

## Coblation<sup>®</sup> inferior turbinate reduction: a long-term follow-up with subjective and objective assessment\*

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### SUMMARY

*This article presents long-term outcomes following Coblation<sup>®</sup> inferior turbinate reduction surgery (CITR) using both subjective and objective outcome measures in a cohort of patients with nasal obstruction secondary to enlarged inferior turbinate. Subjective assessment of the severity of nasal obstruction was assessed using a 100 mm visual analogue scale anchored by the descriptors 'nose completely clear' (0 mm) and 'nose completely blocked' (100 mm). Nasal conductance of airflow was measured by posterior rhinomanometry. Of the original cohort of 18 patients, 13 patients (76%) were available for follow-up at 32 months after surgery. The mean baseline nasal conductance was 248.6 cm<sup>3</sup>/s (range 2.5-614.8), which improved significantly ( $p = 0.033$ ) to 342.1 cm<sup>3</sup>/s (range 166.7-500) at 32 months post-operatively. Improvement in the subjective sensation of nasal obstruction was indicated by a lower VAS score compared to baseline. The mean pre-operative VAS was 72 mm (range 49-98), which improved to 53 mm (range 2-93) but this did not achieve statistical significance (10/13 patients scored improved airflow). This was a pilot study of the long-term outcomes of CITR. Despite the small study cohort, there appears to be sustained improvement in nasal conductance of airflow up to 32 months follow-up. Although there was improvement in the subjective assessment of nasal obstruction, this did not achieve statistical significance.*

*Key words: nasal obstruction, turbinates, electrosurgery, treatment outcome*

### INTRODUCTION

Mucosal swelling of the turbinates is part of the physiologic vascular changes which take place during respiration as part of the nasal cycle<sup>(1)</sup>. Hyperactivity, infection and allergy may enhance these changes causing difficulty in nasal breathing. The severity of nasal obstruction was shown to be inversely proportional with measurements of nasal airflow in patients suffering with persistent allergic rhinitis<sup>(2)</sup>. Nasal obstruction as a consequence of enlarged inferior turbinates is a common problem as evidenced by the myriad of surgical techniques performed to reduce the inferior turbinate<sup>(3)</sup>. Coblation<sup>®</sup> technology is a relatively new technique which uses radiofrequency energy to excite the electrolytes in a conductive medium, such as saline solution, causing tissue to dissolve at relatively low temperatures (typically 40°C to 70°C)<sup>(4)</sup>. Coblation<sup>®</sup> inferior turbinate reduction (CITR) surgery has been suggested as an effective method of improving nasal obstruction, associated with few serious adverse effects<sup>(5)</sup>.

Short-term efficacy of CITR surgery was previously reported by this department<sup>(6)</sup>. Results at 3 months showed significant improvement in nasal resistance and visual analogue scale (VAS) scores for nasal obstruction, but no change in the reported severity of rhinorrhoea, nasal itching or sneezing. This article now presents long-term outcomes following surgery using both subjective and objective outcome measures in the same study cohort. A review of CITR surgery, with a focus on long-term outcomes, will also be presented.

### METHODS

#### *Ethical considerations*

The study was approved by the South East Wales Local Ethics Committee and the Cardiff and Vale National Health Service Trust Research and Development Office. All patients were provided with information about the study and gave full written informed consent. ArthroCare U.K. Ltd. (Harrogate, West Yorkshire, U.K.) provided the disposable surgical equipment and a small unrestricted grant to support this study.

Footnote: Presented at the British Rhinology Society 8<sup>th</sup> Annual Meeting, 15<sup>th</sup> May 2009, Cheltenham, England.

### Participants

Patients in this report were originally enrolled in a prospective, nonrandomized, unblinded, single centre trial. Patient recruitment, surgical technique and early outcomes have been described in the previous report<sup>(6)</sup>. Briefly, patients aged 18 years or more on the University Hospital of Wales waiting list for submucosal diathermy of the inferior turbinates were invited to participate in the study. Patients were screened and were excluded if a severe septal deviation or other condition that could cause nasal obstruction such as nasal polyps was present. Patients who fulfilled the entry criteria were assessed using subjective symptom severity scores and posterior rhinomanometry within 1 month of surgery. Surgery in all patients was performed in August 2006. Patients provided symptom severity scores and had nasal airflow measurement at two weeks, three months and eight months post-operatively before being discharged from further follow-up.

Patients were invited to return to the department in March 2009 for assessment. They were asked to refrain from taking nasal steroids or antihistamines within two weeks, nasal or oral decongestants within 24 hours, alcohol exceeding four units within 24 hours and any products containing menthol (such as menthol lozenges, chewing gum, confectionery containing peppermint) within four hours of the assessment date. Those who had suffered with an upper respiratory tract infection in the preceding two weeks before the assessment date were rescheduled to return in a fortnight.

Upon arrival at the Centre, all volunteers sat in the waiting area at the rhinology lab for a minimum of 30 minutes to acclimatize before assessment. Conditions at the rhinology laboratory were on average 22°C with a relative humidity of 40% throughout the study<sup>(7)</sup>. Patients completed the symptom severity scale scores prior to rhinomanometry.

### Symptom severity scales

A 100 mm VAS anchored by the descriptors 'nose completely clear' (0 mm) and 'nose completely blocked' (100 mm) was used to assess the present severity of nasal obstruction.

### Posterior rhinomanometry

Total nasal resistance of airflow was measured using posterior rhinomanometry using the NR6-2 rhinomanometer (GM Instruments, Kilwinning, Scotland, U.K.) at a sample pressure of 75 Pa. Data acquisition follows standard operating procedures of the centre which have been followed in previously published studies by the Centre<sup>(6-8)</sup>.

### Statistical analysis

Ohm's law was used for the conversion of total nasal resistance to total nasal conductance. The pressure (75 Pa) was divided by the resistance (Pa cm<sup>3</sup>/s) to give conductance in cm<sup>3</sup>/s. The Statistical Package for the Social Sciences (SPSS) version 11 for

the Macintosh was utilized for statistical analysis. Wilcoxon signed ranks test was used and a p value of ≤ 0.05 was deemed to be statistically significant.

### RESULTS

Of the original cohort of 18 patients (13 males, 5 females) who were studied, 13 (76%) were available at 32 months follow-up for analysis, all of whom completed VAS and posterior rhinomanometry. Two patients declined to attend follow-up, two patients had moved away from the region and one patient had further surgical treatment of the inferior turbinates in the preceding 3 months of this study. For comparison of pre- and post-operative outcomes, only data of the 13 patients were analyzed. Data on nasal conductance and VAS were available on all included patients at 3 months and 32 months follow-up, but at eight months, VAS was available for 11 patients and nasal conductance for only nine patients.

The total nasal conductance of each patient is illustrated in Figure 1. At long-term follow-up, 10 patients (77%) had demonstrated improvement compared to the pre-operative (baseline) nasal conductance. The total nasal conductance of one patient (screening number #4) had returned to baseline at 32 months follow-up despite showing improvement up to 8 months after surgery. Interestingly, the two patients (#16 and #22) who had poorer nasal conductance after surgery possessed the highest pre-operative nasal conductance amongst the 13 patients. In these two cases, the reduction in nasal conductance was most apparent by 3 months follow-up and appeared to have stabilized thereafter.

Overall, the mean baseline nasal conductance was 248.6 cm<sup>3</sup>/s (median 202.7, range 2.5-614.8). The mean nasal conductance 3 months after surgery was significantly greater (p = 0.004) than baseline values at 331 cm<sup>3</sup>/s (median 321.9, range 153.5-

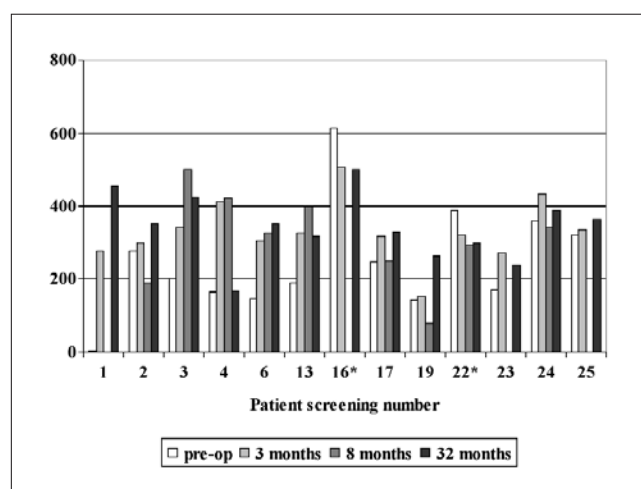


Figure 1. Changes in total nasal conductance pre-operatively, at 3 months, 8 months and 32 months follow-up (asterisk denote patients who had deterioration in post-operative total nasal conductance).

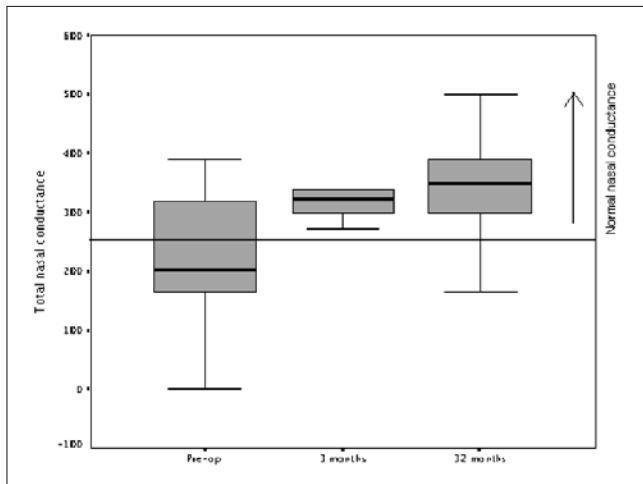


Figure 2. Box plots showing the effect of Coblation inferior turbinate surgery on total nasal conductance of airflow pre-operatively, at 3 months and 32 months follow-up. The median values are indicated by a thick black line and the interquartile range by the shaded box ranging from the 25<sup>th</sup> to the 75<sup>th</sup> percentile. The figure also illustrates a proposed cut off point for normal nasal conductance at 250 cm<sup>3</sup>/s<sup>(20)</sup>.

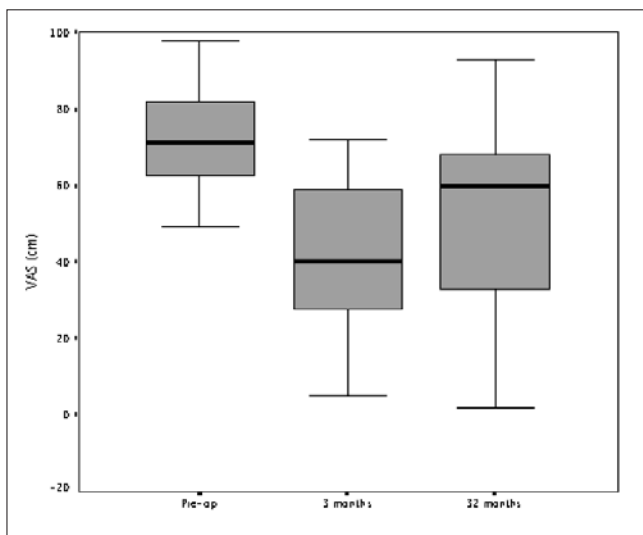


Figure 3. Changes in VAS score following Coblation inferior turbinate surgery at 3 months and 32 months follow-up compared to baseline.

506.8). At eight months, the mean total nasal conductance had reduced ( $p = 0.314$ ) by 26.2 cm<sup>3</sup>/s to 312.3 cm<sup>3</sup>/s (median 310.1, range 78-559.7). The mean total nasal conductance was 342.1 cm<sup>3</sup>/s (median 350.5, range 166.7-500) at 32 months (Figure 2). Compared to the baseline conductance, the mean increase of 93.5 cm<sup>3</sup>/s was statistically significant ( $p = 0.033$ ).

Improvement in the subjective sensation of nasal obstruction is indicated by a lower VAS score compared to baseline (Figure 3). The mean pre-operative VAS was 72 mm (median 71, range 49-98) which improved significantly ( $p = 0.006$ ) to 40 mm (median 40, range 5-72) at three months. The mean VAS score 8 months after surgery were 50 mm (median 65, range 6-83). At 32 months, 10 patients (77%) reported lower

VAS scores compared with baseline, of which nine had associated improvement in nasal conductance of airflow. One patient (#16) who reported subjective improvement in the severity of nasal obstruction had an 18.7% decrease in nasal conductance from baseline of 614.7 cm<sup>3</sup>/s. Of the remaining three patients who reported worsening nasal obstruction, two (#17 and #19) had improved and one (#4) had no change in nasal conductance. The overall mean VAS at 32 months was 53 mm (median 60, range 2-93) which was a 24% improvement from baseline. Although the VAS improvement at 3 months was significant, the VAS changes at 32 months did not achieve statistical significance when compared to pre-operative scores.

## DISCUSSION

Coblation<sup>®</sup> surgery is a method of improving nasal breathing by reducing the volume of the inferior turbinate. The submucosal technique works by reducing soft tissue bulk of the turbinate using low heat radiofrequency energy. According to Berger et al., the resultant vascular damage causes significant submucosal fibrosis, glandular and venous sinusoid depletion<sup>(9)</sup>. Evaluation of the inferior turbinates using magnetic resonance imaging has shown an average 8.7% reduction in turbinate volume following surgery<sup>(10)</sup>. One concern amongst surgeons is that despite an improvement in nasal conductance of airflow, the subjective sensation of nasal patency may be adversely affected by surgical damage to sensory nerves detecting nasal airflow given that significant fibrosis occurs secondary to vascular damage<sup>(9)</sup>. However, these histological changes are not exclusive to CTR surgery but have been demonstrated in other surgical techniques on the inferior turbinate<sup>(11,12)</sup>. These histological changes may result in damage to the cold receptors in the nasal mucosa causing diminution of post-operative sensation of airflow, but this hypothesis remains to be proven. Interestingly when compared to normal specimens, histological changes already occur in pre-operative patients suffering with chronic rhinitis where degeneration of epithelial cells, loss of cilia, disruption of intercellular architecture, edema, increased secretory activity and inflammatory infiltration have been demonstrated<sup>(13-15)</sup>. Nevertheless, surgery does improve the subjective perception of nasal airflow as evidenced in this study which may suggest that the histological damage from surgery is of little consequence or that the increase in airflow achieved with surgery outweighs any decrease in the sensation to nasal airflow caused by damage to sensory nerves.

Few studies have assessed long-term outcomes of CTR surgery beyond 12 months<sup>(16-18)</sup>. Subjective symptom assessments using either the Rhinosinusitis Symptom Inventory<sup>(16)</sup> score or VAS<sup>(18)</sup> showed significant improvement up to 12 months following surgery. Some authors have reported no significant improvement in nasal conductance to airflow during the early post-operative period<sup>(18)</sup>, which is in contrast to our previous report<sup>(6)</sup>. The longest follow-up period to date was

reported by Cavaliere et al. <sup>(19)</sup> who studied a cohort of 75 patients suffering chronic nasal obstruction which was refractory to medical treatment. At 20 months after CTR surgery, the mean VAS score for nasal obstruction had improved by 78% from pretreatment levels. Nasal conductance of airflow, measured by anterior rhinomanometry, improved by 34% at 20 months follow-up. The improvement in nasal conductance was maximal at 1 month but had appeared to diminish slightly and remained stable up to 20 months after surgery. The follow-up period of 32 months in the present study was significantly longer than all previously published reports. Both subjective and objective measures of nasal airflow were better than pre-treatment levels indicating that positive response to CTR surgery was sustained up to nearly 3 years.

Although there was an overall improvement in nasal conductance of airflow after CTR surgery (Figure 2), not all patients derived benefit from the procedure. Two patients (#16 and #22) had lower post-operative nasal conductance values at 3 months which persisted up to 32 months follow-up (Figure 1). If reduction in post-operative nasal conductance was regarded as failure of treatment, the failure rate in the present study was 15% and this was apparent by 3 months. The mixed response to CTR surgery in the present cohort may be due to how patients have been selected for surgery. The patients, invited to participate in this study, were already on the hospital waiting list for turbinate reduction surgery. They had previously been assessed and were offered surgery on the basis of subjective complaint of nasal congestion and clinical appearance of enlarged inferior turbinates. No other assessment modality, objective or subjective, was utilized to further support the decision to offer surgery in the first instance. In our previous report, we demonstrated a significant relationship between pre-operative nasal conductance of airflow and change in nasal conductance after surgery <sup>(6)</sup>. Patients who had low pre-operative nasal conductance experienced greater response to surgery (Spearman's correlation coefficient  $-0.57$ ,  $p = 0.014$ ). Normal nasal conductance is regarded to be  $250 \text{ cm}^3/\text{s}$  and above, which corresponds to a nasal resistance of less than  $0.3 \text{ Pa}/\text{cm}^3/\text{s}$  <sup>(20)</sup>. Five patients (#2, #16, #22, #24, #25) had pre-operative nasal conductance values within normal limits, which explains why the mean nasal conductance of the study cohort was near normal at  $248.6 \text{ cm}^3/\text{s}$ .

Given that turbinate enlargement may be due to the mucosal and/or osseous component, mucosal sparing methods such as Coblation<sup>®</sup> may not be an appropriate technique in cases where the osseous component is the primary reason for turbinate enlargement <sup>(21)</sup>. There is currently no consensus on appropriate clinical assessment of inferior turbinate enlargement. Most authors empirically offer turbinate reduction surgery on the basis of subjective patient complaint of nasal obstruction and the appearance of enlarged inferior turbinates after a period of unsuccessful medical treatment. Seeger et al.

<sup>(22)</sup> had suggested using a topical vasoconstrictor to determine the degree of turbinate decongestion, measured by acoustic rhinometry to select suitable patients for surgery. However, the degree of improvement in the minimum cross-sectional area as a prerequisite for surgery was not described. Other authors have excluded patients from turbinate surgery on the basis of having less than 35% decrease in unilateral nasal resistance at rhinomanometry after application of a topical decongestant <sup>(23,24)</sup>. The low response in nasal resistance was attributed to the presence of structural abnormalities such as septal deviation, conchal hypertrophy or conchal bullosa.

Patients in this study were given detailed instructions about stopping selected medication, confectionery and alcohol prior to attending the Centre. Given that various medications and conditions such as the common cold may affect nasal airflow assessments, we believe the follow-up protocol in the present study was robust and that the results were representative of the patients' true condition after surgery. To our knowledge, no other studies have utilized such prescribed criteria for follow-up assessment and attention is drawn to the importance of minimizing any factors which may affect the assessments of nasal airflow. For example, mentholated products such as chewing gum and lozenges may result in symptomatic improvement of nasal obstruction but no improvement in nasal resistance to airflow <sup>(25)</sup>. Furthermore, it is important to allow sufficient time for the patients to acclimatize to the conditions of the laboratory to minimize any mucovascular variations attributable to the decongestive effect of physical exercise. Analysis of long-term data should ideally be restricted to only those patients who had attended the final assessment, as was done in this study. Some attrition of the study cohort occurs over time and this is to be expected. Comparison with pretreatment data may be distorted if this is not taken into account. For example, the VAS and nasal conductance were significantly higher at 32 months if data of all 18 patients from the original cohort was used.

This was a pilot study on the long-term efficacy of CTR surgery using VAS and posterior rhinomanometry. We acknowledge that the small study cohort and the lack of a control cohort to compare the natural history of patients suffering with chronic nasal congestion may be regarded as shortcomings of this study. Nonetheless, it would appear that the benefits are maintained nearly three years after surgery. The mean nasal conductance to airflow remained statistically higher than pre-operative levels. The subjective assessment of nasal obstruction did not achieve statistical significance although an improvement was demonstrated in this study. Indeed, larger cohort studies of similar follow-up duration would be required to facilitate comparison with other techniques and meta-analysis of outcomes. Response to turbinate surgery can be further enhanced by appropriate patient selection but no gold standard criteria currently exist. We also recommend a combination of

subjective and objective measurements, such as posterior rhinomanometry and visual analogue scale, to be used to assess outcome in the post-operative period.

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Conflicts of interest: None.

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