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TECHNICAL NOTE - FUNCTIONAL

Is capsulectomy a feasible and useful measure in internal pulse generator replacement procedures? A technical note on the use of the PEAK PlasmaBlade™

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Abstract
Background Implantable pulse generator (IPG) replacement is considered a simple procedure, but in case of extension cable damage or IPG pocket infection, it can dramatically affect a patient's quality of life. Higher risk of infection has been reported after IPG replacement procedures rather than after primary deep brain stimulation lead implantation, and some authors suggested that the IPG pocket capsule could play a pivotal role in causing it. In this technical note we present a capsulectomy technique adopted in IPG replacement procedures.
Methods Between July and October 2015, we carried out ten outpatient IPG replacement procedures at the chest and abdomen under local anesthesia for battery depletion using the PEAK PlasmaBlade™. All patients were followed for at least 2 months to rule out any hardware malfunction and infection.
Results All ten procedures were uneventful. No extension cable damage occurred. No IPG pocket infection occurred, also not in the follow-up. Mean surgical time was 30 min.
Conclusions Complete capsulectomy is not feasible with basic surgical instruments, and the PEAK PlasmaBlade™ pencil appears to be a helpful tool in carrying out the procedure.

Keywords Deep brain stimulation · Implantable pulse generator · Adverse event · PEAK PlasmaBlade™

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Introduction

The average implantable pulse generator (IPG) lifespan in deep brain stimulation (DBS) is about 3 to 5 years, depending on the patient's current consumption. Current consumption is related to the features of each specific disease though; for instance, in dystonic patients it is greater than in those with Parkinson's disease (PD) and essential tremor (ET) [3, 6, 11]. IPG replacements are frequently performed in functional neurosurgery units, mostly because the vast majority of implanted devices are not rechargeable, and demand will significantly increase within the next decades. This procedure is considered simple and easy to do, but we do not think this is always the case. Adverse events, such as extension cable damage or an IPG pocket infection, can indeed dramatically affect a patient's quality of life because of a subsequent therapeutic stimulation outage [11]. Moreover, it seems that adverse events related to the surgical technique occur more frequently in IPG replacement than in primary DBS lead implantation, as observed in many secondary infection studies [6, 9].

Over the years, in our center, we encountered several surgical circumstances and adverse events such as IPG pocket hematoma, IPG pocket seroma, IPG pocket empyema, scar tissue keloid, extension cable breakage, and twiddler's syndrome. One of the most important issues from a technical standpoint is the patient's tissue reaction to the implanted hardware. Many times we encountered thick fibrotic tissue encapsulating the extension cables, which sometimes were coiled up over the IPG, beneath the incision line (Fig. 1). This condition mostly happens in patients who undergo multiple IPG replacement procedures, and it gets worse each time. Extension cable damage usually occurs during tissue dissection, mostly when cables lie over the IPG or when the IPG is being pulled out of the pocket. Regarding infection risk, some authors have reported higher infection rates after IPG

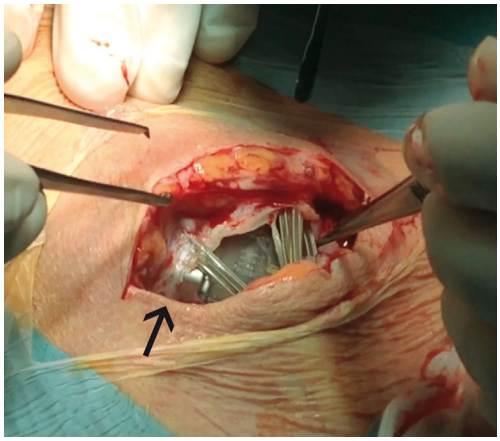

Fig. 1 Extension cables lying over the stimulator after a subclavicular pocket opening. See the white fibrotic tissue (black arrow) encapsulating the extension cables

replacement compared to those occurring in primary DBS procedures [9]. Several explanations have been proposed recently to address this issue: first, IPG replacement is generally performed after primary DBS procedures, mostly in the afternoon, and the infection rate has been demonstrated to increase during daytime in previous studies on cerebrospinal fluid shunting [1, 2, 4]. A second interesting and possible explanation is that the fibrous capsule around the IPG may limit a proper inflammatory response, preventing prophylactic antibiotics from reaching the implanted device [9]. According to this theory, some authors state that lack of local washout during IPG replacement could play an important role, and neomycin/polymyxin washout in conjunction with intravenous antibiotics has been demonstrated to be effective in preventing hardware-related infections [8]. Given this assumption, a total or a subtotal capsulectomy would improve antibiotic penetration and may reduce the risk of infection.

In this article we present our initial experience with the use of the PEAK PlasmaBlade™ on ten patients on whom we performed a total or a subtotal capsulectomy.

Methods and materials

Traditional electrodiathermy applies a continuous radiofrequency (RF) alternating current (AC) that generates a very high current density at the cutting blade tip and tissue interface resulting in resistive heating of local tissue [5]. Conversely, the PEAK PlasmaBlade™ delivers brief and high-frequency pulses of RF energy generating electrical plasma along the edge of a thin (12.5 μm), 99.5 % insulated cutting blade. Due to the thermal protection shield (TPS) technology, the PEAK PlasmaBlade™ operates at significantly lower temperatures than traditional electrocautery (40–170 °C vs. 200–350 °C). Currently implanted leads are made of polyurethane (PU55D) or silicone-polyurethane copolymer as the outer insulation sheath. Given the polyurethane (PU55D) insulation melting point between 185 and 225 °C, the PEAK PlasmaBlade™ can be safely used in direct contact with implanted hardware. Otherwise, lead insulation may be damaged during an IPG replacement procedure by using traditional electrodiathermy technology, and extension cables may be damaged by using scissors and scalpels [7].

Between July and October 2015, we carried out ten outpatient IPG replacement procedures at the chest and abdomen, under local anesthesia, for battery depletion using the PEAK PlasmaBlade™ pencil. The day of the procedure 2 g of intravenous cefazoline was administered 20 min prior to incision. Patients laid in the supine position upon the operating table, and a sterile field was prepped over the chest or the abdomen pocket. The previous incision line was opened using the PEAK PlasmaBlade™ pencil directly on the skin surface. The fibrotic capsule was opened to deliver the IPG. Careful debridement of the extension cables from the capsule was made still using the PEAK PlasmaBlade™ pencil, and then the excess scar tissue was removed (Fig. 2). Once the depleted IPG had been pulled out, a total capsulectomy (6 patients) or subtotal capsulectomy (4 patients) was performed (Fig. 3). The depleted IPG was unplugged from the extension cables, and a new IPG was plugged in. After careful hemostasis, the new IPG was placed into the pocket, and excess cables were coiled up and pushed beneath the IPG. Hemostasis was carried out using bipolar cautery forceps during the entire procedure. We used a PEAK PlasmaBlade™ cut setting of five and coagulate setting of six from the beginning to the end of each procedure.

Results

All procedures were uneventful. No extension cable damage occurred during the capsulectomy, as confirmed by

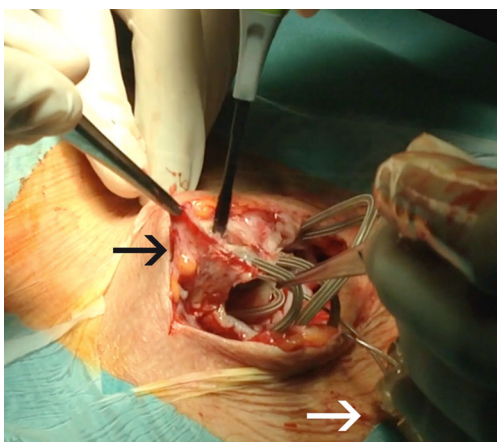

Fig. 2 Once depleted, the IPG is pulled out (white arrow); extension cable debridement is performed by using the PEAK PlasmaBlade™ pencil (black arrow)

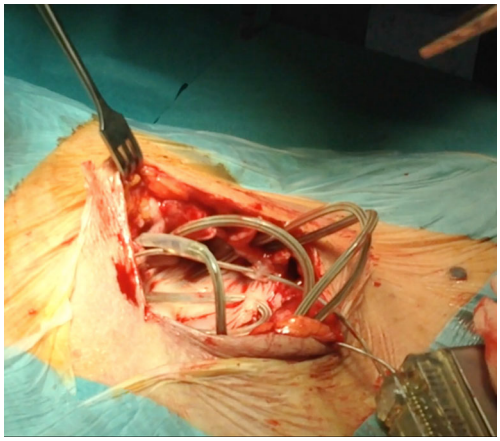

Fig. 3 Extension cables are completely freed and the pocket's external capsule is removed, allowing the surgeon to complete the capsulectomy by removing the deeper layer. See the white fibrotic tissue beneath the extension cables

impedance measurement before and after each procedure. No IPG pocket infection occurred in the 2-month follow-up. The PEAK PlasmaBlade™ pencil has been used multiple times in direct contact with the extension cables, which in two out of ten cases were situated over the IPG just beneath the subclavicle incision line, without causing any damage to the hardware. Mean surgical time was 30 min.

Discussion

In this article, the authors focus on the possibility of carrying out a total or subtotal capsulectomy and cable debriment during IPG replacement procedures. The main purpose of this procedure is to reduce the risk of infection and cable damage. Toia et al. reported 16 exposed implantable device rescues out of a total of 17 by performing a complete capsulectomy and pocket irrigation with n-acetylcysteine solution. n-Acetylcysteine is a glutathione precursor deemed to be effective in destroying bacterial biofilm [12]. Complete capsulectomy requires dangerous surgical maneuvers when using traditional instruments though. Inner scar tissue dissection using a scalpel, scissors and traditional electrosurgical pencil would increase the risk of extension cable damage, which is why we tried a new electrosurgical pencil called the PEAK PlasmaBlade™. The PEAK PlasmaBlade™ has been previously implemented in cardiology in pacemaker (PM) and implantable cardioverter-defibrillator (ICD) implantation and replacement and then in some functional neurosurgery units worldwide [10]. In our experience, the PEAK PlasmaBlade™ enables dissection of inner tissues to free encapsulated cables without damaging them, making the procedure faster and flawless. From a purely technical standpoint, we found this tool easy to use as a traditional electrosurgical pencil, in both handling and cutting efficiency.

In conclusion, we believe that total or subtotal capsulectomy would help in preventing infections in IPG replacement procedures. Further investigations have to be made for ascertainment though. The procedure is not feasible with basic surgical instruments, and the PEAK PlasmaBlade™ appears to be a helpful electrosurgical tool for carrying it out.

Compliance with ethical standards

Funding No funding was received for this research.

Conflict of interest All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements) or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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