# *Office of Evidence Based Practice – Specific Care Question: Plasmablade*

**Specific Care Question:** In the pediatric patient requiring a tonsillectomy, is the plasmablade as effective as electrocautery, or coblation, as measured by hospital readmission, cost, postoperative pain, intraoperative bleeding, postoperative bleeding, and length of surgery?

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**Clinical Bottom-line**

There is insufficient evidence to recommend plasmablade over coblation or electrocautery at this time. The evidence in this review is of very low quality, from one underpowered randomized control trail and three observational studies showing uncertainty about the effects. (Stephens, Singh, Hughes, Goswami, Ghufoor, & Sandhu, 2009; Lane, Dworkin-Valenti, Chiodo, & Haupert, 2016; Spektor, Kay, & Mandell, 2016; Thottam et al., 2015). The included studies provide some indication that the plasmablade is more expensive. There does not appear to be a difference between the plasmablade, coblation, and electrocautery in regard to intraoperative bleeding, pain, and surgery time. Finally, while the plasmablade may result in fewer events of postoperative bleeding compared to coblation, the number of ED visits and hospital readmissions appear to be the same.

**Plain Language Summary from The Office of Evidence Based Practice**

The studies included in this review used the terms plasmablade, plasmaknife, and PEAK PlasmaBlade. Throughout this review plasmablade was used to describe this surgical instrument.

Tonsillectomies are among the most common procedures performed by otolaryngologists (Alexiou, Salazar-Salvia, Jervis, & Falagas, 2011). Various tools and techniques are available for use. The use of cold knife surgery was the standard for many years but more recently a shift has been made to electrosurgical techniques (D'Eredità, 2010). Unfortunately, as new technologies are developed there is limited evidence to assess outcomes.

The plasmablade appears less efficacious than electrocautery in regards when measuring postoperative pain and cost (Stephens et al., 2009; Thottam et al., 2015). The plasmablade is equivocal to electrocautery in regard to postoperative bleeding and surgery time (Clenney, Schroeder, Bondy, Zizak, & Mitchell, 2011; Stephens et al., 2009). The plasmablade is equivocal to coblation when measuring hospital readmission, postoperative pain, intraoperative bleeding, surgery time, and cost (Lane, Dworkin-Valenti, Chiodo, & Haupert, 2016; Spektor, Kay, & Mandell, 2016; Thottam et al., 2015). Based on three observational studies the plasmablade resulted in less postoperative bleeding compared to coblation (Lane et al., 2016; Spektor et al., 2016; Thottam et al., 2015) while emergency department visits and hospital readmissions were not significantly different (Lane et al., 2016; Spektor et al., 2016).

**Literature Summary by Outcome**

**ED Visits and Hospital Readmission**

Based on very low quality evidence, ED visits and hospital readmissions are not different between the plasmablade and coblation. Lane et. al. (2016), *N*=1780, reported no difference in ED visits and hospital admissions between the plasmablade group and the coblation group but the actual number of admissions were not given. Spektor et al. (2016), *N*=100, reported five coblation admissions and two plasmablade admissions however when statistically analyzed, it was not

significantly different. The evidence is downgraded because it is based on too few studies. The results of the evidence may change as more research is produced.

**Cost**

*Plasmablade versus electrocautery*

Based on very low quality evidence, the instrument and surgical time cost for the plasmablade ($246.95) are significantly more expensive than electrocautery ($30.04) (Thottam et al., 2015). The evidence is downgraded due to too few study findings. The results of the evidence may change as more research is produced.

*Plasmablade versus coblation*

Based on low quality evidence, average costs by instrument and surgical time are equivocal for plasmablade $246.95 and coblation $244.32 (Thottam et al., 2015). The evidence is downgraded as it is based on one observational study. The results of the evidence may change as more research is produced.

**Pain**

*Plasmablade versus electrocautery*

Based on very low quality evidence, electrocautery produces less or equivocal post-operative pain as the plasmablade. A randomized control trial by Stephens et al. (2009) compared 98 patients aged 2-16 years. The odds of having swallowing pain at 24 hours was significantly higher in the plasmablade group, *OR* = 3.77, 95% CI [1.42, 10.02]. The odds of having swallowing pain at 7 days was significantly higher in the plasmablade group, *OR* = 2.7, 95% CI [1.19, 6.12]. There was no difference in the amount of analgesia used at day 14, *OR* = 0.93, 95% CI [0.38, 2.28]. The evidence is downgraded due to so few studies. The results of the evidence may change as more research is produced.

*Plasmablade versus coblation*

Based on very low quality evidence, coblation produces equivocal post-operative pain as the plasmablade. A prospective cohort study (*N* = 100) with patients aged 3 to 12 years compared the plasmablade to coblation (Spektor et al., 2016). Both groups demonstrated statistically equivalent pain scores for the first 6 days following the operation, and for the last 5 days of the 14-day follow-up period. From post-operative days #7-9, the difference in median pain scores was statistically different with lower scores in the plasmablade group, but the authors reported the differences were not expected to be clinically significant. The evidence was downgraded because it's based on one observational study. The results of the evidence may change as more research is produced.

**Intraoperative and Postoperative Bleeding**

*Plasmablade versus electrocautery*

Based on very low quality evidence, the odds of having intraoperative bleeding are the same for electrocautery and a plasmablade, OR = 0.35, 95% CI [0.10 to 1.21] (Stephens et al., 2009). The evidence is downgraded because there are so few studies. The results of the evidence may change as more research is produced.

*Plasmablade versus coblation*

Based on very low quality evidence, the relative risk of post-operative bleeds is less with the plasmablade compared to coblation, RR = 0.44, 95% CI [0.29 to 0.69]. The plasmablade group observed 26 events of postoperative bleeding (n=1157, 2.2%) while the coblation group observed 71 events of postoperative bleeding (n=1326, 5.4%). The evidence was downgraded because it's based on three observational studies (Lane et al., 2016; Spektor et al., 2016; Thottam et al., 2015). The results of the evidence may change as more research is produced.

**Surgery Time**

*Plasmablade versus coblation*

Based on very low quality evidence, there is no difference in surgical time between the plasmablade and electrocautery. Stephens et al. (2009) reported surgical time for the plasmablade of 19.5 min (IQR 11-30) and electrocautery of 20.6 min (IQR 12-35); p=0.37. Clenney et al. (2011) reported surgical time for the plasmablade of 8.9 min and electrocautery of 7.7 min; p=0.27. The evidence was downgraded because it's based on so few studies.

*Plasmablade versus coblation*

Based on low quality evidence, plasmablade results in shorter surgery time are equivocal to coblation. Spektor et al. (2016) reported an average surgery time for the plasmablade of 17 minutes and coblation surgery time of 16.2 minutes (the authors state the difference was not significant however a p-value was not provided). Thottam et al. (2015) disclosed an average surgery time for the plasmablade to be 28.42 minutes (SD, 13.41) and surgery time for coblation was 30.9 minutes (SD, 13.38); p=0.01. While statistically significant, clinical significance is questioned based on the wide standard deviation. The evidence is downgraded because it's based on two observational studies.

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**Search Strategy and Results**: **PubMed:** ("Adenoidectomy"[Mesh] OR adenoidectom* OR "Tonsillectomy"[Mesh] OR tonsillectom*) AND ("pulsed-electron avalanche knife" OR plasmablade OR plasmakni* OR "plasma blade" OR "plasma knife" OR coblat* OR "bipolar radiofrequency") ("Adenoidectomy"[Mesh] OR adenoidectom* OR "Tonsillectomy"[Mesh] OR tonsillectom*) AND (("Pulsed-electron avalanche knife" OR plasmablade OR plasmakni* OR "plasma blade" OR "plasma knife") AND ("Ablation Techniques"[Mesh] OR ablat* OR "bipolar radiofrequency" OR coblat*)) **Embase:** ('adenoidectomy'/exp or adenoidect* or 'tonsillectomy'/exp or tonsillect*) and ('pulsed-electron avalanche enife' or plasmablade or plasmakni* or 'plasma blade' or 'plasma knife' or coblat* or 'bipolar radiofrequency') – 201 citations ('adenoidectomy'/exp or adenoidect* or 'tonsillectomy'/exp or tonsillect*) and (('pulsed-electron avalanche knife' or plasmablade or plasmakni* or 'plasma blade' or 'plasma knife') and ('ablation therapy'/exp or 'radiofrequency ablation'/exp or 'radiofrequency ablation device'/exp or coblat* or 'bipolar radiofrequency'))

***Studies included in this review:***

Clenney, T., Schroeder, A., Bondy, P., Zizak, V., & Mitchell, A. (2011). Postoperative pain after adult tonsillectomy with PlasmaKnife compared to monopolar electrocautery. *The Laryngoscope, 121*(7), 1416-1421.

Lane, J. C., Dworkin-Valenti, J., Chiodo, L., & Haupert, M. (2016). Postoperative tonsillectomy bleeding complications in children: A comparison of three surgical techniques. *International journal of pediatric otorhinolaryngology, 88*, 184-188.

Spektor, Z., Kay, D. J., & Mandell, D. L. (2016). Prospective Comparative Study of Pulsed-Electron Avalanche Knife (PEAK) and Bipolar Radiofrequency Ablation (Coblation) Pediatric Tonsillectomy and Adenoidectomy. *American Journal of Otolaryngology*.

Stephens, J., Singh, A., Hughes, J., Goswami, T., Ghufoor, K., & Sandhu, G. (2009). A prospective multi-centre randomised controlled trial comparing PlasmaKnife with bipolar dissection tonsillectomy: evaluating an emerging technology. *International journal of pediatric otorhinolaryngology, 73*(4), 597-601.

Thottam, P. J., Christenson, J. R., Cohen, D. S., Metz, C. M., Saraiya, S. S., & Haupert, M. S. (2015). The utility of common surgical instruments for pediatric adenotonsillectomy. *The Laryngoscope, 125*(2), 475-479.

***Studies not included in this review with rationale for exclusion:***

Lipan, M., Dinh, C., & Younis, R. (2007). Pediatric Tonsillectomy: PlasmaKnife Vs. Coblator. *Otolaryngol Head Neck Surg, 137*(1), 49-53. - Abstract

Vose, J. G., Atmodjo, D., & Weeks, B. H. (2011). A Study of the PEAK PlasmaBlade TnA in Adult Tonsillectomy Compared to Traditional Electrosurgery. *Otolaryngology--Head and Neck Surgery, 145*(2 suppl), P51-P51. - Abstract

**Method Used for Appraisal and Synthesis:** The Cochrane Collaborative computer program, Review Manager (RevMan 5.1.7) (Higgins & Green, 2011) was used to synthesize the five included studies. GRADEpro GDT (Guideline Development Tool) (Schunemann, 2002) is the tool used to create Summary of Findings Tables for this analysis.

**Table 1**
**Grade Summary**
**Question**: Plasmablade Compared to Electrocautery for Tonsillectomy
**Studies included in the meta-analysis:** (Stephens et al., 2009; Clenney et al., 2011; Thottam et al., 2015)

| Quality assessment | | | | | | | № of patients | | Effect | | Quality | Importance |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **№ of studies** | **Study design** | **Risk of bias** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other considerations** | **Plasmablade** | **Electrocautery** | **Relative (95% CI)** | **Absolute (95% CI)** | | |
| Pain on Swallowing at 7 days (high/moderate versus low pain) | | | | | | | | | | | | |
| 1 | randomized trials | serious [1] | not serious [2] | serious [3] | very serious [4] | none | 28/46 (60.9%) | 19/52 (36.5%) | **OR 2.70** (1.19 to 6.12) | **243 more per 1,000** (from 41 more to 414 more) | ⊕○○○ VERY LOW | CRITICAL |
| Pain at 24 hours (high/moderate versus low pain) | | | | | | | | | | | | |

| Quality assessment | | | | | | | Nº of patients | | Effect | | Quality | Importance |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Nº of studies** | **Study design** | **Risk of bias** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other considerations** | **Plasmablade** | **Electrocautery** | **Relative (95% CI)** | **Absolute (95% CI)** | | |
| 1 | randomized trials | serious [1] | not serious [2] | serious [3] | very serious [4] | none | 39/46 (84.8%) | 31/52 (59.6%) | **OR 3.77** (1.42 to 10.02) | **252 more per 1,000** (from 81 more to 341 more) | ⊕◯◯◯ VERY LOW | CRITICAL |
| Intra-operative Bleeding (high/moderate versus minor blood loss) | | | | | | | | | | | | |
| 1 | randomized trials | serious [1] | not serious [2] | serious [3] | very serious [4] | none | 4/46 (8.7%) | 11/52 (21.2%) | **OR 0.35** (0.10 to 1.21) | **126 fewer per 1,000** (from 34 more to 185 fewer) | ⊕◯◯◯ VERY LOW | CRITICAL |
| Use of analgesia (3 to 4 times per day and 1 to 2 times per day versus no analgesia) | | | | | | | | | | | | |
| 1 | randomized trials | serious [1] | not serious [2] | serious [3] | very serious [4] | none | 12/47 (25.5%) | 14/52 (26.9%) | **OR 0.93** (0.38 to 2.28) | **14 fewer per 1,000** (from 146 fewer to 187 more) | ⊕◯◯◯ VERY LOW | CRITICAL |
| Postop Bleeding | | | | | | | | | | | | |
| 2 | observational studies | serious [5] | not serious[8] | not serious | serious [6] | none | 24/1107 (2.2%) | 25/677 (3.7%) | **RR 0.65** (0.37 to 1.14) | **13 fewer per 1,000** (from 5 more to 23 fewer) | ⊕◯◯◯ VERY LOW | CRITICAL |
| Cost | | | | | | | | | | | | |

| Quality assessment | | | | | | | Nº of patients | | Effect | | Quality | Importance |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nº of studies | Study design | Risk of bias | Inconsistency | Indirectness | Imprecision | Other considerations | Plasmablade | Electrocautery | Relative (95% CI) | Absolute (95% CI) | | |
| 1 | observational studies | serious [7] | not serious [2] | not serious | serious [6] | none | Instrument and surgical time cost: Plasmablade $246.95; Electrocautery $30.04 | | | | ⊕◯◯◯ VERY LOW | CRITICAL |
| Time of Operation | | | | | | | | | | | | |
| 2 | randomized trials | serious [1] | not serious [8] | serious [9] | very serious [4] | none | No difference in surgery times. Stephens et al. (2009) reported surgical time for Plasmablade of 19.5 min (IQR 11-30) and Electrocautery of 20.6 min (IQR 12-35); p=0.37. Clenney et al. (2011) reported surgical time for Plasmablade of 8.9 min and Electrocautery of 7.7 min; p=0.27. | | | | ⊕◯◯◯ VERY LOW | CRITICAL |

**CI:** Confidence interval; **OR:** Odds ratio; **RR:** Risk ratio

1. The study has missing data points and did not have enough participants based on the sample size calculation
2. Cannot measure inconsistency based on one study
3. Study does not measure Post-Operative Bleeding or Cost
4. Small number of events
5. Two of the studies were retrospective chart reviews
6. Relatively few patients and events
7. Retrospective chart reviews
8. Too few studies to measure inconsistency
9. Incomplete data

**Table 2**
**Grade Summary**
**Question**: Plasmablade Compared to Coblation for Tonsillectomy
**Studies included in the meta-analysis:** (Lane et al., 2016; Spektor, et al., 2016; Thottam et al., 2014)

| Quality assessment | | | | | | | Nº of patients | | Effect | | Quality | Importance |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Nº of studies | Study design | Risk of bias | Inconsistency | Indirectness | Imprecision | Other considerations | Plasmablade | Coblation | Relative (95% CI) | Absolute (95% CI) | | |
| Postop Bleeding | | | | | | | | | | | | |

| Quality assessment | | | | | | | Nº of patients | | Effect | | Quality | Importance |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Nº of studies** | **Study design** | **Risk of bias** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other considerations** | **Plasmablade** | **Coblation** | **Relative (95% CI)** | **Absolute (95% CI)** | | |
| 3 | observational studies | serious [1] | not serious | not serious | serious [2] | none | 26/1157 (2.2%) | 71/1326 (5.4%) | **RR 0.44** (0.29 to 0.69) | **30 fewer per 1,000** (from 17 fewer to 38 fewer) | ⊕○○○ VERY LOW | CRITICAL |
| Cost | | | | | | | | | | | | |
| 1 | observational studies | serious [3] | not serious [4] | not serious | serious [2] | none | Thottam et al. (2014) (n=1280) Average costs by instrument and surgical time: Plasmablade $246.95; Coblation $244.32 | | | | ⊕○○○ VERY LOW | CRITICAL |
| Time of Operation | | | | | | | | | | | | |
| 2 | observational studies | serious [3] | not serious [5] | not serious | serious [2] | none | Spektor et al. (2016) (n=100) average surgery time for Plasmablade of 17 minutes and Coblation surgery time of 16.2 minutes; not significant (no p-value provided). Thottam et. al. (n=1280) average surgery time for Plasmablade of 28.42 min (SD, 13.41) and Coblation surgery time of 30.9 (SD, 13.38); p=0.01. | | | | ⊕○○○ VERY LOW | CRITICAL |
| Hospital Admission | | | | | | | | | | | | |
| 2 | observational studies | serious [3] | not serious [5] | not serious | serious [2] | none | Lane et al. (2016) (n=1780) reported identical and low ED visits and Hospital admissions. Spektor et. al. (n=100) reported 5 Coblation admission and 2 Plasmablade admissions; not reported as significant. | | | | ⊕○○○ VERY LOW | CRITICAL |
| Medication | | | | | | | | | | | | |
| 1 | observational studies | serious | not serious | not serious | serious [2] | none | Spektor et al. (2016) (n=100) No difference in the total number of doses of acetaminophen, ibuprofen, or narcotic pain medication | | | | ⊕○○○ VERY LOW | CRITICAL |
| Pain Score | | | | | | | | | | | | |

| Quality assessment | | | | | | | № of patients | | Effect | | Quality | Importance |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **№ of studies** | **Study design** | **Risk of bias** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other considerations** | **Plasmablade** | **Coblation** | **Relative (95% CI)** | **Absolute (95% CI)** | | |
| 1 | observational studies | serious | not serious | not serious | serious [2] | none | Spektor et al. (2016) (n=100) The two groups demonstrated statistically equivalent pain scores for the first 6 days following the operation, and for the last 5 days of the 14-day follow-up period. From post-operative days #7-9, the difference in median pain scores was statistically different with lower scores in the Plasma group, but these differences were not expected to be clinically significant | | | | ⊕◯◯◯ VERY LOW | CRITICAL |

**CI:** Confidence interval; **RR:** Risk ratio

1. Two of the studies were retrospective chart reviews
2. Relatively few patients and events
3. Retrospective chart review
4. Cannot determine based on one study
5. Can't determine based on so few studies

**Clenney 2011**

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|---|---|
| **Methods** | Prospective, randomized, single-blinded, self-controlled study |
| **Participants** | **Setting:** USA, Naval Medical Center<br><br>**Number randomized:**<br>• Treatment group, n = 32<br>  ○ Original PlasmaKnife, n = 10<br>  ○ Modified PlasmaKnife, n = 18<br>• Control group: n = 32<br><br>**Number who completed the study:**<br>• Treatment group: n = 28<br>• Control group: n = 28<br><br>**Gender Male (%):**<br>• Treatment/Control group<br>  ○ Original PlasmaKnife, n = 7 (70%)<br>  ○ Modified PlasmaKnife, n = 7 (38.9%)<br>**Age, yrs.:**<br>• Treatment group<br>  ○ Original PlasmaKnife, 27.5<br>  ○ Modified PlasmaKnife, 24.1<br>• Control group: same as treatment group<br><br>**Inclusion criteria:** Adult patients from 18 to 30 years of age undergoing tonsillectomy for recurrent tonsillitis.<br><br>**Exclusion criteria:**<br>• History of peritonsillar abscess,<br>• Severe unilateral tonsil enlargement concerning for neoplasia,<br>• Obstructive sleep apnea,<br>• Pregnancy or lactation.<br><br>**Power analysis:**<br>Group sample sizes of 19 tonsillectomies per group were initially calculated to achieve 81% power to detect a pain difference of 0.6 between the group means. Because of the change in the instrument design during the study, the sample size was increased by nine tonsillectomies per group (total sample size of 28 subjects undergoing 56 tonsillectomies). To allow for dropouts, the authors estimated an enrollment to be 32 subjects (64 individual tonsillectomies) |
| **Interventions** | • **Intervention:**<br>  ○ Original PlasmaKnife: a sheath on top of the shaft doubled as a smoke evacuator/suction tube (used for 10 participants)<br>  ○ Modified PlasmaKnife: the suction tube was relocated to the bottom of the shaft and extended 5 mm toward the active blade (used for 18 participants)<br>• **Control:** standard Bovie monopolar electrocautery tonsillectomy |
| **Outcomes** | **Primary outcome:** Self-rated daily pain assessed using a 10-point scale<br>**Secondary outcome:** operative time, blood loss, and postoperative complications related to each tonsillectomy technique |
| **Notes** | Each subject served as their own control as one tonsil was removed via the PlasmaKnife and the other removed by standard Bovie monopolar electrocautery tonsillectomy |

Risk of bias table

| Bias | Authors' judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | Low Risk | computerized random number generator to select the side allocated to receive the plasmaknife approach and the other tonsil was removed using the standard of care |
| Allocation concealment (selection bias) | Low Risk | sealed, opaque, sequentially numbered envelopes |
| Blinding of participants and personnel (performance bias) | Low Risk | the surgeons were made aware of the intervention and control sides at the time of surgery, the intervention and control sides were not revealed to the participants |
| Blinding of outcome assessment (detection bias) | Low Risk | standardized questions were used by research assistants to prevent bias introduction |
| Incomplete outcome data (attrition bias) | Low Risk | drop outs (4 participants) were not included in the statistical analysis; though the authors identify that the PlasmaKnife device was modified, they analyzed the outcome data as a whole |
| Selective reporting (reporting bias) | Low Risk | research team shared co-founder variables of PlasmaKnife device modification and participant drop-outs |
| Other bias | Low Risk | Data unable to be displayed in table format as the authors only provided *p* values. |

**Stephens 2009**

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| **Methods** | Prospective, multi-centered, double-blinded randomized controlled trial |
| **Participants** | **Setting:** Conducted in several Otolaryngology London centers<br><br>**Randomized into study**: N=100<br>• **Group 1:** PlasmaKnife tonsillectomy n=47<br>• **Group 2:** bipolar electrocautery dissection tonsillectomy n=53<br><br>**Completed study**: N=99<br>• **Group 1:** PlasmaKnife tonsillectomy n=46<br>• **Group 2:** bipolar electrocautery dissection tonsillectomy n=53<br><br>**Gender, males: not reported**<br><br>**Age, years (median):**<br>• **Group 1:** PlasmaKnife tonsillectomy n=73 months<br>• **Group 2:** bipolar electrocautery dissection tonsillectomy n= 69.5 months<br><br>**Inclusion Criteria:**<br>• Children between the ages of 2 and 16<br>• Children with recurrent tonsillitis or obstructive sleep apnea<br><br>**Exclusion Criteria:**<br>• history of bleeding dyscrasis<br>• craniofacial abnormalities<br>• previous tonsillar surgery<br>• concurrent medical problems |

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| | **Power analysis:** it was calculated to identify a 2 point difference in pain scores, which were out of a possible 10, between the 2 independent samples with $p<0.05$ and a power of 80%, 50 patients in each arm would be necessary allowing for a 10% drop out rate. |
| **Interventions** | **Group 1:** PlasmaKnife tonsillectomy<br>• Preformed using standard settings of 95% coagulation and 5% cutting blend with a Gyrus ENT workstation as powersource<br><br>**Group 2:** electrocautery dissection tonsillectomy<br>• Preformed using a single Valleylab base unit set at 10-12 W.<br><br>**Both Groups:**<br>• All staff were experienced in tonsil surgery<br>• received appropriate training on both types of tonsillectomy<br>• performed at least 10 PlasmaKnife tonsillectomies |
| **Outcomes** | **Primary Outcome:**<br>• Post-operative pain at 8 hours, and days 1, 3, 7, and 14<br>  ○ Questionnaire utilizing Wong Baker FACES scale<br><br>**Secondary Outcomes:**<br>• volume of intra-operative bleeding<br>  ○ Minor blood loss = less than 5mL<br>  ○ moderate blood loss = less than 100 mL<br>  ○ major blood loss = over 100 mL<br>• length of procedure<br>• return to normal activities<br>• use of analgesics |
| **Notes** | Unable to table Day 7 Summary of Total Scores as the authors provided the median score and the not the mean. |

Risk of bias table

| Bias | Authors' judgement | Support for judgement |
|---|---|---|
| Random sequence generation (selection bias) | Unclear Risk | Not described |
| Allocation concealment (selection bias) | Low Risk | concealment occurred through the use of numbered sealed opaque envelopes |
| Blinding of participants and personnel (performance bias) | Low Risk | Randomization occurred within the operating suite after induction. Surgeon was not blinded. The data collector, along with patients and parents, was blinded to the type of procedure performed. |
| Blinding of outcome assessment (detection bias) | Low Risk | The data collector was blinded to the type of procedure performed. |
| Incomplete outcome data (attrition bias) | High Risk | There were 2 sets of missing post-op data and one set of pre-op data; the study did not have enough participants based on the sample size calculation |
| Selective reporting (reporting bias) | Low Risk | All outcomes were reported |
| Other bias | Unclear Risk | Gyrus who makes PlasmaKnife provided the wands and study equipment |

**Lane 2016**

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|---|---|
| **Methods** | Cohort study |
| **Participants** | **Participants:** 1780, 51.5% Male, 2-18 years who underwent tonsillectomy, with or without adenoidectomy, at a tertiary pediatric hospital between June 2011 to May 2013 by electric monopolar cautery, coblation, or PEAK PlasmaBlade.<br><br>**Setting:** Academic Medical Center, Children's Hospital of Michigan<br><br>**Retrospective chart analysis:**<br>The following data were extracted from the electronic medical record:<br>1) patient demographic characteristics (e.g. age, gender)<br>2) attending surgeon<br>3) surgical approach<br>• Cautery<br>• Coblation<br>• PEAK<br>4) reason for hospital admission<br>5) frequency of ED visits (21 days post-procedure), including the purpose for each visit.<br><br>**Inclusion Criteria:** Children who underwent extracapsular tonsillectomy, with or without adenoidectomy.<br><br>**Exclusion Criteria:**<br>1) <2 years or >18 years of age<br>2) surgical approach utilized was not electro-cautery, coblation, or PEAK<br>3) history of bleeding disorder<br>4) adenoidectomy only<br>5) incomplete records |
| **Interventions** | **Surgical instrument used for tonsillectomy**<br>• Cautery<br>• Coblation<br>• PEAK |
| **Outcomes** | Primary and Secondary Bleeding<br>ED Admission and Hospital Admission |
| **Results:** | **Subjects:** Among the 1780 children included in this analysis, the majority (97.3%) underwent adenotonsillectomy (1732).<br>• Coblation was performed 771 (43.3%)<br>• PEAK was performed 718 (31.6%).<br>• Electro-cautery was performed the least 446 (25.1%).<br><br>**Post-Operative Bleeding (primary and secondary bleeds):**<br>• Coblation: 52 bleeds (7.7%)<br>• PEAK: 16 bleeds (3.2%).<br>• Electro-cautery: 21 bleeds (5.22%).<br><br>No difference between PEAK and Cautery.<br><br>Children who bled were ~2.5% more likely to have received Coblation than the other procedures (PEAK or Cautery)<br><br>**ED Admission and Hospital Admission:**<br>• No difference between groups. |

**Spektor 2016**

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| **Methods** | Prospective, non-randomized, non-blinded, comparative cohort study |
| **Participants** | **Setting:** Private practice setting in Florida, USA from July 2013 to August 2014<br><br>**Included in study (non-randomized):** *N = 100*<br>• **Group 1:** Pulsed-electron avalanche knife (PEAK) adenotonsillectomy; n = 50<br>• **Group 2:** Bipolar radiofrequency ablation adenotonsillectomy; n = 50<br><br>**Completed Study:** *N = Not disclosed by the authors*<br>• **Group 1:** Pulsed-electron avalanche knife (PEAK) adenotonsillectomy; n = *Not disclosed by the authors*<br>• **Group 2:** Bipolar radiofrequency ablation adenotonsillectomy; n = *Not disclosed by the authors*<br><br>**Gender, males:**<br>• **Group 1:** Pulsed-electron avalanche knife (PEAK) adenotonsillectomy; n = 23 (46)<br>• **Group 2:** Bipolar radiofrequency ablation adenotonsillectomy; n = 26 (52)<br><br>**Age, years (mean):**<br>• **Group 1:** Pulsed-electron avalanche knife (PEAK) adenotonsillectomy; n = (7.1)<br>• **Group 2:** Bipolar radiofrequency ablation adenotonsillectomy; n = (6.0)<br><br>**Inclusion Criteria:**<br>• Children between the ages of 3 to 12 years undergoing outpatient adenotonsillectomy for sleep disordered breathing or recurrent tonsillitis<br><br>**Exclusion Criteria:**<br>• Underlying syndrome<br>• Craniofacial abnormality<br>• Bleeding disorder<br>• Disallowable surgical indications:<br>• History of peritonsillar abscess or surgery performed to rule out malignancy<br><br>**Power Analysis:** Calculated 45 subjects per experimental group (total 90) for a power of 80.4%. |
| **Interventions** | • **Group 1:** Pulsed-electron avalanche knife (PEAK) adenotonsillectomy<br>• **Group 2:** Bipolar radiofrequency ablation adenotonsillectomy<br>"General anesthesia with orotracheal intubation was identical for all patients."<br>"All tonsillectomies were extra-capsular."<br>"As per American Academy of Otolaryngology tonsillectomy guidelines [6], no peri-operative antibiotics were given, no local anesthetic infiltration was used, and every patient received a single IV dose of dexamethasone during surgery" |
| **Outcomes** | **Primary Outcomes:**<br>1. Pain<br>2. Medications<br>3. Bleeding |
| **Results** | **Duration of Surgery: Not significant (no p-value)**<br>• **Group 1:** Pulsed-electron avalanche knife (PEAK): 17 min<br>• **Group 2:** Bipolar radiofrequency ablation: 16.2 min<br><br>**Pain**<br>• "The two groups demonstrated statistically equivalent pain scores for the first 6 days following the operation, and for the last 5 days of the 14-day follow-up period."<br>• "From post-operative days #7-9, the difference in median pain scores was statistically different between the two groups (with lower scores in the pulsed-electron avalanche knife group), but these differences were not expected to be clinically significant, since the largest difference |

between groups on any of these days was 2 points (day #7), which did not reach the difference of 3 that has previously shown to be clinically significant."
- "Also, on post-operative days #8-14, none of the median pain scores in either group were higher than 2, and prior research has shown that scores of 3 or less are not associated with clinically painful situation."2.

**Medications**
- "...there was no difference in the total number of doses of acetaminophen, ibuprofen, or narcotic pain medication taken in the bipolar radiofrequency ablation vs. the pulsed-electron avalanche knife group."
- "The highest number of narcotic doses given was on post-operative day 2 for the bipolar radiofrequency ablation group, and on the day of surgery for the pulsed-electron avalanche knife group."
- "The highest number of ibuprofen doses given was on postoperative day 1 for the bipolar radiofrequency ablation group, and on post-operative day for the pulsed-electron avalanche knife group."
- "...the pulsed-electron avalanche knife group consumed significantly less total doses of acetaminophen on post-operative days 9, 10, and 12."

**Intra-operative bleeding:**
- Loss at 10ml or less in all cases in both groups.

**Post-operative bleeding: Not significant (no p-value)**
- There were no cases of primary bleeding in either group.

**Hospitalization Due to Bleeding:**

**Group 1:** Pulsed-electron avalanche knife (PEAK): n=2 subjects (1 surgical intervention)
**Group 2:** Bipolar radiofrequency ablation: n=5 subjects (1 surgical intervention)

**Minor Bleeding at home: (p=0.0156)**
- **Group 1:** Pulsed-electron avalanche knife (PEAK): n=9
- **Group 2:** Bipolar radiofrequency ablation: n=21
- Subjects in the bipolar radiofrequency ablation group were 2.33 times more likely to experience minor bleeding events (that did not result in hospitalization or surgery) than subjects in the pulsed-electron avalanche knife group (95% CI: 1.19 to 4.58).

**Other:**
- "In an attempt to minimize "learning curve" bias, each surgeon performed as many pulsed-electron avalanche knife adenotonsillectomies as possible in the 6 months prior to initiation of the study (over 20 cases for each surgeon)."
- No mention of financial cost/benefit discussion in study.

**Thottam 2015**

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| **Methods** | Cohort Studies |
| **Participants** | **Participants:** 1280 patients who underwent adenotonsillectomy were evaluated.<br>• Monopolar electrocautery 231 (18.0%)<br>• Radiofrequency ablation 505 (39.5%)<br>• PlasmaBlade 544 (42.5%)<br><br>(No significant overall difference in age, sex, or preop diagnosis identified between 3 instrumentation groups)<br><br>**Age:** 6 months to 20 years<br><br>**Setting:** Study conducted at a tertiary care pediatric hospital (Children's Hospital of Michigan) from 2011 to 2013.<br><br>**Number randomized:** Not randomized: retrospective chart analysis<br><br>**Number complete:** 1,280<br><br>**% Male subjects:** 49.5%<br><br>**Inclusion criteria:** Patients who underwent extracapsular adenotonsillectomy for treatment of SDB (sleep disordered breathing), recurrent tonsillitis, or both.<br>**Exclusion criteria:** Subjects with known bleeding disorders, developmental delay, craniofacial abnormalities, and history of peritonsillar abscesses were excluded from this study.<br><br>**Power Analysis:** cohort, not needed |
| **Interventions** | **1. Instrument comparison of:**<br>• Monopolar electrocautery<br>• Radiofrequency ablation<br>• PlasmaBlade<br><br>For intraoperative **surgical time** and **postoperative hemorrhage rate. Cost analysis performed** using both post induction anesthesia expense and instrument price. |
| **Outcomes** | 1. **Procedure time variance**<br>2. **Postop bleed differences by instrument**<br>3. **Overall average cost** |
| **Results** | **Procedure time variance:** Comparisons identified significantly faster surgical times for monopolar cautery than either both PlasmaBlade or radiofrequency ablation.<br>• Monopolar electrocautery: 26.23 minutes (SD, 13.49), Monopolar vs PlasmaBlade (p=0.03), Monopolar vs Radiofrequency (p<0.001)<br>• Radiofrequency ablation: 30.19 minutes (SD 13.38)<br>• PlasmaBlade: 28.42 minutes (SD 13.41), PlasmaBlade vs Radio frequency (p=0.01)<br><br>**Postop bleed differences by instrument:** Not significantly significant<br>• Monopolar electrocautery: 4 (1.7%)<br>• Radiofrequency ablation: 14 (2.8%)<br>• PlasmaBlade: 8 (1.5%)<br><br>**Overall average costs:** Instrumentation expenses added to anesthesia cost estimated as<br>• Monopolar cautery: $30.04<br>• radiofrequency ablation: $244.32<br>• PlasmaBlade: $246.95 |

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| | **Monopolar cautery was associated with:**<br>• statistically significant lower intraoperative surgical time<br>• similar postoperative hemorrhage rates<br>• lower operative costs<br><br>**Limitations to this study:**<br>• retrospective<br>• impossible to control for all intraoperative decision making<br>• utilization of residents and fellows in a teaching institution may add limitations in procedure time and technique<br>• in this study, fewer patients underwent adenotonsillectomy with monopolar cautery than both the other instruments |

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