**Introduction**

Nasal congestion affects roughly 20% of the worldwide population.1 Nasal congestion can be associated with allergic rhinitis and chronic rhinosinusitis (CRS). Depending on the symptoms and diagnostic criteria, allergic rhinitis affects up to 10-20% of the population,2 and while some overlap is present, CRS affects approximately 5-12% of the population.3

The internal nasal respiratory surfaces are lined by pseudostratified, ciliated, columnar epithelium. A thin, liquid layer lines the upper and lower respiratory tract airway epithelium. This thin, liquid layer is comprised of a pericilial, or sol layer, surrounding the cilia and overlaying the airway mucosa, and an overlying mucus gel blanket facing the airway lumen.4 The airway surface liquid layer hydration and mucociliary clearance are influenced by the airflow-induced shear stress and transepithelial pressure gradients generated by tidal breathing.5  In cystic fibrosis sputum samples, oscillatory therapy can break down high-molecular-weight DNA and decrease mucus viscoelasticity.6 Airflow oscillation may reduce mucus viscoelasticity and enhance mucus clearance.7

Nitric oxide (NO) is produced in the ciliated epithelial cells The paranasal sinuses are a rich endogenous NO source.8,9 Intranasal NO increases nasal blood flow and mucociliary activity.10,11 Humming with the lips closed increases nasal NO levels.12 A randomised controlled study involving sixty people with CRS found that regular humming, as assessed by the Sino-Nasal Outcome Test- 22 (SNOT-22) score, is beneficial in CRS management.13 In a pilot study, a SinuSonic device, which combines acoustic vibration with oscillating expiratory pressure at approximately 128 Hz, improved visual analogue scale (VAS) symptoms of nasal congestion.14 After 2 and 5 weeks of twice-daily treatments, the SinuSonic device improved peak nasal inspiratory flow (NPIF), Total Nasal Symptom (TNS), Nasal Obstruction and Septoplasty Evaluation (NOSE), and SNOT- 22 scores.15

Based on the above observations, a small nasal airflow oscillation device that plugs into the nose to create nasal pressure oscillations at 130 Hz has been developed. Unlike unassisted humming, which can only be done during exhalation and the SinusSonic device, this technology also creates pressure oscillations during inhalation, enabling endogenous NO to be drawn into the airways, rather than mainly exhaled and lost. The purpose of this study is to assess the acceptability and safety, and possible efficacy of this small nasal airflow oscillation device in subjects suffering nasal congestion.

**Subjects and Methods**

Subjects with a known history of persistent nasal congestion, will be approached, and invited to participate. Inclusion criteria are adults aged from 18-80 years with a history of chronic nasal congestion for more than one year. Exclusion criteria include cigarette smoking, a fixed structural cause of nasal congestion (moderate or severe septal deviation), moderate or severe nasal valve collapse, Grade 2-4 polyps, recent upper respiratory illness, nasal decongestant use within the last week, nasal crusting or ulceration on rhinoscopy, a history of severe nose bleeding within the last 3 months, anticoagulant use, known pregnancy, allergic sensitivity to silicone or any other component of device, and inability to read and understand English. All subjects will be provided with written informed consent in accordance with the Health and Disability Ethics Committee (21/CEN/99) and a Universal Trial Number has been obtained (U1111-1259-0704).

All subjects will be evaluated at baseline by an otolaryngologist (JB), who will assess the subjects’ past medical history, and perform rhinoscopy to screen for exclusion criteria. Those patients with prior positive allergen-specific immunoglobulin E (IgE) testing or positive skin testing for environmental allergens will be considered to have allergic rhinitis. Patient demographics and the use of medications for rhinitis symptoms (nasal steroid sprays, nasal antihistamines, oral antihistamines, mucolytics and leukotriene modifiers) will be recorded.

**Baseline assessments**

After initial rhinoscopy, baseline nasal peak inspiratory flow (NPIF) will be performed on each subject.16 The otolaryngologist (JB) will train each patient to perform NPIF. After an initial training run, three runs will be then performed, averaged, and recorded in litres/ minute (L/ minute). Subjects will then be asked to rate individual nasal symptoms including overall sinonasal symptoms using a 10-point visual analogue scale (VAS), with higher scores generally representing greater symptom burden. However, a higher VAS smell score represents a higher sense of smell. The principal investigator will discuss the prototype status of the current device, and the experimental nature before asking the subject to trial it. The subject will then asked to rate their initial experience of breathing at rest on a 1-10 scale (10 is easiest) while wearing the device. The subject will then be asked to wear the device for 20 minutes. The device will then be removed. NPIF will then be repeated on three occasions, averaged, and recorded in L/ minute. The otolaryngologist will the repeated the rhinoscopy. Patients will then re-rate their nasal symptoms using the 10-point VAS.

**Statistical Analysis**

Data will be analysed for within subject differences using basic statistical tests of relationship and difference using two-sided t-tests. A value of p < 0.05 will be considered statistically significant.

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