# Study Protocol

**Title:** *Internal Nasal Dilators After Rhinoplasty: A Randomized Trial on Functional and Aesthetic Outcomes*

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**Collaborating Institutions:**

- Southlake Regional Health Centre, Newmarket, Ontario, Canada
- University of Toronto, Department of Otolaryngology–Head and Neck Surgery
- Ministry of Health, Kuwait
- King Saud Medical City, Riyadh, Saudi Arabia
- Mutah University, Karak, Jordan

**Ethics Approval:**
Approved by Southlake Regional Health Centre Research Ethics Board (Protocol S-015-2223). All participants provided written informed consent.

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## 1. Background and Rationale

Rhinoplasty is one of the most common facial plastic procedures, with postoperative nasal obstruction and nostril asymmetry remaining key sources of patient dissatisfaction. Early healing changes at the internal nasal valve and soft-tissue support can lead to transient collapse and resistance.
Internal nasal dilators (INDs) are silicone devices designed to stent the nasal valve area temporarily, maintaining airway patency and structural balance. Although effective in nonsurgical populations, their role after rhinoplasty has not been systematically studied.
This trial evaluates whether postoperative IND use improves functional and aesthetic outcomes as measured by validated patient-reported instruments.

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## 2. Objectives

- **Primary Objective:** To assess whether postoperative use of internal nasal dilators improves patient-reported nostril symmetry compared with standard care alone.
- **Secondary Objectives:** To evaluate changes in functional and aesthetic outcomes using the Standardized Cosmesis and Health Nasal Outcomes Survey (SCHNOS), as well as patient comfort, adherence, and adverse events.

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## 3. Study Design

Randomized, single-blinded, parallel-group, single-center clinical trial.

**Level of Evidence:** 2 (Therapeutic).

**Randomization and Allocation Concealment:**
Participants were randomized 1:1 to the intervention or control group using a computer-generated sequence. Allocation was concealed in sequentially numbered, sealed opaque envelopes prepared by an independent coordinator not involved in recruitment, surgery, or outcome assessment.

**Blinding:**
Outcome assessors and data analysts were blinded to group assignment. Participants were aware of whether they received the device.

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## 4. Study Population

**Inclusion Criteria:**

- Adults aged 16–55 years
- Undergoing primary open or closed septorhinoplasty
- Ability to provide informed consent

**Exclusion Criteria:**

- Cleft-related deformities or prior nasal reconstruction
- Planned alar base reduction
- Psychiatric conditions affecting compliance
- Use of non-study internal stents

**Sample Size:** 128 participants (64 per arm). Power analysis indicated this provides 80% power ($\alpha = 0.05$) to detect a medium effect size (Cohen's $d = 0.5$) in patient-reported outcomes.

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## 5. Interventions

- **Experimental Group:** Internal nasal dilator (silicone, size-customized) plus standard postoperative care. Patients were instructed to wear the device continuously from postoperative day 3 for 1 week, then nightly through 3 months.
- **Control Group:** Standard postoperative care without internal nasal dilator use.
- **Standard Care:** Antibiotic ointment, saline irrigation, and taping per surgeon protocol.

## 6. Outcomes

**Primary Outcome:**

- *Nostril symmetry* (0–4 Likert scale; 0 = perfect symmetry, 4 = very asymmetrical) at 3 and 12 months postoperatively.

**Secondary Outcomes:**

- Functional and aesthetic SCHNOS scores (validated English/French versions).
- Comfort with device (10-point visual analog scale).
- Adverse events (e.g., mucosal irritation, ulceration, infection).

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## 7. Data Collection and Follow-up

Data collected at baseline, 3 months, and 12 months (±2 weeks).
Retention and compliance assessed by patient logs and clinic checks.

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## 8. Statistical Analysis

- Between-group differences analyzed using t-tests or nonparametric equivalents.
- Repeated-measures mixed-effects model tested the interaction between group and time, adjusting for age, sex, surgical approach (open vs closed), and rhinitis history.
- Two-sided $p < 0.05$ considered significant.
- Analyses conducted on an intention-to-treat basis.

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## 9. Safety Monitoring

Adverse events were documented at each follow-up. No independent Data Safety Monitoring Board (DSMB) was required due to minimal-risk intervention.

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## 10. Data Management and Confidentiality

All data were anonymized and stored in password-protected institutional databases. Only authorized study personnel had access.