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Patient Experience with Rechargeable Implantable Pulse Generator Deep Brain Stimulation for Movement Disorders

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Abstract

Background/Aims: Nonrechargeable deep brain stimulation implantable pulse generators (IPGs) for movement disorders require surgical replacement every few years due to battery depletion. Rechargeable IPGs reduce frequency of replacement surgeries and inherent risks of complications but require frequent recharging. Here, we evaluate patient experience with rechargeable IPGs and define predictive characteristics for higher satisfaction.

Methods: We contacted all patients implanted with rechargeable IPGs at a single center in a survey-based study. We analyzed patient satisfaction with respect to age, diagnosis, target, charging duration, and body mass index. We tabulated hardware-related adverse events.

Results: Dystonia patients had significantly higher satisfaction than Parkinson's disease patients in re-charging, display, programmer, and training domains. Common positive responses were "fewer surgeries" and "small size." Common negative responses were "difficulty finding the right position to recharge" and "need to recharge every day." Hardware-related adverse events occurred in 21 of 59 participants.

Conclusion: Patient experience with rechargeable IPGs was largely positive; however, frustrations with re-charging and adverse events were common. Dystonia diagnosis was most predictive of high satisfaction across multiple categories, potentially related to expected long disease duration with need for numerous IPG replacements.

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Author Contributions

Kyle T. Mitchell: project organization, data collection, data analysis, drafting of the manuscript. Monica Volz: project conception and organization, recruitment, data collection, manuscript review. Aaron Lee: data collection, drafting of the manuscript, manuscript review. Sarah Wang: project conception, data analysis, manuscript review. Philip A. Starr: surgical implantation of devices, recruitment, manuscript review. Paul Larson: surgical implantation of devices, recruitment, manuscript review. Marta San Lucia-no: recruitment, statistical analysis, manuscript review. Nicholas B. Galifianakis: recruitment, manuscript review. Jill L. Ostrem: project conception and organization, recruitment, manuscript review.

Statement of Ethics

The study protocol was approved by the UCSF Institutional Review Board on human research, and all participants signed written informed consent.

Keywords

Deep brain stimulation; Rechargeable; Implantable pulse generators; Patient experience; Movement disorders

Introduction

Deep brain stimulation (DBS) is an effective symptomatic therapy for many movement disorders, including tremor, Parkinson's disease (PD), and dystonia. In its current form, DBS requires chronic, continuous stimulation for ongoing benefit. Nonrechargeable implantable pulse generators (IPGs) with limited battery life require surgical replacement approximately every 3–4 years [1]. In the largest multicenter study, these procedures carried a 3.5% risk of complications requiring subsequent removal due to infection [2], a higher infection risk than after initial implantation [3]. Further, there is often waning of therapeutic benefit if an IPG nears depletion without replacement [4].

With the aim of circumventing further surgical risks and costs, rechargeable (RC) IPGs were introduced in 2008 as Activa RC (Medtronic, Minneapolis, MN, USA). Initial reception has been positive. Efficacy and postoperative stimulation parameters are similar to nonrechargeable IPGs [5–7]. Satisfaction with the devices has been high, with a majority of patients preferring RC to traditional IPGs [5, 8–10]. Further, cost analyses have revealed estimated savings of approximately 1,000–2,000 EUR (~1,150–2,300 USD) per patient per year over the life of the RC IPG, which is estimated at 9 years for the Activa RC [11, 12].

Despite these advantages, a significant subset of patients has voiced frustration with the recharging process. Patients have reported difficulty in coupling the recharger with the IPG as well as inability to effectively use the accompanying recharging harness [5, 7]. Burden of frequent recharging, particularly in older patients, was also noted in a spinal cord stimulator study using similar technology [13]. Given the high risk for development of significant cognitive impairment in PD, these barriers may become more prevalent later in the life of the device.

As RC IPGs become more ubiquitous, it is important to focus on patient experience with the new technology to assist preoperative counseling and patient selection for the devices. Information on frustrations and adverse events with the devices may help guide engineers who are developing the newest generation of RC IPGs. Here, we aim to better understand patient experience with RC IPGs in movement disorders in the largest reported study to date from a single center including long-term experience with the device.

Materials and Methods

Participant Recruitment

From July 2016 to December 2017, we attempted to contact all 119 patients with Medtronic RC IPG devices implanted at our center from 2008 (initial availability of the device) through January 2017. We included only patients with surgical placement of a RC IPG at least 6 months prior to enrollment to allow for adequate experience with the device. Both

participants with conversion from previously implanted nonrechargeable IPGs and those with initial DBS implantation with RC IPGs were included. Participants were either contacted by telephone with the number on file or approached during scheduled follow-up appointments. For patients who were not immediately available, we attempted 2 telephone calls with voicemails. Participation involved one-time completion of a survey either in person, by phone, or returned by mail. The study protocol was approved by the University of California San Francisco (UCSF) Institutional Review Board and all participants signed informed consent.

Surgical Procedure

All IPGs were Activa RC implanted in the chest wall by either of 2 neurosurgeons (P.A.S. or P.L.) at UCSF. Devices were implanted during ambulatory surgeries as replacement IPGs or as initial IPGs after DBS lead placement. Both patients with unilateral and bilateral DBS leads using the dual channel IPGs were included.

Survey

We modified the previously reported multi-domain patient satisfaction Likert scale published by Timmerman et al. [8]. Survey domains included fit/comfort (size and obtrusiveness of IPG), re-charging (convenience, understanding, and comfort with the re-charging process), display (understanding of patient programmer interface), programmer (confidence with battery checks and sense of control), training (from manufacturer materials and clinic sessions), and overall satisfaction. All of the questions were reworded for consistent rating and scoring with 1 corresponding to “completely disagree” and 5 “completely agree” (Appendix Table 1). We supplemented the survey with open-ended questions including “what features do you like about the rechargeable battery?” and “what is most bothersome to you about the rechargeable battery?” We also queried duration of time and number of times per week spent recharging and “would you recommend a rechargeable battery to other patients?”

Statistical Analysis

Likert scale responses were transformed for statistical analysis to the following scores: 1 = 0, 2 = 25, 3 = 50, 4 = 75, 5 = 100. Gender (male vs. female), diagnosis (dystonia vs. PD), target (subthalamic nucleus [STN] vs. globus pallidus internus [GPi]), body mass index (BMI; normal vs. overweight defined as a cutoff BMI of 25 kg/m²), and prior DBS experience (RC IPG as first device vs. conversion from nonrechargeable IPG) were compared in each patient satisfaction domain. Univariate comparisons for individual predictors were performed using Mann-Whitney U two-tailed tests for nonparametric data ($p < 0.01$ was set as the significance level to correct for multiple comparisons). Linear regression models were used for multivariate analyses which included age at time of survey, years since RC IPG implantation, time charged per week, and number of times charged per week as well as the above variables previously compared in univariate analyses. Responses to open-ended questions common to at least 2 patients were tabulated to evaluate frequent positive and negative issues with the device. Adverse events related to the IPGs were collected by chart review of neurology, neurosurgery, and operative notes.

Results

Of the 119 patients with Activa RC IPG at our center meeting study criteria, 59 completed the survey (49.6%). Amongst those who did not participate, 41 could not be reached via phone number on file, 5 declined to participate, and 14 signed the consent form but never returned the survey. Participants carried diagnoses (*n*) of PD (30), dystonia (25), essential tremor (3), and Tourette's syndrome (1) and were slightly male predominant (32 of 59, 54.2%). The majority of participants (48) had a nonrechargeable IPG prior to RC replacement, with the remaining 11 receiving an RC IPG at initial DBS implantation. Mean age at time of questionnaire was 59.5 years with a mean BMI at surgery of 25.4 kg/m². Target choice (*n*) amongst participants with PD included STN (14) and GPi (16). Participants with dystonia had targets of STN (2), GPi (22), and thalamus (1).

The majority of patients had high satisfaction in all domains. The median score (out of a possible range from 0 to 100) and interquartile range were 83.3 (25.0) for fit/comfort, 75.0 (45.2) for recharging, 75.0 (37.5) for display, 75.0 (37.5) for programmer, 81.3 (50.0) for training, and 91.7 (33.3) for overall satisfaction. Eighty-six percent (51 of 59) reported they would recommend the RC IPG to other prospective patients.

Diagnosis of dystonia was the most consistent and robust predictor of patient satisfaction with significantly higher satisfaction in all domains except fit/comfort and overall satisfaction (Fig. 1). The subgroup of patients with dystonia was younger and more female predominant than the subgroup of patients with PD (Table 1). Participants with GPi target had higher satisfaction than those with STN target in the display (median 87.5 [25.0] vs. 68.8 [50.0], *p* = 0.01) and recharging domains (median 81.3 [33.3] vs. 46.9 [26.3], *p* < 0.01) with trends towards higher satisfaction in the programmer, training, and overall satisfaction domains (data not shown). Women had a nonsignificant trend towards higher satisfaction than men in the programmer, training, and display domains (data not shown). Normal versus overweight BMI and first-time DBS placement versus conversion from nonrechargeable IPG showed no differences in any patient satisfaction domain.

In a multivariate model to evaluate for independent predictors of patient experience (Appendix Table 2), participants with dystonia had significantly higher satisfaction in recharging, display, and training domains with nonsignificant trends in all other domains in the same direction as the univariate analyses. None of the other variables from the univariate analyses showed significant differences in the multivariate model. Age, years of experience with RC device, and recharging metrics likewise were not significant predictors of patient satisfaction in any individual domains. Coefficients and confidence intervals are presented in Appendix Table 2. BMI did not have an independent effect, so it was excluded from the multivariate model to improve statistical efficiency.

Common answers to qualitative questions are reported in Table 2 with the most frequent positive answer of "fewer replacement surgeries" and negative answer of difficulty pairing or "finding the right spot" to recharge.

The recharging process was time intensive with a mean charging time of 185.8 (range 25–830) min divided over a mean of 4.5 (range 0.5–14) charging sessions per week. Participants

with PD and dystonia had a similar charging time in minutes per week (median 150 vs. 133, $p = 0.857$) and number of charging sessions per week (median 4 vs. 7, $p = 0.939$). There were also no significant differences between STN and GPi targets in charging parameters amongst all participants.

Hardware-related adverse events were reported in 21 of 59 subjects (35.6%). Five patients had accidental battery depletion and 2 inadvertently turned off the stimulator during the recharging process. IPG depletion prompted an emergency department visit due to return of severe motor symptoms in 1 subject and multiple days of hospitalization due to delayed discovery that stimulation was off at an outside center. In 1 subject who reported inadequate charging, the RC IPG was found to be flipped on X-ray and was corrected by manual external manipulation in the clinic. Two hardware infections occurred, both of which prompted removal of RC IPG and intracerebral lead. Both of these infections were in patients with known infections in prior nonrechargeable IPG systems that had been treated with a full course of intravenous antibiotics after hardware removal and prior to implantation with a RC IPG. The RC IPG was placed in these cases with the goal of limiting future replacement surgeries and corresponding infection risk. Issues with impedances (excessively high or low) were reported in 6 patients. One patient had partial intracerebral lead migration but had continued symptom control after reprogramming. Seven patients reported malfunction of external recharging equipment and need for replacement by the vendor.

Discussion/Conclusion

This large, survey-based study provides a comprehensive analysis of patient experience with RC IPGs. Experience with the devices was overall positive, with the majority of participants reporting high satisfaction in all domains and expressing the opinion that these devices are worth recommending to future patients. The smaller size and ability to reduce the frequency of future replacement surgeries with their associated risk were the primary drivers of positive experience. That said, a significant subset of participants reported frustrations, particularly with the recharging process.

Our analysis revealed that a diagnosis of dystonia was the strongest predictor of patient satisfaction. Though these participants were of younger age on average, age did appear not to play a strong role, and the GPi target amongst all participants with PD and dystonia was not as strongly predictive of positive experience as diagnosis of dystonia alone. Further, while GPi target and a diagnosis of dystonia typically have higher energy stimulation requirements for clinical benefit [14], recharging practices and time requirements were similar in this study regardless of diagnosis or target. This significance held for multivariate analyses, suggesting that dystonia is an independent predictor of positive patient experience with RC IPGs compared to PD, which may be clinically relevant in patient selection. The cause for this higher satisfaction in dystonia is unclear and was not seen in prior studies [8]. We speculate that the longer expected disease duration with dystonia versus PD, a neurodegenerative disease with a more finite course, and ability to reduce the numerous expected IPG replacements over the life of an individual with dystonia were primary factors in the higher satisfaction scores. Indeed, a higher portion of dystonia patients described

fewer IPG replacement surgeries as a positive factor compared to PD patients, though this difference was not significant (18 of 25 vs. 14 of 30, $p = 0.11$).

We found a relatively high incidence of hardware-related adverse events. Recharging can be a complex process, and the potential for accidental battery depletion or deactivation should be discussed with patients during the training process, as more severe adverse events, including hospitalization due to clinical decompensation, can occur if not promptly discovered. Flipping of this smaller IPG in the chest wall markedly reduces or prevents the ability to recharge the device, and plain-film X-rays are a logical first step to investigate this newly reported adverse event. Finally, infection and hardware malfunction remain a risk as in all implanted IPGs.

The study has several strengths as the largest study to date examining patient experience with RC IPGs. Limiting the analysis to the experience of a single experienced center reduces variability introduced by different centers, such as differences in surgical techniques and in counseling. Open-ended qualitative answers and exploration of recharging habits provide insight into the key frustrations with RC IPGs, including difficulty coupling the IPG with the recharger, short duration of charge, and need for frequent recharging. Future generations of devices should be engineered with these complaints in mind. Unlike prior studies with RC IPGs [8, 13], age did not have a strong correlation with patient experience in this study. Duration of experience with these IPGs likewise did not significantly predict patient satisfaction. These results reflect that dissatisfaction with RC IPGs had more to do with frustration with the coupling process than comfort with the technology. Of note, this study had a longer minimum follow-up time than prior studies, which may have allowed for adjustment to the charging routine.

While this study provides a comprehensive investigation of patient experience with RC IPGs, there are several factors which may limit its interpretation. Though significance was set at $p < 0.01$ to adjust for multiple comparisons and multivariate analysis was performed to assess for independent predictors, this was a retrospective, survey-based study with inherent biases. Cognitive capability by the patient or caregiver to manage the recharging system likely influences the patient experience; however, cognitive baselines and caregiver support were not formally assessed in this study. Many potential participants were not successfully contacted, which is of unknown significance. Further, the study population was heterogeneous with a variety of diagnoses, targets, and demographic factors, which can limit/underpower statistical comparisons between groups. Participants who planned to remain under the care of our center after completing this survey may have been reluctant to voice complaints. This potential selection bias could have resulted in inflated satisfaction scores. Finally, none of these participants converted from RC IPGs to primary cell IPGs, which limits within-patient comparisons, although this was not an aim of this particular study.

RC IPG technology will likely improve in the future. A version has already been developed in China with potential for shorter recharging times [15], and another manufacturer has made RC IPGs standard for DBS therapy [16]. Perhaps an ideal option would be an IPG that could be set to both RC and primary cell modes to provide flexibility for an individual

patient's needs. As with any new technology, this study reveals the importance of evaluating patient experiences with new devices to help drive both preoperative counseling and future innovation.

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Disclosure Statement

Dr. Kyle T. Mitchell has been a consultant for Boston Scientific and received travel support from Medtronic. Dr. Paul Larson has received honoraria from Medtronic. Dr. Philip A. Starr has received fellowship and research support from Medtronic. Dr. Jill L. Ostrem has been a consultant for Medtronic and received programmatic fellowship support from Medtronic. The other authors have no conflicts of interest to declare.

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Appendix

Appendix Table 1

Likert scale portion of the study survey, modified from Timmerman et al. [8]

Domain	Item	Completely agree	Mostly agree	Not sure	Mostly disagree	Completely disagree
Fit/comfort	(1) I am pleased with the fit of the battery	5	4	3	2	1
	(2) The battery does not bother me	5	4	3	2	1
	(3) The size of the battery is no concern for me	5	4	3	2	1
Recharging	(4) I have no problem with wearing the shoulder or waist belt for recharging	5	4	3	2	1
	(5) The shoulder or waist belt that I wear for recharging is comfortable	5	4	3	2	1
	(6) I do not find it difficult to understand the recharging process	5	4	3	2	1
Display	(7) The need to keep recharging the device is not inconvenient	5	4	3	2	1
	(8) Recharging the device is no bother to me	5	4	3	2	1
	(9) I am comfortable with the need to recharge the device	5	4	3	2	1
Programmer	(10) I find the display on the patient programmer clear and easy to understand	5	4	3	2	1
	(11) The display screen is clear to me	5	4	3	2	1
	(12) The patient programmer gives me a real sense of control over my disease	5	4	3	2	1
	(13) The sound alerts that are produced by the patient programmer are useful	5	4	3	2	1

Domain	Item	Completely agree	Mostly agree	Not sure	Mostly disagree	Completely disagree
Training	(14) I do not find it difficult to check the status of my battery	5	4	3	2	1
	(15) The patient programmer gives me confidence	5	4	3	2	1
	(16) I value the patient programmer	5	4	3	2	1
	(17) I rely on the patient programmer to check my battery levels	5	4	3	2	1
	(18) The training materials were not confusing	5	4	3	2	1
	(19) The training I received was excellent	5	4	3	2	1
	(20) I did not need help understanding the training materials	5	4	3	2	1
	(21) The training materials and DVD clearly explained everything I need to know	5	4	3	2	1
	(22) Deep brain stimulation controls the symptoms of my disease	5	4	3	2	1
	(23) I think the rechargeable DBS device suits my needs better than other therapies I have used	5	4	3	2	1
Overall satisfaction	(24) Overall, I am very satisfied with the rechargeable DBS device	5	4	3	2	1

Appendix Table 2

Multivariate analyses for independent predictors

Predictor	Fit/comfort			Recharging			Display			Programmer			Training			Overall		
	coef	95% CI	p_value	coef	95% CI	p_value	coef	95% CI	p_value	coef	95% CI	p_value	coef	95% CI	p_value	coef	95% CI	p_value
Female	-12.4	-25.5, 0.7	0.06	-10.8	-26.7, 5.1	0.18	-6.0	-23.4,11.4	0.49	3.0	-8.9, 14.9	0.61	0.7	-15.8,17.3	0.93	-1.6	-16.3,13.1	0.82
Age	0.3	0.0, 0.7	0.08	0.4	-0.1,0.9	0.10	0.0	-0.5,-0.5	0.97	0.2	-0.2, 0.5	0.30	-0.1	-0.7,0.4	0.57	0.4	-0.1,0.8	0.11
First IPG	-2.1	-17.8, 13.6	0.79	-1.6	-20.6,17.5	0.87	-16.7	-38.8, 5.3	0.13	-0.5	-14.7, 13.7	0.95	-1.9	-21.3,17.5	0.84	-8.1	-25.7,9.5	0.36
Dystonia	14.2	-1.3,29.7	0.07	24.5	5.6,43.3	0.01	29.7	9.1,50.3	<0.01	14.1	0.1, 28.2	0.05	41.4	23.0,60.8	<0.001	9.52	-7.9,26.9	0.28
Years with IPG	2.7	-0.4,5.9	0.09	2.3	-1.5,6.2	0.23	1.9	-2.6,6.3	0.40	1.2	-1.7, 4.0	0.42	-0.3	-4.2,3.6	0.89	2.1	-1.4,5.7	0.23
GPI	4.3	-12.4,21.0	0.62	21.3	1.0,41.6	0.04	8.6	-13.6, 30.8	0.44	13.0	-2.2, 28.1	0.09	-12.5	-32.1,8.1	0.23	12.5	-6.3,31.2	0.19
Time charged	0.0	0.0, 0.1	0.37	0.0	0.0,0.1	0.41	0.0	-0.1,0.1	0.72	0.0	0.0, 0.0	0.85	0.0	-0.1,0.0	0.28	0.0	0.0,0.1	0.26
Charging sessions	-0.4	-3.0,2.1	0.72	-0.4	-3.4,2.7	0.80	1.0	-2.4,4.3	0.57	1.5	6.6, 63.8	0.02	3.7	0.6,6.8	0.02	-0.1	-2.9,2.7	0.95

coef, coefficient; CI, confidence interval; IPG, implantable pulse generator; GPI, globus pallidus internus.

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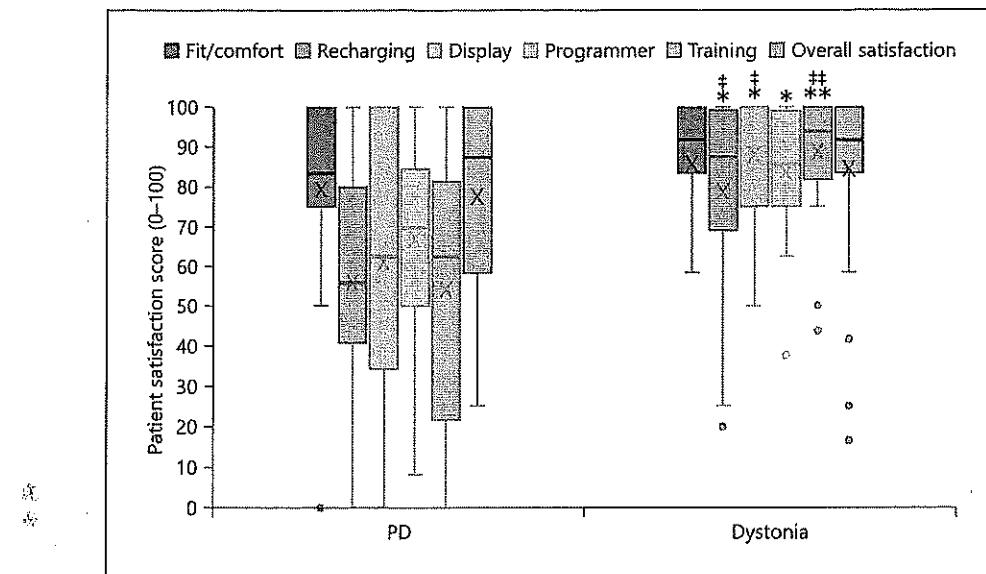


Fig. 1.

Patient satisfaction by diagnosis. Patients with dystonia had significantly higher satisfaction scores than those with PD in recharging (median 87.5 vs. 56.0, $p < 0.01$), display (100.0 vs. 62.5, $p < 0.01$), programmer (85.4 vs. 69.8, $p < 0.01$), and training (93.8 vs. 62.5, $p < 0.001$) domains. x indicates the median, boxes represent inter-quartile range, whiskers represent range with outliers as single points, higher scores represent higher satisfaction on a scale of 0–100. PD, Parkinson's disease. Univariate: * $p < 0.01$, ** $p < 0.001$. Multivariate: † $p < 0.01$, ‡‡ $p < 0.001$.

Baseline characteristics by diagnosis

	Dystonia	PD	p value
Age at survey, years	60.0 [34.0]	65.5 [9.0]	<0.05
BMI in kg/m ² , >25/≥25	12/7	11/14	0.208
Gender, female/male	16/8	9/21	0.007
Target, GPi/STN/thalamus	21/2/1	16/14	<0.003
DBS, first/replacement IPG	7/17	3/27	0.072
Minutes spent charging per week	133.0 [131.8]	150.0 [144.5]	0.857
Times charged per week	3.5 [5.6]	7 [4.2]	0.58
Years with IPG	2 [4]	2 [2]	0.23

Values are n/total or median [interquartile range]. PD, Parkinson's disease; BMI, body mass index; GPi, globus pallidus internus; STN, subthalamic nucleus; DBS, deep brain stimulation; IPG, implantable pulse generator.

Table 1.

Additional aspects of patient experience

Table 2.

Common answers to "What features do you like about the rechargeable battery?" (<i>n</i>), listed responses with <i>n</i> > 2	Fewer replacement surgeries/long battery life (35) Easy to use/convenient (14) Smaller size (11) Ability to track battery level (7) Enjoy recharging routine (4)
Common answers to "What is most bothersome to you about the rechargeable battery?" (<i>n</i>), listed responses with <i>n</i> > 2	Pairing the recharger/finding the "right spot" (20) Feeling "tethered"/length of time to charge (8) Difficulty tracking charge/poor display (8) Short-lasting charge (6) Difficulty transporting (5) Sensory: hot/cold/"electric" feelings when charging (4) Battery too large/obtrusive (4)
Average time charging per week in min, mean \pm SD	185.8 \pm 139.5
Number of times charging per week, mean \pm SD	4.5 \pm 2.8
"Would you recommend the rechargeable battery to other patients?" (yes/no)	Yes: 51 (86%) No: 6 Undecided: 2