

**Title: Rechargeable vs Non-rechargeable internal pulse generators in the management of dystonia**

**Running title:** Rechargeable IPGs in dystonia

**Authors:** Martin J. Gillies<sup>1</sup> PhD\*, Carole Joint<sup>1</sup> PhD, Beth Forrow<sup>1</sup> BSc, Clare Fletcher<sup>1</sup> BSc, Alexander L Green<sup>1,2</sup> MD, & Tipu Z. Aziz<sup>1,2</sup> FMedSci

1. Department of Neurological Surgery, Oxford University Hospitals, Oxford, United Kingdom.

2. Nuffield Department of Surgery, University of Oxford, Oxford, United Kingdom.

\*=Corresponding author

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**Correspondence:**

Martin J. Gillies

Nuffield Department of Surgical Sciences and Department of Neurosurgery,

Oxford University Hospitals,

Oxford, OX3 9DU, UK.

Telephone: +44 1865 741166

Fax: +44 1865 231885

Email: [martin.gillies@ouh.nhs.uk](mailto:martin.gillies@ouh.nhs.uk)

## **Abstract**

### **Rechargeable vs Non-rechargeable internal pulse generators in the management of dystonia**

Martin J. Gillies PhD\*, Carole Joint PhD, Beth Forrow BSc, Clare Fletcher BSc, Alexander L Green MD  
& Tipu Z. Aziz F.Med.Sci.

**Objective:** To test if DBS treatment of dystonia was similar in patients before and after implantation of rechargeable IPGs.

**Methods:** BFMDRS severity and disability scores were compared in patients before DBS insertion, 24 months after DBS insertion with a non-rechargeable IPG and after implantation of a rechargeable IPG.

**Result:** No significant differences were observed between dystonia control in patients before and after implantation of a rechargeable IPG.

**Conclusion:** Rechargeable IPGs should be the IPGs of choice for dystonic patients receiving DBS as they offer similar treatment efficacy as non-rechargeable IPGs with advantages in terms of cost and reductions in re-implantation frequency.

#### **Keywords:**

Deep brain stimulation

Dystonia

Internal pulse generators

## Article

### Introduction

Deep brain stimulation (DBS) has become the surgical treatment of choice for drug refractory dystonia <sup>(1)</sup>. Nonetheless deep brain stimulation for dystonia has disadvantages. A major disadvantage is that the treatment parameters required to control dystonia often limit the life span of non-rechargeable internal pulse generators to approximately 2 years, thus necessitating repeat surgery to replace the IPGs frequently, with attendant risks of morbidity and financial costs <sup>(2)</sup>.

A possible solution to this disadvantage is to implant rechargeable internal pulse generators. The projected lifespan for rechargeable batteries is approximately 9-10 years, reducing the frequency of reimplantation surgeries with attendant reductions in surgical morbidity and costs.

However, the general physical properties of batteries may in theory mean the management of a patient's dystonia may be adversely affected by implantation of an internal pulse generator (IPG) with a rechargeable battery compared to a non-rechargeable battery. Electromotive force (voltage) of a battery is not a constant, but varies with battery internal resistance. Battery internal resistance in turn varies with the amount of charge stored within the battery. In the case of rechargeable batteries, as the battery charges and discharges frequently, internal resistance will consequently vary frequently. Since voltage, current and resistance are intimately related according to Ohm's law, as resistance fluctuates during the charge-discharge cycle, so also may the battery output, thereby having an influence on therapeutic effect of the IPG. Adjustment of treatment parameters in this context would have limited utility since the output of the battery would be constantly changing depending on charge status. The same problem could apply to non-rechargeable batteries, but given the long discharge period of non-rechargeable IPGs, periodic adjustments in output settings may overcome this problem.

If this theoretical problem applies to rechargeable IPGs in practice, the practical consequence of this could manifest as deterioration in dystonic symptoms in patients with DBS who have changed from non-rechargeable to rechargeable batteries. The specific mechanism by which DBS treats dystonia is not certain, but clinical studies emphasise that improvement depends on continuous delivery of treatment over an extended period of time <sup>(3)</sup>. Indeed patients may not achieve maximal benefit until a year or more after the onset of therapy. Conversely, cessation of DBS can lead to clinical deterioration within minutes to hours.

We compared dystonic scores in patients with generalised dystonia for whom we had preoperative DBS, postoperative DBS with non-rechargeable IPG and post implantation of rechargeable IPG scores to attempt to identify if there was a difference between dystonia control with rechargeable versus non-rechargeable IPGs.

## **Materials and methods**

36 dystonic patients in our practice have rechargeable IPGs implanted currently (22 ActivaRC, Medtronic, Minneapolis, MN, USA: 14 Brio, St Jude Medical Inc., St Paul, MN, USA): 22 generalised dystonia, 7 focal, 1 multifocal, 3 segmental, 2 drug-induced and 1 hemidystonia. The principal technical difference between the 2 units is that ActivaRC has constant voltage and constant current delivery modes, whereas Brio is a constant current delivery mode only device. 17 had onset of dystonia in adulthood and 19 had paediatric onset. All patients in this group had bilateral GPI stimulation leads inserted. Operations and follow up took place in the John Radcliffe Hospital, Oxford between 2000 and 2012. Preoperative dystonia status and postoperative response to treatment were assessed using Burke-Fahn-Marsden Dystonia rating scale (BFMDRS) or Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS). Of the 36 patients, 8 had rechargeable units inserted at original DBS surgery and are not included in analysis. Of the remaining 28, 13 patients

had assessments preoperatively, 24 months postoperatively and at least 3 months after implantation of a rechargeable IPG unit (range: 3 months to 3 years). All 13 of these patients had generalised dystonia, therefore no patient included in this analysis had focal dystonia. The remainder did not have assessments at all three of these time points largely owing to geographical reasons: our unit treats patients from Republic of Ireland and Northern England, most of whom we have found to be reluctant to attend routine follow up in Oxford in the absence of a problem potentially requiring surgery (e.g. battery change, loss of treatment efficacy). These 13 patients are the basis of the results described below. Results are expressed as mean  $\pm$  standard error of the mean. Paired 2 tailed Student's T tests were used to test the null hypothesis that there was no difference in mean score between the 2 groups tested. We have not distinguished between treatment effects in patients with Brio compared to Activa RC devices as our data do not allow a robust comparison (4 Brio vs 9 Activa RC).

## **Results**

All patients in this sample benefitted from deep brain stimulation with non-rechargeable IPGs (Figures 1 & 2). The mean preoperative severity score (BFMDRS) in the sample was 62.9 ( $\pm$  5.4), improving to a mean post operative score at 24 months was 37.9 ( $\pm$  5.2). Similarly, disability improved from a mean of 15.0 ( $\pm$  1.4) to 8.7 ( $\pm$  1.42).

Mean severity scores after implantation of a rechargeable IPG were 31.0 ( $\pm$  4.9). This score was not significantly different from scores recorded at 24 months after the original operation. Mean disability scores were 9.5 ( $\pm$  1.0), which were not significantly different from scores recorded 24 months after original surgery. Improvements in severity and disability were statistically significant (paired t test,  $P < 0.001$ ) compared to pre-operative status with rechargeable IPGs.

1 patient suffered a post operative wound infection after implantation in this group. None of the 13 has required reoperation for device malfunction.

## **Discussion**

In this sample, implantation of a rechargeable IPG did not adversely affect dystonia management compared to a non-rechargeable IPG: Patients who benefitted from DBS with a non-rechargeable battery continued to experience a measurably similar level of benefit with a rechargeable unit. The study does not allow conclusions to be drawn about any opportunity costs involved in using rechargeable IPGs rather than non-rechargeable IPGs, for example whether patients with non-rechargeable IPGs improve over time to a greater extent than patients with rechargeable IPGs. Our patient database does not allow robust comparisons at this stage between long term effects of non-rechargeable IPGs on treatment efficacy vs rechargeable IPGs .

In our unit's experience of deep brain stimulation, we would argue that rechargeable IPGs should be the first choice of IPG to implant in patients undergoing DBS for dystonia of whatever aetiology. The main advantages we observe in our practice are: reduction in operation frequency and reduction in costs. The group of 36 patients described above had on average required a new non-rechargeable IPG every 15 months. Over the lifetime of one rechargeable IPG, patients in the group could potentially require eight non-rechargeable IPGs. Despite the greater purchase costs of a rechargeable IPG, money is saved in the longer term by a combination of reduced number of IPGs purchased and reduced number of surgeries per patient. At 2011 prices in our area, using a

rechargeable IPG saves the department approximately £150,000 per decade per patient in the absence of complications, assuming rechargeable IPGs will achieve the advertised life times in this patient group. Money is additionally saved by reducing the number of complications suffered per patient in line with the reduced number of surgeries. A recent study <sup>(4)</sup> suggests the risk of infection, the most frequent complication of deep brain stimulation surgery, is three times greater during IPG reimplantation surgery than during original surgery (i.e. intracranial lead placement with IPG insertion surgery).

We have not systematically compared patient satisfaction with rechargeable IPGs against non-rechargeable IPGs, nor have we compared satisfaction with Brio IPGs compared to Activa RC IPGs. Our experience is that the brio device is easier to charge because it can be located deeper under the skin therefore the charging antenna does not need to be so exactly over the IPG unit to charge effectively. In contrast the Activa RC unit must be less than 1cm under the skin to allow effective percutaneous charging therefore the charging antenna must be more fastidiously positioned during charging. Nonetheless, no patients to our knowledge have had significant problems with the charging process itself. Certainly none have required revision IPG surgery to reposition a functioning rechargeable IPG to allow effective recharging where recharging has been ineffective after original implantation surgery. The principle drawback we have observed with rechargeable IPGs is the design of the recharging antenna and power pack. Some of our patients have experienced breakage of the recharging unit (specifically the connection between the antenna and power pack), necessitating replacement.

In summary, rechargeable IPGs appear to perform as well as non-rechargeable IPGs in the management of dystonia, and offer additional benefits that make them the IPG of choice in the management of dystonic patients.



## References

1. Deep Brain Stimulation for Primary Generalized Dystonia: Long-term Outcomes. Ioannis U. Isaías, MD; Ron L. Alterman, MD; Michele Tagliati, MD. Arch Neurol. 2009;66(4):465-470
2. Battery lifetime in pallidal deep brain stimulation for dystonia. C. Blahak, H.-H. Capelle, H. Baezner, T. M. Kinfe, M. G. Hennerici and J. K. Krauss. European Journal of Neurology 2011, 18: 872–875
3. Deep brain stimulation for generalised dystonia and spasmodic torticollis. Bittar RG, Yianni J, Wang S, Liu X, Nandi D, Joint C, et al. J Clin Neurosci. 2005 Jan;12(1):12-6.
4. The risk for hardware infection in deep brain stimulation surgery is greater at impulse generator replacement than at the primary procedure. Joshua Pepper , Ludvic Zrinzo , Bilal Mirza , Thomas Foltynie , Patricia Limousin, & Marwan Hariz. Stereotactic and Functional Neurosurgery, in press.