

Deep Brain Stimulation Generator Replacement Surgeries : Safety and Efficacy of PEAK Plasmablade TMX and Analysis of Wound Healing Complications

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Objective : This study aimed to assess the safety and efficacy of using the PEAK Plasmablade TMX (PBX) in deep brain stimulation (DBS) of implantable pulse generator (IPG) replacement surgeries, alongside identifying potential risk factors for postoperative complications.

Methods : A prospective study was conducted on 50 patients undergoing IPG replacement with PBX, compared to 150 historical controls. Demographic data, surgical characteristics, and postoperative outcomes were analyzed. Logistic regression was used to identify predictors of surgical complications.

Results : The demographic and clinical profiles of patients in the PBX group were comparable to those in the control group. PBX significantly reduced surgical duration ($p=0.005$) and did not result in impedance abnormalities. While wound complications did not significantly differ between groups, logistic regression identified diabetes as a significant predictor of wound dehiscence or delayed healing ($p=0.012$).

Conclusion : The findings support the safety and efficacy of PBX in DBS IPG replacement surgeries, offering advantages such as reduced surgical duration and minimized risk of impedance abnormalities. However, diabetes emerged as a significant predictor of adverse wound outcomes, highlighting the need for tailored preoperative assessment and management strategies.

Key Words : Deep brain stimulation · Wound healing · Implantable neurostimulators.

INTRODUCTION

Deep brain stimulation (DBS) is a surgical intervention used

to treat movement disorders like Parkinson's disease, essential tremor, and dystonia, as well as some psychiatric disorders, and epilepsy. Although recent advancements in technology have

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extended the lifespan of implantable pulse generator (IPG), they typically require replacement every 3–5 years for non-rechargeable systems and 7–10 years for rechargeable models. As survival period following initial DBS surgery has improved dramatically, the number of individuals requiring IPG replacements is steadily increasing.

Unipolar electrocautery (BOVIE), frequently employed in surgery, is used to facilitate dissection procedures. However, its use in IPG replacement surgery is contraindicated due to the risk of energy transfer to the implanted system, potentially resulting in hardware damage, tissue injury, and serious complications^{7,11}. Therefore, traditional tools such as scissors and knives have been predominantly utilized for replacement surgery to date. However, damage to the device can occur during this process, and in the worst case, the device system could become unusable. Consequently, this surgery takes a lot of time and places considerable stress on the surgeon. Additionally, in the event of equipment damage, both financial and human costs are incurred.

The PEAK PlasmaBlade™MX (PBX; Medtronic, Minneapolis, MN, USA) (Fig. 1 and Supplementary Video 1) is a novel surgical device that generates high-frequency pulses to induce electrical plasma along the edge of a thin (12.5 µm), almost entirely (99.5%) insulated electrode. Operating at substantially lower temperatures (40–170°C) compared to conventional unipolar electrocautery (200–350°C), PBX operates well below the melting temperature of neurostimulation electrodes (188°C) or intrathecal catheter coatings (200–210°C)⁶. When utilized with implantable cardiac electronic devices, including pacemakers and defibrillators, the risk of hardware or lead damage is nota-

bly minimized rendering its adoption increasingly prevalent⁴. IPG in DBS share a remarkably similar structure to cardiac electronic devices. Additionally, the safety of utilizing a PBX for replacing a DBS device has been documented by a British research group¹³.

In this study, we aimed to confirm the safety and effectiveness of using PBX for DBS IPG replacement surgery, as well as to identify potential risk factors for complications associated with IPG replacement procedures.

MATERIALS AND METHODS

Patients

After obtaining institutional IRB approval of Severance hospital (1-2021-0063), a prospective study was conducted on patients requiring IPG replacement following DBS at a single institution (Severance Hospital) from July 2022 to August 2023. IPG replacement surgery was performed using PBX on 50 patients who obtained consent after receiving adequate explanation. These patients were followed up at an outpatient clinic at intervals of 1 day, 2 weeks, 1 month, 3 months, and 6 months after surgery to evaluate impedance abnormalities, surgical complications, and clinical status.

In parallel, the control group was established through a retrospective cohort consisting of 150 consecutive patients who had undergone IPG replacement surgery prior to July 2022. The patients were also checked for abnormal impedance, surgical complications, and clinical status up to 6 months after surgery. Surgeries in both the prospective and retrospective groups were performed by three surgeons: JWC, KWC, and SWH.

IPG replacement surgical procedure

All surgeries involved the replacement of the IPG into the subfascial space within chest wall below the clavicle. Both the target group (PBX group) and the control group (conventional method group; non-PBX group) underwent surgery under general anesthesia.

Evaluation

The age, sex, underlying diseases (hypertension, diabetes, use of antiplatelet or anticoagulant drugs), diagnosis that required DBS surgery, whether unilateral or bilateral surgery was performed, and the number of reoperations in the same area were



Fig. 1. Plasmablade TMX (PBX) generator and handpiece used in this study. Image provided by Medtronic (Minneapolis, MN, USA). Used with permission. All rights reserved.

compared between the two groups. Additionally, surgery time, impedance abnormalities, and surgical site complications (hematoma, dehiscence or delayed healing, and infection) were evaluated. Surgical time was defined as the duration from skin incision to closure.

Impedance was considered abnormal if it exceeded the cutoff value (3000 Ω) or if an open circuit occurred at any contact. Delayed wound healing was defined as a scenario where stitch removal was not feasible on the 9th day after surgery (the standard stitch removal date at our institution), necessitating stitch removal 2 weeks after surgery, or requiring additional wound management thereafter.

Statistical analysis

The statistical analysis was conducted using SPSS Statistics for Windows, version 26.0 (SPSS Inc., Chicago, IL, USA). Fisher's exact test was used when the expected frequency of a nominal variable was 5 or less, and the chi-square test was used for higher frequencies to confirm statistical significance. Continuous variables were analyzed using the Student's t-test for normal distributions or the Wilcoxon rank sum test for non-normal distributions.

A binary logistic regression analysis was performed to assess the factors affecting wound dehiscence and delayed healing. Variables such as PBX usage, age, gender, comorbidities, diagnosis, and the number of reoperations were included as independent variables. A receiver operating characteristic (ROC) curve was generated using probability values from the logistic regression analysis. Statistical significance was set at $p < 0.05$.

RESULTS

Table 1 presents the basic demographics of the patient cohort analyzed in this study. The average age was 63.92 years in the PBX group and 61.65 years in the non-PBX group, with no statistical difference between the two groups ($p = 0.285$). Regarding sex distribution, there were 28 males and 22 females in the PBX group, and 78 males and 72 females in the non-PBX group, with no statistical difference between the two groups ($p = 0.744$). In terms of comorbidities, there was no statistically significant difference between the PBX and non-PBX groups regarding hypertension, diabetes, and previous use of antiplatelet agents or anticoagulants (18 vs. 45, 11 vs. 22, and 3 vs. 9, respectively;

$p = 0.645$, $p = 0.598$, $p = 1.000$, respectively).

In terms of diagnoses for which DBS was performed, the most common diagnosis in both groups was Parkinson's disease (28 in the PBX group, 87 in the non-PBX group), followed by dystonia (13 in the PBX group, 29 in the non-PBX group), and essential tremor (six in the PBX group, 27 in non-PBX group). Statistical analysis revealed no significant difference between the two groups ($p = 0.599$).

There were 12 patients in the PBX group and 36 patients in the non-PBX group underwent replacement surgery on both sides with no statistically significant difference observed ($p = 0.848$).

Regarding the number of reoperations in the same area, the PBX group had 11 individuals vs. 36 individuals in the non-PBX group for two operations, 24 vs. 75 individuals for three operations, 12 vs. 33 individuals for four operations, 3 vs. 6 individuals for five times. Once again, no statistical difference

Table 1. Basic demographics of the patient cohort

	PBX (n=50)	Non-PBX (n=150)	p-value
Age (years)	63.92±12.34	61.65±13.15	0.285
Sex, male : female	28 : 22	78 : 72	0.744
Co-morbidity			
Hypertension	18	45	0.645
Diabetes mellitus	11	22	0.598
Antiplatelet/anticoagulants	3	9	1.000
Not all three	27	91	
Disease			0.599
Parkinson's disease	28	87	
Dystonia	13	29	
Essential tremor	6	27	
Others	3*	7 [†]	
Unilateral/bilateral surgery			0.848
Unilateral	12	36	
Bilateral	38	114	
Revision			0.902
2	11	36	
3	24	75	
4	12	33	
5	3	6	

Values are presented as mean±standard deviation or number. *Cerebral palsy (1), epilepsy (1), Tourette syndrome (1). [†]Cerebral palsy (1), epilepsy (2), Tourette syndrome (2), obsessive-compulsive disorder (1). PBX : plasmablasde TMX, non-PBX : non-plasmablasde TMX

was found ($p=0.902$).

Table 2 shows the surgical complications observed in both groups. In the PBX group, there was no significant change in impedance before and after surgery in any patient. There was also no significant change in impedance at the 6-month post-surgery checkup. In the non-PBX group, six patients showed electrode abnormalities within the normal impedance range before surgery, and this remained the same when measured 6 months after surgery.

In terms of surgery time, a statistically significant difference was noted between the two groups, with a median of 31 minutes in the PBX group and 33.5 minutes in the non-PBX group ($p=0.005$). Although impedance abnormalities occurred only

in the non-PBX group, this disparity between the two groups was not statistically significant ($p=0.334$). Two of the six patients had issues with the electrodes they were using, requiring one patient to have their symptoms managed with alternative contacts, while another patient had to have all extensions replaced after reopening a previous scalp wound.

When examining complications related to surgical wounds, postoperative hematoma occurred in two patients in the PBX group and seven patients in the non-PBX group, but the difference was not statistically significant ($p=0.677$). Wound dehiscence or delayed wound healing manifested in three patients in the PBX group and 10 patients in the non-PBX group; however, this disparity did not reach statistical significance ($p=1.000$). Postoperative infection did not occur in the PBX group and occurred in two patients in the non-PBX group. However, there was no statistical difference ($p=1.000$). Overall wound-related complications showed no statistical difference between the PBX group and the non-PBX group, with five and 19 patients, respectively ($p=0.249$).

Table 3 integrates the two groups and categorizes them into those experiencing wound dehiscence and delayed healing, and those without such complications. PBX usage, age, gender, comorbidities, diagnosis, and number of reoperations were included as dependent variables. The results stem from binary logistic regression analysis with these independent variables. The significance probability according to the Hosmer test was 0.965, and the Nagelkerke R^2 (coefficient of determination) was 0.558.

Table 2. Surgical complications

	PBX (n=50)	Non-PBX (n=150)	p-value
Operation time per generator (minutes)	31 (27–35)	33.5 (29–38.5)	0.005
Impedance abnormality	0	6	0.334
Wound related complications			
Hematoma	2	7	0.677
Dehiscence/delayed healing	3	10	1.000
Infection	0	2	1.000
Total	5	19	0.249

Values are presented as median (interquartile range) or number. PBX : plasmablade TMX, non-PBX : non-plasmablade TMX

Table 3. Results of binary logistic regression analysis divided into groups in which wound dehiscence and delayed wound healing occurred and those in which it did not

	Odds ratio	95% confidence interval		p-value
		Upper limit	Lower limit	
Group	0.799	0.052	12.257	0.872
Age	0.883	0.772	1.01	0.070
Sex	1.398	0.125	15.653	0.786
Comorbidity				
Hypertension	1.22	0.071	21.102	0.891
Diabetes mellitus	20.495	1.952	215.216	0.012
Antiplatelet/anticoagulant	59.987	0.064	56487.3	0.241
Disease				
Parkinson's disease	0.000	0.000		0.997
Dystonia	0.000	0.000		0.996
Essential tremor	1.877	0.115	30.654	0.659
Number of re-operation	2.836	0.435	18.435	0.276

Other variables were not statistically significant, but diabetes mellitus was statistically significantly ($p=0.012$), with an odds ratio of 20.495.

Fig. 2 draws the ROC curve generated using the probability value of derived from the binary logistic regression analysis. The area under the ROC curve (AUC) was 0.962, with a standard error of 0.023 and a significance probability of 0.000.

DISCUSSION

IPG replacement surgery is not recognized as a major surgery, but as mentioned earlier, the frequency of surgery is increasing, making its importance greater than before. This study is also significant because, to the best of the authors' knowledge, it is the first paper to prospectively and retrospectively analyze the usefulness of new surgical instruments and risk factors for surgical complications, specifically focusing on IPG replacement surgery.

The authors believe that the small sample size in the PBX group likely contributed to the lack of statistical significance. A reverse calculation, based on the observed incidence of abnormal impedance in the PBX group (0%, 0/50) and the non-PBX group (4%, 6/150), suggests that a statistically significant difference would only be observed if no adverse events occurred in

approximately 4906 patients. This is attributable to the inherently low incidence of abnormal impedance, even with the conventional method. Nevertheless, despite the absence of statistical significance, the finding is noteworthy, as not a single patient in the PBX group exhibited an impedance abnormality. This suggests that the mechanism of the new device—operating at a temperature below the melting point of the neurostimulator—is effective, which is consistent with previous findings¹³⁾.

There was no statistically significant difference in the basic characteristics of the two groups (Table 1). Additionally, since all the surgeons involved had more than 2 years of experience performing this surgery, it can be presumed that there is no significant learning curve. Therefore, there are no major issues in comparing the surgical outcomes between the two groups (Table 2). However, it's important to note that in the analysis of comorbidity, only the three most common and influential factors on postoperative wounds were considered. This limitation may affect the interpretation of the results.

Complications

In terms of surgery time, although non-parametric analysis was conducted due to the non-normal distribution of data in both groups, a statistically significant difference was observed (Table 2). As mentioned earlier, while no statistical difference was detected in impedance abnormalities, it is noteworthy that no impedance issues in the PBX group. Furthermore, consistent with the previous reports, we observed no issues when the PBX tip made direct contact with a non-isolated part of the hardware. Even in cases where dissection was necessary due to adhesion of the extension line to the fascia layer, the operator could perform dissection with confidence by using the PBX. This likely contributed to the reduction in surgery time.

Although there was no statistical difference between the prospective and the retrospective groups in the terms of postoperative wound-related complications, the PBX group appeared to have a lower complication rate. Despite the lack of a statistical difference, it may be inferred that this new surgical instrument does not lead to a higher incidence of surgical wound complications compared to traditional surgical methods.

Studies examining the use of PBX to other surgeries have reported similar findings. A report on PBX use in traumatic retinal detachment highlighted its advantages in dissolving dense fibrovascular bands, minimizing bleeding, and performing

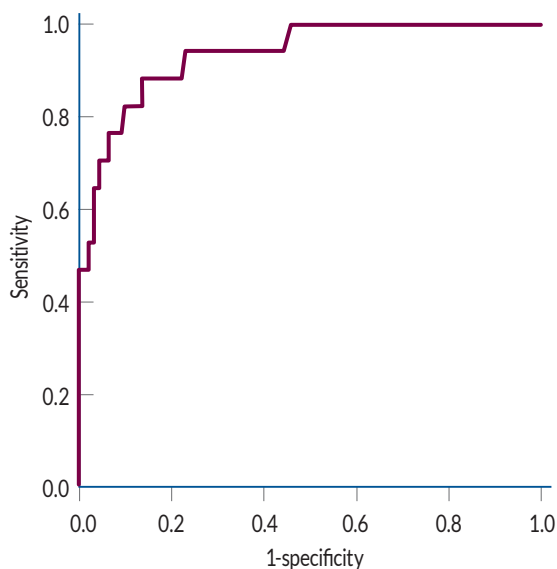


Fig. 2. Receiver operating characteristic (ROC) curve using the probability value of derived from the binary logistic regression analysis divided into groups in which wound dehiscence and delayed wound healing occurred and those in which it did not.

surgery without tractional tears¹²⁾. Similarly, a study involving tonsillectomy reported an odds ratio of 1.20 (95% confidence interval, 0.52 to 2.72) for postoperative bleeding in the PBX group, indicating no significant difference in safety related to bleeding compared to traditional monopolar coagulators.

Although this study did not investigate cosmetic outcomes, a report indicated that cosmetic results in the group utilizing PBX during cesarean sections were significantly better than in the scalpel group²⁾. Moreover, in a study involving canine mastectomies, a device similar to PBX showed a lower degree of necrosis due to thermal damage extending beyond 1000 μm ⁵⁾. Even when used in non-invasive blepharoplasty due to its mechanism of contracting the epidermis and dermis³⁾, it was reported that the surgery was performed without complications.

Regression analysis

When logistic regression analysis was performed, only diabetes history was found to have a significant effect on postoperative dehiscence and delayed healing (Table 3). A regression analysis of other complications such as hematoma, infection, and overall complications did not identify any significant coefficients. Fig. 2 shows that the AUC is 0.962, with a standard error of 0.023 and a significance probability of 0.000, indicating that the prediction performance through binary logistic regression analysis was excellent and statistically significant.

It is well-known that diabetes can lead to delayed wound healing⁸⁾. In diabetic patients, various factors contribute to this delay, including stress, decreased oxygen supply, infection, reduced blood flow, impaired proliferation and migration rates, diminished growth factor production, impaired proliferation and migration of keratinocytes, and altered vascular endothelial mediators⁹⁾. Although a more detailed analysis (e.g., whether blood sugar was controlled after surgery) was not included, Table 3 confirms that diabetes has adverse effects on surgical wounds in IPG replacement surgery.

Another noteworthy observation is that the number of reoperations was not related to complications, contrary to expectations. After IPG is implanted, it becomes encapsulated by fibrous tissue and biofilm over time¹⁾, and IPG replacement carries a three-fold higher risk of infection compared to the initial surgery¹⁰⁾. It could be easily assumed that the risk of complications such as infection would increase with the number of surgeries, but statistical analysis showed no significant differ-

ence between the first and subsequent reoperations.

Limitation

Limitations of this study include potential biases arising from the comparison between a prospective group and a retrospective control group. Additionally, since the study was not conducted as a blind test, inherent biases may have influenced the outcomes. The relatively small sample size also suggests that further large-scale studies are necessary to fully validate these findings.

CONCLUSION

This study provides valuable insights into the application of the PEAK PBX for DBS IPG replacement surgeries. Our findings suggest that PBX offers a safe and effective alternative to conventional techniques, with notable reductions in surgical duration and no observed impedance abnormalities. While wound complications did not significantly differ between groups, diabetes emerged as a significant predictor of adverse outcomes, underscoring the importance of preoperative risk assessment and tailored management strategies.

Further research involving larger cohorts and prospective designs is warranted to corroborate these findings and elucidate additional factors influencing surgical outcomes. Despite the limitations of this study, including the potential biases arising from comparing a prospective group with a retrospective control group, the results support the utility of PBX in DBS IPG replacements.

AUTHORS' DECLARATION

Conflicts of interest

Hyun Ho Jung has been editorial board of JKNS since May 2017. He was not involved in the review process of this original article.

The authors declare that Medtronic provided financial support and supplied the necessary equipment for this study through the External Research Program. However, Medtronic had no role in the study design, data collection, analysis, interpretation of results, or manuscript preparation. The authors affirm that the study was conducted independently, and the re-

sults reflect their unbiased scientific findings.

Informed consent

Written informed consent was obtained from all participants before enrollment in the study. The study was conducted in accordance with ethical guidelines and was approved by the Institutional Review Board of Severance Hospital [1-2021-0063].

Author contributions

Conceptualization : SWH, KWC; Data curation : SHP, HHJ; Formal analysis : DDP, JWC; Funding acquisition : KWC, JWC; Methodology : SWH, KWC; Project administration : SWH, SHP; Visualization : SWH; Writing - original draft : SWH; Writing - review & editing : DDP, HHJ, JWC

Data sharing

The datasets generated and analyzed during the current study are not publicly available but are available from the corresponding author on reasonable request.

Preprint

None

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• Supplementary materials

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