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Use of a Pulsed Radiofrequency Energy Device (PEAK Plasmablade™) in Neuromodulation Implant Revisions

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Use of a pulsed radiofrequency energy device (PEAK Plasmablade™) in neuromodulation implant revisions

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Key Words: Monopolar, Electrosurgery, DBS, Revision, IPG,
PlasmaBlade™, Neuromodulation, VNS

Abbreviations: DBS Deep Brain Stimulation
VNS Vagal Nerve Stimulation
IPG Implanted pulse generator
RF Radiofrequency
CIED Cardiac implantable electronic devices
ITB Intrathecal baclofen

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declare

Abstract

Background: Battery replacement or revision surgery for neuromodulation implants is conventionally performed using sharp dissection. Meticulous dissection within thick scar tissue is vital to avoid damage to surrounding lead(s) which could result in more extensive revision surgery. Traditional electrosurgery devices are contraindicated as the emitted energy can be transferred to the hardware resulting in implant or tissue damage with severe consequent complications.

Objective: We report our experience and potential applications of a novel, pulsed monopolar radiofrequency energy device (PEAK PlasmaBlade™, Medtronic plc) which facilitates dissection around implants without the risk of damaging or transmitting energy through the system.

Methods: A two-centre retrospective study to review the indications, safety and efficacy of the PlasmaBlade in 57 cases requiring either neuromodulation system replacement or revision. Deep brain stimulator (DBS) battery replacements were undertaken in 45 cases, 8 vagal nerve stimulator battery revisions, 2 intrathecal baclofen system revision, 1 DBS extension revision and 1 DBS scar revision around the cranial portion of the lead.

Results: All cases proceeded without adverse event, damage to lead/generator and with a subjective and objective impression of significant time savings. Average operating times for battery replacements were reduced from 37 to 26 minutes ($p=0.015$).

Conclusion: In our experience, the PlasmaBlade is safe to use in revising/replacing neuromodulation implants. We observed no damage or transmission of energy to the implants or leads; additional advantages of the system include reduced operating times, less damage to surrounding tissue and the potential to facilitate revision procedures in awake patients under local anaesthesia.

Introduction

Neuromodulation system implantations continue to rise annually with now over 100,000 deep brain stimulators alone implanted worldwide. Accordingly, demand for replacement of implanted pulse generators (IPG) and revision of neuromodulation systems is expected to increase over the next few decades.

Conventionally, IPG replacement is performed using sharp dissection through scar tissue. This technique carries the risk of damaging the electrode leads, subsequently requiring a more extensive, invasive and expensive procedure, and putting the patient at greater risk of adverse sequelae. Monopolar electrosurgery and diathermy devices, which could facilitate dissection around electrode leads, are contraindicated as the energy from these devices can be transferred to the implanted system, damaging either the hardware or leads, and resulting in tissue damage and severe consequent complications¹⁻⁴.

Comparatively, the PEAK PlasmaBlade™ (Figure 1) is a novel surgical device which delivers high frequency pulses of radiofrequency (RF) energy to induce electrical plasma along the edge of a thin (12.5µm), 99.5% insulated electrode. As the system operates at a much lower temperature than traditional monopolar electrosurgery (40 - 170°C vs. 200 - 350°C) and melting point of the coatings of neurostimulation electrodes (188° C) or intrathecal catheters (200-210° C)⁵, the risk of damage to the hardware or leads as demonstrated in its use with cardiac implantable electronic devices (CIEDs), including pacemakers and defibrillators, is significantly lower⁶.

Similar to traditional electrosurgery devices, two modes are available for the PlasmaBlade, CUT and COAG. Typically, the CUT mode (range 4 – 5) which also has haemostatic properties is utilised when dissecting around leads and hardware. Dissection around the leads is performed in parallel rather than perpendicular direction. COAG mode is not recommended in close proximity to any IPG components.

We report our experience of the PlasmaBlade™ with a variety of implants including intrathecal baclofen (ITB) drug delivery system, deep brain (DBS) and vagal nerve stimulators (VNS).

METHODS

We conducted a retrospective review at two neurosurgical centres (King's College Hospital London & University Hospitals Birmingham, UK) to evaluate the indications, safety and efficacy of the PEAK PlasmaBlade™ for replacement or revision of a variety of neuromodulation implants. Prior to the introduction of this device all such procedures were undertaken using traditional sharp dissection techniques. Subsequent introduction of the device at both centres led to the adoption of PlasmaBlade for all such cases. This change of practice forms the basis of this review rather than a trial with data compared from the historical group whom had traditional dissection methods versus the cohort who subsequently had procedures undertaken with PlasmaBlade.

Our PlasmaBlade cohort consisted of a variety neuromodulation implants (Table 1) and was undertaken between December 2014 and August 2017 by both trainee and consultant neurosurgeons. The indication for implantable pulse generator (IPG) replacement was depletion; lead revision was undertaken for lead failure with high impedance on telemetry. In one case, scar revision around a DBS lead and anchoring device (Stimloc, Medtronic plc) was performed to remove a reactive granuloma. All generators are commercially available (Medtronic plc, St Jude Medical, LivaNova).

We investigated if any lead damage, generator or lead malfunction, haematomas or infections occurred within 30 days of the procedure. Follow up assessments included a wound examination as well as generator interrogation and lead impedance check to ensure no delayed malfunction.

RESULTS

Study Population

Fifty seven (57) patients underwent procedures on their neuromodulation implants using the PlasmaBlade. Of these thirty eight (38) patients underwent IPG/ITB replacement under local anaesthesia. Indications, type of anaesthesia and device manufacturer are detailed in Table 1.

There were no occurrences of lead or implant damage/failure using the PlasmaBlade, nor did we observe any haematomas or wound infections. Where performed under local anaesthesia the patients tolerated the procedure well enough to be discharged the same day.

Compared to equivalent numbers of patients who underwent IPG replacement, the time taken for this procedure using PlasmaBlade was statistically significantly shorter compared to sharp dissection techniques (25.6 vs. 36.7 minutes, $p=0.015$). In addition to the objective outcomes, each surgeon also felt more comfortable and confident in performing the procedure with the PlasmaBlade™ in the knowledge that damage to the leads was minimal and consequently, subjectively felt that operating times were reduced.

DISCUSSION

Traditionally IPG replacement and neuromodulation implant hardware revisions are performed using sharp dissection techniques assisted with bipolar electrosurgery devices to control bleeding. Meticulous technique has to be employed when dissecting through thick fibrotic scar tissue to avoid damaging embedded leads. This can be challenging and time consuming if the leads have been unconventionally implanted anterior to the device or extensive dissection is required to revise larger proportions of the hardware, (e.g. spinal cord stimulators) increasing the risk of iatrogenic damage. In our series, use of the PlasmaBlade has demonstrated a number of advantages over traditional methodology.

Energy transfer / damage to hardware: We observed no damage to leads or hardware, or transference of energy via the hardware to tissues at short interval (30 days) or where available longer term follow-up of up to 24 months. Direct contact with traditional monopolar or bipolar electrosurgery is considered contraindicated⁴, though Ng et al have reported their experience of using the ultra-sharp monopolar tip restricted to the insulated portion of VNS leads to assist removal⁷. In our experience, no issues were identified when using the PlasmaBlade tip to make direct contact with the non-insulated portions of hardware in order to dissect free the scar tissue surrounding the device (Figure 2). We believe this is due to the design of the device, as detailed above.

Weisberg et al⁸ compared the effects of the PlasmaBlade with conventional electrosurgery instruments *in vivo* and noted that polyurethane and copolymer materials are highly susceptible to thermal damage when subjected to exposure to the latter and that PlasmaBlade greatly reduces the risk of thermal damage to these materials regardless of mode or orientation of approach on both naked and microscopic examination (Figure 3).

Rarely IPGs have been noted to migrate (e.g. behind breast adipose tissue in chest implantations) making the dissection for replacement more difficult. Exposure of the IPG could be easily facilitated using the PlasmaBlade.

Reduced operating time: Eliminating the risk of hardware damage using the PlasmaBlade has afforded the surgeons in this review significantly reduced apprehension customary to these procedures. Furthermore the ability to cut down directly from the skin to the hardware, essentially as a single layer, reduces the number of instrument exchanges needed at surgery. Consequently, these allowed for decreased operating times in our series compared with traditional techniques.

Local anaesthesia: IPG/intrathecal drug delivery system replacement under local anaesthesia, though feasible, has the potential in patients with movement disorders to be challenging. This is especially so after repeated battery changes when the scar may be particularly thick and extensive, making surgery under local anaesthesia lengthy and uncomfortable. The design of the PlasmaBlade electrode allows the device to cut the skin safely and function continuously, even when completely submerged in aqueous solution or liquefied fat – environments where traditional electrosurgical devices suffer performance degradation. Thus, the functionality and reduced operating times with the PlasmaBlade have allowed for the procedure to be tolerable and performed under local anaesthetic and on a daycase basis. This is advantageous for ageing patients with medical co-morbidities unsuitable for general anaesthesia, as well as improving theatre efficiency by reducing the overall time taken for the procedure by eliminating intubation and cost of anaesthesia medications.

Decreased bleeding & infection: Sharp dissection techniques increases the risk of ooze from the surgical cavity – especially when extensive dissection is required to expose surrounding wires – increasing the risk of post-operative pocket haematoma. Use of the PlasmaBlade reduces this risk⁵ and, by extension, may influence the risk of infection that has been linked to haematoma formation⁹.

With time, implants become surrounded by a fibrotic capsule and biofilm¹⁰ which may harbour microbial organisms in up to 45% of cases without clinical manifestation of infection¹¹. IPG replacement is known to be associated with three-fold increased risk of infection compared with the primary implant operation¹². This may be due to mechanical 'insult' to the biofilm resulting in the release of microbial organisms, immunological defences being

overwhelmed and ultimately conversion of colonisation to overt infection. For this reason some physicians undertaking cardiac pacemaker implant replacement advocate complete removal of capsule surrounding the generator and lead with resultant lower infection rates⁶. Though this practice is not routinely undertaken with neurostimulators, Servello et al¹³ have recently reported their experience of capsulectomy in 10 cases during IPG replacement using the PlasmaBlade. They conclude that similar to our experience, capsulectomy as a means of preventing infection was greatly facilitated by the PlasmaBlade, which otherwise would be difficult with traditional surgical instruments.

Decreased smoke: Given the concerns of inhaling smoke plume intra-operatively¹⁴, the CUT mode of PlasmaBlade has the advantage of significantly reduced smoke compared with traditional electrosurgery (1.8 vs. 38.7 mg average mass of smoke particulate).

Capsule dissection and cavity exposure: New models of VNS have allowed for closed-loop stimulation using the Cardiac Sensing Model 106 (Cyberonics). This model has the disadvantage of being larger than older generations (Models 103 & 104). Thus, during replacement of the latter with the larger models, extensive capsule dissection and exposure must be performed to allow for satisfactory positioning of the IPG within the cavity, without damaging leads embedded within the capsule. In our experience this is significantly easier, safer and quicker using PlasmaBlade.

Improved healing: As the operating temperature of the PlasmaBlade is lower, healing has been noted to be improved compared with traditional electrosurgery devices with significantly less acute thermal damage and inflammatory response¹⁵ (Figure 4). This has the potential for improved post-operative wound healing with histologic scoring for injury and wound strength revealing equivalence with scalpel incisions but three fold increased strength compared with conventional electrosurgery⁵. Beside applications in functional neurosurgery, this could prove an advantage in neurosurgical cases where CSF fistula from poor wound healing is an issue (e.g. posterior fossa approaches, spinal intradural cases) or for complex shunt revisions, though well designed trials would be required to prove this.

Efficiency & expense: Operating room costs form a large burden on the healthcare system with typical costs of running a theatre in the UK ranging from £600 to £960 per hour¹⁶. Unfortunately, theatre inefficiency is a well recognised source of financial waste with a single-centre service evaluation reported potential savings of approximately £3000/day in its

hospital if delays of only 16 min per operation could be avoided¹⁷. Our review has confirmed a significant reduction in operating times using the PlasmaBlade allowing for greater efficiency and improved utilisation of theatre time. We estimate that on average per list we have been able to undertake an extra battery change increasing remuneration of up to £1000 per list. Further, the consequence of lead damage during battery replacement carries significant morbidity and mortality risk, including increased length of stay and serious financial implications averaging between £5000 and £20,000 per incident depending on the parts of the hardware damaged¹⁸. Improved efficiency combined with this potential to reduce complications has the potential to provide significant cost savings⁶.

Surgical practioners: As the number of patients requiring IPG replacements increase annually, elimination of the risk of inadvertent damage and potential for reduced haematoma/infection could allow for a more cost effective option of training surgical practioners to undertake the procedure.

General applications: Patients with neuromodulating systems in situ may require unrelated surgery for a variety of reasons e.g. it is not uncommon for patients with Parkinson's disease treated with DBS to require lumbar spine surgery for degenerative spine disease. Given the contraindication of monopolar diathermy usage in patients with neuromodulation implants, sharp dissecting techniques need to be applied which can lead to increase blood loss and prolonged operation. PlasmaBlade can be safely substituted for conventional diathermy in these patients, providing the surgeons with a greater repertoire of instruments to achieve their goals.

Though we report on a relatively small number of cases operated upon using the PlasmaBlade, this technology represents a major advance in surgical tool design. It is expected that this will feature as a regular tool in the armamentarium of neurosurgeons undertaking IPG replacement/ hardware revision given the advantages over traditional electrosurgical devices.

CONCLUSION

In our experience, use of the PlasmaBlade for IPG changes and hardware revisions was safe with a variety of neuromodulation devices and eliminated the risk of iatrogenic lead damage or transfer of energy along the hardware to surrounding tissues. Additional observed advantages include reduced operating times, reduced damage to surrounding tissue and

therefore enhanced healing with reduced infection risk, improved operative exposure and the potential to facilitate revision procedures under local anaesthesia with associated cost savings.

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LEGENDS

Figure 1 : AEX Generator & PEAK PlasmaBlade™

Figure 2 : Intra-operative exposure of IPG using PlasmaBlade

Figure 3 : Copolymer lead, perpendicular device orientation, CUT mode

A) PlasmaBlade Setting 5

B) Traditional electrosurgery unit, 30 watts.

Figure 4: Thermal Injury Profile comparing

A) Scalpel

B) PlasmaBlade

C) Electrosurgery

Patient	Anaesthesia	Procedure	Device
1	LA	DBS IPG Replacement	Medtronic
2	LA	DBS IPG Replacement	Medtronic
3	GA	DBS IPG Replacement	Medtronic
4	GA	DBS IPG Replacement	Medtronic
5	GA	DBS IPG Replacement	Medtronic
6	GA	DBS IPG Replacement	Medtronic
7	GA	DBS Wound Revision	Medtronic 3389 & Stimloc
8	GA	DBS Lead Revision	Medtronic 95cm lead
9	GA	VNS IPG replacement	LivaNova 104
10	GA	VNS IPG replacement	LivaNova 106
11	GA	VNS IPG replacement	LivaNova 106
12	LA	DBS IPG replacement	Medtronic
13	LA	DBS IPG replacement	Medtronic
14	LA	DBS IPG replacement	Medtronic
15	LA	DBS IPG replacement	Medtronic
16	LA	DBS IPG replacement	Medtronic
17	LA	DBS IPG replacement	Medtronic
18	LA	DBS IPG replacement	Medtronic
19	LA	DBS IPG replacement	Medtronic
20	LA	DBS IPG replacement	Medtronic
21	GA	DBS IPG replacement	Medtronic
22	GA	DBS IPG replacement	Medtronic
23	GA	VNS IPG Replacement	LivaNova Model 106
24	GA	VNS IPG Replacement	LivaNova Model 106
25	GA	VNS IPG Replacement	LivaNova Model 106
26	GA	VNS IPG Replacement	LivaNova Model 106
27	GA	VNS IPG Replacement	LivaNova Model 106
28	GA	ITB pump replacement	Medtronic Synchromed II
29	LA	DBS IPG replacement	Medtronic
30	LA	DBS IPG replacement	St Jude Medical
31	LA	DBS IPG replacement	Medtronic
32	GA	DBS IPG replacement	Medtronic
33	GA	DBS IPG replacement	Medtronic
34	LA	DBS IPG replacement	Medtronic
35	LA	DBS IPG replacement	Medtronic
36	LA	DBS IPG replacement	Medtronic
37	LA	DBS IPG replacement	Medtronic
38	LA	DBS IPG replacement	Medtronic
39	LA	DBS IPG replacement	Medtronic
40	LA	DBS IPG replacement	Medtronic
41	LA	DBS IPG replacement	Medtronic
42	LA	DBS IPG replacement	Medtronic
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51	LA	DBS IPG replacement	Medtronic
52	LA	DBS IPG replacement	Medtronic
53	LA	DBS IPG replacement	Medtronic
54	LA	DBS IPG replacement	Medtronic
55	LA	DBS IPG replacement	Medtronic
56	LA	DBS IPG replacement	Medtronic
57	LA	DBS IPG replacement	Medtronic

Table 1: Indication for operation, type of anaesthesia and device manufacturer.

A

B