What has NAIROS taught us about septoplasty?

BY SEAN CARRIE AND JAMES O'HARA

Septoplasty is a commonly performed procedure worldwide for nasal obstruction associated with a deviated nasal septum. In the UK, with long waiting lists for septoplasty, there is a large and unexplained variation in the incidence of this procedure between individual NHS ENT providers, by as much as a factor of five [1]. Consequently, questions are raised about its rationale and value. Indeed, until recently, there were no definitive guidelines on patient selection for surgery. Generally, the decision to perform septoplasty is made on clinical grounds through history and an 'eyeball assessment' of airflow and Thudicum speculum examination of the anterior nares, supplemented by an endoscopic examination of the nasal passages. In a minority of healthcare systems, objective assessment of the nasal airway such as rhinomanometry or acoustic rhinometry is undertaken but the evidence underpinning such assessments in septal surgery assessment can be conflicting.

In the UK, concerns regarding surgical efficacy and cost effectiveness mean that access to septoplasty surgery is subject to geographic variation. In many instances, a six-month trial of nasal steroid treatment in primary care is required before sanctioning referral to secondary ENT services. A 2015 US-based clinical consensus statement agreed a trial of medical therapy with nasal steroid spray was not mandatory because some patients' septal deviation is so severe that nasal sprays cannot penetrate the airway [2]. Rudy et al (2019), in a single central, placebo controlled double-blind trial of 42 patients found no significant effect of intranasal steroids on nasal obstruction compared with placebo [3].

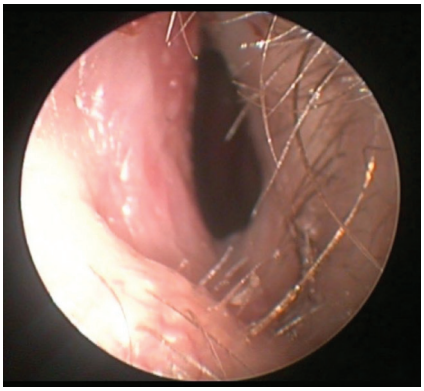

Figure 1: Clinical example of deviated septum into left nostril.

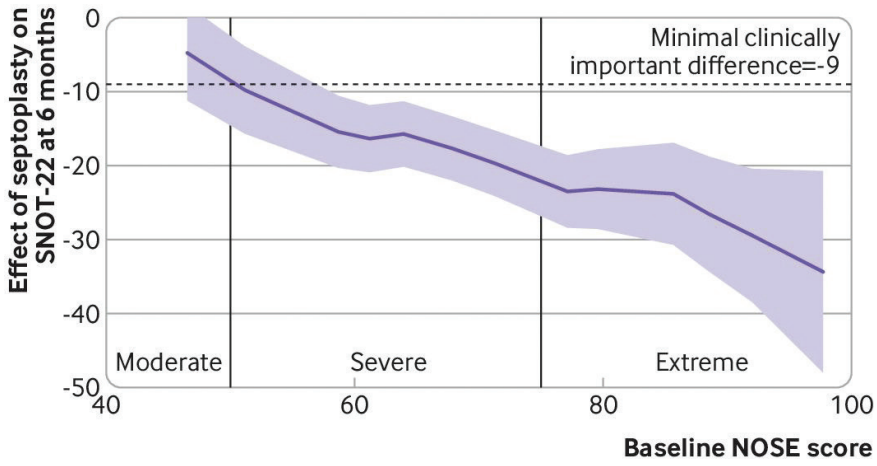

Figure 2: STEPP analysis. Reproduced with permission from the BMJ [4]. Outcome data using subpopulation treatment effect pattern plot to assess individual changes in SNOT-22 scores from baseline to six months. Purple line shows average effect of being randomised to septoplasty for those with specific NOSE scores at baseline, and shading represents 95% confidence intervals. Minimal clinically important difference is nine points on SNOT-22. NOSE=Nasal Obstruction and Symptom Evaluation; SNOT-22=Sino-Nasal Outcome Test-22.

The results of the Nasal Airway Obstruction Study (NAIROS) trial were published in the *BMJ* in October 2023 [4]. This trial was commissioned by the National Institute for Health and Care Research (NIHR) to assess the clinical and cost effectiveness of septoplasty across 17 secondary UK NHS hospitals. Participants, ≥18 years referred with symptoms of nasal obstruction associated with deviated nasal septum, were offered entry into the trial if their Nasal Obstruction and Symptom Evaluation (NOSE) score was ≥30, differentiating patients with nasal obstruction from those without. Patients were randomised to either septoplasty with or without turbinate reduction, (+/- IT reduction) or medical management, stratified by sex and baseline severity. The primary outcome measure was the SNOT score at six months post randomisation. Six months allowed for postoperative healing to settle, minimised default and reduced the effect of patients crossing over from the conservative to the surgical group. Those randomised to septoplasty underwent a semi-standardised surgical procedure, allowing for unilateral IT reduction on the wider side at the discretion of the surgeon, reflecting the considerable variation in UK practice. Medical management participants were treated with six months of Mometasone furoate nasal steroid spray and Sterimar spray twice daily. As such, NAIROS is the first RCT to directly compare septoplasty to nasal steroid / saline sprays.

Patient-reported symptoms improved in both groups. On average, the septoplasty group reported 20.0 units greater improvement in SNOT22 compared to those randomised to medical management (a minimum clinically important difference of nine points had been used in the design of the trial). Improvements were noted in all four domains of the SNOT22 score: nasal, sleep, aural and psychological. The improvement in SNOT22 scores in the septoplasty group remained at 12 months, although the average difference in SNOT22 between the two groups fell to 10.1 units, which may reflect the effect of patients crossing over randomised groups to receive a septoplasty. A Dutch national RCT of septoplasty published in 2019 similarly concluded septoplasty was more effective than non-surgical management [5].

Previous studies have identified the impact of preoperative symptom severity on septoplasty outcomes. NAIROS modelling (STEPP analysis) assessed the improvements in SNOT22 in the surgery group as a relation to the baseline NOSE score (Figure 2). Participants with a preoperative NOSE score of up to 50 had

Table 1: Complications of Septoplasty. Reproduced with permission from NIHR [6].	
Complication	**Rate**
Bleeding requiring readmission to hospital	4%
Infection requiring antibiotic treatment	12%
Reduced sense of smell	11%
Change in appearance of the nose	10%
Dental numbness	11%
Other complications	4%
Perforation of septum*	3%
Adhesions*	4%
* Assessed by nasal endoscopy	

an improvement of 10 units compared to medical management; those with a score of 60 improved by 15 units whereas those with more extreme baseline NOSE scores improved by up to 30 units.

This analysis allows surgeons to quantify expected improvements in patients undergoing septoplasty predicated on taking a baseline NOSE score. As such, the NAIROS team recommend performing nasal endoscopy and NOSE score assessment as part of surgical selection criteria. Participants with the most severe symptoms (NOSE >55) before treatment showed most improvement, a useful finding to inform septoplasty counselling. People with moderate symptoms (NOSE 30-50) may be less likely to benefit meaningfully from septoplasty, and a more careful / guarded discussion about outcomes is required.

NAIROS cannot comment on the impact of IT reduction in addition to septoplasty. IT reduction was not related to the SNOT 22 outcome on univariate analysis, but that does not mean it may have no additional benefit; IT reduction was not randomised. Enlarged turbinates may therefore have been reasonably treated at the surgeons' discretion. Further RCTs are required to define the impact of IT reduction on septoplasty.

Patients should understand the risks of surgery. During the trial, complications of septoplasty were recorded and shown in Table 1. The rates are somewhat higher than in previous studies, a reflection of the rigorous participant assessment at data timepoints, postoperatively.

Surgical RCTs have limitations in their generalisability to clinical practice. Selection bias and operative technique standardisation are well recognised issues. In particular, the lack of a universally accepted classification of septal deformity extent and site meant NAIROS could not predict which types of deformity are best served by septoplasty. Additionally, the impact of nasal valve collapse was not assessed and allergic rhinitis not measured, however, this was mitigated by the randomisation process of patients to two groups.

In summary NAIROS, a large multicentre RCT, analysed over 378 patients demonstrating superiority of septoplasty over medical management, with improvements in nasal obstruction and quality of life. It provides novel data to translate into day-to-day clinical practice to improve the quality of discussion with patients about potential outcomes of surgery and the risks, both short and medium term, of septoplasty.

References

1. ENT UK. Waiting times in ENT- a new year update from GIRFT. 2024. https://www.entuk.org/news_and_events/news/303/waiting_times_in_ent_a_new_year_update_from_girft/ [Last accessed September 2024].
2. Han JK, Stringer SP, Rosenfeld RM, et al. Clinical Consensus Statement: Septoplasty with or without Inferior Turbinate Reduction. *Otolaryngol Head Neck Surg* 2015;**153(5)**:708–20.
3. Rudy SF, Kandathil C, Spataro EA, et al. Effect of Nasal Steroids on Nasal Obstruction in Septal Deviation: A Double-Blind Randomized Controlled Trial. *Facial Plast Surg Aesthet Med* 2020;**22(4)**:243–8.
4. Carrie S, O'Hara J, Fouweather T, et al. Clinical effectiveness of septoplasty versus medical management for nasal airways obstruction: multicentre, open label, randomised controlled trial. *BMJ* 2023;**383**:e075445.
5. van Egmond MMHT, Rovers MM, Hannink G, et al. Septoplasty with or without concurrent turbinate surgery versus non-surgical management for nasal obstruction in adults with a deviated septum: a pragmatic, randomised controlled trial. *Lancet* 2019;**394(10195)**:314–21.
6. Carrie S, Fouweather T, Homer T, et al. Effectiveness of septoplasty compared to medical management in adults with obstruction associated with a deviated nasal septum: the NAIROS RCT. *Health Technol Assess* 2024;**28(10)**:1–213.

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