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RESEARCH ARTICLE

# Patient perspectives on the efficacy of a new kind of rechargeable deep brain stimulators<sup>1</sup>

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**Purpose/Aim of the study:** Rechargeable deep brain stimulation (DBS) system with longer battery life has become available for treating movement disorders. However, little information exists about the safety and management after implantation. Therefore, there is an urgent need to evaluate the recharging performance through long-term observations. **Materials and methods:** Fifty-three Parkinson's disease (PD) patients were implanted with a new rechargeable device (G102R, PINS Medical). They were observed at the baseline and 3 months, 6 months and 12 months after surgery, with measurement of the acceptance, frequency, recharging time and feeling during recharging. **Results:** The patients with the ages between 34 and 70 ( $57.64 \pm 7.34$ ) years thought the system was very easy to recharge. The favorite time interval for recharging was 1 week, and 10 days and half a month also chosen. Most of the patients spent around 1 hour recharging, with no unacceptable hot feelings reported. **Conclusions:** The PD patients could easily and safely recharge this new rechargeable implantable neurostimulators. Thus, these neurostimulators might be an excellent choice for PD patients.

**KEYWORDS:** Parkinson's disease, deep brain stimulation, rechargeable, battery life, safety

## Introduction

Deep brain stimulation (DBS) has become a well-established treatment for movement disorders [1]. Additionally, several recent clinical studies have indicated great potential for DBS in treating psychiatric disorders [2]. However, implantable neurostimulators (INS) used for DBS have several limitations. Traditional INS devices are battery powered but not rechargeable, such that the device must eventually be replaced. Factors leading to high-energy consumption with respect to INS technology have been identified; these include higher voltages, broader pulse widths and monopolar settings [3]. DBS of the globus pallidus generally requires a higher stimulation amplitude and a longer pulse width [4–6], resulting in a battery life of 1–4 years. In patients

with Parkinson's disease (PD) who receive DBS in the subthalamic nucleus (STN), the life of the INS ranges from 4 to 5 years. The devices are programmed after implantation to maximize the benefit to the patient, where the goal is to address motor deficits while minimizing potential side effects. Decreased energy consumption is a current goal in the development of DBS devices, as this would enable a longer INS lifetime and thus reduce the frequency of operations required to replace the INS. In clinical use, functional voltages and pulse widths are minimized, especially in patients with dystonia, and essential tremor (ET) patients are strongly encouraged to switch off the battery of their INS devices when not needed (e.g. while sleeping). Although it is possible to check the battery status of traditional INS devices, some patients experience a pronounced deterioration of their clinical symptoms before the actual end-of-life of their device. It is possible that the abovementioned energy-saving strategies and limitations on consumption reduce the efficacy of DBS treatment.

Taken together, the complications associated with the short lifespan of INS devices present a significant danger to patients with dystonia and PD. Adding to this,

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a recent study [7] indicated that the risk of infection, which is the most frequent complication associated with DBS surgery, is three times greater during IPG reimplantation surgery than during the original surgery (i.e. intracranial lead placement with IPG insertion). Furthermore, replacing an INS every 3–5 years involves additional hospital stays, sedation during the operation and additional scarring of previously operated tissue. Other disadvantages of currently available INS devices are the weight and size of the units, which can limit their use, especially in children and underweight patients.

In an attempt to overcome these issues, several groups are developing rechargeable devices for DBS. The first rechargeable INS (Activa RC, Medtronic) was implanted in October 2008 in a PD patient in Germany. The device was approved by the FDA in 2009 [8]. Four years later, a variation of this device (G102R, PINS Medical) was implanted in a patient in China. However, there is little information about the use of rechargeable DBS devices, especially with respect to patient recharging behavior. This makes it difficult to guide patients in developing efficient and convenient recharging routines. In this article, we describe a multi-medical center patient evaluation study, focused on PD patients, which explored safety and patient management of rechargeable implantable pulse generators (RPGs). We found that the optimal recharging schedule was approximately once per week for about 1 h.

## Materials and methods

### Device

The rechargeable DBS systems used in this study were manufactured by Beijing PINS Medical Co., Ltd. (Beijing, China), and approved by the China Food and Drug Administration (CFDA) in autumn 2014. The system includes an RPG and a recharging device. During the recharging process, there are four optional channels could be set according to the patient experience and preferences. The charging power increases from channel 1 to 4, whereas charging rate decreases respectively. Thus one skilled patient theoretically need less time with higher channel to recharge, and vice versa.

### Patients

Three Chinese medical centers took part in this study: the Beijing Tiantan Hospital, the Peking Union Medical College Hospital and the Zhujiang Hospital of the Southern Medical University. All medical teams had experience in implanting DBS devices and the appropriate hospital ethics boards approved the study.

Patients with idiopathic PD received rechargeable DBS devices with the STN as the chosen target. The pa-

tients were trained to perform the recharging process before and after surgery, and completed a survey measuring their satisfaction with the rechargeable device during the first year. The recharging rates used by each patient were recorded throughout the study.

## Questionnaire and interviews

The questions concerned RPG use in home and work settings and covered the following topics: (1) ease of recharging, (2) frequency of recharging, (3) recharging rates, (4) the time needed to recharge for each channel and (5) thermal sensations during recharging. The first and last questions were rated using a 5-point Likert scale. The patients completed all questionnaires during routine outpatient visits or at home 1, 3, 6, and 12 months after surgery.

## Statistics

To ensure reliable data analysis, the statistics were analyzed by an independent institution (Statistics Center of the Fuwai Hospital of Cardiovascular Disease, Beijing, China). The means and standard deviations were calculated using SPSS version 17.

## Results

During June and December 2012, 53 patients (40 men and 13 women) with idiopathic PD were enrolled in the study. Each participant provided written informed consent. Of these patients, 31 were treated at the Beijing Tiantan Hospital, 14 at the Peking Union Medical College Hospital and 8 at the Zhujiang Hospital of the Southern Medical University. The participants ranged in age from 34 to 70 years (mean  $57.64 \pm 7.34$  years) and were grouped according to decade, with the largest group ( $n = 24$ ) aged 51–60 years. The mean duration since diagnosis was  $11 \pm 4.05$  years (Table 1).

After training regarding the recharging process, most patients (38 (71.7%) before surgery and 52 (98.1%) at the end of the follow-up) believed that they could easily handle the process. The number of participants who

Table 1. Patient characteristics.

Characteristic	Value	Percentage (%)
Sex (no. of patients)		
Male	40	75.5
Female	13	24.5
Mean age (SD)/age in categories	$57.64 \pm 7.34$	
31–40 years	1	1.9
41–50 years	8	15.1
51–60 years	24	45.3
61–70 years	20	37.7
Duration of disease (years)	$11 \pm 4.05$	

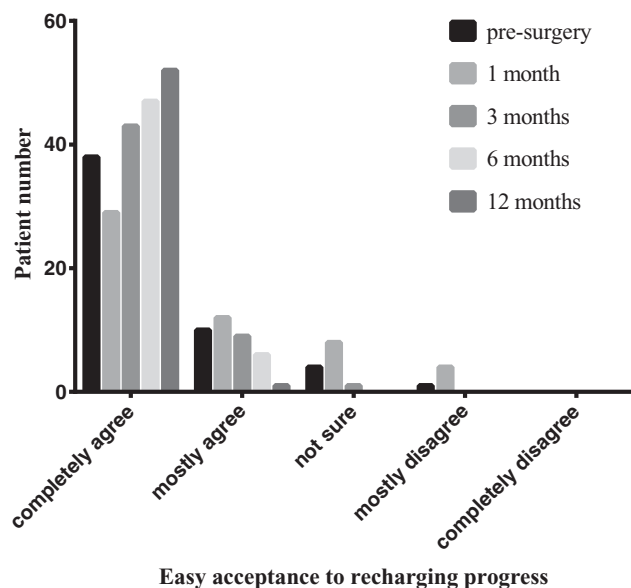


Figure 1. Degree of acceptance to recharging progress and the change in the number of patients at different follow-ups. The figure shows nearly all patients believed they could easily handle the recharging process by themselves 12 months after surgery.

stated that they could easily handle the recharging process dropped to 29 one month after surgery. This may have been due to an underestimation of the impact of the impulse generator location on the ease of the recharging process. As shown in Figure 1, no patient completely disagreed with the statement that the recharging process was easy to learn. We found no correlation between age and convenience of use.

The patients were instructed to recharge their device once at the beginning of each week. We chose this frequency because it seemed like it would be easy to remember, and daily recharging appeared to be inconvenient. At the first follow-up assessment, all patients had chosen to follow their doctor's advice regarding recharging frequency. Most participants maintained this pattern, with more than 40 patients continuing to recharge their device weekly. Some patients chose other frequencies; the most popular of these were once every 10 days and twice a month. Only four patients chose the longest duration, and one patient decided to recharge more frequently because of the long recharging time, as shown in Figure 2.

Because of concerns about safety, 28 (52.8%) patients used channel 1, which had the lowest recharging rate, at the beginning of the follow-up. This resulted in long recharging times. All of these patients chose to change their recharging rate at subsequent follow-up visits. Channel 2 was the most popular choice after the 3-month follow-up, with 47 (88.7%) patients using channel 2 at their last visit. Channel 4 had the fastest en-

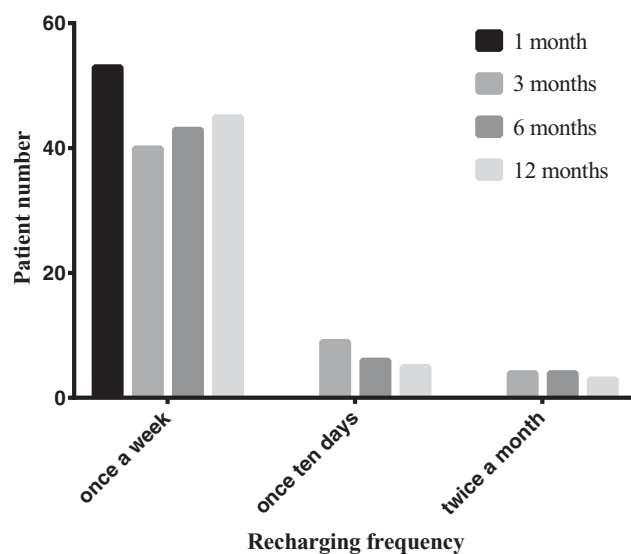


Figure 2. Three chosen recharging frequencies during the study – once a week, once every 10 days and twice a month – with the first being the favorite.

ergy recharge rate; however, patients were more likely to have abnormal thermal sensations during recharging with this mode. As shown in Figure 3, only one patient was using channel 4 at the end of the study.

The recharge time depended not only on the frequency, but also on the recharging rate. The patients recorded their recharging times and provided these at follow-up assessments. As shown in Figure 4, patients using channel 1 needed about 150 min for recharging. This recharging length may be difficult for PD patients to tolerate. In subsequent visits, patients took about 1 h to complete the entire process, and the charging time at

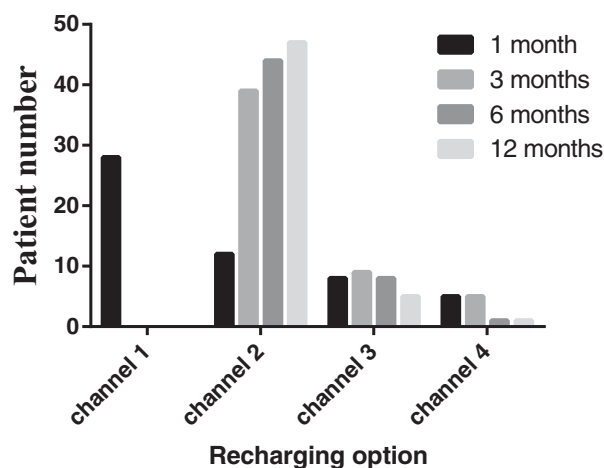


Figure 3. Four optional channels for recharging, with channel 1 having the lowest speed. The majority of patients tended to choose channel 2, and none of them chose channel 1 because of the long duration.

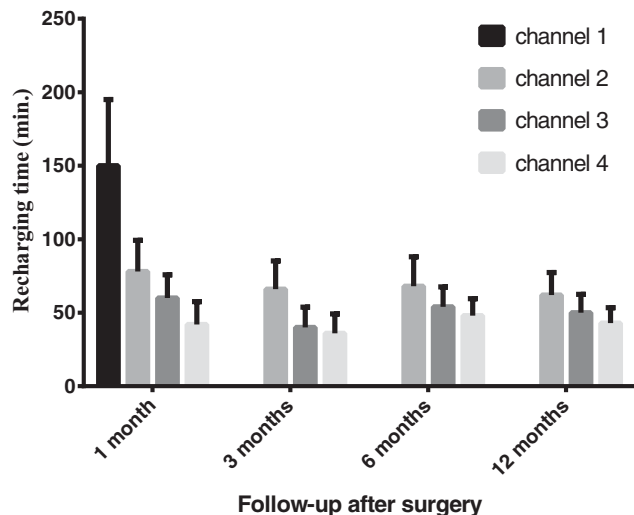


Figure 4. Recharging time taken by each patient for each channel, with channel 1 needing more than 2 hours, which seems to be too long to tolerate for PD patients. Experience and skill shortened the time at later follow-ups.

12 months was slightly less than that at 6 months, probably because of increased experience and skill.

As shown in Figure 5, no patients reported hot sensations during the study, although several patients felt some warmth at the stimulator site during charging. However, they reported that they still felt it was safe despite this thermal sensation. The majority of the participants responded that they felt no thermal sensations during recharging.

## Discussion

According to Harries et al. [9], patients should be advised about the potential problems associated with Medtronic recharging device prior to DBS surgery. To reduce the occurrence of such problems, our participants were carefully trained about the recharging process at the beginning of the study. As a result, most of them reported that they believed they could easily handle the entire recharging process. However, this number had declined at the 1-month follow-up, potentially owing to an underestimation of the importance of maintaining a close proximity between the recharging system and the RPG during charging. During recharging, the patients usually chose to lie down to reduce their movements, and placed the recharger under a tight fitting wrap to maintain a better connection. Timmermann et al. [10] found that elderly patients were less satisfied with the recharging process compared with younger patients. They hypothesized that this result could be because of age-related differences in familiarity with technically advanced processes such as recharging. As a

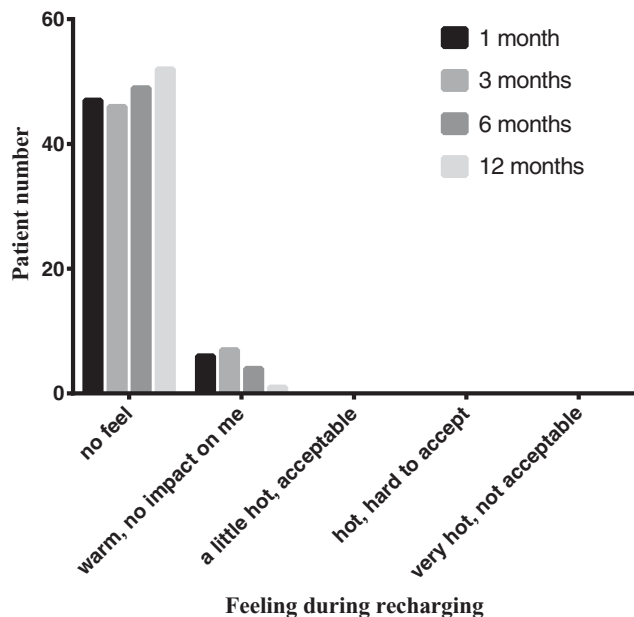


Figure 5. Showing thermal distribution being the main consideration during recharging. No patient reported hot feeling throughout the study, although a few patients felt warm at the stimulator site during recharging, which they thought was safe for them. The majority responded with no feeling.

result, they suggested only implanting RPGs in younger PD patients without signs of cognitive problem who had sufficient technical literacy. However, we found no correlation between age and participant comfort with the recharging process in this study. It may be that patients in this study were carefully trained before surgery, so the recharging process seemed easy for them to handle, regardless of age. As mentioned earlier, RPGs carry the benefit of a reduced risk of infection by lowering the frequency of INS replacement, which may be especially important in elderly patients. Although we recognize that cognitive problem could preclude the use of a rechargeable device, we believe that rechargeable devices are still the best choice for competent elderly patients.

While Harries et al. [9] reported a mean recharging time of 108 min (30–240 min) every 3.6 days (1–17.5 days) with Medtronic RPG, we found that participants had a mean recharging time of about 1 h every 7 days (7–15 days) at the last observation period. Two patients in the Harries study felt that recharging the INS interfered with their lives and was a daily reminder that they had a deep brain stimulator system *in situ*; thus, they would not recommend the RPG. Similarly, in a survey of patient perspectives on rechargeable spinal cord stimulators (RSCS), Lam and Rosenow [11] stated that patients who found the burden of recharging their RSCS systems to be greater than the benefit obtained reported a significantly greater number of recharge sessions per

month (mean 10.4 vs. 4.5 times per month). Additionally, those patients who stated that they would accept an increase in battery size spent significantly more time charging their devices compared with those who would not change their battery size (mean 2.6 vs. 1.5 h) [11]. These results, together with our findings, indicate that both the recharging duration and the time interval are important factors that impact the user experience. Both the recharging frequency and the duration, which depend on the treatment parameters and the recharging rate, negatively impacted patient satisfaction.

RPG systems have the significant advantage of a longer useful lifetime, especially for individuals requiring higher stimulation parameters. The main limitation of RPG systems is the production of thermal sensations caused by eddy currents in the metal shell and copper losses in the coils [12]. This heat generation is related to the electromagnetic coupling conditions (e.g. distance, angle, alignment) and has the potential to cause thermal injury or even tissue necrosis. Recently, St. Jude Medical reported three cases of skin-surface burns (one second-degree and two first-degree burns) with its Eon and Eon Mini charging systems [12]. The RPG used in this study has a wireless chargeable implant system that monitors the temperatures of both the device and the adjacent skin and will not operate if the skin temperature is greater than 41 °C [12]. This approach guarantees that implant patients can easily charge their device at home with no thermal risk, which eases patient anxiety and improves clinical outcomes. No thermal complications were observed in this study.

Thermal problems are related to the charging rate because high rates will generate more heat. The heat generation at the lowest rate in our study was very low; however, recharging took more than 2 h, which seemed too long to tolerate, as mentioned in a previous study [11]. We found that no patients continued to use channel 1 throughout the entire study period. Channel 4 had the highest recharge rate, but the temperature was more likely to reach the limit, automatically shutting off the power, and thus extending the recharging time. As a result, the majority of our patients were most comfortable using the recharging rate corresponding to channel 2.

The present study had several limitations. First, there are validated scales for analyzing patient satisfaction with an RPG. We, therefore, designed a survey that covered items that we expected to be of importance to our patients. This approach carries a possible bias in the choice of topics and the wording of the questions. Second, although this study had more patients with RPGs than in previous studies, the study population was still too small to definitively answer urgent questions related to patient selection, patient education and the equipment itself. Third, it is likely that patients gradually become accustomed to the handling of the recharging

system for a new RPG. Therefore, we expect patient satisfaction to change with time, and to be different a few weeks after the initial implantation compared to a longer duration, i.e. 1 year after implantation. Finally, because we did not systematically record adverse events in this survey, we cannot estimate whether the overall complications were higher or lower in patients with a rechargeable DBS system. For example, one of the major adverse events associated with INS surgery is skin infection localized to the battery. Increasing the time intervals between INS surgeries might help reduce this risk. These shortcomings can only be addressed by large-scale controlled trials with patients who have rechargeable DBS systems. Such studies should not only focus on motor outcomes but also consider various aspects of handling the INS and the ease of recharging. Nevertheless, these data are a valuable first step in analyzing patient perceptions and challenges with a new generation of INS devices.

Based on our study results, we recommend that standard clinical practice includes a discussion with the patient and the family regarding the pros and cons of rechargeable DBS devices prior to surgery, as well as education about battery recharging at home. After the implantable pulse generator parameters are set, it should be possible to manage the recharging process in a safe way that balances the recharging frequency and time spent.

## Conclusions

PD patients can easily and safely recharge RPG devices. This system may be an especially good choice for young PD patients. Shorter recharging times will encourage patients to accept this new technology. However, more studies with larger sample populations are needed to establish a standard protocol for selecting and managing patients.

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## Declaration of Interest

The authors reported no conflicts of interest.

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