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**CADTH RAPID RESPONSE REPORT:**
**SUMMARY WITH CRITICAL APPRAISAL**

# Pulsed Electron Avalanche Knife (PEAK) PlasmaBlade versus Traditional Electrocautery for Surgery: A Review of Clinical Effectiveness and Cost-Effectiveness


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## Abbreviations

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| APC | Argon plasma coagulation |
| CI | Confidence interval |
| EC | Electrocautery |
| ED | Emergency department |
| LD | Latissimus dorsi |
| OSA | Obstructive sleep apnea |
| PEAK | Pulsed Electron Avalanche Knife |
| RCT | Randomized controlled trial |
| RF | Radiofrequency |
| UHS | Ultracision Harmonic Scalpel |
| VAS | Visual analog scale |

## Context and Policy Issues

Electrosurgical instruments are some of the most often used tools at the surgeon's disposal.[1] Benefits thought to be associated with these devices range from decreased post-operative pain and intraoperative bleeding, increased surgical speed, and reduced risk of post-surgical hemorrhage.[2] Traditional electrocautery (EC) applies radiofrequency (RF) alternating current to generate high current density at the cutting blade tip and tissue interface resulting in extreme resistive heating of local tissue. that provides effective cutting and coagulation due to instantaneous boiling of fluid and tissue vaporization.[3,4] The device operates at temperatures of between 300ºC–350ºC and the generated heat provides effective cutting and coagulation due to instantaneous boiling of fluid and tissue vaporization.[3,5]

It has been reported that the high temperature of the EC procedure is associated with some drawbacks, such as significant thermal damage to incised tissues, reduced surgical precision compared with a scalpel, potential injury to adjacent structures, and delayed wound healing.[4,6] The cauterized surface area also increases subsequent inflammation and fluid sequestration into newly created tissue planes, resulting in seroma formation and increased risk of post-operative complications, such as infection.[4]

Pulsed-electron avalanche knife (PEAK) PlasmaBlade is a relatively new electrosurgical technology developed to minimize the collateral tissue damage caused by higher-heat instruments such as EC. It uses high-intensity RF pulses to create electrical plasma along the edge of a thin, flat, insulated electrode.[5,7] The PEAK PlasmaBlade (PPB) system uses a lower amount of energy translating into operating temperatures of about 40–140 °C, with a corresponding reduction in heat transfer and reduction in depth of thermal damage to adjacent tissues of approximately 50–90%.[5,8] The PPB devices are available in several models designed for specific applications and are intended for tissue cutting and coagulation during general surgery.[7]

The objective of this report is to summarize the evidence regarding the comparative clinical effectiveness of PPB soft tissue dissection devices versus traditional EC for surgery and the cost-effectiveness of PPB use for surgery.

## Research Questions

1. What is the comparative clinical effectiveness of Pulsed Electron Avalanche Knife (PEAK) PlasmaBlade soft tissue dissection device versus traditional electrocautery for surgery?
2. What is the cost-effectiveness of PEAK PlasmaBlade soft tissue dissection device for surgery?

## Key Findings

Limited evidence suggested that surgery with PEAK PlasmaBlade (PPB) resulted in significantly better outcomes than traditional electrocautery (EC) as indicated by shorter time to wound healing, duration of post-operative hospital stay, pain-free swallowing, and length of time for which drains remained in place. Patient satisfaction was also significantly higher, whereas damage to device leads during generator replacement surgery, and thermal damage to tissues in the area of incision were substantially lower with PPB than EC. However, there were inconsistencies in evidence about the comparative effectiveness of two instruments concerning the length of procedure time, drainage volume, and post-operative infection rates, with some studies reporting significantly shorter times for PPB or EC, or not finding a significant difference between the two modalities. It was unclear if the inconsistencies might be due to the differences in processes involved in surgeries for the different indications. Limited evidence from one retrospective study suggested that the use of PPB for latissimus dorsi flap reconstruction resulted in a significantly lower incidence of seroma then using EC. However, one randomized controlled trial found no significant difference in the rates of seroma between PPB and EC among patients who underwent abdominoplasty. Overall, the evidence from the studies included in this report was limited and insufficient to determine the comparative clinical effectiveness PPB versus EC for surgery in general though it suggests that outcomes may differ depending on the type of surgery. Sources of uncertainty included low methodological quality that suggested a high potential risk of bias, and inconsistencies in evidence, with some studies reporting better results with PPB while others found better outcomes in favor of traditional EC, while others found no difference between the two modalities.

No relevant evidence regarding the cost-effectiveness of PEAK PlasmaBlade for surgery was identified.

## Methods

### Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including PubMed, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused Internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concept was PEAK Plasma blade. No filters were applied to limit retrieval by publication type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents but not limited by publication date.

### Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed, and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

## Table 1: Selection Criteria

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| **Population** | Q1-Q2: Patients undergoing surgery |
| **Intervention** | Q1-Q2: PEAK PlasmaBlade soft tissue dissection device |
| **Comparator** | Q1: Traditional electrocautery<br>Q2: Any comparator |
| **Outcomes** | Q1: Clinical effectiveness (e.g., wound healing, harms)<br>Q2: Cost-effectiveness |
| **Study Designs** | Health technology assessments, systematic reviews and meta-analyses, randomized controlled trials, non-randomized studies, economic evaluations |

PEAK = Pulsed Electron Avalanche Knife.

### Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1 or were duplicate publications. Budget impact analyses or basic costing exercises that did not describe costs and benefits did not meet the requirements for cost-effectiveness studies. Therefore, while the relevant clinical effectiveness aspects of such studies[3,9-11] were considered for inclusion, the costs portions were excluded.

### Critical Appraisal of Individual Studies

The included studies[2,3,5,8-12] were critically appraised by one reviewer. Randomized controlled trials (RCTs)[5,8,10] were assessed using the Scottish Intercollegiate Guidelines Network (SIGN) methodology checklist 2: randomized controlled trials.[13] The Risk of Bias Assessment tool for Non-randomized Studies (RoBANS)[14] was used to appraise the retrospective studies,[2,3,9,11,12] Summary scores were not calculated for the included studies; instead, a review of the strengths and limitations of each included study were described narratively.

## Summary of Evidence

### Quantity of Research Available

A total of 49 citations were identified in the literature search. Following screening of titles and abstracts, 29 citations were excluded, and 20 potentially relevant reports from the electronic search were retrieved for full-text review. The grey literature search did not identify any additional relevant publications. Of the 20 potentially relevant articles, 12 papers were excluded for various reasons, and eight reports that met the inclusion criteria were included in this review. These comprised three RCTs[5,8,10] and five retrospective cohort study.[2,3,9,11,12] Appendix 1 presents the PRISMA[15] flowchart of the study selection steps.

## Summary of Study Characteristics

### *Study Design*

Three RCTs[5,8,10] and five retrospective cohort studies[2,3,9,11,12] were included in this report. Two RCTs were published in 2019 while one was published in 2018. They were all single-centre trials, with one being an open-label study[10] with four arms, one a double-blinded trial that blinded all patients and outcome accessors,[8] and one a single -blind study that did not specify the blinded party.[5] The retrospective studies[2,3,9,11,12] were published between 2015 and 2018. Two of them used registry data,[3,11] while three were based on medical chart analysis.[2,9,12]

### *Country of Origin*

One RCT[10] and two retrospective studies[3,11] were conducted in Austria, while two retrospective studies were undertaken in the United States of America (USA).[2,9] One RCT each was carried out in Italy[5] and Singapore,[8] and one retrospective study was conducted in Japan.[12]

### *Patient Population*

Patients in the three RCTs[5,8,10] were adults, with a mean age varying from 28 to 62 years across the studies. The patients underwent the surgical interventions to treat either abdominoplasty,[10] tonsillectomy,[8] or surgical debridement of chronic ulcers unresponsive to non-surgical management.[5] The sample sizes of the RCTs varied from 45 to 58 across the studies.

Patients in two of the retrospective cohort studies[3,11] were undergoing surgery to replace implantable medical devices, described as generators in both studies. The devices were implantable cardioverter-defibrillators, cardiac resynchronization therapy defibrillators, cardiac resynchronization therapy pacemakers, as well as single and dual chamber ventricular pacemakers.[3,11] One of the studies involved 762 patients,[11] and the other had 611 patients.[3] The study population in both studies was predominantly male (≥60%) and elderly, with mean age of 74.4 years in one study[3] and 74.8 years in the other.[11] One retrospective study[12] was done in 44 women who underwent breast reconstruction surgery with latissimus dorsi (LD) flaps. The mean patient age in that study was 50 years. Two retrospective cohort studies[2,9] were conducted in children who underwent tonsillectomy. One of the studies involved 1,780 patients (48.5% female),[2] while the other had 1.280 patients (50.5% female).[9] The mean patient age was 7.0 years, in both studies.[2,9]

### *Interventions and Comparators*

The intervention and comparator of interest were surgical procedures with PPB and EC, respectively. Although one RCT[10] and two retrospective cohort studies[2,9] investigated other electro-surgery modalities in addition to these two (see Table 2 and Table 3), discussions in this review is limited to PPB and EC.

### *Outcomes*

Outcomes reported by the studies[2,3,5,8-12] included procedure time, duration of hospital stay, bleeding, drainage quantity, drainage indwelling time, and wound complications. Outcome definitions were not uniform or provided in all the included studies. For instance, of three studies that defined procedure time (duration of surgery), two studies[3,11] referred to it as time from first skin incision until end of surgery (not defined), while one defined it as time

between first incision and last stitch.[10] In two studies,[10,12] drainage was collected by inserting tubes (drains), and measured daily until the output was less than 30mL per 24 hour, at which point the drains were removed. One study[9] used a visual analog score of 0 to 10 to assess pain (0 being no pain and 10 being extreme pain) and overall patients' satisfaction (0 being unsatisfied and 10 being extremely satisfied). The incidence of post-operative infections was evaluated by microbial culture, whereas time to wound healing was defined as ulcer closure either spontaneously or achieved by reconstruction techniques.[5]

Specifics complications included the formation of seromas and/or hematomas, infection rates, and damage to generator leads. In one RCT,[10] suspicion of clinical seroma was verified by ultrasound,[10] whereas, in a retrospective study,[12] seroma was defined as the persistence of seroma for more than four weeks post-operatively. The method of identifying what constituted seroma was not specified.[12] A lead damage was defined as either an insulation defect upon visual inspection of the lead or an impairment of electrical parameters during generator replacement or during post-operative hospital stay.[3,11]

## Summary of Critical Appraisal

Additional details regarding the strengths and limitations of included publications are provided in Appendix 3.

### *Randomized controlled trials*

The three RCTs[5,8,10] clearly defined their objectives and presented elements that were relevant to the research question. Two of the RCTs[8,10] described methods of randomization, which suggested that adequate concealment was achieved. While one of these two RCTs was an open-label study,[10] all patients and the researcher analyzing the data in the other RCT[8] were blinded to the method of surgery the patients had undergone. The third RCT[5] did not describe the method of randomization, and it was unknown how blinding, or concealment was achieved. The baseline demographic characteristics of patients in one RCT[8] were similar across the treatment and control groups. However, in two RCTs,[5,10] the baseline characteristics of patients were not provided or were inadequately described, making it impossible to determine if the treatment and control groups were similar at the start of the trial. Therefore, for these studies,[5,10] it was uncertain whether the reported outcomes were due only to the treatments under investigation or some unidentified differences between groups. Two RCTs[5,10] provided results based on objective outcomes measured with standard, validated, and reliable methods, whereas on RCT[8] had patient-reported outcomes with potential for significant interpatient variability, resulting in difficulty determining if the findings would be generalizable in other patients. Two RCTs[5,8] included data from all patients in the study, and there were no missing data. However, another RCT[10] (with four arms) reported that five (8.8%) patients, including two (16.7%) patients in the PPB and one (7.1%) patient from the EC groups, were excluded from analysis because they did not complete follow-up assessment. However, it was unclear how that could impact the reported findings.

### *Retrospective cohort studies*

The retrospective character of the studies[2,3,9,11,12] was a limitation since they lacked the risk-diminishing effects of randomization. Four of the included retrospective cohort studies[3,9,11,12] had similar patients' demographic characteristics across the PPB and EC groups, suggesting low risk of selection bias due to inadequate selection of participants. In another study,[2] patients' characteristics were reported for the entire study population,

without specifics for the treatment groups that were being compared. Therefore, the risk of selection bias due to inadequate selection of participants in this study[2] was unclear.

None of the retrospective cohort studies[2,3,9,11,12] identified potential confounders or considered them during analysis. Thus, the risk of selection bias due to inappropriate confounder confirmation and consideration was high in all the studies. In three of the studies[3,11,12] surgery with PPB and EC were performed in two separate periods. Thus, a time trend bias and risk of bias in selection of participants cannot be ruled out in these studies.[3,11,12]

One study[11] reported that all device replacements were performed by specialists with seven to 20 years practical working experience, and in another study,[9] all surgical procedures were under the directions of four fellowship-trained pediatric otolaryngologists. Therefore, the risk of performance bias due to variability in exposure to intervention was low in these studies.[9,11] In contrast, two studies[3,12] provided no information about the skill and experience of the individuals who performed the surgical procedures, and another study[2] was based on data obtained from medical charts of several different surgeons with varying degrees of expertise. Therefore, it is unclear whether there were performance biases due to inadequate administration of the interventions in these two studies.[2,3,12]

Four studies[2,3,11,12] specified objective outcomes defined to apply similarly to both treatment groups; thus, minimizing the risk of detection bias caused by inappropriate outcome assessment. In contrast, the definition of the key outcome in one study[9] was subjective and raised the risk of detection bias due to inappropriate outcome assessment. One study[12] did not describe the methods evaluating outcomes, and it was unknown if they were applied similarly across the two interventions. Therefore, the risk of detection bias caused by inappropriate outcome assessment was unclear. In another study,[2] one outcome (bleeding rate) of three that were stated was reported in a manner that allowed comparison of PPB and EC, whereas two outcomes (hospitalization and ED visits) were reported for the entire study population, without specific reference to either of the surgical modalities. Thus, the risk of reporting bias due to selective outcome reporting was high. In all the retrospective studies,[2,3,9,11,12] information was available for all patients in the two study groups. In one study,[3] ejection fraction data at baseline were missing for similar proportions of patients in the EC and PPB groups and was unlikely to affect the reported findings. The other four studies[2,9,11,12] had no missing data. Thus, the risk of attrition bias due to inappropriate handling of incomplete data was low in all the retrospective studies.[2,3,9,11,12]

In the opinion of the author of this Rapid Response report, the overall quality rating of all the included studies is fair to unclear.

## Summary of Findings

Appendix 4 presents a table of the main study findings and authors' conclusions. No information was found about the prevalence of skin flap or nipple necrosis that results from breast reconstruction surgeries, or the cost of skin flap or nipple necrosis to the health care system.

*Comparative Clinical Effectiveness of Pulsed Electron Avalanche Knife (PEAK) PlasmaBlade versus traditional electrocautery for surgery*

**Wound Healing**

One RCT[5] reported that among patients who underwent surgical treatment of chronic ulcers, time to both spontaneous healing and healing achieved by reconstruction techniques was significantly shorter in patients treated with PPB than with EC. The mean time to healing was 30 days with PPB compared with 36 days with EC ($P < 0.05$) for patients who had spontaneous ulcer closures.[5] Similarly, the mean time to wound healing achieved by reconstruction techniques was 16.9 days for patients who underwent PPB compared with 22.3 days for those treated with electrocautery ($P < 0.05$).[5]

Another RCT[10] reported that the incidence of wound disorder (not defined) was higher with EC (50%) but not significantly different than with PPB. Although a graphical presentation was provided, the specific values for wound disorders were not reported clearly for PPB.

**Procedure Time**

Duration of surgery was reported by five of the included studies.[3,9-12] However, the findings were inconsistent. Whereas one RCT[10] and one retrospective cohort study[12] found no significant differences between the PPB and EC regarding procedure time for abdominoplasty[10] and LD flap breast reconstruction,[12] two retrospective cohort studies[3,11] observed significantly shorter procedure times with PPB in surgical replacement of generators than EC (28.4 to 34.1 minutes for PPB versus 47.5 to 47.9 minutes for EC; $P$ <0.001 in all comparisons) . However, another retrospective study[9] identified significantly faster surgical times for EC than PPB for adenotonsillectomy in children (26.23 ± 13.58 minutes versus 28.42 ± 13.41 minutes; $P = 0.03$).

**Duration of Hospital stay**

Three retrospective cohort studies[3,11,12] reported that the length of hospital stay after surgery was significantly shorter for patients treated with PPB than those treated with EC. One of the studies[12] found that among patients who underwent LD flap procedure for breast reconstruction, the median length of hospital stay was 11.7 days in the PPB group compared with 14.1 days in the EC group ($P$ <0.011). In two studies[3,11] evaluating patients who underwent surgical replacement of generators, the mean duration of hospital stay was 2.1 to 2.4 days for patients in the PPB group compared with 3.1 to 3.2 days for those in the EC group ($P$ <0.001 in all comparisons).

**Drainage Volume and Duration of Indwelling Drain**

One RCT[10] and one retrospective cohort study[12] reported drainage volume results following surgery. In the RCT,[10] the average post-operative drainage volume after abdominoplasties ranged from 50 to 700 mL for four electrosurgery methods (including PPB and EC) that were evaluated. Although a graphical presentation of the findings was provided, the specific quantities of drainage were not reported clearly for the individual modalities. However, the lowest average drainage volume was with PPB, although, according to the authors, there were no significant differences in drainage volume between groups. Unlike the RCT,[10] the retrospective study[12] found that the total drainage volume was significantly ($P = 0.0358$) lower in the PPB group (624.4 ± 441.8; 95% CI: 449.9 to 798.9) than in the EC group (883.8 ± 339.2; 95% CI: 717.0 to 1,050.5). Also, the retrospective study[12] found that the drain indwelling period was shorter in the PPB group (7.9 ± 3.27 days; 95% CI: 6.34 to 9.47) than the EC group (9.43 ± 3.76 days; 95% CI: 7.94 to10.9), but not statistically

significantly (*P* = 0.16). The RCT[10] did not report the duration drains remained in placement.

**Time to pain-free swallowing, normal diet, and normal activities**

One RCT[8] in adult patients who underwent tonsillectomy found that patients in the PPB group achieved pain-free swallowing in statistically significantly shorter time than those in the EC group (13.28 days versus 15.76 days; *P* = 0.035). However, in the same study, no significant difference was observed between the two groups regarding time taken to return to normal diet and normal activities. Also, no statistically significant differences were observed between the groups in daily visual analog score for pain, number of tablets of analgesia taken per day, and time taken to return to soft diet.

**Patients' satisfaction**

One RCT[8] in adult patients who underwent tonsillectomy found that patients in the PPB group had a significantly higher mean satisfaction score than those in the EC group (8.92 versus. 8.24 out of 10; *P* = 0.046).

**Complications**

Post-operative bleeding

One RCT[10] and two retrospective cohort studies[2,9] found no statistically significant difference in post-operative bleeding between PPB and EC. The RCT[8] and one retrospective study[2] in adults and children, respectively; who underwent tonsillectomy found no statistically significant difference between PPB and EC in post-operative hemorrhage. Similarly, in the other retrospective study[9] in children who underwent adenotonsillectomy, the difference in the incidence of post-operative bleeding between the EC and PPB groups was not statistically significantly different.

Post-operative hematoma

One RCT[10] and two retrospective cohort studies[3,11] found no statistically significant difference in the incidence of post-operative hematoma between PPB and EC. In the RCT[10] conducted in patients who underwent abdominoplasty, no hematoma was observed in patients in the PPB group, whereas three patients (21.4%) in the EC group had post-operative hematoma. However, due to the low number of hematomas, the two groups did not differ statistically significantly. The incidence of post-surgery hematoma did not differ statistically significantly between the EC and PPB groups in the in the two retrospective cohort studies,[3,11] both of which were conducted in patients undergoing surgery to replace generators.

Post-operative seroma

One RCT[10] and one retrospective cohort study[12] reported post-operative seroma outcomes, although the results were inconsistent. The RCT[10] found that among patients undergoing abdominoplasty, seroma occurred in one patient (8.3%) treated with PPB and two patients (14.3%) treated with EC, with no significant differences in incidence between the groups. However, the retrospective study[12] found that in patients undergoing breast reconstruction with LD flap procedure, seroma occurred in four patients (19.0%) in the in the PPB group compared with 11 patients (47.8%) in the EC group, and the difference in incidence was statistically significantly (*P* < 0.043).

Post-operative infections

One RCT[5] and two retrospective cohort study[3,11] reported post-operative infection rates; however, the results were inconsistent. The RCT[5] found that among patients receiving surgical treatment for chronic ulcers, the incidence of post-operative infection was statistically significantly lower with PPB compared with EC (31% .versus 69%; $P < 0.05$). However, no significant differences in the incidence of post-operative infection was observed between the EC and PPB groups in the two retrospective cohort studies[3,11] conducted in patients undergoing generator replacement surgery.

Damage to Device Lead

Two retrospective cohort studies[3,11] conducted in patients undergoing surgical replacement of generators found that damage to device leads occurred statistically significantly less often with PPB than with EC ($P \leq 0.008$). A lead damage was defined as either an insulation defect upon visual inspection of the lead or an impairment of electrical parameters during generator replacement or during the index hospital stay.[11]

Thermal Damage and Inflammatory response

One RCT[5] in patient receiving surgical treatment for chronic ulcers found that treatment with PPB resulted in significantly less thermal damage compared with EC (0.019 ± 0.01 mm vs. 0.40 ± 0.02 mm, respectively; $P = 0.001$). Although the study also found no significant difference between the two groups regarding inflammatory response, the evaluation was based on cellular level analysis (immunohistochemical staining techniques) and its clinical relevance was unclear.

### *Cost-Effectiveness of PEAK PlasmaBlade soft tissue dissection device for surgery*

The literature search for this review did not identify any relevant evidence regarding the cost-effectiveness of PEAK PlasmaBlade soft tissue dissection device for surgery; therefore, no summary can be provided. It should be noted that four[3,9-11] of the included studies in this report presented costs estimates based on analysis using data from their countries of origin. However, because the estimated costs had no corresponding estimates of health-related value (benefit), the information provided in those studies were not considered relevant in answering the cost-effectiveness question.

## Limitations

A significant limitation was the low quality of the includes studies.[2,3,5,8-12] For the RCTs, [5,8,10] key sources of uncertainty were lack of information to assess the similarity of patients' characteristic in two studies[5,10] and the subjectivity of patient reported outcomes in the other.[8] Concerning the retrospective studies,[2,3,9,11,12] the study design raised the risk of bias due to potential confounders. Also, none of the studies had mechanisms of identifying or adjusting for potential confounders in analysis. Thus, the risk of selection bias due to inappropriate confounder confirmation was high in all the studies.[2,3,9,11,12]

Further, there was no direct comparison between PPB and EC in any of the retrospective studies, and in three of the studies,[3,11,12] the two strategies were used in different periods, thus introducing uncertainty about the objectivity in comparing the findings. With the probable exception of surgical replacement of implantable medical devices, the evidence from the included studies in this report was not enough to objectively evaluate which of the two surgical modalities was more effective. Two retrospective studies[3,11] were consistent in

finding that use of PPB for replacing generators compared with EC resulted in significantly shorter durations in procedure time and hospital stay, without a significant difference in complications between the two groups. However, both studies were from the same research team, and the study characteristics suggests a possible overlap in the patient population involved in the two studies. It was also challenging to determine the overall comparative effectiveness of the two instruments from all the findings because it was unclear if the processes involved in the different surgical procedures (abdominoplasty, adenotonsillectomy or tonsillectomy, breast reconstruction with LD flap, replacement of devices, and surgical debridement of chronic ulcers) influenced the measured outcomes to the same extent. Thus, it was unclear if the inconsistent results reported across some studies might be indication-related and not necessarily due to the surgical modality employed.

Furthermore, the literature search for this report did not identify any relevant evidence regarding the cost-effectiveness of PPB for surgery. Also, no information was found about the prevalence of skin flap or nipple necrosis that results from breast reconstruction surgeries, or the cost of skin flap or nipple necrosis to the health care system. However, the search was limited to English language documents, and it is unknown if potentially relevant articles in other languages were missed. The studies[2,3,5,8-12] included in this report were conducted outside Canada. Therefore, the generalizability of the findings to the Canadian context is unclear, given the potential for differences in practice patterns that might impact the interpretation of the results or the resources used to achieve them.

## Conclusions and Implications for Decision or Policy Making

Three RCTs[5,8,10] and five retrospective cohort the studies[2,3,9,11,12] provided the information in this report. Surgical procedures performed in these studies were abdominoplasty,[10] adenotonsillectomy or tonsillectomy,[2,8,9] breast reconstruction with LD flap,[12] replacement of implanted medical devices,[3,11] and surgical debridement of chronic ulcers.[5] Data from these studies suggest that surgery with PPB resulted in significantly better outcomes than EC as indicated by shorter time to wound healing,[10] duration of post-operative hospital stay,[3,11,12] pain-free swallowing,[8] and length of time for which drains remained in placement.[12] Patient satisfaction[8] was also significantly higher, whereas damage to device leads[3,11] and thermal damage to tissues in the area of incision[5] were substantially lower with PPB than EC. However, no significant differences were observed between the two surgical modalities regarding post-operative bleeding,[2,9,10] post-operative hematoma,[3,10,11] and inflammatory response.[5] There was inconsistent evidence about the comparative effectiveness of PPB and EC concerning the length of procedure time, with some studies reporting significantly shorter times for PPB[3,11] or EC,[9] or not finding a significant difference between the two.[10,12] There were inconsistencies in the results for drainage volume,[10,12] post-operative seroma,[10,12] and post-operative infection rates;[3,5,11] with some studies finding significant differences in favor of PPB while other found no significant differences. It was unclear if the inconsistencies might be due to the differences in processes involved in surgeries for the different indications.

With the probable exception of surgical replacement of implantable medical devices, the evidence from the included studies in this report was not enough to objectively evaluate which of the two surgical modalities was more effective. Two retrospective studies[3,11] were consistent in finding that use of PPB for replacing generators compared with EC resulted in significantly shorter durations in procedure time and hospital stay, without a significant difference in complications between the two groups. However, both studies were from the

same research team, and the study characteristics suggests overlap in the patient population involved in the two studies. Providing an overarching assessment of comparative effectiveness from all the findings was also challenging because it was unclear if the processes involved in the different surgical procedures (abdominoplasty, adenotonsillectomy or tonsillectomy, breast reconstruction with LD flap, replacement of devices, and surgical debridement of chronic ulcers) affected the measured outcomes to the same extent. Therefore, overall, there was insufficient evidence to conclude on the clinical effectiveness of PPB compared with EC for surgery.

No relevant evidence regarding the cost-effectiveness of PPB for surgery was identified.

Given the limitations, there is a need for additional rigorous research to compare the clinical effectiveness of PPB compared with EC, and to determine the cost-effectiveness of PPB for surgery.

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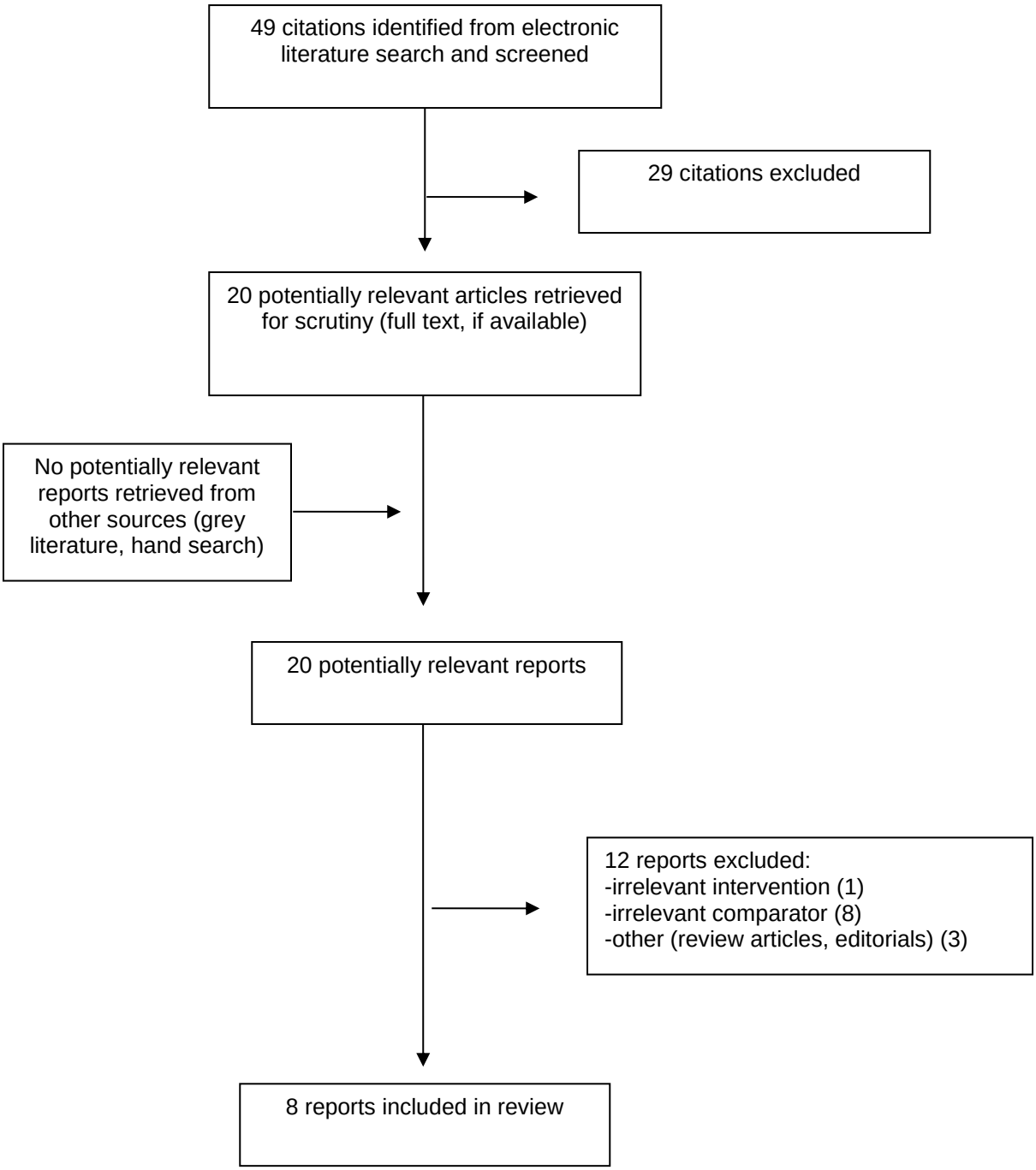
## Appendix 1: Selection of Included Studies



# Appendix 2: Characteristics of Included Publications

## Table 2: Characteristics of Included Randomized Controlled Trials[5,8,10]

| First Author, Publication Year, Country | Study Design | Population Characteristics | Intervention and Comparator(s) | Clinical Outcomes, Length of Follow-Up |
|---|---|---|---|---|
| **Duscher e al., 2019**[10]<br><br>**Austria** | A single-centre, four-armed, open-label randomized trial (with cost assessment) | A total of 57 patients undergoing abdominoplasty between April 2014 and June 2016.<br><br>The patients were predominantly female (93%), with average of age 38 years (range: 23 to 52 years).<br><br>Sex ratios and age distribution for the study groups were not reported. | PPB, EC, UHS, and APC compared with each other | • Procedure time<br>• Intraoperative blood loss<br>• Drainage quantity<br>• Wound complications<br><br>Mean follow-up was one year |
| **Tan et al., 2019**[8]<br><br>**Singapore** | A single-centre prospective double-blinded randomized controlled trial | A total of 58 patients with recurrent or chronic tonsillitis, previous peritonsillar abscess, snoring and OSA, recruited from January 2013 and December 2014.<br><br>The ratio of male to female patients was identical in both groups (69% male vs. 31% female).<br><br>The mean age of patients was 27.62 ± 9.13 years in the PPB group and 29.38 ± 9.9 years in monopolar EC group, *P* = 0.487)) | PPB versus monopolar EC for tonsillectomy | • Post-operative pain<br>• Complications<br>• Number of pain-killer tablets taken<br>• Days taken to return to soft diet<br>• Days taken to return to normal diet<br>• Days taken to return to normal activities<br>• Days taken to return to achieve pain-free swallowing<br>• Patient satisfaction<br><br>Follow-up was four weeks |

| First Author, Publication Year, Country | Study Design | Population Characteristics | Intervention and Comparator(s) | Clinical Outcomes, Length of Follow-Up |
|---|---|---|---|---|
| **Marangi et al., 2018**[5]<br><br>**Italy** | A single-centre prospective, single-blind randomized controlled trial | A total of 45 chronic ulcer patients treated from December 2012 to January 2016. They were not responsive to previous non-surgical management.<br><br>The mean age of the overall study population was 62 years (no measure of variability provided).<br><br>No information about sex ratios or age distribution for the study groups were not reported. | PPB versus EC for surgical debridement from December 2012 to January 2016. | • Thermal and mechanical damage at the incision site<br>• Inflammatory response<br>• Granulation tissue/ Collagen deposition<br>• Incidence of post-operative infection<br>• Healing time<br><br>Follow-up for assessment of histological and microbial outcomes was two weeks. Also, patients were followed-up to assess the healing time, the development of complications, and the clinical evolution of the lesions for an unspecified time. |

APC = argon plasma coagulation; EC =electrocautery; OSA = obstructive sleep apnea; PEAK = pulsed electron avalanche knife; PPB = PEAK PlasmaBlade; UHS = Utraasicion Harmonic Scalpel.

## Table 3: Characteristics of Included Non-randomized Studies[2,3,9,11,12]

| First Author, Publication Year, Country | Study Design | Population Characteristics | Intervention and Comparator(s) | Clinical Outcomes, Length of Follow-Up |
|---|---|---|---|---|
| **Kypta et al., 2018**[11]<br><br>**Austria** | A retrospective cohort study (with cost assessment) based on patient data from registries of two hospitals. | A total of 762 patients who underwent surgical replacement of implantable devices (generators) between 2003 and 2015 (EC = 508 PPB = 254).<br><br>The mean age: EC = 74.3 ± 12.3 years; PPB = 75.7 ± 12.7 years; *P* = 0.113.<br><br>Proportion of males: EC = 59.8%; PPB = 60.2%; *P* = 0.938 | PPB versus EC.<br><br>The strategies were used at different periods (not specified) and never used side by side. | • Procedure time<br>• Hospital stay<br>• Complication rates<br>• Lead damage<br><br>The duration of follow-up was not specified |
| **Sowa et al., 2018**[12]<br><br>**Japan** | A retrospective cohort study based on data from medical charts. | A total of 44 patients who underwent breast reconstruction with LD flaps from August 2015 to April 2017<br><br>The mean age of patients was 50.3 ± 9.1 years in the PPB group and 50.1 ± 9.4 years in EC group, *P* = 0.95).<br><br>Information about sex distribution was not provided. However, it is reasonable to assume the study population was all female, given that they underwent breast reconstruction procedure. | PPB versus EC in the use of LD flap for breast reconstruction | • Procedure time<br>• Hospital stay<br>• Seroma formation<br>• Post-operative bleeding<br>• Drainage indwelling time<br>• Drainage volume<br><br>The duration of follow-up was not specified. |
| **Lane et al., 2016**[2]<br><br>**USA** | A retrospective cohort study using chart analysis. | A total of 1780 patients who underwent tonsillectomy, with or without adenoidectomy, between June 2011 to May 2013 | PPB, monopolar EC, and coblation compared to each other | • Post-operative bleeding<br>• Hospital admission<br>• ED visits<br><br>The duration of follow-up was not specified |

| First Author, Publication Year, Country | Study Design | Population Characteristics | Intervention and Comparator(s) | Clinical Outcomes, Length of Follow-Up |
|---|---|---|---|---|
| | | The mean patient age was 6.9 ± 3.6 years (range: 2 – 18 years).<br><br>Proportion of females in the overall study population was 48.5%. The sex distribution across the two groups was not reported. | | |
| **Kypta et al., 2015**[3]<br><br>**Austria** | A retrospective cohort study (with cost assessment) based on registry data from a single center. | A total of 611 patients who underwent surgical replacement of generators between March 2003 and January 2014 (EC = 509 and PPB = 102).<br><br>The mean age: EC = 74.2 ± 12.6; PPB = 75.1 ± 12.8 years; *P* = 0.510<br><br>Proportion of males: EC = 59.5%; PPB = 63.7%; *P* = 0.441 | PPB versus EC.<br><br>PPB was used between October 2012 and January 2014, whereas EC was used between March 2003 and October 2012 | • Procedure time<br>• Hospital stay<br>• Complication rates<br>• Lead damage<br><br>Follow-up was up to six months |
| **Thottam et al., 2015**[9]<br><br>**USA** | A retrospective cohort study (with cost assessment) using chart analysis. | A total of 1.280 pediatric patients who underwent adenotonsillectomy from 2011 to 2013<br><br>The mean age was 7.09 (3.71), 7.09 (3.89), and 6.90 (3.71), for PPB, EC, and radiofrequency ablation, respectively; *P* = 0.69.<br><br>Proportion of females: EC = 46.8%; PPB = 50.0%; and RF-Ablation = 52.7% *P* = 0.32. | PPB, monopolar EC, and RF-Ablation compared to each other | • Procedure time<br>• Post-operative bleeding<br><br>The duration of follow-up was not specified |

EC =electrocautery; ED = emergency department; LD = latissimus dorsi; PEAK = pulsed electron avalanche knife; PPB = PEAK PlasmaBlade; RF = radiofrequency; USA = United States of America

# Appendix 3: Critical Appraisal of Included Publications

## Table 4: Strengths and Limitations of Randomized Controlled Trials using SIGN Methodology Checklist 2: Randomized Controlled trials[13]

| Strengths | Limitations |
|---|---|
| **Duscher e al., 2019**[10] | |
| • A well-defined objective was specified, and the elements of the research question were present.<br>• The patients were randomly assigned into four treatment groups – PPB, EC, UHS, and APC.<br>• Allocation concealment was achieved by a nurse randomly selecting a paper to find a patient's assigned group after they agreed to participate.<br>• All relevant outcomes were measured in a standard, valid, and reliable way. | • It was an open-label study; therefore, there was no means of ensuring blinding and associated potential bias.<br>• Baseline characteristics of patients were not adequately described, and it was impossible to determine if the treatment and control groups were similar at the start of the trial. Therefore, it was uncertain whether the only differences between groups were the treatments under investigation.<br>• Overall, five (8.8%) patients were excluded from analysis because they did not complete follow-up assessment. They comprised two (16.7%) patients in the PPB group, two (14.3%) in the UHS group, and one (7.1%) in the EC group. The impact of missing data from these patients on the reported findings was unclear.<br>• No information was provided about whether all the patients were analyzed in the groups to which they were randomly allocated. Thus, it is unknow if the analysis was based on the ITT or another population set. |
| **Tan et al., 2019**[8] | |
| • The objectives of the study was well-defined, and the elements of the research question were present.<br>• The study patients selected were randomized to be treated with either PPB or monopolar EC using a computer randomization program, which ensured adequate concealment.<br>• All patients and the researcher analyzing the data and pain diary were also blinded to which method of surgery the patients had undergone. Also, the researcher responsible for data analysis was not involved in any of the surgical operations.<br>• The baseline demographic characteristics of patients were similar across treatment and control groups.<br>• All randomized patients (29 in each treatment arm) underwent the surgery, completed the pain diary, and follow-up assessments. There were no missing data. | • Patients' experiences of post-operative pain were self-assessed using a 0 to 1 VAS and recorded in pain diaries. A method to ascertain if the pain was procedure-related was not described.<br>• Other outcomes including pain on swallowing, number of pain-killer tablets taken per day, ability to take soft diet or normal diet, and ability to return to normal activities, were all patient-reported and without any standardization. The potential for significant interpatient variability made it difficult to determine if the findings will be generalizable in other patients.<br>• It was not reported if the analysis was based on the ITT or another population set. |
| **Marangi et al., 2018**[5] | |
| • The objectives of the study were well-defined, and the elements of the research question were present.<br>• All relevant outcomes were measured in a standard, valid, and reliable way.<br>• No patients were lost during follow-up, and there were no missing data. | • The method of randomization was not described.<br>• It was unknown how blinding was achieved or if an adequate concealment method was used.<br>• Overall patients' characteristics at baseline were not without assignment to the interventions under investigation. Therefore, it was impossible to |

| Strengths | Limitations |
|---|---|
| | determine if the treatment and control groups were similar at the start of the trial, or whether the only differences between groups were the treatments to which they were assigned.<br>• It was not reported if the analysis was based on the ITT or another population set. |

APC = argon plasma coagulation; EC =electrocautery; ITT = intent-to-treat; PPB = PEAK PlasmaBlade; UHS = Ultracision Harmonic Scapel; VAS = visual analog scale

## Table 5: Strengths and Limitations of Non-randomized Studies using RoBANS[14]

| Strengths | Limitations |
|---|---|
| **Kypta et al., 2018[11]** | |
| • Propensity score matching was performed in the study population to eliminate the effect of treatment-selection bias, resulting in similar baseline patients' characteristics across treatment groups. Further, sensitivity analysis using the unmatched population resulted in similar findings as the propensity-matched population. Thus, the risk of selection bias due to inadequate selection of participants was low.<br>• All generator replacements were performed by three experienced operators with two of them having more than 20 years practical working experience and one of them having more than seven years. Therefore, the risk of performance bias due to variability in exposure to intervention was rated low.<br>• The study reported objective outcomes defined to apply similarly to the study groups. Thus, the risk of detection bias caused by inappropriate outcome assessment was low.<br>• Although a study protocol was not available, expected outcomes were reported in the study descriptions. Thus, the risk of reporting bias due to selective outcome reporting was considered low.<br>• There were no missing data; therefore, attrition bias due to inappropriate handling of incomplete data was low. | • The retrospective character of the study was a limitation since it lacked the risk-diminishing effects of randomization<br>• The PPB and the conventional strategy with EC were never used side by side during the study. The traditional ED approach was stopped after the implementation of the PPB. Thus, a time trend bias and risk of bias in selection of participants cannot be ruled out.<br>• Potential confounders were neither mentioned nor considered during analysis. Thus, the risk of selection bias due to inappropriate confounder confirmation and consideration was high.<br>• The number of patients treated with the conventional method were twice as many as those treated with PPB. The impact of this disparage group sizes on the findings was unclear. |
| **Sowa et al., 2018[12]** | |
| • The patients' demographic characteristics were similar across the PPB and EC groups, suggesting low risk of selection bias due to inadequate selection of participants.<br>• Medical charts were reviewed to obtain objective outcomes information for the study. Therefore, the risk of detection biases caused by inadequate blinding of outcome assessment was considered low.<br>• Information was available for all patients in the two study groups. There were no missing data; therefore, attrition bias due to inappropriate handling of incomplete data was low. | • The retrospective character of the study was a limitation since it lacked the risk-diminishing effects of randomization<br>• Patients in the study were received treatment in two separate periods for the interventions being compared. Whereas patients in the PPB group were treated between February 2016 and December 2017, patients in the EC group were treated between August 2015 and February 2016. There is uncertainty about time trend bias and risk of bias in selection of participants. |

| Strengths | Limitations |
|---|---|
| • Although a study protocol was not available, expected outcomes were reported in the study descriptions. Thus, the risk of reporting bias due to selective outcome reporting was considered low. | • Potential confounders were neither mentioned nor considered during analysis. Thus, the risk of selection bias due to inappropriate confounder confirmation and consideration was high.<br>• There was no information about the skill and experience of the individuals who performed the surgical procedures. Therefore, it is unclear whether there were performance biases due to inadequate administration of the interventions.<br>• Although objective outcomes were reported, the methods of assessment were not described, and it was unknown if they were applied similarly across the two interventions. Therefore, the risk of detection bias caused by inappropriate outcome assessment was unclear. |
| **Lane et al., 2016**[2] | |
| • The outcome of interest was defined and applied similarly across study groups. Thus, the risk of detection bias caused by inappropriate outcome assessment was low.<br>• Two physicians (judges) who were unfamiliar with the patients in the study independently performed all medical chart extractions to ensure data reliability. Thus, the risk of confirmation bias due to inappropriate blinding of assessors was low.<br>• For acceptable inter-rater reliability, the judges had to achieve 100% consensus on all entries. Further, 25% of the charts were re-examined by the judges several weeks after their initial reviews. The acceptability on this measure required the judges to be 100% in agreement with themselves on all data gathered for analyses. Therefore, confirmation bias due to inappropriate outcome assessment methods was low.<br>• There were no missing data; therefore, attrition bias due to inappropriate handling of incomplete data was low | • The retrospective character of the study was a limitation since it lacked the risk-diminishing effects of randomization.<br>• A breakdown of patient's characteristics across study groups was not provide. Therefore, the risk of selection bias due to inadequate selection of participants was unclear.<br>• Potential confounders were neither mentioned nor considered during analysis. Thus, the risk of selection bias due to inappropriate confounder confirmation and consideration was high.<br>• The results were obtained from medical charts of several different surgeons with varying degrees of experience. Therefore, it is unclear whether there were performance biases due to inadequate administration of the interventions caused by variability in skills.<br>• A study protocol was not available. Of the three outcomes that were stated in the study one (bleeding rate) was reported in a manner that allowed comparison between the study interventions whereas two (hospitalization and ED visits) had no reference to the surgical modality used. Thus, the risk of reporting bias due to selective outcome reporting was high. |
| **Kypta et al., 2015**[3] | |
| • The patients' demographic characteristics were similar across the PPB and EC groups, suggesting low risk of selection bias due to inadequate selection of participants.<br>• Information was available for all patients in the two study groups. Similar proportions of ejection fraction data were missing for patients in the EC and PPB groups (8.6% versus 5.9 %), and it was unlikely that this could affect the reported findings. Thus, the risk of attrition bias due to inappropriate handling of incomplete data was low.<br>• Although a study protocol was not available, expected outcomes were reported in the study descriptions. Thus, | • The retrospective character of the study was a limitation since it lacked the risk-diminishing effects of randomization.<br>• There was no direct comparison between the two PPB and traditional strategy with EC. Procedures involving EC were performed between 2003 and 2012, whereas PPB was used from 2012 to 2014 during which time the EC was no longer applied. Thus, a time trend bias and risk of bias in selection of participants cannot be ruled out.<br>• Potential confounders were neither mentioned nor considered during analysis. Thus, the risk of selection |

| Strengths | Limitations |
|---|---|
| the risk of reporting bias due to selective outcome reporting was considered low.<br>• The study reported objective outcomes defined to apply similarly to the study groups. Thus, the risk of detection bias caused by inappropriate outcome assessment was low. | bias due to inappropriate confounder confirmation and consideration was high<br>• The number of patients treated with EC were five times as many as those treated with PPB. The impact of this disparage group sizes on the findings was unclear.<br>• There was no information about the skill and experience of the individuals who performed the surgical procedures. Therefore, it is unclear whether there were performance biases due to inadequate administration of the interventions |
| **Thottam et al., 2015**[9] | |
| • There was no significant overall difference in patients' demographic characteristics or preoperative diagnosis identified between the three instrumentation groups. Therefore, risk of selection bias due to inadequate selection of participants was low.<br>• Before the procedure, all children met criteria for adenotonsillectomy as defined by the American Academy of Otolaryngology–Head and Neck Surgery Clinical Practice Guidelines on Tonsillectomy in Children. Thus, the risk of selection bias due to inappropriate selection of patient group was low.<br>• All surgical procedures were under the directions of four fellowship-trained pediatric otolaryngologist. Therefore, the risk of performance bias due to variability in exposure to intervention was rated low.<br>• To ensure data reliability, two data collectors not involved in the procedures conducted all chart reviews independently. Thus, the risk of confirmation bias due to inappropriate blinding of assessors was low.<br>• Test-retesting measure were put in place to ensure inter-rater reliability. Therefore, confirmation bias due to inappropriate outcome assessment methods was low.<br>• Information was available for all patients in the two study groups. There were no missing data; therefore, attrition bias due to inappropriate handling of incomplete data was low. | • The retrospective character of the study was a limitation since it lacked the risk-diminishing effects of randomization.<br>• Potential confounders were neither mentioned nor considered during analysis. Thus, the risk of selection bias due to inappropriate confounder confirmation and consideration was high.<br>• The number of patients in the PPB group was more than twice as many those treated with EC. The impact of this disparage group sizes on the findings was unclear<br>• Post-operative hemorrhage (the key study outcome) was defined if any physician on physical exam noted active bleeding or the presence of fresh blood clots, and/or if the patient required bedside or further operative intervention. Due to the subjectivity in this definition, the risk of detection bias caused by inappropriate outcome assessment was unclear. |

# Appendix 4: Main Study Findings and Authors' Conclusions

## Table 6: Summary of Findings of Included Randomized Controlled Trials

| Main Study Findings | Authors' Conclusion |
|---|---|
| **Duscher e al., 2019**[10] | |
| **Wound disorders**<br>• 19 (33%) of minor and major wound healing disorders were observed with electrocautery having the largest number of patients affected (seven patients [50%]). Although a graphical presentation was provided, the specific values for wound disorders were not reported clearly for the other methods of surgery. However, the authors found no significant differences between group.<br>**Procedure Time**<br>• There were no significant differences in surgery time between the different techniques. The average surgery time of PPB was 1 hour 21 minutes ± 24 minutes compared with I hour 27 minutes ± 31 minutes for electrocautery, I hour 28 minutes ± 24 minutes for UHS, and I hour 19 minutes ± 39 minutes for APC.<br>**Drainage fluid volume**<br>• The average post-operative drainage fluid volume ranged from 50 to 700 mL for the four surgery methods, with the lowest average volume in PPB abdominoplasties. Specific values were not reported clearly for the individual modalities, although a graph was presented. There were no significant differences in drainage volume between groups.<br>**Complications**<br>• Post-operative hematoma occurred in three patients (21.4%) in the electrocautery group and one patient (7.1%) in the UHS group. Hematomas were not observed in patients who underwent surgery with either PPB or APC. According to the authors, the groups did not significantly differ based on the low number of hematomas.<br>• Seroma occurred in one patient (8.3%) treated with PPB, compared with one patient (5.9%) in the APC group, two patients (14.3%) treated with electrocautery, and three patients (21.4%) in the UHS group. There were no significant differences between the groups. | "Our data reveal a trend toward reduced surgery time with PEAK PlasmaBlade, indicating its suitability as an alternative to conventional electrocautery." (p6)[10] |
| **Tan et al., 2019**[8] | |
| **Swallowing Pain**<br>• Patients in the PPB group achieved pain-free swallowing in 13.28 days (95% CI: 11.69 to 14.86) compared with 15.76 days (95% CI: 14.01 to 17.50) for patients in the electrocautery group. The difference was statistically significant ($P$ = 0.035)<br>• No statistically significant differences were observed between the groups in daily visual analog score for pain and the number of tablets of analgesia taken per day. | • "PEAK PlasmaBlade tonsillectomy allowed adult patients to achieve pain-free swallowing earlier compared to monopolar electrocautery tonsillectomy. Although there were no obvious post-operative pain benefits, patients were found to be more satisfied with the PEAK PlasmaBlade technique. The results from this study showed that the use of this new electrosurgical technology (PEAK PlasmaBlade) appears to offer a couple of advantages over traditional electrosurgery, |

| Main Study Findings | Authors' Conclusion |
|---|---|
| **Time to normal diet**<br>• Compared to those in the electrocautery group, patients in the PPB group had a shorter time taken to return to normal diet (10.52 vs. 11.97 days; *P* = 0.206) and normal activities (7.83 vs. 9.17 days; *P* = 0.351) was shorter in, although the differences were not statistically significant.<br>• No statistically significant differences were observed between the groups in the time taken to return to soft diet.<br>**Post-operative bleeding**<br>• Post-operative bleeding occurred in three patients (10.3 %) in the PPB group compared with six patients (20.7 %) in the monopolar electrocautery group, although the difference was not statistically significant (*P* = 0.163).<br>**Patients' satisfaction**<br>• Patients in the PPB group tonsillectomy had a significantly higher satisfaction score than those in the electrocautery group (8.92 ± 1.01 vs. 8.24 ± 1.43 out of 10; *P* = 0.046). | notably in reducing time taken to achieve pain-free swallowing post-operatively." (p4)[8] |
| **Marangi et al., 2018**[5] | |
| **Wound healing time**<br>• Spontaneous ulcer closure occurred in 12 patient who underwent PPB in mean time to healing of 30 ± 5.5 days compared to 10 patients treated with EC with mean time to healing of 36 ± 4 days. The difference was statistically significant (*P* < 0.05).<br>• The mean time to wound healing achieved by reconstruction techniques was 16.9 ± 2 days for patients who underwent PPB compared with 22.3 ± 4.2 days for those treated with EC. The difference was statistically significant (*P* < 0.05).<br>**Thermal Damage**<br>• Comparison of the width of coagulation necrosis at the incision margins indicate that treatment with PPB resulted in significantly less thermal damage compared with EC (0.019 ± 0.01 mm vs. 0.40 ± 0.02 mm, respectively; *P* = 0.001).<br>**Post-operative infection**<br>• The results of the microbial culture showed a significantly lower incidence of post-operative infection rate in patient who underwent treatment with PPB compared with those treated with electrocautery (31% vs. 69%, respectively; *P* < 0.05). | • "The study demonstrated, based on the results, that the new technology with the use of a lower temperature electrosurgical device represents an effective therapeutic weapon for the surgical treatment of skin ulcers, both vascular and extravascular types." (p1)[5]<br>• "Based on our experience, we can state that the efficacy and safety of this low-temperature electrosurgical device can help to improve the field of plastic and reconstructive surgery, not only in the surgical treatment of ulcers but also in other types of treatments, as recent literature confirmed." (p5)[5] |

APC = argon plasma coagulation; CI = confidence interval; EC =electrocautery; PEAK = pulsed electron avalanche knife; PPB = PEAK PlasmaBlade; UHS = Ultracision Harmonic Scalpel.

## Table 7: Summary of Findings of Included Non-randomized Studies

| Main Study Findings | Authors' Conclusion |
|---|---|
| **Kypta et al., 2018[11]** | |
| **Procedure time**<br>• Mean procedure time was 34.1 ± 18.1 minutes for PPB versus 47.9±24.9 minutes for EC; *P* <0.001.<br>• **Duration of hospital stay**<br>• Mean length of hospital stay was 2.4 ± 3.4 days for PPB versus 3.2 ± 2.7 days for EC; *P* <0.001.<br>**Complications**<br>• Three patients (1.2%) treated with PPB had hematomas requiring evacuation compared with seven patients (1.4%) in the EC group. The difference was not statistically significant (*P* = 1 .000).<br>• Five patients (2.0) in the PPB group had mild hematoma compared with 11 (2.2%) in the EC group. The difference was not statistically significant (*P* = 1 .000).<br>• Infection occurred in two patients (0.8%) who underwent PPB compared with three infections (0.6%) in the EC group. The difference was not statistically significant. (*P* = 1.000).<br>**Damage to Device Lead**<br>• Lead damages occurred significantly less frequent with PPB than with EC (0.4% versus 5.3%; *P* < 0.001) | |
| **Sowa et al., 2018[12]** | |
| **Procedure time**<br>• The median duration of operation with PPB 169.9 minutes (range: 113 – 300; 95% CI: 52.0 to 93.0) compared with 170.1 minutes (range:115 – 244); 95% CI: 151.6 to 188.6) with EC. the difference was not statistically significant *P* = 0.98)<br>**Duration of hospital stay**<br>• The median length of hospital stay was significantly (*P* <0.011) shorter in the PPB group (11.7 days; range; 6–17 days; 95% CI: 10.4 to 13.1) than the EC group (14.1 days; range; 9–21; 95% CI: 12.9 to 15.4).<br>**Drainage volume**<br>• The total drain discharge volume was significantly (*P* =0.0358) lower in the PPB group (624.4 ± 441.8; 95% CI: 449.9 to 798.9) than in the EC group (883.8 ± 339.2; 95% CI: 717.0 to 1,050.5)<br>**Drainage indwelling time**<br>• The indwelling period of drainage was shorter in the PPB group (7.9 ± 3.27 days; 95% CI: 6.34 to 9.47) than the EC group (9.43 ± 3.76 days; 95% CI: 7.94 to10.9), but not statistically significantly *P* = 0.16).<br>**Seroma**<br>• Seroma occurred in four patients (19.0%) in the in the PPB group compared with 11 patients (47.8%) in the EC group. The difference in the incidence of seroma was significantly lower with the PPB procedure than in the EC (*P* < 0.043). | "In summary, this study demonstrated that use of PPB in an LD flap procedure can reduce seroma formation and the lengths of the drainage period and the hospital stay." (p3)[12] |

| Main Study Findings | Authors' Conclusion |
|---|---|
| **Lane et al., 2016**[2] | |
| **Post-operative bleeding**<br>• Among the 90 patients with a post-operative bleeding, bleed frequency was 16 (17.8%) with PPB, 21 (23.3%) with EC, and 53 (58.9%) with coblation. Chi-squared analysis revealed a statistically significant difference in bleed rate between by instrument group ($\chi^2$ = 11.17, df = 2, *P* = 0.004). However, the difference was not statistically significant between PPB and EC. | • "Results of this investigation of nearly 1800 children demonstrated that PEAK surgical intervention is safe and effective for adenotonsillectomy, with statistically less post-operative bleeding complications than the coblation technique and a slightly better outcome when compared to cautery." (p4-5)[2] |
| **Kypta et al., 2015**[3] | |
| **Procedure time**<br>• Mean procedure time was 28.4 ± 9.0 minutes for PPB versus 47.5 ± 24.0 minutes for EC; *P* <0.001.<br>**Duration of hospital stay**<br>• Mean length of hospital stay was 2.1 ± 2.2 days for PPB versus 3.1 ± 2.4 days for EC; *P* <0.001.<br>**Complications**<br>• Two patients (2.0%) treated with PPB had hematomas requiring evacuation compared with five patients (0.9%) in the EC group with hematomas requiring surgical intervention. The difference was not statistically significant (*P* = 0.331)<br>• One patient (1.0) in the PPB group had mild hematoma compared with nine (1.8%) in the EC group. The difference was not statistically significant (*P* = 1 .000).<br>• No procedure-related infection occurred in patients who underwent PPB compared with three infections (0.6%) in the EC group requiring complete device removal. The difference was not statistically significant. (*P* = 1.000).<br>• No periprocedural deaths occurred in either group<br>**Damage to Device Lead**<br>• There were no damaged leads with PPB compared with 29 (5.7%) damaged leads with EC (*P* = 0.008). | "Device replacements are associated with a notable complication risk. Our investigation showed that the use of PEAK PlasmaBladeTM is a safe, efficient, and cost-effective tool for generator replacement, resulting in a significantly reduced procedure time while avoiding lead damages. On the basis of our data the PEAK PlasmaBladeTM should have utility for device upgrades, revisions, and extractions." (p7)[3] |
| **Thottam et al., 2015**[9] | |
| **Procedure Time**<br>• The overall average surgical time, regardless of instrumentation was 28.72 minutes ± 13.49. The mean surgical time was 26.23 ± 13.58 minutes for monopolar EC, 28.42 ± 13.41 minutes for PPB, and 30.19 ± 13.38 minutes for radiofrequency ablation procedure.<br>• A post-hoc pairwise comparisons showed a significantly faster surgical times for monopolar EC than either PPB (*P* = 0.03) or radiofrequency ablation (*P* < 0.001).<br>**Post-operative bleeding**<br>• The total number of individuals with reported post-operative bleeds for the entire cohort was 26 (2.0%). They comprised 14 (1.1%), eight (0.6%), and four (0.3%) | "The ideal surgical instrumentation should be cost and time efficient with a low complication rate. Monopolar cautery was associated with a statistically significant lower intraoperative surgical time, similar post-operative hemorrhage rates, and lower operative costs when compared to radiofrequency ablation and PlasmaBlade." (p2)[9] |

| Main Study Findings | Authors' Conclusion |
|---|---|
| patients in the radiofrequency ablation, PPB, by monopolar cautery groups, respectively<br>• The difference in the number of patients who experienced a post-operative bleed by instrument was not statistically significant ($\square^2$ = 2.36; = 0.31). | |

CI = confidence interval; EC =electrocautery; LD = latissimus dorsi; PEAK = pulsed electron avalanche knife; PPB = PEAK PlasmaBlade.