

## PEAK PlasmaBlade versus monopolar electrocautery tonsillectomy in adults: A prospective double-blinded randomized controlled trial<sup>☆,☆☆,☆☆☆,☆☆☆☆</sup>

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### ARTICLE INFO

#### Keywords:

Tonsillectomy  
PEAK PlasmaBlade  
Monopolar  
Electrocautery  
Postoperative recovery  
Postoperative pain  
Adults

### ABSTRACT

**Objective:** To evaluate the efficacy and compare postoperative pain and recovery following PEAK PlasmaBlade and monopolar electrocautery tonsillectomy in adults.

**Study design:** Prospective double-blinded randomized controlled trial.

**Methods:** Fifty-eight patients were recruited and randomized into 2 groups: PEAK PlasmaBlade (n = 29) or monopolar electrocautery (n = 29) tonsillectomy. Postoperative pain, complications, patient satisfaction, number of tablets of analgesia taken and days taken to return to soft diet, normal diet, normal activities and achieve pain-free swallowing were compared and analysed, with the aid of a pain diary given to patients. Statistical analysis was performed with SPSS 13.0 with statistical significance set at  $P < 0.05$ .

**Results:** Patients in the PEAK PlasmaBlade group were able to achieve pain-free swallowing in a shorter time compared to the electrocautery group (13.28 versus 15.76 days,  $P = 0.035$ ). Patients were also more satisfied with PEAK PlasmaBlade tonsillectomy ( $P = 0.046$ ). No significant differences in the incidence of postoperative haemorrhage, daily visual analog score for pain, number of tablets of analgesia taken and time taken to return to soft diet, normal diet and activities were seen for both groups.

**Conclusions:** This study showed that PEAK PlasmaBlade tonsillectomy has a faster recovery period in terms of time taken to achieve pain-free swallowing and may offer advantages when compared to monopolar electrocautery tonsillectomy.

**Level of evidence:** 1b.

### 1. Introduction

Tonsillectomy is one of the most commonly performed surgeries in Otolaryngology around the world. The usual indications for tonsillectomy include chronic or recurrent tonsillitis, peritonsillar abscess, snoring, obstructive sleep apnoea (OSA), and to obtain histological diagnosis for malignancy [1].

Tonsillectomy is usually performed under general anaesthesia. This procedure results in an open wound which is left to heal by secondary intention. The major postoperative morbidities include pain and

haemorrhage. Pain is the result of disruption of mucosa and glossopharyngeal and/or vagal nerve fibers, followed by inflammation and spasm of the pharyngeal muscles that lead to ischaemia and a protracted cycle of pain. This postoperative pain typically is debilitating and the main deterring factor for patients considering the surgery. This pain is usually severe enough to affect oral intake and cause limitations in normal daily activities. The pain usually subsides only after 2 to 3 weeks following surgery, when the muscle becomes covered with mucosa [2].

Due to these morbidities, there is a constant push to develop new techniques that are relatively pain-less and allow the shortest recovery

<sup>☆</sup> This study was funded by the Changi General Hospital Research Grant (Singapore) 2013.

<sup>☆☆</sup> The authors have no other funding, financial relationships, or conflicts of interest to disclose.

<sup>☆☆☆</sup> This work was done in Changi General Hospital, Singapore.

<sup>☆☆☆☆</sup> Presented at the 69th Annual General and Scientific Meeting of the New Zealand Society of Otolaryngology, Head and Neck Surgery (NZSOHNS) in Christchurch, New Zealand, on 16–19 October 2016 & the Eastern Health Alliance Scientific Meeting 2016, in Singapore on 3 November 2016.

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period. Some techniques that have been developed over the years include cold-knife dissection, guillotine excision, laser dissection, monopolar or bipolar electrocautery, cryosurgery, harmonic scalpel, coblation, and most recently PEAK PlasmaBlade tonsillectomy [3].

The PEAK PlasmaBlade is a new electro-surgical device that uses PEAK Surgical's proprietary Pulsed Plasma Technology for soft tissue cutting and coagulation with minimal thermal injury. It uses very brief, high frequency pulses of radiofrequency energy to induce electrical plasma along the edge of a thin insulated electrode [4].

The PEAK system uses about one half the amount of energy used by traditional electro-surgical technology to achieve similar cutting and coagulation results. This translates to operating temperatures of about 40–140 °C, which is about one half those of electrocautery with a corresponding reduction in heat transfer and an approximately 50–90% reduction in depth of thermal damage in adjacent tissues. Significant bleeding control is built into the PEAK technology. On the 'low cut' settings, there is 60% less bleeding than with a scalpel. On the higher cut settings and in coagulation mode, the PEAK system achieves haemostasis equivalent to traditional electrocautery, but with half the amount of thermal injury. This new system has also been shown to cut easily and smoothly, requiring just one quarter the force needed for cutting tissue with a scalpel and one half that needed for cutting with electrocautery. The PlasmaBlade device has been shown to operate in both wet and dry fields, thus allowing a surgeon to maintain superior cutting performance even through a surgical field that contains blood, liquefied fat or local anaesthesia. This system also generates significantly less surgical smoke than electrocautery when used in cut mode. Wounds created by the PEAK system healed virtually identically to scalpel wounds. The reduced thermal injury from the PEAK system also resulted in a reduction in inflammatory response and an increase in wound strength. When compared to electrocautery, the PEAK system wounds had 66% less scarring [5–9].

The PEAK system is United States FDA (Food and Drug Administration) approved for use in cutting and coagulation of soft tissue during Otolaryngology surgical procedures. However, there are no published trials or studies to date comparing its benefit in adult tonsillectomy over conventional electrocautery method.

This study aims to evaluate the efficacy and compare PEAK PlasmaBlade and monopolar electrocautery tonsillectomy in adults, in terms of patient satisfaction, postoperative pain, complications, number of tablets of analgesia required, time taken to return to soft diet, normal diet, normal activities and achieve pain-free swallowing.

## 2. Materials & methods

This study is a prospective double-blinded randomized controlled trial comparing PEAK PlasmaBlade versus monopolar electrocautery tonsillectomy in adults. Patients included in this study comprised of those above the age of 18 years, and whose indication for tonsillectomy were recurrent or chronic tonsillitis, previous peritonsillar abscess, snoring and OSA. Those below the age of 18 years, known history of coagulopathy, undergoing concurrent oral cavity or oropharyngeal procedures (e.g. palatal or tongue base surgery) and whereby the indication for surgery was for histological diagnosis (e.g. asymmetrically enlarged tonsils or suspected tonsillar neoplasm) were excluded from this study. The patients selected were subsequently randomized using a computer randomization program into either the PEAK PlasmaBlade or monopolar electrocautery group. All patients were blinded with regard to their study group. The researcher (main author) analysing the data and pain diary was also blinded with regards to which method of surgery the patients had undergone, and was not involved in any of the surgeries.

A standardized protocol was used for the general anaesthetic technique. Induction was conducted using intravenous fentanyl 100 µg, propofol 2–3 mg/kg, and atracurium 0.5 mg/kg. Intubation was performed with an oral south Rae tracheal tube of the appropriate size and maintenance of anaesthesia was achieved with a gas mixture of nitrous oxide, oxygen and desflurane. Fentanyl boluses of 25 µg were given when blood pressure and

heart rate increased by > 20% during surgery. Following reversal and during recovery, intravenous tramadol 50 mg was given if the pain score exceeded 5 on a visual analog scale of 0 to 10.

Patients in the PEAK PlasmaBlade group had tonsillectomy performed using the PEAK PlasmaBlade system (Medtronic, USA), with the coagulation setting set at 6. Those in the monopolar electrocautery group had tonsillectomy performed at the same setting of 18 for both coagulation and cutting (Valleylab Force 40 Electro-surgical Unit, DRE Inc. Louisville, KY, USA). All tonsillectomies were performed by attending-level otolaryngologists of seniority equivalent to Associate Consultant and above.

In both treatment groups, no perioperative antibiotics, topical anaesthesia, or steroids were given. Postoperative analgesia and discharge medications were standardized for both groups of patients. All of them were given Paracetamol 500 mg/Codeine phosphate 30 mg, Amoxicillin 500 mg, Benzylamine lozenges and gargle postoperatively and upon discharge. A pain diary was given to each patient upon discharge for which they had to record the following details on a once-daily basis for 21 days following surgery: 1) visual analog score for pain of 0 to 10, 0 being no pain and 10 being extreme pain; 2) presence of bleeding from mouth; 3) number of tablets of analgesia taken for that day; 4) ability to take soft diet or normal diet; 5) ability to return to normal activities; 6) experience of pain on swallowing.

All patients were admitted as inpatients and discharged 1 day after the surgery. At the end of the 21 days of charting, patients had to answer 2 questions in the diary pertaining to their overall satisfaction with the surgery (on a scale of 0 to 10, 0 being unsatisfied and 10 being extremely satisfied) and the likelihood that they would recommend the surgery to their friends or relatives. All patients were reviewed 2 and 4 weeks following surgery and the pain diary was collected from them at the end of follow-up for analysis by the main author.

The study protocol was approved by Changi General Hospital (Singapore) Institutional Review Board.

All statistical analyses were performed with SPSS 13.0 with statistical significance set at  $P < 0.05$ . Differences in quantitative data (days taken to return to soft diet, normal diet, normal activities and pain-free swallowing) between the 2 groups were analysed using 2-sample *t*-test with a multiple linear regression performed adjusting for age and sex. Associations between the categorical variables (sex and recommendation of surgery) and the 2 groups were assessed using Chi-squared or Fisher's Exact test. A logistic regression was also performed for recommendation of surgery adjusting for age and sex. Differences in the visual analog score and total number of analgesia tablets between the 2 groups were assessed using repeated-measurement analysis for both unadjusted and adjusted (for age and sex) analyses. Descriptive values are presented as mean (standard deviation, SD).

## 3. Results

A total of 60 patients were initially recruited over a 2 year period (January 2013 to December 2014) for this study, with 30 in each treatment group. However 2 patients dropped out of the study (1 decided not to take part, 1 defaulted follow-up). That resulted in 58 patients (29 in each treatment arm) who underwent the surgery, completed the pain diary and made a full recovery by the end of the follow-up period (Fig. 1). Table 1 shows the demographic data of these patients. The ratio of male to female patients was identical in both groups (69% male vs 31% female) and the mean age of patients in both groups were relatively similar (27.62 years in PEAK PlasmaBlade group vs 29.38 years in monopolar electrocautery group,  $P = 0.487$ ).

The results of the outcome measures are shown in Table 2. Patients in the PEAK PlasmaBlade group were able to achieve pain-free swallowing in a shorter time compared to the monopolar electrocautery group (13.28 [95% CI 11.69–14.86] vs 15.76 [95% CI 14.01–17.50] days,  $P = 0.035$ ). The time taken to return to normal diet (10.52 vs 11.97 days,  $P = 0.206$ ) & normal activities (7.83 vs 9.17 days,

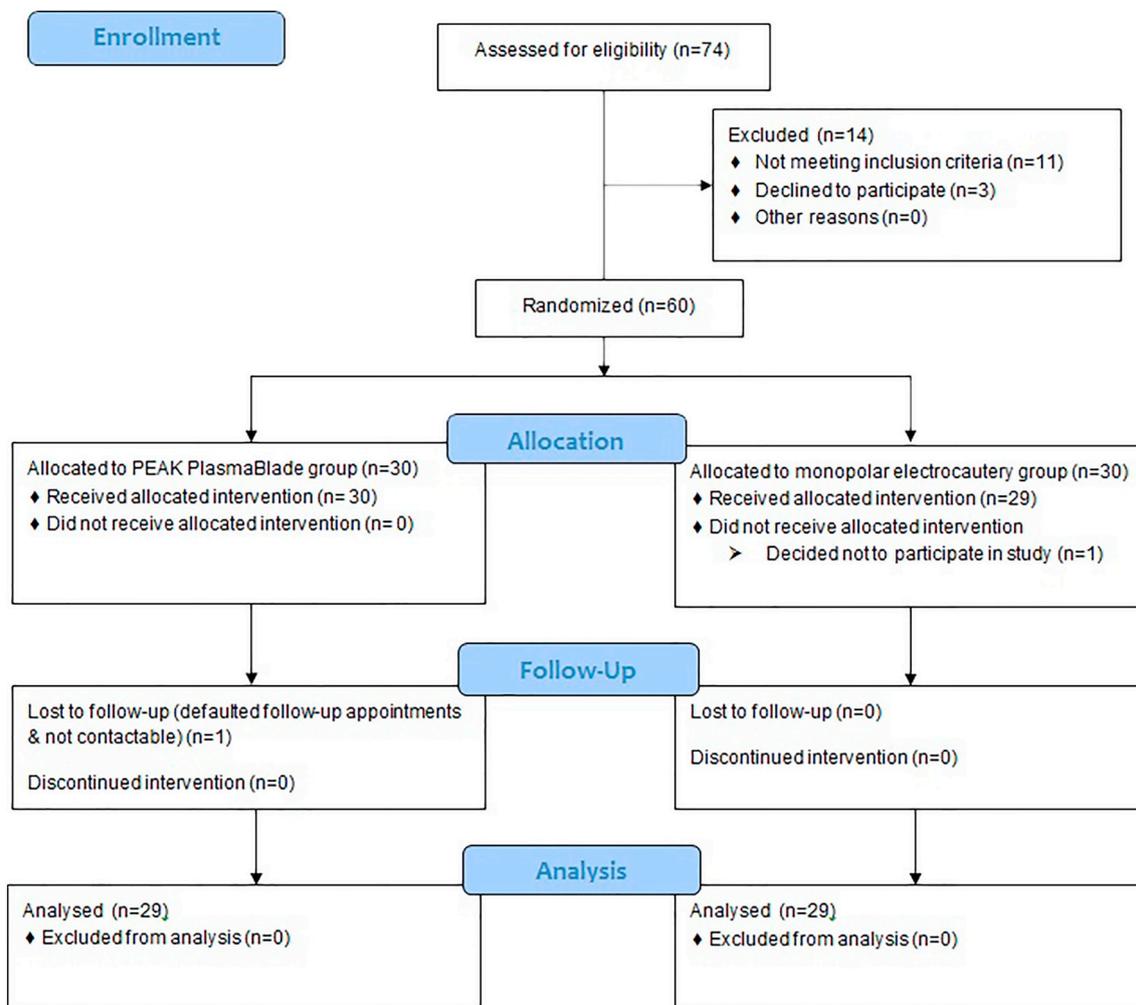


Fig. 1. Patient flow diagram (CONSORT).

$P = 0.351$ ) was shorter in the PEAK PlasmaBlade group, although these results were not statistically significant (Fig. 2 & Table 2).

No statistically significant differences in daily visual analog score for pain, number of tablets of analgesia taken per day and time taken to return to soft diet were seen for both groups. The usage of benzydamine lozenges and gargle did not have any significant correlation with the use of oral analgesia.

Patients who had underwent PEAK PlasmaBlade tonsillectomy had a higher satisfaction score than those who underwent the procedure with the monopolar electrocautery technique (8.92 [SD 1.01] vs 8.24 [SD 1.43] out of 10,  $P = 0.046$ ), and this was statistically significant.

93.1% of patients in the PEAK PlasmaBlade group said they would recommend the surgery to their friends or relatives, while 89.7% of the monopolar electrocautery group patients said likewise. This difference was not statistically significant ( $P = 0.324$ ).

The incidence of postoperative haemorrhage in the PEAK PlasmaBlade group ( $n = 3$ ) was half of that of the monopolar electrocautery group ( $n = 6$ ), although not statistically significant ( $P = 0.163$ ). There were 2 cases of monopolar electrocautery

tonsillectomy with secondary haemorrhage that required haemostasis under general anaesthesia and 1 case in the PEAK PlasmaBlade group. This result was not statistically significant ( $P = 0.470$ ). With regards to secondary haemorrhage that required haemostasis under local anaesthesia, there was 1 case in the monopolar electrocautery group while there was none in the PEAK PlasmaBlade group. This result was also not significant ( $P = 0.322$ ). All these patients made a good and complete recovery by the end of the follow-up period.

There were no cases of primary haemorrhage or admission for dehydration following tonsillectomy in this study.

#### 4. Discussion

A search of the medical literature showed that there are no other published studies to date, comparing PEAK PlasmaBlade and monopolar electrocautery tonsillectomy in adults. This is the first prospective double-blinded randomized controlled trial comparing these two methods of tonsillectomy in adults, in terms of postoperative pain and recovery.

**Table 1**  
Demographic data of patients.

Method of tonsillectomy	Number of patients	Male	Female	Mean age (SD) (years)	Age range (years)
Peak PlasmaBlade	29	20 (69%)	9 (31%)	27.62 (9.13)	20–56
Monopolar electrocautery	29	20 (69%)	9 (31%)	29.38 (9.99)	19–54

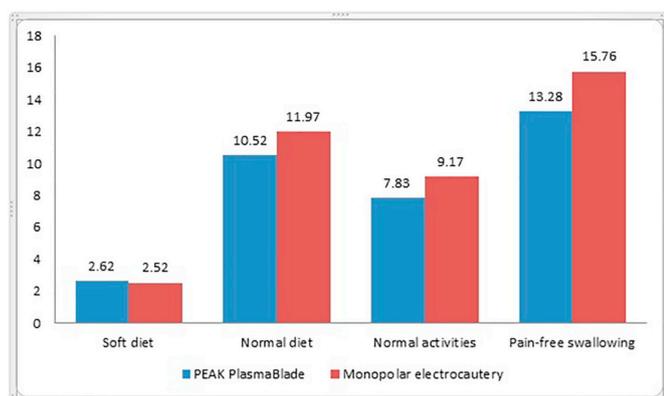
SD, standard deviation.

**Table 2**  
Outcome measures.

	PEAK PlasmaBlade (n = 29)	Monopolar electrocautery (n = 29)	Adjusted <i>P</i> value <sup>a</sup>
Soft diet (days)			
Mean (SD)	2.62 (2.47)	2.52 (2.60)	0.877
Range	1–9	1–12	
Normal diet (days)			
Mean (SD)	10.52 (4.14)	11.97 (4.48)	0.206
Range	4–18	1–22	
Normal activities (days)			
Mean (SD)	7.83 (5.01)	9.17 (5.84)	0.351
Range	1–18	1–22	
Pain-free swallowing (days)			
Mean (SD)	13.28 (4.16)	15.76 (4.59)	0.035
Range	6–22	5–22	
Satisfaction score			
Mean (SD)	8.92 (1.01)	8.24 (1.43)	0.046
Range	6.9–10.0	3.8–10.0	
Recommend surgery			
Yes	93.1%	89.7%	0.324

SD, standard deviation; VAS, visual analog scale.

<sup>a</sup> Adjusting for age, sex.



**Fig. 2.** Time taken for postoperative recovery in both groups, mean (days).

A point to note is that this study only involved adult patients, which could explain why the pain scores of patients did not reveal any significant differences between the two groups. It is well known that paediatric tonsillectomy is easier to perform than adult tonsillectomy as there is generally less scarring in paediatric tonsils and hence, there is usually more postoperative pain following adult tonsillectomy. This could potentially mask any pain benefits from the technique of PEAK PlasmaBlade tonsillectomy. This could be a reason why the PEAK PlasmaBlade group of patients did not experience a better pain score, despite having a faster recovery period in terms of time taken to achieve pain-free swallowing.

Pain, a very subjective symptom, is a difficult outcome measure to study as there can be significant interpatient variability. It will likely vary from patient to patient even if all other factors remain constant. This could also be the reason for the lack of significant difference in the daily visual analog scores for pain and amount of analgesia taken between both groups of patients. Similar results, with regard to postoperative pain scores, were seen in a study by Spektor et al. [10] which compared PEAK PlasmaBlade and coblation tonsillectomy and adenoidectomy in children. Spektor et al. [10] conducted a prospective, non-randomized, non-blinded comparative cohort study of 100 paediatric patients. The study showed that there were no clinically relevant differences in postoperative pain scores, and total doses of analgesics were similar between the two groups.

The results from this study suggest that PEAK PlasmaBlade tonsillectomy may offer advantages over monopolar electrocautery tonsillectomy in adults as it allows patients to achieve pain-free swallowing faster postoperatively. PEAK PlasmaBlade allows a faster recovery because it operates at a much lower temperature, thus reducing thermal damage in adjacent tissues and enabling faster healing when compared to monopolar electrocautery [5]. Patients also claimed to be more satisfied with this new technique.

Although not statistically significant, the results showed that patients who underwent PEAK PlasmaBlade tonsillectomy had a faster postoperative recovery with regards to time taken to return to normal diet and activities, and the incidence of postoperative haemorrhage was only half of that of the monopolar electrocautery group. Larger studies would be necessary to evaluate these objectives.

There are other studies which compared these 2 techniques of tonsillectomy, but in children. A study by Lane et al. [11] supported the result of PEAK PlasmaBlade tonsillectomy having a lower incidence of postoperative haemorrhage. Lane et al. [11] conducted a retrospective chart analysis of 1780 paediatric patients who had tonsillectomy or adenotonsillectomy via monopolar electrocautery, coblation or PEAK PlasmaBlade method. It was shown that significance was evident between postoperative bleeding rate and instrumentation ( $P = 0.004$ ). The majority of bleeds occurred with coblation (58.9%), followed by monopolar electrocautery (23%) and PEAK PlasmaBlade (17.8%).

## 5. Conclusion

PEAK PlasmaBlade tonsillectomy allowed adult patients to achieve pain-free swallowing earlier compared to monopolar electrocautery tonsillectomy. Although there were no obvious postoperative 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, notably in reducing time taken to achieve pain-free swallowing postoperatively.

## Acknowledgements

Source of funding: Changi General Hospital Research Grant (Singapore) 2013.

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