The Safety to Switch from Constant Voltage to Constant Current with a Mixed Internal Pulse Generator in Deep Brain Stimulation

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Abstract

Background: Deep brain stimulation (DBS) is an efficient modality for the treatment of movement disorders. Differing from the constant voltage (CV)-DBS devices, constant current (CC)-DBS devices may allow more precise stimulation of the target brain regions since they are less influenced by impedance. If internal pulse generators (IPGs) of DBS devices are required to be connected with electrodes of different brands, employing proper adapters is necessary. Such connected DBS devices are called mixed or hybrid devices. **Objectives:** As there is sparse information about the clinical mixed devices, we studied their safety and efficacy. **Materials and Methods:** Clinical scores of 13 patients implanted with mixed DBS devices were determined with the Unified Parkinson's Disease Rating Scale (UPDRS) in Parkinson's disease (PD) (n = 10) and with the Burke–Fahn–Marsden Dystonia Rating Scale (BFMDRS) in dystonia (n = 3). Patient satisfaction was assessed with the Timmerman questionnaire. The Clinical Global Impression Improvement (CGI-I) Scale was also evaluated. **Results:** Patients' overall satisfaction was considerably higher with mixed devices. The UPDRS and BFMDRS clinical scores did not significantly differ after switching to a mixed DBS device. Three patients before the DBS switch suffered from side effects under the CV mode. These patients got rid of the side effects in their follow-up with a reduction in pulse width values. **Discussion:** Mixed devices working in CC mode are well tolerated with high patient satisfaction. **Conclusion:** Besides patient satisfaction, mixed IPGs are also considered safe.

Keywords: Constant current, constant voltage, deep brain stimulation, internal pulse generator

INTRODUCTION

Since Benabid *et al.*'s first definition in 1987, deep brain stimulation (DBS) has emerged as an important therapeutic modality for different movement disorders, especially when patients become unresponsive to pharmacological interventions.[1-5] DBS is an efficient and important treatment option for Parkinson's disease (PD), essential tremor, and dystonia with proper patient selection.[4,6] Initially, DBS devices could only be programmed in constant voltage (CV) mode, but relatively recently, they can also be used in constant current (CC) mode.[6] Impedance—resistance to the employed electrical stimulation—plays an essential role in brain stimulation, which may change over different time frames. CV-DBS devices provide an adjustable voltage across the stimulating electrodes, and in these devices, the tissue volume and the current stimulated in CV-internal pulse generators (IPGs) may exert differences due to fluctuations in the tissue–electrode interface and the tissue impedance.[6] The current distribution defines the activated tissue volume (ADV) with specific stimulation parameters. The benefit of CC stimulation is that it provides a constant ADV by adjusting the voltage according to the tissue impedances. With adapter support, the electrodes of CV devices may be combined with batteries of different brand CC devices, which are called mixed devices. Various centers have shared their experiences with the compatibility of electrodes and batteries of different brands with adapter support in these mixed devices. Nonetheless,

sufficient information lacks about the reliability of these mixed devices and the regulation in programming. Few publications exist in the literature on mixed implants switched from CV to CC in DBS.[6-9] In this study, since only Boston Scientific was available as a rechargeable (RC) battery during the study conduction, we combined Medtronic's systems in patients with the Vercise (Boston Scientific) system with the help of an adapter and examined the satisfaction status and side-effect profile of the transition from CV to CC in this mixed system.

METHODS

This retrospective clinical study completely complies with the principles of the Helsinki Declaration of 1964 and its

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latest amendments. No procedures were applied to patients that would bring additional health risks or financial burdens except those that were obligatory for their treatment. Pictures or any other relevant data were omitted that might disclose the patient's identity. All patients signed informed consent forms for participation in the study. Ethical approval was obtained from the responsible ethical committee with decision number 52 (Memorial Hospital Ethical Committee, Istanbul, Turkey). This study conducted in the Neurosurgery Department of Memorial Hospital (Sisli, Istanbul, Turkey) from April 2019 to July 2020 included 13 patients who switched from CV to CC in which a single surgeon performed DBS-IPG replacement. All implants before the exchange were implanted with quadripolar DBS electrodes (Model 3387, Medtronic), and the electrodes were connected with Medtronic Activa® PC (Medtronic). Before the switch, all IPG types were in CV mode and all were replaced by Vercise RC™ (Boston Scientific). A connection was performed with the Vercise M8 Adapter Kit. We used Boston Scientific RC-IPGs because the Medtronic RC-IPGs were not accessible in our country at that time. After replacement, the old contact settings in CV mode were activated in CC mode. Patients with PD were evaluated before and after the procedure with the Unified Parkinson's Disease Rating Scale (UPDRS)-3 (motor scale, drug "off," stimulation "on" state), and patients with dystonia were evaluated with the Burke–Fahn–Marsden Dystonia Rating Scale (BFDMRS). Pre- and postoperative stimulus settings and impedances were compared. For the comparison of the DBS parameters before and after implantation of RC-IPGs, a retrospective chart was utilized in the patients who switched from depleted non-RC-IPG to RC-PG. Patient satisfaction was assessed with the Timmerman questionnaire. According to the questionnaire created by Timmermann *et al.*, 1. fit comfort, 2. recharging, 3. display, 4. programmer, 5. training, and 6. overall satisfaction were questioned (questions described by Timmermann *et al.*).[10] Answers to each question were scored between 1 and 5, and there were three, four, four, six, four, and three questions for the fit comfort, recharging, display, programmer, training, and overall satisfaction ratings, respectively. The change in side effects was evaluated in detail in three patients. Preoperative and postoperative therapeutic current flow and impedances of each patient were compared as right and left, and the statistical significance of the changes was analyzed. The impedances measured were electrode impedances. The Clinical Global Impression Improvement (CGI-I) Scale, whose rates change from initiation, was used to evaluate the recovery of patients after replacement surgery by the patient and the clinician. CGI-I is an easily understandable seven-point scale, which was evaluated by patients and clinicians.

Statistical analysis

Statistical analyses were performed using a commercially available software package (Statistical Package for the Social Sciences (SPSS) version 19.0. IBM Corp., Armonk, NY). We analyzed and compared parameters including amplitude (V/mA), pulse width (ms), frequency (Hz), impedance, Timmerman questionnaire, CGI-I Scale, and UPDRS -3, between the preoperative and postoperative follow-up. Data are presented as mean ± standard deviation (SD). Differences between the two groups were assessed by the Mann–Whitney U-test. Probabilities of less than 0.05 were considered significant.

RESULTS

Patient demographics and main DBS parameters

Thirteen patients, whose CV non-RC battery system was replaced with an RC battery system, were included in our study, and their demographic and clinical features are summarized in Table 1. Six (46.2%) participants were female, and seven (53.8%) were male. DBS was implanted in 10 patients due to PD (DBS target: 10 Subthalamic Nucleus [STN]) and in three patients due to dystonia (DBS target: 3 Globus pallidus interna [Gpi]). The mean time spent with DBS in 13 patients before RC-IPG was 83 months ± 39 (range: 43–147 months), and the total mean number of battery changes before switching to RC-IPG was 3 ± 1.5 (range: 2–7). The mean age at the time of RC-IPG implantation was 54.2 ± 17.1 years (range: 24–76 years). The average follow-up time after battery replacement was 30.5 ± 16.7 months (range: 6–61 months). Patients recharged the battery every 4 days (±1.91 days) on average and spent an average of 34 ± 11 minutes. None of our patients developed perioperative and postoperative complications, and all patients were alive at the end of our study. In the changes made, IPG dysfunction was not observed in the early and late follow-ups. The satisfaction of patients implanted with mixed DBS devices is demonstrated in Figure 1. Eleven patients answered "completely agree" to the evaluation of all-over satisfaction after the RC system, and two of them gave the answer "mostly agree."

Table 2 summarizes the mean UPDRS-3 (drug "off," stimulation "on" state) and BFMDRS scores of patients. The UPDRS of 10 patients with PD remained stable for four patients in the last follow-up, while a slight decrease was observed in four patients, and a slight increase was observed in two patients. While one of three patients with a diagnosis of dystonia remained stable on the BFMDRS, a decrease was observed in two of them. None of these clinical scale

Table 1: General demographic and clinical features of patients

Patients' demographics and diseases	Numeric and percentage values
Number of patients (*n*)	13
Female (*n*)	6 (46.2%)
Male (*n*)	7 (53.8%)
Mean age at the switching (year)	54.2±17.1 (range: 24–76)
Mean follow-up (months)	30.5±16.7 (range: 6–61)
Parkinson's disease (*n*)	10
Dystonia (*n*)	3
Mean time spent with DBS before switching	83 months±39 (range: 43–147 months)
Mean number of IPG replacement	3±1.5 (range: 2–7)

changes were statistically significant ($P = 0.757$). A CGI-I score of 4 (suggesting no clinical change) was reported for 10 subjects by both patients themselves and the attending clinician. Three patients, including two PD (patients 1 and 10) patients and one dystonia (patient 11) patient, declared a slightly better well-being state (CGI-I score: 3, suggesting minimal improvement), but an improvement was considered for only two of these by the clinician (CGI-I score: 3).

The changes in amplitude, pulse width (ms), frequency (Hz), and impedance of the electrodes are shown in Table 3. There were no significant differences in any of these parameters in both the PD and dystonia groups. In Table 3, exact numerical P values were given to ascertain whether there are statistical differences, yet only "na" (not available) was written for dystonia patients, as only three patients existed in this group, hindering statistical calculations. In PD, therapeutic current flow with CV and the first programming of current flow with CC-DBS did not differ significantly ($p_{right} = 0.293$, $p_{left} = 0.976$). In a total of 26 electrodes, the amplitude decreased in two and remained stable in 24 immediately after the battery change. During follow-up, amplitude reduction was applied in two patients, slight increase in nine patients, and no change in two patients. At the end of the follow-up period, the amplitude value of 16 (61.5%) of a total of 26 electrodes was slightly increased, while it remained unchanged in seven (27%) electrodes and decreased in three (11.5%) electrodes. In PD patients, there were no statistically significant differences between therapeutic pulse width (ms), frequency (Hz), impedance (Ω) values, and non-RC period before and after RC DBS system

placement (($p_{right} = 0.936$, $p_{left} = 0.912$), ($p_{right} = 0.226$, $p_{left} = 0.226$), ($p_{right} = 0.242$, $p_{left} = 0.121$), respectively). In dystonia patients, there were no differences between therapeutic pulse width (ms), frequency (Hz), impedance (Ω) values, and non-RC period before and after RC-DBS system placement. Minimal changes were considered nonsignificant (ns), and exact P values were not given due to a very small sample size (n = 3).

Three patients before the IPG switch suffered from side effects under the CV mode, but all three patients got rid of the side effects in their follow-up with a reduction in the pulse width values while also achieving efficient symptom control [Table 4]. As will be detailed below, one had dysarthria, one had minimal arm contraction, and the last one suffered from paresthesia in the arm. The dysarthria that existed before the IPG change was improved by decreasing the pulse width. For patient 1, while the patient's tremor control was easily achieved with the settings made, the complaint of contraction in the arm, which was present before, disappeared with the new settings. The setting adjustments included increasing the frequency and changing the pulse width from 60 to 40 without changing the contact in the left STN during the programming after the change. In patient 10, it was observed that the paresthesia in the right hand, which occurred during the tremor control in both hands, was relieved when the frequency was increased and the pulse width decreased during the programming. Patient 11 had dysarthria, which was uncomfortable in the programming settings, in which dystonia was controlled, and it was observed that the dysarthria was relieved when the pulse width was decreased bilaterally.

Lastly, considering medications, no changes were made in levodopa dosages in any of the patients after the CV-to-CC switch.

Discussion

Utilization of mixed devices in movement disorders

Preda et al.[6] conducted a retrospective analysis of multicenter data including 19 patients (13 PD and 6 dystonia) who underwent IPG replacements from CV to CC as mixed

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Table 2: Mean UPDRS and BFMDRS scores of Parkinson's disease (PD) and dystonia patients, respectively

Mean UPDRS scores (for PD)
  Before: 38.7±13.47 (range: 19–65)
  After replacement: 37.7±13.47 (range: 18–65)
  Last follow-up: 37.7±12.94 (range: 19–65)
Mean BFMDRS scores (for dystonia)
  Before: 26.3±3.56 (range: 21–31)
  After replacement: 24.7±2.3 (range: 21–27)
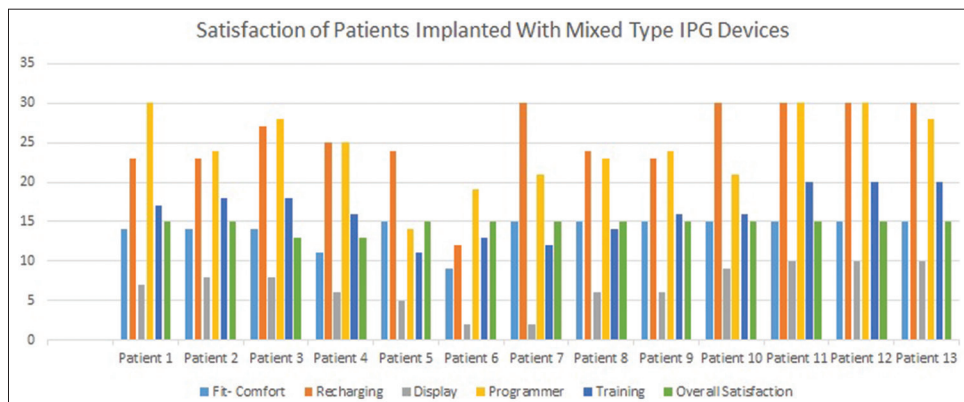 Last follow-up: 22.3±4.3 (range: 17–29)

Figure 1: Satisfaction scores of patients according to Timmermann questionnaire

Table 3: Amplitude, pulse width, frequency, and impedance values applied for patients with Parkinson's disease and dystonia

	Parkinson's disease patients						Dystonic patients					
	Right		*P*	Left		*P*	Right		*P*	Left		*P*
	Pre-replacement	Post-replacement		Pre-replacement	Post-replacement		Pre-replacement	Post-replacement		Pre-replacement	Post-replacement	
Amplitude (V/mA)	3.26±0.7	3.44±0.71	0.293	2.7±0.5	2.8±0.49	0.976	5.06±0.4	5.23±0.4	na	4.46±0.55	4.53±0.38	na
Pulse width (ms)	63±4.83	62±9.19	0.936	63±4.83	60±11.54	0.912	80±17.3	73.3±28.9	na	80±17.3	73.3±23.1	na
Frequency (Hz)	133±6.74	139±9.94	0.226	133±6.74	139±9.94	0.226	143.3±23.1	150±20	na	143.3±23.1	150±20	na
Impedance (Ω)	652.9±271.8	534±212	0.242	725.5±100.8	611±167.1	0.121	318.3±158.9	303.3±147.4	na	810±36.1	833.3±28.9	na

"*P*" indicates significance. na: "not available" statistical comparison due to low number of patients

Table 4: Detailed documentation of impedance (IMP), intensity (INT), and pulse width (PW) adjustments in three patients for whom the side effects can be controlled after IPG switching

P.	Dis. and Tar.	IMP BFS R-L	IMP AFS R-L	IMP LF R-L	INT BFS (V) R-L	INT AFS (mA) R-L	INT LF (mA) R-L	FR BFS (Hz) R-L	FR AFS (Hz) R-L	FR LF (Hz) R-L	PW BFS (µs) R-L	PW AFS (µs) R-L	PW LF (µs) R-L
1	PD-STN	1050-750	907-650	808-689	3.1-2.8	3.1-2.8	3.6-3.1	130-130	130-150	130-150	60-60	60-40	60-40
10	PD-STN	350-753	308-607	324-605	3.6-2.7	3.6-2.5	3.8-2.7	130-130	130-150	130-150	90-90	90-50	90-50
11	Dys.-Gpi	351-757	333-715	304-659	4.7-3.9	4.7-3.8	5-4.1	180-180	180-180	180-180	60-60	50-50	50-50

P.: patient number; Dis.: disease; Targ.: target; Dys.: dystonia; BFS: before switching, AFS: after switching; LF: last follow-up; R: right; L: left

implants. Before replacement, all patients were implanted with Medtronic Kinetra™ or Soletra™ (Medtronic Inc., USA) IPGs functioning in CV mode. Before total exhaustion of the batteries, CV-IPGs were changed with CC-IPGs (Libra XP™ or Brio™; St. Jude Neuromodulation, USA) by the employment of an adapter (IS-1 Pocket Adapter; St. Jude). In their long-term follow-up, they found stable clinical outcomes. Among the six dystonic patients analyzed, the BFDMRS scores exerted a trend of an improvement of 8% after 3 months and of 10% after 6 months of CC stimulation.[6] All these patients had multisegmental dystonia with profound cranial (swallowing and speech difficulties) and cervical involvement, and this clinical improvement, though small, impacted life quality. The major improvements were achieved in patients where CV stimulation provided suboptimal results. In these cases, CC stimulation ameliorated oromandibular condition, torticollis and trunk control, and dysarthria.[6]

Wolf *et al.*[9] prospectively investigated the use of mixed implants in the transition from non-RC-CV to RC-CC battery in 11 consecutive patients who underwent DBS. Eleven consecutive patients with dystonia (n = 7), PD (n = 3), and essential tremor (n = 1) underwent IPG switching from a CV-NRC system (Activa® PC; Medtronic) to a CC-RC system (Vercise® RC; Boston Scientific). In this study, in all dystonia patients but one, stimulation intensities had to be enhanced during follow-up similar to those encountered with previous CV stimulation. Interestingly, impedance values did not significantly change; hence, the requirement to enhance the current in dystonic patients was attributed to either disease

progression or functional adaptation of brain tissue to the chronic stimulus. The clinicians reported that the interchange of these different DBS technologies is highly safe and feasible.[9] Still, the investigators commented that hybrid systems have limitations such as lesser MR safety and the vulnerability of DBS adaptors to hardware complications.[9] Soh *et al.*[7] reported that they switched to the Boston Scientific system in two essential tremor patients and utilized mixed implants. These two patients were initially implanted with Medtronic IPGs, and despite several adjustments, they responded suboptimally to therapeutic stimulation because of side effects. Considering the theoretical efficacy of a pulse width lower than 60 µs (not achievable with Medtronic IPG), patients accepted to switch to a Boston Scientific IPG. A Vercise M8 Adapter Kit was utilized to connect the newly implanted IPG with the previously inserted Medtronic electrodes 3387. With this change and without a revision surgery, they were able to use safer and more effective low pulse widths to reach the therapeutic effect with fewer side effects.[7]

Wirth *et al.*[8] prospectively collected data from 30 PD patients with STN-DBS, who underwent the replacement of a non-RC-IPG (Activa PC or Kinetra, Medtronic, USA) by a CC-RC one (Vercise RC™ or Gevia RC™, Boston Scientific, USA) as mixed implants. For comparison, they also utilized a reference retrospective cohort including 39 PD patients who underwent an IPG replacement using the non-RC device. According to their 3-month follow-up experience in the switch from CV to CC as mixed implants, they witnessed that this transition is safe.[8] They reported that they had to make changes

in the programming of all patients who underwent CC-RC but only in 19% of the CV-non-RC group. In their study, the amplitude was the only parameter adjusted in 37 electrodes but fitted strictly to the prediction according to Ohm's law in only eight electrodes. For most patients, the final amplitude was even higher than 20% of the predicted amplitude.[8] They underlined that patients undergoing an RPG replacement from a CV device to a CC device with low active contact impedance should be attentively followed up after the surgery.[8] The broad possibilities of parameter settings (different frequencies, decreased pulse width, and current steering) offered by CC-RPGs were used to handle difficult-to-manage patients, especially those with axial signs but also continual fluctuations in motor functions.[8] In our study, we witnessed that the overall satisfaction rate of the patients carrying mixed devices was considerably high, suggesting that these hybrid devices are safe and clinically efficient.

The role of impedance and its changes during device switch of DBS

The efficacy and side effects of DBS are highly dependent on impedance, which is the resistance to the spread of electrical current. Impedance differs considerably between patients and substantially affects the extent of tissue activation, as it influences the amount of current being transmitted to the brain.[11] The tissue volume stimulated by DBS is inversely related to impedance. An important determinant of impedance is the foreign body reaction surrounding the electrode contacts, which is featured by gliosis, accretion of extracellular matrix proteins, a glial fibrillary acidic protein (GFAP)-positive capsule, and appearance of giant cells.[6,12] A thicker capsule and more intense gliosis around the DBS electrode are associated with increased impedance values. Tissue conductivity has a key role in DBS impedance measurements, but considerable variability exists within the available estimates. The mean values are 0.15 S/m for white matter, 0.45 S/m for gray matter, and 0.17 S/m for mean conductivity.[13] Particularly, a gradual decrease in impedance over time may also occur due to the accretion of cerebrospinal fluid around the electrode, as observed in cerebral atrophy in PD or normal aging.[11,14] In our study, we also encountered a decrease in impedance values in PD patients evaluated immediately after switching to the mixed devices and at their last follow-up, but these changes were not statistically significant.

Programming and adjustments of DBS devices after CV-to-CC switch

There is yet no accepted programming clarity in the transition from CV to CC. As for the device adjustment examples employed in various centers, either the same preoperative settings are used and changes are performed according to the patient clinical features, or by calculating ohm values initially, patients are adjusted for low amplitude.[9] After the replacement of CV-IPGs, the impedance of the stimulation circuit may exert changes, causing a decline or an increase in the current transmitted to the target tissue.[6] Dysfunctions of electrodes and the increase in leads' impedance may be encountered more commonly following IPG replacement: A noteworthy

rate of intolerable side effects and/or reduced clinical efficacy are reported mostly if high intensities are utilized before replacement.[6] CC-IPGs are programmed to maximize patients' benefits by controlling motor deficits while minimizing side effects. Optimization of program adjustments may take days or weeks (~3–4 weeks) to obtain the same clinical results provided before the substitution.[6] Waln and Jimenez-Shahed[15] analyzed parameters changed due to conversion from CC to CV-IPGs and determined that the stimulation frequency, pulse width, and mean amplitude were mildly lower after the switch regardless of the patient diagnosis and remained at reduced levels after three postswitch reprogramming. There also occurred a slow drift of amplitude back to preconversion settings, which was encountered more in the Gpi group. They stated that their clinical practice involves a lowering of the stimulation amplitude by 10–25% in the operating theater based on the manufacturer's recommendations immediately following the replacement of any depleted IPG with an RC or non-RC device.[15]

A possible benefit of the CC programming is the lowering of impedance, which extends the battery life, without adversely affecting the clinical outcome.[16] In our study too, impedance values tended to lower after CV-to-CC switch in PD patients, albeit these changes were not statistically significant. Some groups determined that there is no direct correlation between the clinical improvement and total electrical energy transmitted to tissue in dystonic patients, and a patient-tailored stimulation of the right target regions could provide improved outcomes and avoid untoward effects on neighboring structures.[2,3,6] While minimizing stimulation-associated side effects, optimal clinical results in PD can be achieved in patients by adjusting pulse width, electrode frequency, polarity, and voltage.[17] For instance, bipolar stimulation can narrow the tissue activation volumes to save the fibers of the internal capsule or the other eloquent brain regions. In PD, reducing the pulse width <60 μs may enhance the stimulations' therapeutic window by adjusting amplitudes that provide clinical benefits with fewer side effects.[17] In our study, the slight increase in amplitude witnessed in the follow-up of the patients may associate with the progression of the disease. Both after the early IPG switch and at the last follow-up, minimal programming changes were made including a slight increase in pulse frequency with a slight increase in pulse width in both PD and dystonia patients. These modifications did not create a significant change in the clinical motor scales but helped to control the side effects in three patients.

Efficacy and safety issues regarding the switch from CV- to CC-DBS devices

In a retrospective analysis, Lettieri et al.[14] reported that CC stimulation may be a better choice in terms of effectiveness than CV stimulation in dystonia patients. Comparing patients with CC- or CV-controlled DBS stimulation, a statistically significant improvement in BFMDRS scores at the first 6 months of follow-up was not found, while a significantly better outcome was encountered in the CC-controlled group at the 6–12 months of follow-up.[14] It is suggested that the treatment efficiency with the IPGs using the CC mode is at least as efficient as the CV mode and

it is a more stable and sustainable treatment than the CV mode. In a prospective study, Amami *et al*.[16] analyzed the efficacy and safety of converting from CV to CC-IPG devices (both from the same brand, Medtronic) in 20 PD patients who underwent STN-DBS and declared that the patients were stable after the transition and a new adjustment (the active contact, pulse width, or PD medication) were not required. Executive deteriorations, especially inhibitory processing, may be encountered in PD patients with STN stimulation under CV mode. Converting to CC was found safe considering cognitive abilities.[16] In our study, while no significant changes were encountered in clinical scales, additional side effects were also not observed.

Limitations of the Study and Future Prospects

There are some limitations of our study. The patient cohort is relatively small, and the study has a retrospective nature. As a short-term observational study, to analyze whether CV-to-CC switch with mixed devices is safe, our results indicate considerable safety as a proof of principle. Of course, randomized controlled trials and longer follow-ups are necessary, which we are currently performing. Our clinical observations also suggest that other complaints of patients and life qualities were not negatively impacted after the CV-to-CC switch in all patients, but rather significantly improved in some. Nonetheless, other quantitative surveys are required for definite comments on these issues. Also, future studies would reveal additional insights, which will compare the patient satisfaction scores before and after switching.

Conclusions

In our experience, mixed devices are well-tolerated and safe options in the treatment of PD and dystonia patients. All of our patients reported high levels of satisfaction, while none of them had worsening symptoms. Furthermore, we observed that in three patients suffering from side effects, the CV-to-CC-mode switch of DBS with mixed implants provided symptom relief and improved their condition. No major changes were necessitated in device settings except mild increases in current amplitude and frequencies, while slight reductions in the pulse widths were made, especially in patients with side effects encountered under previous CV-mode treatment. Furthermore, we did not require changing medication dosages after the device switch. Despite the abovementioned limitations, our short-term results are encouraging and suggest that a DBS switch is a plausible option in countries where the same DBS device brands of electrodes and IPGs are not accessible.

Availability of data

Data can be provided by the responsible author upon reasonable request.

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Conflicts of interest

Dr. Ozturk has disclosures with Boston Scientific, in terms of proctorship. However, as can be seen in the article, the superiority of any brand over the other has not been discussed and the sensitivity required to avoid bias has been considered. Dr. Paksoy has no disclosures. Both authors also declare that all other financial and personal relationships that might bias their work do not exist.

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