators (IPGs). As more device manufacturers have entered the market, some IPG technology has been designed to be compatible with brain electrodes from other manufacturers, which has facilitated the hybridization of implant technology. The aim of this study was to assess the benefits of hybridization of non-rechargeable, constant voltage IPGs to rechargeable, constant current IPGs.

Methods: A list of DBS movement disorder patients who had their non-rechargeable, constant voltage IPGs replaced with rechargeable, constant current IPGs from a different manufacturer was compiled. Structured surveys of these patients, and their caregivers when applicable, were undertaken to determine both patient and caregiver satisfaction in this DBS hybridization strategy.

Results: Eighteen patients met inclusion criteria and twelve patients or their caregivers completed the structured survey (67% response rate). Nine patients had Parkinson's disease (75%), three had essential tremor (25%). Nine (75%) were converted from bilateral single-channel IPGs, and three (25%) were converted from a unilateral dual-channel IPGs. Overall, 92% of patients and caregivers surveyed reported improvement or no change in their symptoms, 92% reported a decrease or no change in their medication requirements, and 92% report they are satisfied or very satisfied with their IPG hybridization and would recommend the surgery to similar patients. There were no immediate surgical complications.

Conclusion: In this series of movement disorder DBS patients, surgery was safe and patient and caregiver satisfaction were high with a hybridization of non-rechargeable, constant voltage IPGs to rechargeable, constant current IPGs.

1. Introduction

Deep brain stimulation (DBS) is an effective therapy for movement disorders such as Parkinson's disease (PD), essential tremor (ET), and dystonia [1–5]. DBS incorporates implantable pulse generators (IPGs) to deliver current to electrodes placed in specific deep brain structures [4]. The IPG may be non-rechargeable or rechargeable and may be classified as constant current, constant voltage, or both. As more device manufacturers have entered the market and as patients with aging implants increase, there have been new demands on methods to upgrade devices. Some IPG technology has been designed to be compatible with brain electrodes from other companies which has facilitated the "hybridization" of implant technology. We present a method of hybridizing either bilateral single-channel/unilateral dual channel, non-rechargeable, Medtronic IPGs to unilateral, dual channel, rechargeable, Boston Scientific IPGs and a satisfaction survey of its patients/caregivers.

2. Methods

Eighteen patients who underwent replacement of their Medtronic, non-rechargeable, constant voltage IPG with a Boston Scientific unilateral, rechargeable, constant current IPG with at least 6 months of follow up data were identified through previous medical records, and a patient list was compiled (Table 1.). In all eighteen cases, IPG replacement was performed due to insufficient batteries. Every patient/caregiver was informed pre-operatively about the difference between hybridization and non-hybridization plus the associated advantages/disadvantages of each route. A structured survey (Figs. 1 and 2) of these patients, and caregivers when applicable, was conducted to determine patient and caregiver satisfaction (Table 2.). Survey topics include programming, recharging, symptom control, and medication requirements. The survey answers were compiled for descriptive statistical analysis. Further chart review was undertaken on each patient to evaluate for potential harm to patients due to loss of MRI conditionality, for any reprogramming challenges after hybridization, and for any other complications.

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Table 1
Patient Demographics.

Patient no.	Age (y)	Sex	Duration (y)	Diagnosis	Prior IPG Replacements	Pre-hybridization IPG	Post-hybridization IPG
1	72	M	10	PD	1	Medtronic Activa SCs	Boston Scientific Vercise DB-1110-C
2	84	M	6	ET	0	Medtronic Activa SC	Boston Scientific Vercise DB-1110-C
3	58	M	9	PD	3	Medtronic Activa SCs	Boston Scientific Vercise DB-1110-C
4	73	M	7	PD	2	Medtronic Activa SCs	Boston Scientific Vercise DB-1110-C
5	66	M	6	PD	0	Left Chest Medtronic Activa PC	Boston Scientific Vercise DB-1110-C
6	82	M	7	PD	2	Medtronic Activa SCs	Boston Scientific Vercise Gevia DB-1200-S
7	71	M	10	PD	3	Medtronic Activa SCs	Boston Scientific Vercise Gevia DB-1200-S
8	75	M	8	PD	1	Right Chest Medtronic Activa PC	Boston Scientific Vercise Gevia DB-1200-S
9	69	F	8	ET	1	Medtronic Activa SCs	Boston Scientific Vercise Gevia DB-1200-S
10	69	M	20	ET	4	Abdominal Medtronic Activa PC	Boston Scientific Vercise Gevia DB-1200-S Boston Scientific Vercise Gevia DB-1200-S
11	78	F	8	PD	1	Medtronic Activa SCs	Boston Scientific Vercise Gevia DB-1200-S
12	53	M	9	PD	3	Medtronic Activa SCs	Boston Scientific Vercise Gevia DB-1200-S

Abbreviations: M, Male; F, Female; Age, age at time of survey; Duration, duration of DBS treatment, PD, Parkinson's Disease; ET, essential tremor.

Caregiver Questionnaire:

Hello, this is Dr. ___ from the AGH department of neurosurgery, calling with a quick survey of your experience with your DBS generator. This survey should only take approximately 5-10 minutes.

Today's interview will consist of seven questions. As I mentioned, you have the right to defer any question or to end the interview at any time. There is a possible risk of loss of confidentiality of your protected health information, but your answers will be kept confidential. There will be no identifying data on survey linking you to the questions that you answered.

1. Since [patient name] elected to switch to rechargeable internal pulse generators, have his/her symptoms improved or become worse in any fashion?
1- significantly worse 2- worse 3- stayed the same 4- better 5- significantly better

2. Since [patient name] elected to switch to rechargeable internal pulse generators, have his/her medications changed in any fashion?
1- Significantly more 2- Some more 3- stayed the same 4- Little less 5- significantly less

3. Compared to [patient name]'s original setup, has the programming process been easier or more challenging in any fashion?
1- significantly harder 2- harder 3- stayed the same 4- easier 5- significantly easier

4. Since [patient name] elected to switch to rechargeable internal pulse generators, how often has the setup malfunctioned?
1- never 2- rarely 3- sometimes 4- frequently 5- practically daily

5. How much difficulty have you experienced recharging [patient name]'s internal pulse generator?
1- none 2- minimal 3- some 4- significant difficulty 5- tremendous difficulty

6. Overall, how much of a burden has the transition to rechargeable internal pulse generator caused you as a caregiver/LAR?
1- none 2- minimal 3- some 4- significant burden 5- tremendous burden

7. Overall, how satisfied are you and [patient name] with his/her decision to switch to a rechargeable internal pulse generator?
1- very dissatisfied 2- dissatisfied 3- neutral 4- satisfied 5- very satisfied

This concludes the interview. If you have any questions or concerns about the study you can contact the neurosurgery office ___ and ask to get in touch with either Dr. ___ or Dr. ___. If you have any questions about study participant's rights you can reach out to Allegheny Health Network Research Institute Institutional Review Board (IRB) ___. Thank you very much for your time. Enjoy the rest of your day.

Patient Questionnaire

Hello, this is Dr. ___ from the AGH department of neurosurgery, calling with a quick survey of your experience with your DBS generator. This survey should only take approximately 5-10 minutes.

For the Patient

Today's interview will consist of six questions. As I mentioned, you have the right to defer any question or to end the interview at any time. The questions are based on a 1-5 scale, but you may provide open ended details in addition to numbers if you wish. There is a possible risk of loss of confidentiality of your protected health information, but your answers will be kept confidential. There will be no identifying data on survey linking you to the questions that you answered.

1. Since you elected to switch to rechargeable internal pulse generators, have your symptoms improved or become worse in any fashion?
1- Significantly worse 2- worse 3- stayed the same 4- better 5- significantly better

2. Since you elected to switch to rechargeable internal pulse generators, have your medication doses Changed in any fashion?
1- Significantly more 2- Some more 3- stayed the same 4- Little less 5- significantly less

3. Compared to your original setup, has the programming process been easier or more challenging in any fashion?
1- Significantly worse 2- worse 3- stayed the same 4- better 5- significantly better

4. Since you elected to switch to rechargeable internal pulse generators, how often have you had difficulty with the set up?
1- Never 2- rarely/monthly 3- sometimes/weekly 4- frequently 5- daily

5. How much difficulty have you experienced recharging your internal pulse generator?
1- none 2- minimal 3- some 4- significant difficulty 5- tremendous difficulty

6. Overall, how satisfied are you with the switch to a rechargeable internal pulse generator?
1- very dissatisfied 2- dissatisfied 3- neutral 4- satisfied 5- very satisfied

This concludes the interview. If you have any questions or concerns about the study you can contact the neurosurgery office at ___ and ask to get in touch with either Dr. ___ or Dr. ___. If you have any questions about study participant's rights you can reach out to Allegheny Health Network Research Institute Institutional Review Board (IRB) ___. Thank you very much for your time. Enjoy the rest of your day.

Fig. 1. Legend- These were the scripts used for patient and caregiver interviews. Answers to each question were based on a 1–5 scale.

Our method for conversion of bilateral single channel Medtronic Activa SC IPGs to a unilateral dual channel Boston Scientific Vercise or Vercise Gevia IPG is as follows. Pre-operatively, the existing IPGs are interrogated with a Medtronic (MDT 8840) programmer, and their therapy settings, therapy impedance, and system impedance are recorded. The patient is identified, marked, and taken to the operating room. The existing non-rechargeable IPGs are exposed and removed bilaterally through the prior incision sites. On one side, a 55 cm extension/conversion lead developed by Boston Scientific is attached to the existing Medtronic extension and tunneled subcutaneously across the anterior chest to the pocket on the other side. A 15 cm extension/conversion lead is attached to the existing Medtronic extension on the side that will receive the dual channel Boston Scientific IPG. The fastening site in the M8 adaptor has a rubber flange covering the fastener screw with a slit to allow tightening. This septum seal plug is sealed with medical adhesive (Dow Corning Silastic® Medical Adhesive Silicone) on both adaptors after tightening and prior to closure. Both adaptor leads are then connected to the now unilateral IPG, it is placed in the pocket, and impedance is checked prior to closure.

Pre-operatively, the current delivery settings are recorded in voltage given the constant voltage nature of the Medtronic IPG. Post-operatively, the current delivery settings are converted from voltage to milliamps (mA) due to constant current status of the new IPG. Settings are programs to a value 0.5 mA lower than the pre-operative current delivery setting, with the patient/caregiver given a range of +/-1 mA of adjustability through their new Boston Scientific programmer. No changes are made to pre-operative pulse width or frequency settings (Table 3). The patient is checked by neurosurgery, and the patient plus caregivers are introduced to the Boston Scientific representative prior to discharge. Patients/caregivers are given contact information for both neurosurgery and the Boston Scientific coordinators. The patient is seen in clinic two weeks afterwards for symptomatology evaluation, wound

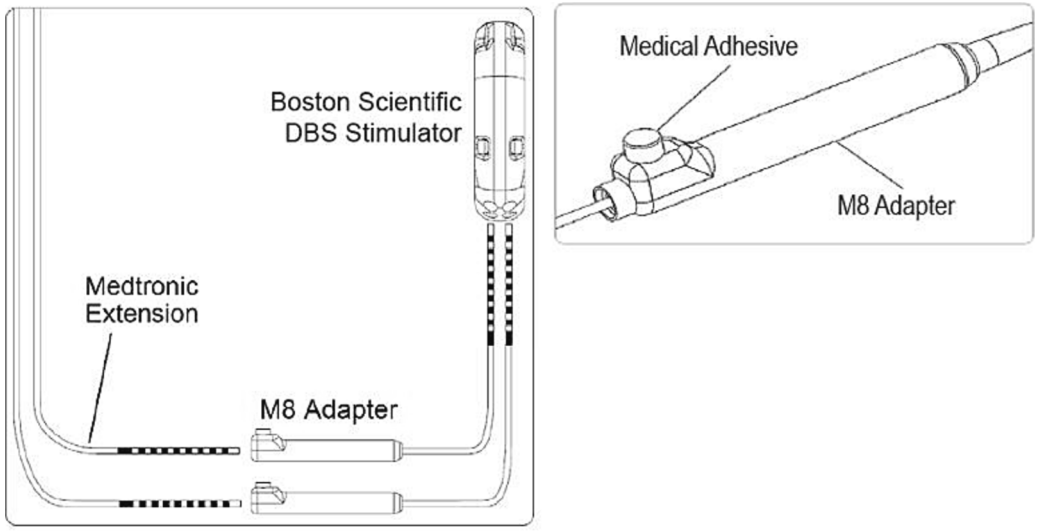

Fig. 2. Legend- Connections of Vercise™ Adaptors to Medtronic Lead Extensions and Boston Scientific IPG and Medical Adhesive Covering the Septum Seal Plug[39], (Dow Corning Silastic® Medical Adhesive Silicone)[39].

Table 2
Survey Responses.

Patient no.	Question 1	Question 2	Question 3	Question 4	Question 5	Question 6	Question 7
1	3	2	5	1	1	5	
*2	2	3	4	2	3	1	2
3	4	4	3	1	1	5	
*4	4	3	3	1	1	1	5
5	4	5	5	1	3	5	
6	4	5	2	1	3	4	
7	3	3	3	1	1	5	
*8	3	3	4	1	1	1	5
9	3	5	3	1	1	5	
10	3	3	3	1	1	5	
*11	3	3	3	1	1	1	5
12	3	3	4	1	1	5	

*caregiver surveys.

check, and programming check. The IPG is re-programmed as needed from that point either in the neurosurgery functional clinic or the neurology office. All data analyzed in this study is included in this article. This study was conducted in accordance with Institutional Review Board approval. Consent was obtained from all participating patients.

3. Results

Across the eighteen identified patients, two were deceased, and four more were unable to be reached. In total, 12 patients or their caregivers were reached for our structured survey (Table 2), a 67 % response rate (mean age 70.8 years). Nine (75 %) were converted from bilateral, Medtronic Activa SC IPGs, and three (25 %) were converted from a unilateral Medtronic PC IPG. Five (42 %) were implanted with Vercise DB-1110-C IPGs, and seven (58 %) were implanted with Vercise Gevia DB-1200-S IPGs. Nine (75 %) had Parkinson's disease (mean age 69.78 years), and three (25 %) had essential tremor (mean age 74 years). 92 % of respondents reported either improvement or no change in symptomatology since conversion, 92 % reported a decrease or no change in medication requirements, and 92 % reported satisfaction with their new generators and would recommend them. Two patients reported initial difficulty with learning to recharge their IPG early after implantation but stated there was no difficulty after the initial learning process. One patient reported rare difficulty with remembering to charge his system with rare interruptions in therapy as a result.

There were no immediate surgical complications reported from the hybridization procedure. One patient reported dissatisfaction with his symptom control after conversion to a rechargeable system and requested re-implantation of Medtronic non-rechargeable IPGs. His condition continued to deteriorate after re-implantation of a Medtronic system, and he experienced delayed post-operative infection requiring removal of his generators and extension cables. He also experienced an overall decline in his health, likely explaining his dissatisfaction. A final patient experienced left scalp incision breakdown several months post conversion, but this was not an incision opened during the procedure. Two attempts at wound revision were undertaken, and finally, his left extension cable was removed to allow full wound healing before re-implantation. Three patients had been denied an MRI after this conversion, two for low back pain with neurogenic claudication or radiculopathy who both required CT myelograms, and one for altered mental status who underwent CT perfusion to rule out stroke. There were no complications from the myelograms, and the altered mental status was due to non-compliance with psychiatric medication. Stroke was successfully ruled out without MRI.

Eight patients (67 %) reported stable to improved symptoms immediately after conversion, while four (33 %) required additional visits for programming to achieve optimal control. Of those four, only one was unable to achieve satisfactory symptomatic control including after re-implantation, while the rest (n = 11 or 92 %) reported stable to

Table 3
Pre and Post Op Generator Settings.

Patient	Pre-op Settings	Most Recent Follow Up Settings
1	Left 5.8 V 70 pw 180 Hz	Left 5.4 mA 70 pw 179 Hz
	Right 5.4 V 70 pw, 180 Hz	Right 5.0 mA 70 pw 179 Hz
2	Left 5.3 V 90 pw 180 Hz	Left 8.4 mA 120 pw 180 Hz
3	Left 5.0 V, 80 pw, 190 Hz	Left 6.2 mA, 70 pw, 143 Hz
	Right 3.6 V, 60 pw, 180 Hz	Right 3.2 mA, 60 pw, 179 Hz
4	Left 4.4 V, 60 pw, 160 Hz	Left 5.0 mA, 60 pw, 132 Hz
	Right 5.2 V, 160 pw, 145 Hz	Right 4.8 mA, 60 pw, 132 Hz
5	Left 3.6 V, 80 pw, 165 Hz,	Left 2.5 mA, 80 pw, 136 Hz
	Right 4.1 V, 90 pw, 165 Hz	Right 3.3 mA, 90 pw, 170 Hz
6	Left 2.6 V, 60 pw, 160 Hz	Left 2.5 mA, 80 pw, 170 Hz
	Right 5.1 V, 150 pw, 200 Hz	Right 5.2 mA, 150 pw, 200 Hz
7	Left 2.5 V, 60 pw, 160 Hz	Left 4.4 mA, 60 pw, 159 Hz,
	Right 4.4 V, 90 pw, 160 Hz	Right 4.7 mA, 70 pw, 159 Hz
8	Left 4.3 V, 60 pw, 160 Hz	Left 4.2 mA, 60 pw, 159 Hz,
	Right 4.3 V, 60 pw, 160 Hz	Right 4.9 mA, 60 pw, 159 Hz
9	Left 3.5 V, 80 pw, 130 Hz	Left 3.9 mA, 90 pw, 130 Hz
	Right 4.8 V, 90 pw, 130 Hz	Right 3.8 mA, 90 pw, 140 Hz
10	Left 5.0 V, 60 pw, 170 Hz	Left 3.6 mA, 60 pw, 170 Hz
	Right 4.6 V, 110 pw, 170 Hz	Right 3.1 mA, 90 pw, 170 Hz
11	Left 5.1 V, 60 pw, 145 Hz	Left 4.2 mA, 50 pw, 170 Hz
	Right 5.0 V, 60pw, 145 Hz	Right 5.8 mA, 80 pw, 170 Hz
12	Left 4.6 V, 70 pw, 170 Hz	Left 4.2 mA, 50 pw, 170 Hz
	Right 5.8 V, 90 pw, 170 Hz	Right 5.8 mA, 80 pw, 170 Hz

Abbreviations: V, volts; pw, pulse width; Hz, Hertz; mA, milliamps. Note: The Medtronic devices use voltage by convention because they are constant voltage, some with additional constant current settings. Boston Scientific programmers use milliamps by convention, all are constant current.

improved control after hybridization (Table 2).

4. Discussion

There are three manufacturers of DBS systems approved by the FDA for implantation in the United States, Medtronic, Boston Scientific, and Abbott Neuromodiulation [4,6,7], with additional systems now in production [7] that are not FDA approved. Historically, non-rechargeable IPG replacement could be necessary as often as yearly depending on the specific device and programming settings, and each surgery carries risks of infection, device failure, electrode damage, etc [1,3,8,9]. The early movement disorder DBS patient population from this institution, consisting of PD and ET patients, was implanted with Medtronic bilateral sub clavicular IPGs that were non-rechargeable. Rechargeable IPGs were introduced with the aim of lowering replacement frequency and complication risks [1,8,10,11]. In some series, rechargeability was correlated with higher risk of need for explanation in spinal cord stimulation [12,13], but this does not appear to be the case with DBS to date [1,2,8]. A commonly implanted non-rechargeable IPG is the Medtronic Activa PC, which has an average battery lifespan ranging from 2.6 to 4.5 years [7,14,15]. In currently available rechargeable systems, battery lifespan ranges from 10 to 25, years [7,16].

Very few of our early patients were converted to Medtronic rechargeable IPGs due to replacement burden, but in our local health care market, the Medtronic rechargeable IPG has generally been cost prohibitive due to fees and specifics of local insurance policy. Boston Scientific developed a method of connecting a Medtronic DBS brain lead to their Vercise rechargeable IPG line by developing the Vercise M8 adaptor, which is available in both 15 and 55 cm lengths.

Early IPGs had a single source supplying all of the electrode contacts, while newer devices were developed that had multi-source power delivery [5]. Multiple source current delivery was later developed plus directional contacts, allowing for more precise programming, battery usage, and effective modulation [4,10,16]. Early single channel systems required bilateral IPGs for bilateral cranial leads, with the first dual channel unilateral IPG that could provide stimulation to bilateral cranial leads appearing in 1998 [8,17]. Unilateral IPGs reduce surgical incisions with accompanying reduction in possible operative morbidity [4,16].

The therapeutic impact of DBS is related to the amount of current delivered to neural tissue. An IPG can deliver current on a constant voltage basis, a constant current basis, or both [18–22]. Early DBS IPGs were developed as an adaptation of constant voltage cardiac pacemakers, and thus operated on a constant voltage basis [18]. The impedance effect of the interface between the lead and the neural tissue varies over time due to changes in the micro-environment, especially in the weeks and months following surgery as encapsulation occurs.

The primary driver of hybridization in these cases was to provide rechargeability, but a preliminary financial review was undertaken. Hybridization of bilateral non-rechargeable Medtronic IPGs to a unilateral Boston Scientific rechargeable IPG reduced implant expense by $30,000. This is compared to conversion of bilateral non-rechargeable Medtronic IPGs to bilateral Medtronic rechargeable IPGs. Hybridization also allowed patients with more insurance carriers to be offered a rechargeable system. Further follow up will be necessary to determine the cost savings over time given the longer battery life in a rechargeable system. Several series revealed significant long term cost savings in patients who received rechargeable IPGs due to reduced battery replacement surgeries [11,23,24]. As for the safety of switching manufacturers, a previous study from 2019 investigates 10 patients who switched from Medtronic to Boston Scientific, and it reflects stable clinical outcomes with no post operative complications [22]. Information on patient safety is limited at this time due to a small sample size, but there is also no data in current literature to suggest that DBS hybridization puts its patients at risk.

Longer term complications specific to rechargeable IPGs include failed recharges, occurring in 8.7 % of cases in one series, with 3.7 % experiencing unintended temporary interruption of therapy [8]. In rare cases, the failures of recharging can require reoperation for repositioning of the IPG [25]. In prior DBS series, most patients have not found rechargeable IPGs difficult to recharge, but some clinicians have expressed concerns with elderly, cognitively impaired patients [1,8]. The frequency of recharging varies from daily to once weekly, based on the indication for DBS and the stimulation parameters [1,2,8,16,26]. Several DBS series show that patients also favored the rechargeable variants based on durability and cost, but few evaluate the role of the caregiver [2,11,24,26,27].

In this series, only one patient reported rare therapy interruptions due to forgetting to recharge his IPG.

Another concern with the hybridization of DBS technology is the immediate loss of MRI conditionality. One study estimated that 56–57 % of DBS patients will need an MRI within 5 years, and 66–75 % would need an MRI within 10 years [28]. Several series show it appears generally safe to use MRI in these patients, but concern for MRI related injury, mostly due to potential for heating of electrode leads or interruption of IPG function, remains [5,29–36]. The major manufacturers maintain strict policies of MRI conditionality for their respective systems, with limitations on field strength and other parameters of scanning [5,32,37,38]. Hybridization of neuromodulation technology like DBS abolishes MRI conditionality in most cases. However, Boston Scientific has published approval of certain hybrid systems in certain select situations [38]. For example, if a patient is converted from a unilateral Medtronic Activa PC to a Vercise Genus, and if they are not implanted with both a Medtronic 95 mm extension and a 55 mm Vercise M8 adaptor. Overall, it is unlikely that FDA approval would ever be warranted for the majority of these patients [22]. In our series, three patients were recommended for MRI and were unable to undergo the study due to their IPG hybridization and loss of MRI conditionality. Two underwent CT myelograms of the lumbar spine and another CT perfusion of the brain. Aside from the additional need for the intrathecal injection of contrast and ionizing radiation, no apparent harm has been caused by the lack of MRI conditionality in this series to date. Further follow up will be necessary to determine the potential risk of harm to these patients from loss of MRI conditionality. It is also important to discuss the loss of MRI conditionality with patients and the potential risks prior to

hybridization.

This is a relatively new procedure with somewhat low numbers performed to date. The survey sample size in our survey is small, with only four caregiver surveys and eight patient surveys. It was hoped that it would be possible to interview both patient and caregiver for as many cases as possible, but it was found that when the patient was reached, they felt that they exclusively managed their own DBS routine. When a caregiver was reached, they reported that the patient had little involvement in their own IPG management due to overall health and functional status. Therefore, this study is limited in regards to assessing caregiver education about IPG usage, which is especially important to consider among patients with cognitive impairment.

Another limitation in this study is the lack of pre and post hybridization standardized objective measures, like UDPRS scores on this patient cohort. The IPGs in this series are managed in more than one clinic, and thus in this series these measures are not always obtained or documented. Also, objective measures would be needed to determine if symptomatic improvement is due to patient novelty bias, placebo effect, or if there were objective improvements after conversion to constant current programming.

5. Conclusion

The primary objectives of IPG hybridization in our movement disorder patients were to achieve IPG longevity and reduced replacement burden. We did not suggest to patients a guaranteed improvement of symptomatic control. However, many reported subjective improvement after conversion to constant currant programming. In this series, reprogramming after hybridization was generally effective and was accomplished with minimal to no additional appointments. Both patient and caregiver satisfaction are high with the addition of rechargeability. We experienced no major, immediate post-operative complications and no unexpected morbidity or mortality. Overall, our hybridization strategy appears to be a safe and effective procedure for carefully selected and informed patients. Further follow up with more objective measures will be needed to determine if symptom control is improved after conversion to constant current programming. Careful patient selection and discussions of risks and benefits remain key in patient safety and satisfaction.

Author Contributions

Dr. Nathan Esplin: Conceptualization, Data curation, Formal analysis, Methodology, Writing – original draft. **Dr. Dorian Kusyk:** Conceptualization, Data curation, Writing – review and editing. **Dr. Seung W. Jeong:** Data curation, Writing – review and editing. **Dr. Shahed Elhamdani:** Data curation, Writing – review and editing. **Khaled Abdel Aziz, BS:** Writing – review and editing. **Amanda Webb, PAC:** Investigation, Validation, Project administration. **Cindy Angle, RN:** Investigation, Validation, Project administration. **Donald Whiting, MD** Investigation, Validation, Project administration. **Nestor Tomycz, MD** Investigation, Validation, Project administration.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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