

# The use of internal nasal dilators to improve breathing and symmetry after rhinoplasty surgery

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<b>Registration date</b> 04/11/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/11/2025	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Some people who have nose reshaping surgery (rhinoplasty) find it harder to breathe or notice that their nostrils look uneven while they heal. This study looked at whether using a small, soft device placed inside the nose could help improve breathing comfort and make the nostrils look more even during recovery.

### Who can participate?

Adults who had septorhinoplasty (a type of nose surgery that includes reshaping the septum) at Southlake Regional Health Centre in Ontario, Canada, were invited to take part.

### What does the study involve?

Participants were randomly placed into one of two groups. One group used a soft silicone nasal device inside their nose for one week all day, and then only at night for three months. The other group received standard care without the device. Everyone had the same surgery and follow-up visits. Participants filled out surveys about their breathing and how their nose looked before surgery, and again at 3 and 12 months after surgery.

### What are the possible benefits and risks of participating?

The nasal device may help improve breathing and nostril appearance during healing. The study also looked at how comfortable the device was and whether it caused any side effects. Risks were expected to be low, but any discomfort or issues with the device were recorded.

### Where is the study run from?

The study was carried out at Southlake Regional Health Centre in Ontario, Canada.

### When is the study starting and how long is it expected to run for?

The study began in December 2022 and is expected to finish in May 2025.

### Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Raisa Chowdhury, [raisa.chowdhury@mail.mcgill.ca](mailto:raisa.chowdhury@mail.mcgill.ca)

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

The functional and aesthetic effects of internal nasal dilator device use following septorhinoplasty: a randomized, single-blinded controlled trial

### Acronym

IND-R Trial

### Study objectives

Primary Objective:

To determine whether the use of an internal nasal dilator (IND) during the postoperative healing period after septorhinoplasty improves patient-reported nostril symmetry compared with standard postoperative care alone.

Secondary Objectives:

1. To assess whether IND use enhances functional breathing outcomes as measured by the functional domain of the Standardized Cosmesis and Health Nasal Outcomes Survey (SCHNOS).
2. To evaluate aesthetic satisfaction and overall quality of life using the SCHNOS aesthetic

domain and total score.

3. To measure device comfort, adherence, and safety, including incidence of mucosal irritation, ulceration, or infection.

4. To explore whether baseline characteristics (e.g., presence of rhinitis, surgical indication, or approach) influence the functional or aesthetic effects of IND use.

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

approved 01/12/2022, Southlake Regional Health Centre Research Ethics Board (596 Davis Dr, Newmarket, L3Y 2P9, Canada; +1 (905) 895-4521; moreinfo@ontariohealthathome.ca), ref: S-015-2223

### **Study design**

Randomized single-blinded parallel-group controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Postoperative nasal obstruction and nostril asymmetry after septorhinoplasty (rhinoplasty). The study examines whether internal nasal dilators improve functional breathing outcomes and aesthetic nasal symmetry during postoperative healing.

### **Interventions**

Participants in the intervention group received a soft, silicone internal nasal dilator inserted on postoperative Day 3 and worn continuously for 1 week, then nightly through 3 months, in addition to standard postoperative care. The control group received standard care alone. The device was intended to support the internal nasal valve, improve breathing, and maintain nostril-base symmetry during healing. The study used a 1:1 randomized, single-blinded, parallel-group design with follow-up to 12 months.

Participants were randomized 1:1 to the internal nasal dilator plus standard care group or standard care only using a computer-generated randomization sequence. Allocation concealment was maintained using sequentially numbered, sealed opaque envelopes prepared by an independent coordinator who was not involved in participant recruitment, surgery, or data analysis.

### **Intervention Type**

Device

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Internal nasal dilator

### **Primary outcome(s)**

Patient-reported nostril symmetry measured using a 5-point Likert scale (0 = perfectly symmetrical; 4 = very asymmetrical) at 3 and 12 months after septorhinoplasty

### **Key secondary outcome(s)**

1. SCHNOS functional domain scores (nasal breathing) at baseline, 3, and 12 months.
2. SCHNOS aesthetic domain scores at baseline, 3, and 12 months.
3. Total SCHNOS score combining functional and aesthetic domains at baseline, 3, and 12 months.
4. Device comfort rated on a 10-point VAS at 1 week and 3 months.
5. Incidence of device-related or postoperative adverse events (irritation, ulceration, infection) through 12 months.

### **Completion date**

01/05/2025

## **Eligibility**

### **Key inclusion criteria**

1. Adults aged 16–55 years undergoing primary open or closed septorhinoplasty (cosmetic, functional, or combined)
2. Provide informed consent
3. Able to complete questionnaires in English or French
4. Comply with scheduled follow-up visits at baseline, 3 and 12 months

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

16 years

### **Upper age limit**

55 years

### **Sex**

All

### **Total final enrolment**

112

### **Key exclusion criteria**

1. Cleft-related nasal deformities
2. Planned alar base reduction
3. Revision rhinoplasty

4. Prior nasal surgery
5. Psychiatric or cognitive disorders affecting compliance
6. Concurrent use of internal nasal stents
7. Active nasal infection
8. Silicone allergy
9. Pregnancy or lactation

**Date of first enrolment**

15/01/2023

**Date of final enrolment**

30/06/2023

## **Locations**

**Countries of recruitment**

Canada

**Study participating centre**

**Southlake Regional Health Centre, Department of Otolaryngology–Head and Neck Surgery**

596 Davis Drive

Newmarket

Canada

L3Y 2P9

## **Sponsor information**

**Organisation**

Southlake Regional Health Centre – Research Ethics Board

## **Funder(s)**

**Funder type**

Not defined

**Funder Name**

Investigator initiated and funded

## **Results and Publications**

## Individual participant data (IPD) sharing plan

Individual participant data will not be shared publicly. De-identified data may be available upon reasonable request to the corresponding author, in accordance with institutional and ethics board policies.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>			04/11/2025	No	No