Evidence in focus

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COBLATION^{*} **Technology in ENT** A collection of evidence



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Parsons SP, 2006: COBLATION tonsillectomy significantly reduced severity of postoperative pain compared to electrocautery and Harmonic Scalpel^{TM 6}

Mularczyk C, 2018: COBLATION adenoidectomy significantly reduced duration of pain in children compared to microdebrider with touch-up electrocautery⁷

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Chang KW, 2008: Postoperative benefits with COBLATION intracapsular tonsillectomy versus subcapsular tonsillectomy in patients with obstructive sleep apnoea¹⁰

Zhang L-Y, 2017: Fewer postoperative complications with tonsillotomy compared to tonsillectomy in children with sleep-disordered breathing¹¹

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Roy S, 2010: COBLATION Technology eliminated risk of fire in a mechanical model of oropharyngeal surgery, compared to rapid ignition with electrocautery¹²

Roy S, 2015: No risk of ignition with COBLATION Technology in simulated airway surgery¹³

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Benninger MS, 2018: Initial outcomes suggest COBLATION cordotomy is safe, efficient and effective for patients with bilateral vocal fold immobility¹⁴

Rachmanidou A, 2011: COBLATION resection was safe and effective in a 32-month-old girl with laryngeal papilloma¹⁵

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Shah AN, 2015: COBLATION Technology significantly reduced early postoperative pain compared to bipolar cautery for inferior turbinate hypertrophy (p<0.02)¹⁶

Farmer S, 2009: COBLATION Technology significantly improved nasal function at 3 months compared to preoperative measures (p=0.001)¹⁷

Khong GC, 2018: COBLATION TURBINATOR^o wand comparable to microdebrider in initial experience in 22 patients undergoing septoturbinoplasty¹⁸

Roje Z, 2011: COBLATION channelling of the inferior turbinate safe and effective for inferior turbinate reduction¹⁹

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Siméon R, 2010: COBLATION Technology resolved nasal obstruction and improved quality of life in children with allergic rhinitis²¹

Leong CS, 2010: Improvements in nasal airflow sustained to 32 months in patients receiving COBLATION Technology for inferior turbinate reduction²²

Cukurova I, 2011: Patient-reported and objective benefits of COBLATION Technology for inferior turbinate hypertrophy sustained to 60 months²³

COBLATION° Plasma Technology



A minimally invasive, low thermal technology for effective dissection and removal of tissue, COBLATION Technology has been used for ENT procedures such as tonsillectomy, turbinate reduction, laryngeal lesion debulking and soft palate.^{1,2}

While conventional electrosurgical devices use high temperatures to remove and cut tissue, our COBLATION Technology creates a controlled, stable plasma field to precisely remove tissue at a low relative temperature, resulting in minimal thermal damage to surrounding soft tissues.¹⁻³

>10 million

Procedures performed with COBLATION Technology⁴

1. Woloszko J, Kwende M, Stalder KR. Coblation in otolaryngology. *Proc SPIE*. 2003; 4949:341-353; 2. Thiagarajan B. Coblation an overview. *Otolaryngology Online Journal*. 2014;4(1.5); 3. Amiel D, Ball ST, Tasto JP. Chondrocyte viability and metabolic activity after treatment of bovine articular cartilage with bipolar radiofrequency: an in vitro study. Arthroscopy 2004;20(5):503-510; 4. This figure was calculated by capturing the number of COBLATION wands sold during the timeframe of July 2008 to May 2016.



COBLATION° tonsillectomy significantly reduced duration of severe pain in children versus monopolar electrocautery



Parker NP & Walner DL. Clin Otolaryngol. (2011)

Tonsils and adenoids > **Pain**



Study overview

- Randomised trial comparing the duration of postoperative pain in children (mean age, 5.6 years) undergoing tonsillectomy with COBLATION Technology (n=40) or monopolar electrocautery (n=40)
- Following surgery, patients and caregivers completed a two-week pain evaluation survey

Key results

- Significant reduction with COBLATION tonsillectomy versus monopolar electrocautery in (Figure):
 - Mean duration of severe pain (p<0.001)
 - Mean duration of pain \geq 5 on Wong-Baker FACES Pain Rating scale (p<0.05)
 - Mean number of days until resumption of normal diet (p<0.05)



Conclusion

By reducing the duration of severe pain, COBLATION tonsillectomy may enhance patient recovery compared to electrocautery.

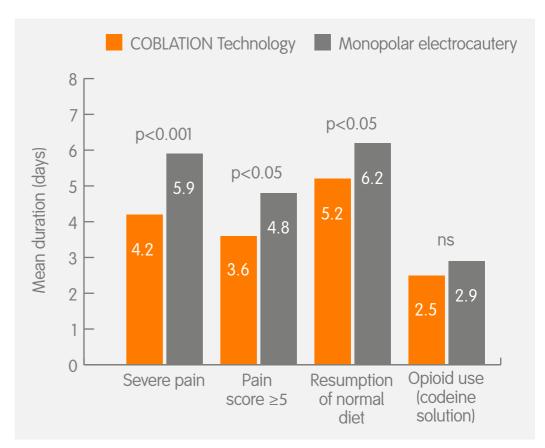


Figure. Mean duration of patient-reported outcomes ns, not significant

COBLATION° tonsillectomy significantly reduced severity of postoperative pain compared to electrocautery and Harmonic Scalpel™

Parsons SP, et al. Otolaryngol Head Neck Surg. (2006)

Tonsils and adenoids > **Pain**



Study overview

- Randomised trial comparing the severity of postoperative pain in adults and children undergoing tonsillectomy with COBLATION Technology (n=25; mean age, 9.5), Harmonic Scalpel (Ethicon, Bridgewater, NJ, USA; n=17; mean age, 10.1 years) or electrocautery (n=19; mean age, 10.9 years)
- Patients included in comparisons completed a pain diary for 10 consecutive days postoperatively; 134 patients were enrolled, however, only 61 patients returned their pain diaries, a 64% dropout rate

Key results

- Patients treated with COBLATION Technology reported the lowest mean pain score versus patients treated with electrocautery and Harmonic Scalpel (p=0.007; Figure)
- Time to return to normal diet was lowest in the COBLATION Technology group but did not reach significance (p=0.08)
- No differences between groups in postoperative activity level

Conclusion

Following surgery, patients receiving COBLATION tonsillectomy reported less severe pain over 10 days compared to those treated with electocautery and Harmonic Scalpel.

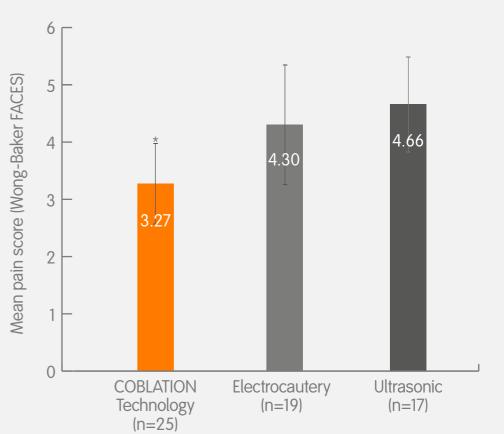
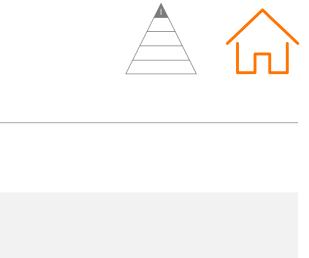


Figure. Mean (\pm standard deviation) pain score (Wong-Baker FACES Pain Rating scale) in patients who completed a pain diary following tonsillectomy

* COBLATION Technology had the lowest mean pain score when comparing the three groups (p=0.007)



COBLATION° adenoidectomy significantly reduced duration of pain in children compared to microdebrider with touch-up electrocautery (ME)



Mularczyk C, et al. Int J Pediatr Otorhinolaryngol. (2018)

Tonsils and adenoids > **Pain**



Study overview

- Randomised trial comparing outcomes following adenoidectomy with COBLATION Technology (n=50) or ME (n=51) in children (mean age, 4.8 years)
- Analysis controlled for factors that might affect the results, eg, adenoid size for duration of pain and surgical site exposure for duration of surgery



Key results

- Patients treated with COBLATION Technology reported a significantly shorter mean duration of pain versus those treated with ME (p=0.045) (Figure)
- Significant reduction with COBLATION Technology versus ME in:
 - Mean duration of surgery (5.50 vs 9.47min; p<0.001)
 - Volume of intraoperative blood loss (p<0.001)
- No significant difference in maximum severity of pain experienced by day 3



Conclusion

COBLATION Technology potentially offers advantages over ME for adenoidectomy by reducing duration of pain, duration of surgery and intraoperative blood loss.

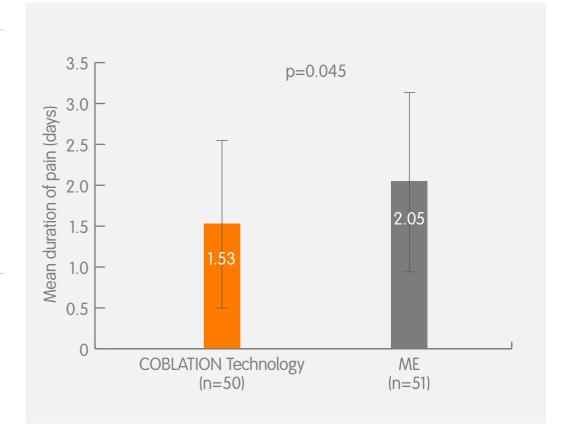


Figure. Mean (\pm standard deviation) duration of pain reported on postoperative day 3

Low rates of post-tonsillectomy haemorrhage (PTH) seen across commonly used techniques



Francis DO, et al. Otolaryngol Head Neck Surg. (2017)

Tonsils and adenoids > **PTH**



Study overview

 Systematic literature review and meta-analysis assessing estimates of PTH and related health utilisation in children undergoing tonsillectomy for obstructive symptoms or recurrent tonsillitis (n=6,898 from comparative studies)



Key results

- Pooled rates of PTH occurred in ≤4% of tonsillectomies with similar rates among commonly used techniques (Figure)
 - COBLATION^o Technology, 3.3%; cold dissection, 3.8%; electrocautery, 4.9%
- No significant difference between COBLATION Technology and other commonly used techniques for primary and secondary PTH in either partial or total tonsillectomy (Figure)
- Total tonsillectomy was associated with higher PTH rates than partial tonsillectomy



Conclusion

Pooled rates of PTH were ≤4% for tonsillectomies, with no significant difference in frequency between COBLATION Technology and other techniques.

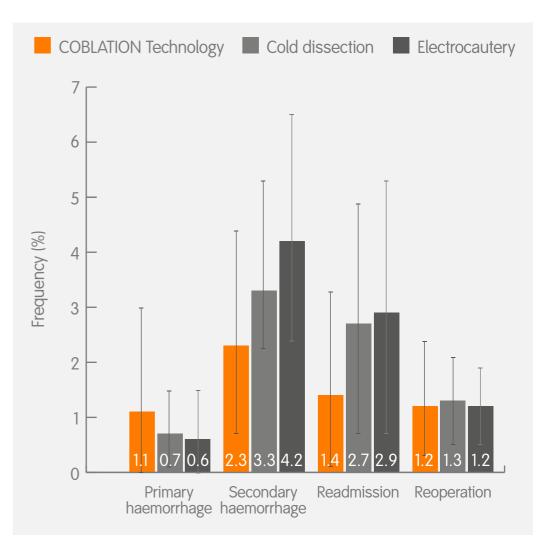


Figure. Frequency of PTH following total tonsillectomy with the three most commonly used techniques identified by literature review

COBLATION° intracapsular tonsillectomy (IT) shows excellent results for both obstructive and infective symptoms



Hoey AW, et al. Clin Otolaryngol. (2017)

Tonsils and adenoids > Intracapsular tonsillectomy



Study overview

- Prospective case series of 500 consecutive paediatric patients (mean age, 5.1 years) undergoing COBLATION IT for obstructive or infective indications
- Mean follow-up was 7.4 months

Key results

- Excellent symptom control shown by highly significant improvements in obstructive, infective and combined domains of T-14 questionnaire (p<0.0001)
- No primary haemorrhages, very low frequency of secondary bleeds (Table)
- Revision tonsillectomy in 12/500 (2.4%) patients (Table)
- No delayed discharges or readmissions with pain
- Most patients returned to nursery or school within 1 week (mean, 6.7 days)



Conclusion

COBLATION IT led to excellent symptom control, comparing favourably with existing literature for extracapsular tonsillectomy. There was a low rate of complications and rapid patient recovery.

| | Percentage (n/N) |
|-------------------------------------|------------------|
| Primary haemorrhages | 0 |
| Secondary haemorrhages | 0.4% (2/500) |
| Revision tonsillectomy | 2.4% (12/500) |
| Readmitted for pain | 0 |
| Parents who would recommend surgery | 99% (497/500) |

Table. Frequency of events in case series of 500 patients treated with COBLATION $\ensuremath{\mathsf{IT}}$

^{9.} Hoey AW, Foden NM, Hadjisymeou Andreou S, et al. Coblation[®] intracapsular tonsillectomy (tonsillotomy) in children: A prospective study of 500 consecutive cases with long-term follow-up. *Clin Otolaryngol.* 2017;42(6):1211-1217.

Postoperative benefits with COBLATION° intracapsular tonsillectomy (IT) versus subcapsular tonsillectomy (ST) in patients with obstructive sleep apnoea

Wand: EVAC° T and A

Chang KW. Otolaryngol Head Neck Surg. (2008)

Tonsils and adenoids > Intracapsular tonsillectomy

Study overview

- Randomised trial comparing patient recovery following IT (n=34) or ST (n=35) with COBLATION Technology in children (mean age, 6.2 years) with sleep apnoea or sleep-disordered breathing
- Outcomes were assessed on either day 1 or 2 and day 5 or 6 postoperatively

Key results

- Patient-reported pain was similar between methods at day 1 or 2, but was significantly lower with IT by day 5 or 6 (p<0.05) (Figure)
- Patients were able to eat more following IT versus ST at both day 1 or 2 (p=0.055) and day 5 or 6 (p=0.001)
- Patients were more active following IT versus ST at both day 1 or 2 (p=0.031) and day 5 or 6 (p=0.002)

Conclusion

Children receiving COBLATION IT for sleep apnoea or sleep-disordered breathing had better postoperative recovery versus those receiving COBLATION ST, most pronounced at a delayed time point (5 or 6 days), rather than early (1 or 2 days).

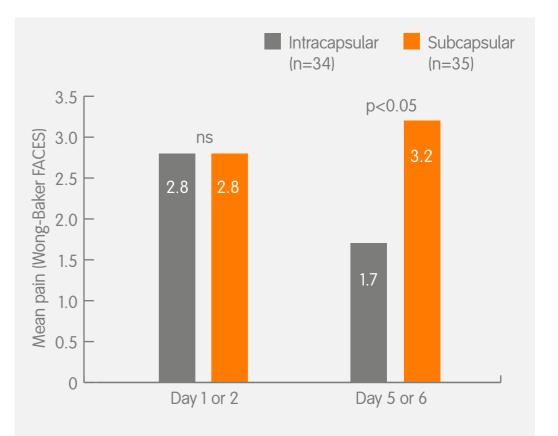


Figure. Mean patient-reported pain scores from Wong-Baker FACES Pain Rating scale ns = not significant

Fewer postoperative complications with tonsillotomy compared to tonsillectomy in children with sleep-disordered breathing



Zhang L-Y, et al. Int J Pediatr Otorhinolaryngol. (2017)

Tonsils and adenoids > Intracapsular tonsillectomy



Study overview

Key results

 Systematic literature review and meta-analysis of studies (19 randomised, 13 non-randomised) directly comparing tonsillotomy and tonsillectomy for children with sleep-disordered breathing (n=19,181)

- Significant reduction with tonsillotomy versus tonsillectomy in: (Table)
 - Odds of secondary haemorrhage, 79% reduction (p<0.01)
 - Odds of readmission, 62% reduction (p<0.01)
 - Duration of analgesia, 2.7 fewer days (p<0.01)
 - Time to return to normal oral intake, 2.8 fewer days (p<0.01)
- Symptom recurrence was, on average, slightly greater with tonsillotomy versus tonsillectomy (3.99% vs 3.21%)
- No difference between methods in patient satisfaction or quality of life in any long-term effectiveness study

Conclusion

In children with sleep disordered breathing, tonsillotomy offers reduced haemorrhage and pain with a faster return to normal diet and activity versus tonsillectomy.

| | Favours tonsillotomy | No difference |
|----------------------------------|-------------------------|------------------|
| Odds of primary haemorrhage | * | |
| Odds of secondary haemorrhage | ~ | |
| Odds of readmission | ~ | |
| Duration of analgesia | ~ | |
| Return to normal oral intake | ~ | |
| Operating time | | ~ |

Table. Significant differences found in statistical comparisons of relevant studies. No factor subjected to meta-analysis significantly favoured tonsillectomy

* Not significant once single large non-randomised study removed from sensitivity analysis COBLATION° Technology eliminated risk of fire in a mechanical model of oropharyngeal surgery, compared to rapid ignition with electrocautery

Roy S & Smith LP. Otolaryngol Head Neck Surg. (2010)

Laryngeal > Airway fire risk



Study overview

- Mechanical model of oropharyngeal surgery used to evaluate the airway fire risk of electrocautery and COBLATION Technology
- ETTs inserted into cavity of raw, degutted chickens
- 100% $\rm O_{_2}$ piped into cavity (10L/min) before device activation on tissue near the tip of the ETT

Key results

- Rapid ignition of the ETT with electrocautery (Table)
- No ignition on any COBLATION setting after 4min of activation (Table)
- No ignition following 20min of direct COBLATION application at end of ETT
 - Ignition within 25sec when re-testing the same chicken with electrocautery



Conclusion

Electrocautery presented a substantial risk of fire in a mechanical model of oral cavity and airway surgery. Even under worst-case circumstances, the risk of fire was eliminated when using COBLATION Technology.

| Setting | Power (W) | Time (sec) | Result |
|----------------|--------------|---------------|-----------------------------|
| Electrosurgery | 15 | 45 | Ignition and sustained fire |
| Electrosurgery | 15 | 55 | Ignition and sustained fire |
| RF ablate | 9 | 240 | No ignition or fire |
| RF ablate | 7 | 240 | No ignition or fire |
| RF ablate | 5 | 240 | No ignition or fire |
| RF ablate | 3 | 240 | No ignition or fire |
| RF coagulate | 5 | 240 | No ignition or fire |
| RF coagulate | 3 | 240 | No ignition or fire |

Table. Electrocautery and COBLATION Technology tests, at 100% $\mathrm{FiO}_{\mathrm{2}}$

 $ETT = endotracheal tube; FiO_2 = fraction of inspired oxygen; RF = radiofrequency$

12. Roy S & Smith LP. Device-related risk of fire in oropharyngeal surgery: a mechanical model. Otolaryngol Head Neck Surg. 2010;31:356-359.



No risk of ignition with COBLATION^o Technology in simulated airway surgery Roy S & Smith LP. Am J Otolaryngol Head Neck Med Surg. (2015)



Laryngeal > Airway fire risk



Study overview

- Mechanical model of endoscopic airway surgery used to evaluate the risk of ignition with COBLATION Technology or CO₂ laser on traditional and 'laser safe' ETTs
- COBLATION Technology or CO₂ laser directly applied to ETT at various O₂ concentrations

Key results

Conclusion

- No ignition of either ETT with COBLATION Technology on any setting (Table)
- Rapid ignition of traditional ETT with the CO₂ laser within 7.5sec at 21% O_2 and sustained flames within 2sec from $44\% O_2$ (Table)
- No ignition of laser safe ETT with CO₂ laser (Table); however, the nonreinforced distal tip was as flammable as a traditional ETT

There is no risk of ignition with COBLATION Technology in simulated airway surgery. Laser safe ETTs should be used with CO, lasers, while remaining aware of the non-reinforced distal tip.

| | Traditional ETT | | Laser-safe ETT | |
|----------------|------------------------------|-------------------------|-----------------------|-------------------------|
| 0 ₂ | CO ₂ laser | COBLATION Technology | CO ₂ laser | COBLATION Technology |
| 21% | Ignition only | No ignition | No ignition | No ignition |
| 29% | Ignition only | No ignition | No ignition | No ignition |
| 44% | Ignition and sustained flame | No ignition | No ignition | No ignition |
| 53% | Ignition and sustained flame | No ignition | No ignition | No ignition |
| 60% | Ignition and sustained flame | No ignition | No ignition | No ignition |

Table. Trials of CO₂ laser and COBLATION applied to laser safe and traditional ETT at varying O₂ concentrations

ETT = endotracheal tube

13. Roy S & Smith LP. Prevention of airway fires: testing the safety of endotracheal tubes and surgical devices in a mechanical model. Am J Otolaryngol Head Neck Med Surg. 2015;36:63-66.

Initial outcomes suggest COBLATION° cordotomy is safe, efficient and effective for patients with bilateral vocal fold immobility (BVFI)



Benninger MS, et al. JAMA Otolaryngol Head Neck Surg. (2018)

Laryngeal > Effectiveness



Study overview

- Retrospective case series of 19 consecutive adult patients (mean age, 56 years) undergoing COBLATION cordotomy to treat BVFI; only patients without stenosis (n=15) were included in subsequent analysis
- OR time was scheduled based on institutional historical records for cordotomy



Key results

- Improvements in patient-reported outcomes versus preoperative measures at a mean follow-up of 516 days
 - Shortness of breath in 10/14 (71%) of patients
 - Stridor in 10/12 (83%) patients
 - Vocal cord function, mean effect size of -29 on Voice Handicap Index
- Mean time spent in the OR was 25min shorter than the scheduled time (63 vs 88min, respectively)
- COBLATION cordotomy was cost effective (Figure)

Conclusion

COBLATION cordotomy is safe, efficient and effective for BVFI, with a short operating time and significant postoperative patient benefits.



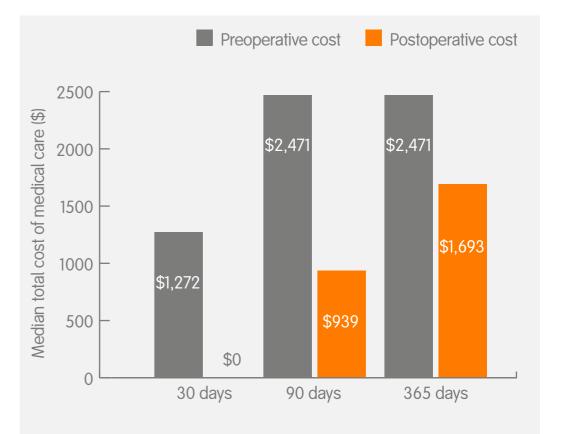


Figure. Comparison of median total cost of medical care for each patient. Charges captured up to 365 days pre- and postadmission and divided into 30-, 90- and 365-day windows

COBLATION° resection was safe and effective in a 32-month-old girl with laryngeal papilloma



Rachmanidou A & Modayil PC. J Laryngol Otol. (2011)

Laryngeal > Effectiveness



Study overview

• Case study of a 32-month-old girl receiving COBLATION resection of a large papillomatous lesion reported as laryngeal papilloma on histological analysis



Key results

- Uneventful postoperative recovery; same day discharge following 8 hours of observation
- Minimal bleeding during procedure
- No signs of recurrence postoperatively and a dramatic improvement in the patient's voice, aided by speech therapy sessions (Figure)

Conclusion

COBLATION resection of laryngeal papilloma was safe and effective in a 32-month-old girl, with minimal bleeding, uneventful recovery and no recurrence at 18 months.



Figure. Postoperative patient follow-up after treatment with **COBLATION Technology**

COBLATION° Technology significantly reduced early postoperative pain compared to bipolar cautery for inferior turbinate hypertrophy

Wand: REFLEX[®] ULTRA 45

Shah AN, et al. Ann Otol Rhinol Laryngol. (2015)

Turbinates > Short-term outcomes

Study overview

- Prospective comparison of outcomes following COBLATION Technology or intramural bipolar cautery for inferior turbinate hypertrophy refractory to medical therapy in adults (n=41; mean age, 38 years)
- Patients were treated with COBLATION Technology in one nostril and intramural bipolar cautery in the other



Key results

- Patients reported significantly less pain with COBLATION Technology versus bipolar cautery during the procedure (p=0.03) and during the early postoperative period (p<0.02; Figure), with less crusting at 3 weeks (p=0.009)
- At 6 weeks, 24/41 patients completed VAS for nasal obstruction; improvements from baseline were comparable between groups (COBLATION Technology, 63%; bipolar cautery, 54%), with no significant difference between methods (p=0.14)
- Both modalities were well tolerated with minimal complications

Conclusion

COBLATION Technology for inferior turbinate hypertrophy led to reduced discomfort during the procedure and in the early postoperative period versus bipolar electrocautery, with comparable effectiveness and safety.

VAS = visual analogue scale

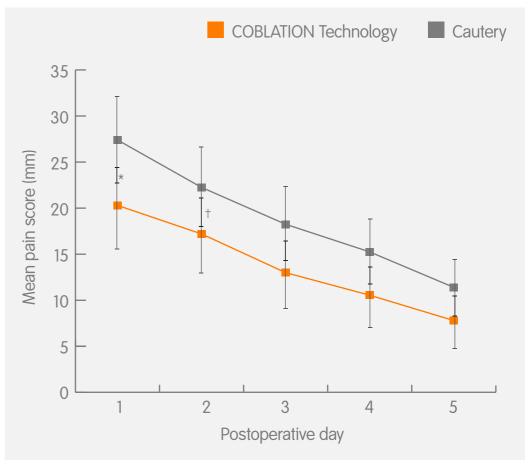


Figure. Postoperative mean pain scores, measured with a VAS *p=0.002. ^{+}p =0.02

COBLATION[°] Technology significantly improved nasal function at 3 months compared to preoperative measures



Farmer S, et al. J Laryngol Otol. (2009)

Turbinates > Short-term outcomes



Study overview

- Prospective case series evaluating the efficacy of inferior turbinate reduction with COBLATION Technology for the treatment of nasal obstruction in adults (n=19; mean age, 32 years)
- Nasal function was assessed using both posterior rhinomanometry and VAS



Key results

- Increased nasal conductance in 13 patients (68%) at 2 weeks and 15 patients (83%) at 3 months
- Significant increase in nasal conductance, from 203cm³/sec preoperatively to 324cm³/sec at 3 months (p=0.004; Figure); no significant difference at 2 weeks
- Significant improvement in patient-reported nasal function (VAS) at 2 weeks and 3 months versus pre-treatment scores (p=0.046 and p=0.001, respectively)



Conclusion

This study confirms the short-term efficacy of inferior turbinate reduction with COBLATION Technology for the treatment of nasal obstruction.

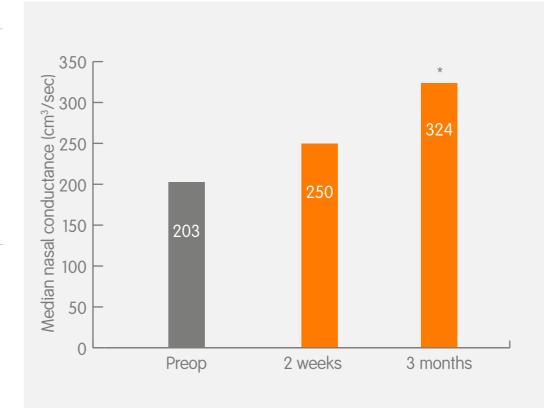


Figure. Effect of COBLATION Technology on median nasal conductance measured by posterior rhinomanometry (n=19) *p=0.004 at 3 months versus preoperative measures

VAS = visual analogue scale

17. Farmer S, Quine S, & Eccles R. Efficacy of inferior turbinate coblation for treatment of nasal obstruction. J Laryngol Otol. 2009;123:309-314.

COBLATION° TURBINATOR° wand comparable to microdebrider in initial experience in 22 patients undergoing septoturbinoplasty



Khong GC, et al. Clin Otolaryngol. (2018)

Turbinates > Short-term outcomes



Study overview

- Comparison of outcomes following septoturbinoplasty with TURBINATOR wand (n=22) or microdebrider (n=22) for nasal obstruction caused by inferior turbinate hypertrophy
- Outcomes included change in NOSE scale score and PNIF at 12 weeks

Key results

- Significant and consistent improvement in mean NOSE score (Figure 1) and PNIF (Figure 2) for both groups at 12 weeks versus preoperative measures
- Unilateral nasal packing required for 2 patients in the microdebrider group, none required in the TURBINATOR group
- Bolster changes were required in microdebrider group (median of 2; range, 0-4); none were required in the TURBINATOR group

In the first study investigating outcomes with the COBLATION TURBINATOR wand, patients had comparable outcomes to patients treated with microdebrider.

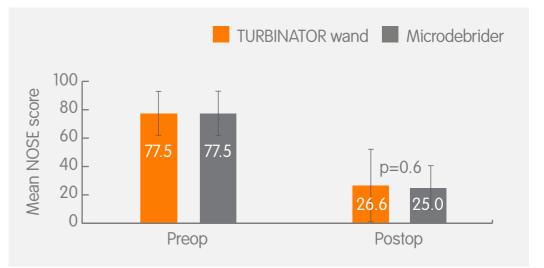


Figure 1. Change in mean NOSE score (\pm standard deviation) preto postoperative period

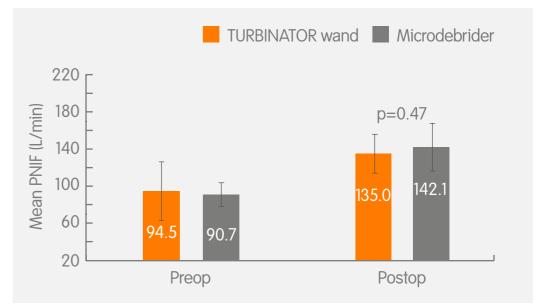


Figure 2. Change in mean PNIF (L/min; \pm standard deviation) from pre- to postoperative period

NOSE = Nasal Obstruction Symptoms Evaluation; PNIF = peak nasal inspiratory flow rate

18. Khong GC, Lazarova L, Bartolo A, et al. Introducing the new Coblation Turbinator turbinate reduction wand: Our initial experience of twenty-two patients requiring surgery for nasal obstruction. *Clin Otolaryngol.* 2018;43:382-385.

COBLATION° channelling safe and effective for inferior turbinate reduction

Wand: REFLEX° ULTRA 45

Roje Z, et al. Collegium Antropologicum. (2011)

Turbinates > Short-term outcomes



Study overview

- Prospective case series evaluating COBLATION channeling in 52 patients (mean age 28.5 years) with inferior turbinate hypertrophy refractory to medical therapy
- Outcomes assessed before and 8-weeks post-treatment included measurement of nasal obstruction by rhinomanometry and a 10cm VAS grading nasal obstructions



Key results

- Significant improvement in patient-reported nasal obstruction, with a decrease in VAS from a median of 7 at baseline (range 2–9) to 1 postoperatively (range 0–3; p<0.001)
- Significant decrease in nasal resistance by rhinomanometry from 0.44±0.50Pa at baseline to 0.24±0.11Pa postoperatively (p=0.005)
- Significant improvement postoperatively in all patient-reported outcomes from baseline (hyposmia [p=0.005], nasal drainage [p=0.003] and post-nasal drip [p<0.001]; Figure)

Conclusion

COBLATION channelling for the reduction of inferior turbinates is safe and effective.

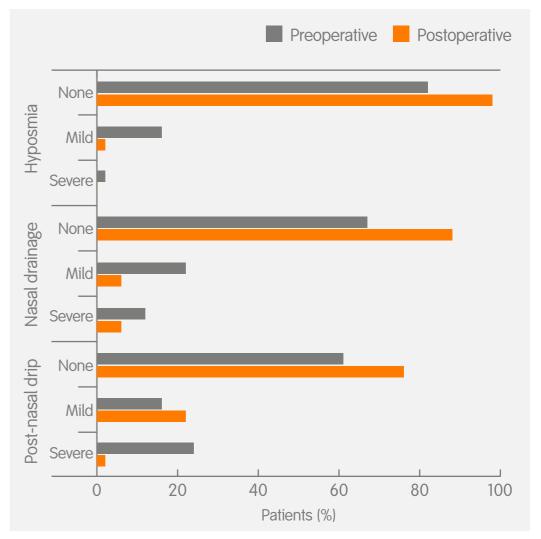


Figure. Pre- and postoperative (8 weeks) symptoms. Overall significant postoperative severity reduction in hyposmia (p=0.005), nasal drainage (p=0.003) and post-nasal drip (p<0.001)

VAS = visual analogue scale

COBLATION[°] Technology and somnoplasty demonstrated comparable efficacy for bilateral turbinate hypertrophy



Cavaliere M, et al. Otolaryngol Head Neck Surg. (2007)

Turbinates > Long-term outcomes



Study overview

- Randomised trial comparing efficacy and morbidity of COBLATION Technology (n=75) or somnoplasty (n=75) of inferior turbinates for bilateral turbinate hypertrophy (mean age, 23 years)
- Outcomes included patient-reported and objective nasal function from baseline to 20 months postoperatively

Key results

- Earlier postoperative improvements with COBLATION Technology versus somnoplasty in:
 - Nasal obstruction (Figure), from day 7 with COBLATION Technology (p<0.05) versus month 1 with somnoplasty (p<0.0001)
 - Turbinate oedema, from day 7 with COBLATION Technology (p<0.0001) versus month 1 with somnoplasty (p<0.0001)
 - Comparable improvements in nasal symptoms, nasal volume and decrease in nasal resistance at months 1 and 3 (p<0.0001 for all endpoints)
- No decrease in objective or subjective function measures between 3 and 20 months postoperatively

Conclusion

COBLATION Technology and somnoplasty offer equivalent long-term efficacy in measures of nasal function. Patient-reported recovery was faster with COBLATION Technology than with somnoplasty.

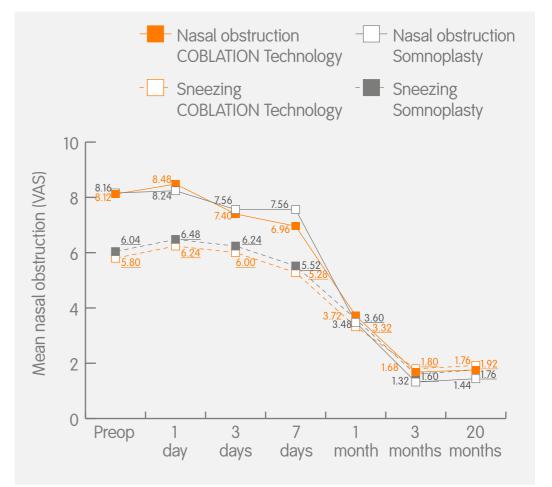


Figure. Nasal subjective symptoms, nasal obstruction and sneezing, graded using a visual analogue scale ranging from 0 (no symptoms) to 10 (the most severe symptoms)

COBLATION° Technology resolved nasal obstruction and improved quality of life in children with allergic rhinitis

Siméon R, et al. Eur Ann Otorhinolaryngol Head Neck Dis. (2010)

Turbinates > Long-term outcomes



Study overview

- Prospective case series evaluating the efficacy of COBLATION Technology for the treatment of allergic rhinitis refractory to medical therapy in children (n=9; mean age, 12.7 years)
- Nasal obstruction was assessed postoperatively by rhinomanometry and VAS; functional impact was assessed on the PRQLQ at 1, 3 and 6 months



Key results

- Significant decrease in binasal resistance in all patients at 6 months (>50%; p=0.0015)
- Mean VAS decreased from 9.1 to 1.2 for daytime symptoms and from 9.8 to 0.6 for night-time symptoms at 6 months (Figure)
- Highly significant improvement from baseline in PRQLQ at 1, 3 and 6 months (p<0.0001)



Conclusion

COBLATION Technology resolved nasal obstruction and seemed to have a favourable impact on associated respiratory symptoms in children with allergic rhinitis refractory to medical therapy.

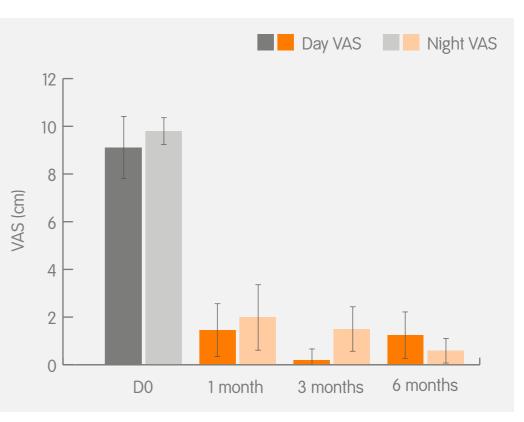


Figure. Mean (\pm standard deviation) day and night-time nasal obstruction scores before (D0) and after COBLATION Technology; p<0.0001 at all time points

PRQLQ = Paediatric and Adolescent Rhinoconjunctivitis Quality of Life Questionnaire; VAS = visual analogue scale

21. Siméon R, Soufflet B, Delacour IS. Coblation turbinate reduction in childhood allergic rhinitis. Eur Ann Otorhinolaryngol Head Neck Dis. 2010;127:77-82.



Improvements in nasal airflow sustained to 32 months in patients receiving COBLATION[®] Technology for inferior turbinate reduction

Leong CS, et al. *Rhinology*. (2010)

Turbinates > Long-term outcomes



Study overview

- Prospective case series evaluating long-term outcomes following inferior turbinate COBLATION Technology for the treatment of nasal obstruction in adults
- Nasal function was assessed using both posterior rhinomanometry and VAS; 13/18 patients (76%) were available for follow-up at 32 months



Key results

- Significant increase in nasal conductance from 248.6cm³/sec at baseline to 342.1cm³/sec at 32 months (p=0.033; Figure)
- Reduction in patient-reported symptom severity (VAS) in 10/13 patients (77%) at 32 months
- Mean decrease in VAS score from 72mm at baseline to 53mm at 32 months did not reach significance in the 13 patients available at follow-up

Conclusion

Objective measures of nasal airflow were better than pre-treatment levels at 32 months, indicating a sustained positive response to COBLATION Technology following inferior turbinate reduction. Wand: REFLEX° ULTRA 45

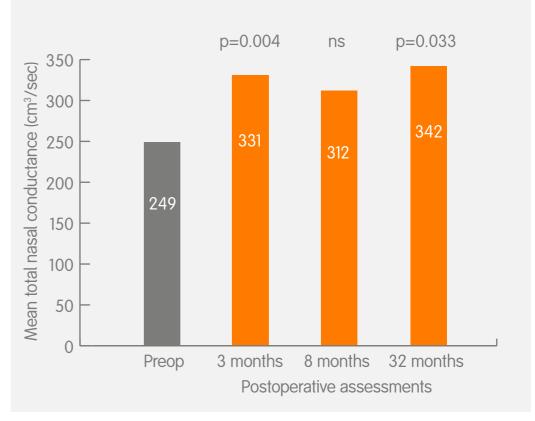


Figure. Effect of COBLATION Technology on mean nasal conductance measured by posterior rhinomanotery. All significance values versus preoperative measures ns = not significant

VAS = visual analogue scale

Patient-reported and objective benefits of COBLATION^o Technology for inferior turbinate hypertrophy sustained to 5 years



Cukurova I, et al. J Laryngol Otol. (2011)

Turbinates > Long-term outcomes



Study overview

- Case series evaluating COBLATION Technology for the treatment of inferior turbinate hypertrophy refractory to medical therapy in adults (n=180 available for follow-up; mean age, 33 years)
- Outcomes including VAS for nasal obstruction, VAS for discharge and acoustic rhinometry were assessed up to 5 years postoperatively



Key results

- Revision surgery was required in 32/180 patients (18%) by 12 months; patients receiving revisions were excluded from subsequent analyses
- Significant improvement in postoperative nasal capacity sustained to 5 years versus preoperative values (p<0.05; Figure)
- Significant reduction in VAS scores for nasal obstruction and discharge sustained to 5 years versus preoperative values (p<0.001)

Conclusion

COBLATION Technology for the treatment of inferior turbinate hypertrophy was effective to 5 years postoperatively in both objective and subjective measures of nasal function.

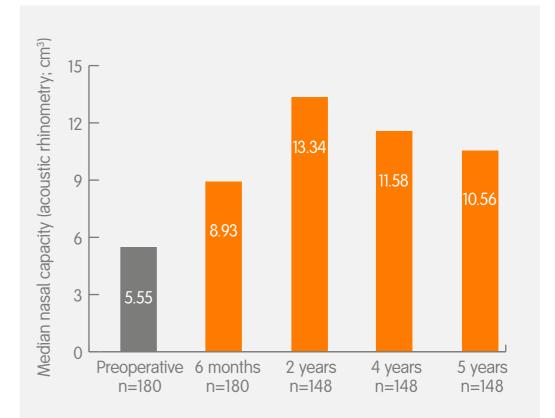


Figure. Median nasal capacity measured by acoustic rhinometry p<0.05 at all time points versus preoperative values

VAS = visual analogue scale

23. Cukurova I, Demirhan E, Cetinkaya EA, et al. Long-term clinical results of radiofrequency tissue volume reduction for inferior turbinate hypertrophy. J Laryngol Otol. 2011;125:1148-1151.