ISRCTN13835640 https://doi.org/10.1186/ISRCTN13835640

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

Submission date
03/11/2025

Recruitment status
No longer recruiting

Registration date
04/11/2025

Overall study status
Completed

Last Edited
04/11/2025

Condition category
Surgery

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Ms Raisa Chowdhury

ORCID ID
https://orcid.org/0009-0000-5433-5808

Contact details
6553 Rue Léon Derome
Montréal
Canada
H1M 1S3
5148063787
raisa.chowdhury@mail.mcgill.ca

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
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?
Protocol file			04/11/2025	No	No