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ORIGINAL RESEARCH—SLEEP MEDICINE

Clinical evaluation of a novel internal nasal dilation stent for the improvement of nasal breathing

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OBJECTIVE: This study assessed rhinometric improvement in nasal airflow, perceived comfort, and the utility of nasal dilation devices for individuals with nasal obstruction treated with an external nasal dilator (END) or a novel internal nasal dilation stent (INDS).

STUDY DESIGN: Prospective, randomized, crossover trial.

SUBJECTS: Individuals with symptoms of nasal obstruction.

METHODS: Twenty-three participants underwent rhinometry and a trial with a novel INDS and a validated END. Devices were used in a randomized, crossover fashion. Nasal airflow, maximum use, continuous use, comfort, and challenge with these devices were assessed.

RESULTS: The END and INDS showed greater nasal airflow from baseline, with the INDS being significantly better than the END. The INDS was used significantly more than the END, and demonstrated significantly greater comfort and less associated challenge.

CONCLUSIONS: The novel INDS showed 3.4 times improved nasal airflow from baseline, was used maximally and continuously longer than a validated END, and was judged to be significantly more tolerable.

Subjective nasal obstruction is a common problem that has been shown to impact on mood, energy, recreation, sleep, and overall quality of life.[1-4] Although the cause and level of severity of the obstruction are varied, the final common pathway is a reduction in nasal airflow.[5] Poiseuille's law identifies the radius of the nasal passage as being the most important variable in nasal airflow,[6] and thus highlights the role of the internal nasal valve in nasal obstruction.[7-10]

Many therapies have been described for improving nasal airflow. One such treatment is the use of nasal dilators. Both internal and external nasal dilators have been described with the bulk of the literature focusing on an external nasal dilator (Breathe Right nasal strip, GlaxoSmithKline, Brentford, Middlesex, United Kingdom). This dilator increases the nasal valve area via the transmittance of an indirect lateralizing force across the skin of the nasal alae. Because the nasal valve is not being directly stented, the strip may not completely dilate the valve. Other concerns with this device are the visibility of the strip, dermatitis from the tape, and potential loosening, and hence, loss of lateralization force on the strip due to variability in skin type and perspiration.

A more direct treatment of the nasal valve involves the use of an internal nasal dilator. This dilator applies a direct outward force on the internal nasal valve, thus increasing the cross-sectional area of the valve. Of the available devices, the Nozovent (Scandinavian Formulas, Sellersville, PA) and Nasanita (Siemens and Co, Bad Ems, Germany) are best described.[10,11] Both devices have shown improvement in nasal airflow among healthy subjects with no predilation symptoms of decreased nasal breathing.[11-14] Although these nasal devices demonstrate efficacy, few devices have come to market. Perhaps one reason for this limitation pertains to issues of patient comfort. At present there has been little research related to measures of wearer comfort in the use of nasal dilation devices; when it has been considered, data have suggested some level of discomfort with their use.[11] Thus, although internal nasal dilation devices may be effective, further research directed at their comfort is essential.

To date, there has been no study that compared the perceptions of wearer comfort with assessments of nasal airflow. Furthermore, there is no comparative information between an internal nasal dilation device and external nasal dilators among individuals with subjectively poor nasal breathing. Given the paucity of research in these areas, the purpose of this study was to compare comfort, utility, and objective rhinometric improvement in nasal airflow among individuals with poor nasal breathing treated with an external nasal dilator or a novel internal nasal dilation stent. In addition, this study proposed a novel assessment instrument for investigating wearer tolerance when using nasal dilation devices.

MATERIALS AND METHODS

Ethics approval was obtained via the University of Western Ontario Health Sciences Research Ethics Board (Review 13513E).

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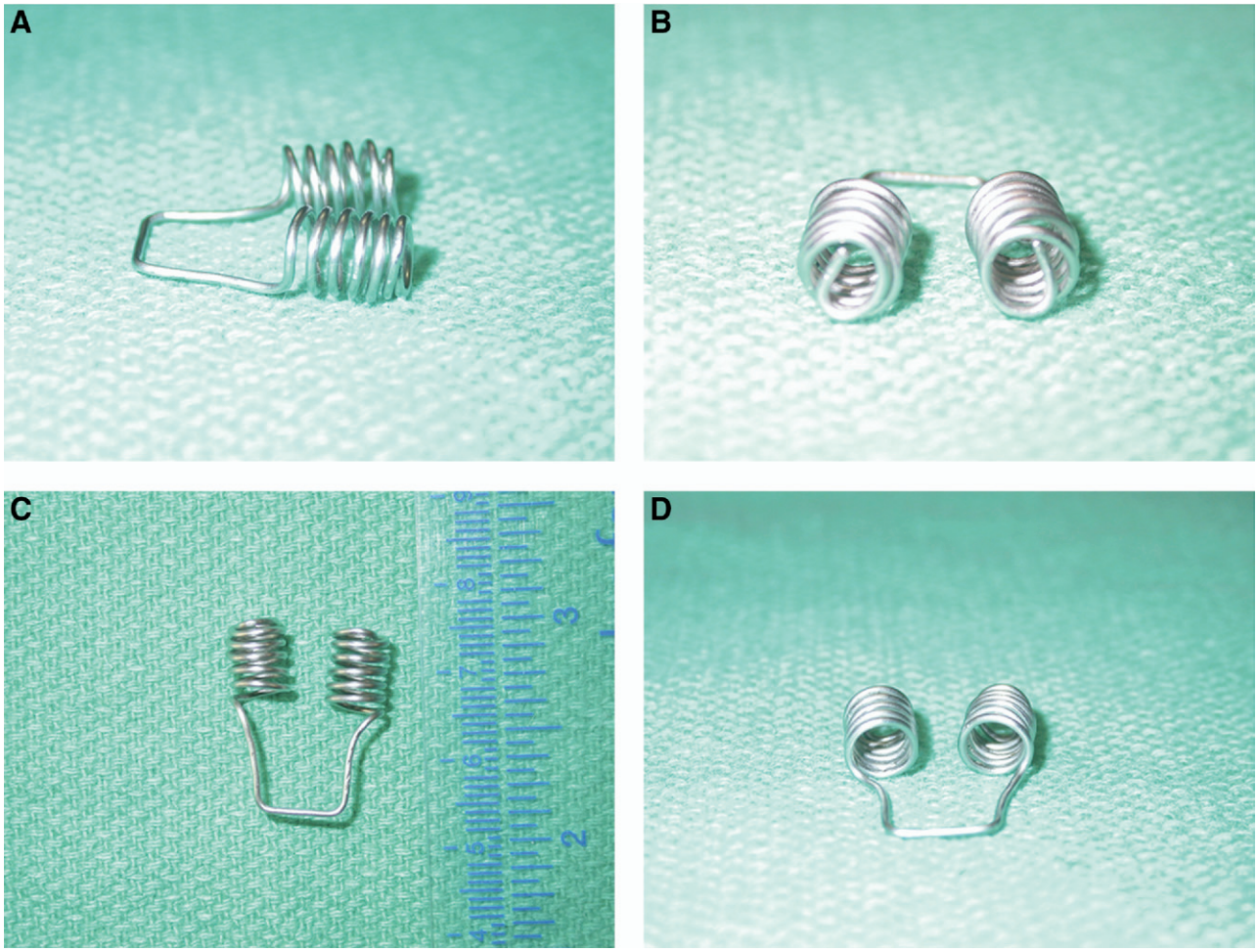

Figure 1 Images of the internal nasal dilation stent (INDS) device from various perspectives: **(A)** lateral, **(B)** superior, **(C)** anterior, **(D)** inferior.

Device Description

A novel internal nasal dilation stent (INDS) was designed (CCM, MGB). This device consists of a conjoined set of stainless steel springs (Figs 1 and 2) designed to apply even pressure to the internal nasal valve, while dispersing the point of contact to minimize potential mucosal irritation and discomfort. Correct placement of the device is controlled via a bridge between the conjoined springs ensuring proper location and limiting the depth of insertion. The device was not submitted to the Health Canada or the U.S. Food and Drug Administration for approval at the time of this study (Class I device), and no patent

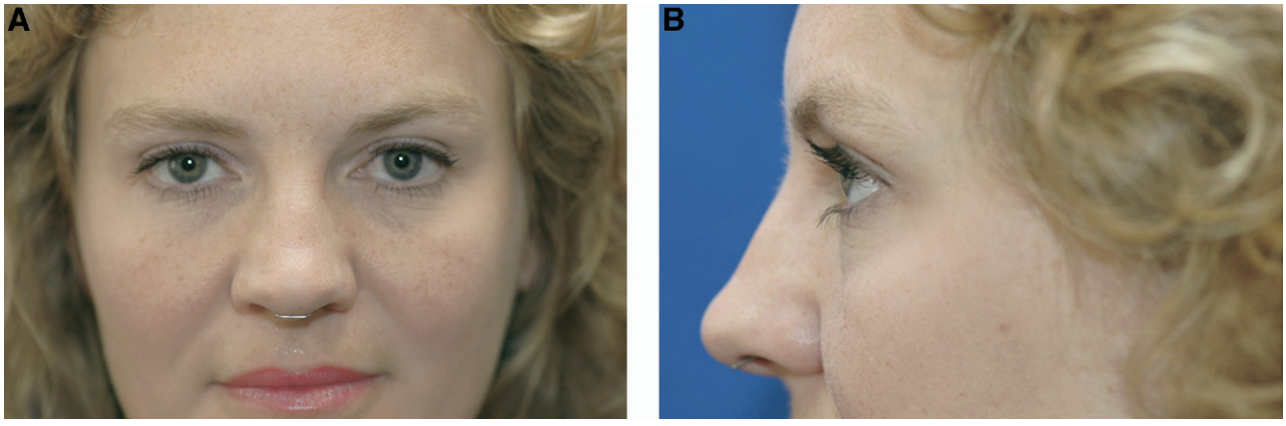

Figure 2 Images of the INDS device in use: **(A)** anterior, **(B)** lateral.

was held for the device during the administration of the study.

Given the potential for a conflict of interest, an independent study administrator (clinical nurse) was chosen to coordinate the study. This individual demonstrated the application of the devices, randomly assigned the participants to experimental conditions, assigned coded data collection sheets, and retained all study data until the completion of the study.

Development of Scale to Evaluate Comfort and Challenge

The comfort and challenge questionnaire, termed the "Western Nasal Dilation Tolerance Scale" (WNDTS), was developed based on the Voice-Related Quality of Life (V-RQOL) instrument by Hogikyan et al.[15] An example of the WNDTS appears in the online Appendix (www.http://journal.entnet.org). The face validity of measuring the concepts of "comfort" and "challenge" was considered through a literature review and clinical observations. Following this determination, a series of questions was developed and evaluated for content validity to insure that both constructs (ie, comfort and challenge) were adequately and explicitly addressed. The questions were then re-evaluated for both importance and redundancy and thus further refined. As a result, the WNDTS emerged as a ten-item tool that addresses two subdomains of assessment. The first subdomain is termed "Patient Comfort" and consists of six questions that generally pertain to perceived levels of comfort when wearing a device. The second subdomain, "Patient Challenge," is composed of four questions; these questions were included to obtain information on perceived challenge experienced by the wearer. These two subdomain scores also can be used to calculate a total score termed "Overall Tolerance" that reflects both areas of concern. Regardless of whether a single subdomain or the entire tool is used, the scoring procedure is designed such that a higher raw score will reflect a less favorable outcome, and thus yield a lower transformed score (ie, greater challenge with a device would yield a higher raw discomfort score and would transform to a score reflecting less perceived comfort).

Participants

Participants included adult (≥18 years of age) individuals with symptoms of decreased nasal breathing referred to a tertiary care otolaryngology clinic. Patients with obstructive nasal pathology (ie, septal deviation, rhinosinusitis) were included, and no other treatments (ie, steroids) were provided. Patients were excluded from participation if they had any significant nasal pathology such as nasal tumor or polyposis. The study administrator discussed the study with potential participants, informed them that the INDS device had not yet been submitted to Health Canada or the U.S. FDA for formal approval, and obtained written informed consent.

Study Protocol

Twenty-three individuals participated in the study. Each underwent rhinometry by an independent rhinometry technician (Toronto Rhinometry System Head-Out Body Plethysmograph — Model RCPC-P — Rhino-Med Research Inc, Mississauga, Ontario). Each participant underwent baseline rhinometric testing and further evaluation with the external nasal dilator (END, Breathe Right nasal strip) or the internal nasal dilation stent (INDS). Participants underwent initial testing with the END or INDS in a randomized crossover fashion. A ten-minute washout period took place between the first and second device assessment. The rhinometry technician observed the application of the devices, and the side of greater airflow resistance was documented for the purposes of the study.

After rhinometric testing, the study administrator randomized the participants to one of two groups. Each group received a randomly selected nasal dilation device, either the END or the INDS. The participants were instructed to use the device as tolerated both during the day and while sleeping over a period of seven days. During this trial, participants recorded the cumulative number of hours of device use within each 24-hour period, as well as the longest (maximum) duration of single wear within that same 24-hour period. Participants also noted (yes/no) whether the device provided them with subjective improvement of their obstructive symptoms. All information was returned on a coded feedback sheet. At the end of the seven-day trial, participants completed a coded WNDTS questionnaire. The coded feedback sheet and questionnaire were collected, and the participants were then provided with the alternative, second nasal dilator. Participants trialed the second device and provided feedback as described for the first device.

All coded data were entered into a database (Microsoft Excel, Microsoft Corporation, Redmond, VA). At the completion of data entry, all data were decoded and statistical analysis was performed.

Sample Size and Statistical Analysis

Based on an estimated 25% improvement (from baseline) in nasal airflow,[11-13] and a paired sample design using an α of 0.05 and a β of 0.8, the prestudy determination of sample size required 22 participants.

Statistical analysis was performed with the SPSS 14.0 (SPSS Inc, Chicago, IL) statistical software package. Paired sample *t* tests were used to evaluate the rhinometeric data, the mean cumulative and maximum usage of the devices, and the mean results of the WNDTS. An analysis of variance (ANOVA) was used to compare differences based on which device was used first. Finally, regression analysis was used to assess the relationship between the results of the WNDTS and the usage of the devices.

RESULTS

All 23 participants completed the study (demographic data appear in Table 1). Rhinometric testing identified no statis-

Table 1
Demographics, history, physical findings, and side of rhinometry for the patient participants

Demographics	n	Average
Males	13	
Females	10	
Age		43.43 (± 3.43)
History		**n**
Poor nasal breathing		23
Sneezing		7
Rhinorrhea		10
Itchy nose		12
Snoring		16
Allergies		15
Physical findings		**n**
Septal deviation		
L		8
R		3
Edematous mucosa		
L		2
R		4
Nasal valve collapse		
L		6
R		0
Side of rhinometry		**n**
L		13
R		10

tically significant differences between the groups based on the initial device used. In addition, there were no differences between the groups randomized to undergo the initial trial with either nasal dilation device. Given the absence of intergroup disparity, device data were combined to allow for paired comparisons between the two nasal dilation devices (END vs INDS).

Airflow rhinometery data appear in Figure 3. When compared with baseline scores (3.67 ± 0.83 cm/H_2O/L/s) (mean ± Standard Error reported throughout), significantly less nasal airflow resistance was demonstrated when using the END (2.19 ± 0.37 cm/H_2O/L/s, $P \leq 0.01$) or INDS (1.07 ± 0.18 cm/H_2O/L/s, $P \leq 0.005$). The INDS demonstrated significantly less nasal airflow resistance when compared with the END ($P \leq 0.005$).

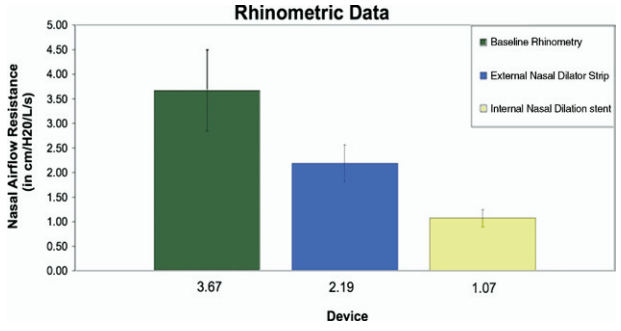

Figure 3 Airflow rhinometry data. INDS demonstrated significantly less nasal airflow resistance compared with baseline scores and when compared with the END.

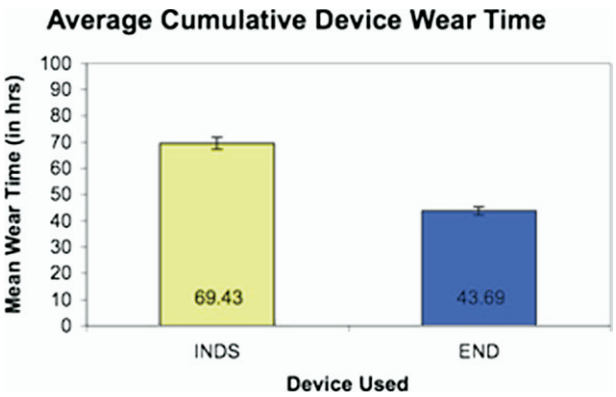

Figure 4 Average cumulative device wear time over a period of 7 days. *Error bars* reflect standard error of the mean. The INDS was worn for a significantly greater period of time than the END.

Comparing average device wear times, the mean cumulative wear time over the seven-day period for the INDS was 69.43 ± 2.27 hours, while the END was worn for 43.91 ± 1.56 hours, a statistically significant ($P \leq 0.001$) increase of more that 50 percent (Fig 4). The average maximum wear time over a 24-hour period was 9.92 ± 0.32 hours for the INDS and 6.27 ± 0.22 hours for the END, a difference that also was found to be statistically significant ($P \leq 0.0001$) (Fig 5).

All participants reported a subjective improvement in nasal obstructive symptoms compared with baseline when using either nasal dilation device. There were no statistically significant differences between the INDS and END groups.

The patient comfort and challenge raw score data obtained from the WNDTS instrument were transformed to inverse standard scores that ranged from 0 to 100, where 0 indicates substantial discomfort and great challenge in using a device, and 100 indicates comfort and easy of use (Appendix).

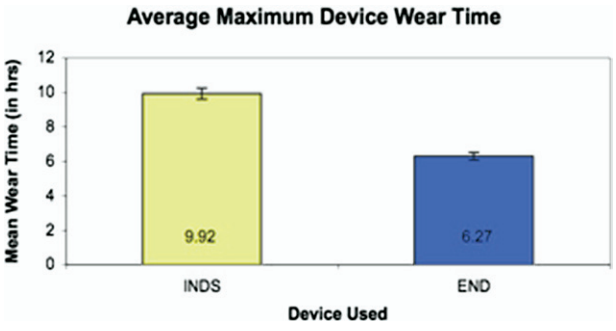

Figure 5 Average maximum device wear time within a 24-hour period. *Error bars* reflect standard error of the mean. The INDS was worn for a significantly greater period of time than the END.

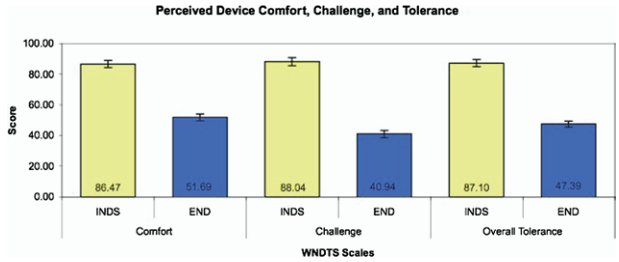

Figure 6 Perceived device comfort, challenge, and overall tolerance. *Error bars* reflect standard error of the mean. The INDS device was significantly more comfortable, significantly less challenging, and had significantly greater overall tolerance than the END device.

Following data conversion, the total score, as well as Patient Comfort and Patient Challenge subscales, was compared for the END and INDS (Fig 6). The INDS was found to be significantly more comfortable ($P \leq 0.001$) than the END with mean values of 86.47 ± 2.39 and 51.69 ± 2.25, respectively. The INDS was also judged to be significantly less challenging (more easy) to use than the END ($P \leq 0.001$) with mean values of 88.04 ± 2.71 and 40.94 ± 2.34, respectively. Finally, the combined overall tolerability scores were significantly ($P \leq 0.001$) better for the INDS (87.10 ± 2.38) when compared with the END (47.39 ± 1.95).

An analysis of the total cumulative wear time over 7 days and average maximum wear time in 24 hours for both the INDS and END were compared with the overall tolerance and patient "Comfort" scores with correlational analysis. Overall tolerance was found to be significantly correlated with total cumulative wear time for both the INDS and END ($r^2 = 0.59$, $P < 0.01$; $r^2 = 0.59$, $P < 0.01$, respectively). Overall tolerance also correlated well with the average maximum wear time in 24 hours for both the INDS and END ($r^2 = 0.59$, $P < 0.01$; $r^2 = 0.44$, $P < 0.05$). A statistically significant relationship between the patient "Comfort" subscale and the total cumulative wear time was seen with both the INDS and END ($r^2 = 0.45$, $P < 0.05$; $r^2 = 0.54$, $P < 0.01$). Finally, the average maximum wear time in 24 hours was strongly correlated with the patient "Comfort" subscales for both the INDS and END ($r^2 = 0.45$, $P < 0.05$; $r^2 = 0.44$, $P < 0.05$).

With the use of correlational analysis, the total cumulative wear time over seven days was compared with the patient "Challenge" subscale of the WNDTS. Both the INDS and END demonstrated a statistically significant correlation ($r^2 = 0.70$, $P < 0.001$; $r^2 = 0.44$, $P < 0.05$).

Neither complications nor adverse events were reported with the use of either device.

DISCUSSION

This study compared comfort, utility, and rhinometric improvement in nasal airflow among 23 individuals with poor nasal breathing. All participants were treated with an external nasal dilator (END) and a novel internal nasal dilation stent (INDS) in a randomized crossover design. In addition, this study used a novel tool that evaluated the comfort and challenge associated with the use of nasal dilation devices.

The results appear consistent with previous evaluations of nasal airflow with the use of nasal dilators and demonstrated a decrease in nasal airflow resistance of 40 percent when using the END and 70 percent when using the INDS.[11-13] Both devices showed significant improvement ($P < 0.01$) from baseline; the INDS demonstrated significantly less resistance than the END ($P < 0.005$). The 70 percent improvement in nasal airflow observed with the INDS supports the proposition that a direct force acting on the internal nasal valve will demonstrate greater improvement in nasal airflow than an indirect lateralizing force.

Similar to previous reports, participants who used both devices demonstrated subjective improvement in nasal airflow compared with baseline. Although it has been well established that nasal dilation devices improve both subjective and objective nasal airflow, little research has been done on factors that limit their use. This study has introduced and preliminarily evaluated the Western Nasal Dilation Tolerance Scale (WNDTS). The results of this tool suggest a statistically significant correlation between the total cumulative wear time of the devices over a seven-day period and the overall tolerance of the device on the WNDTS. Total cumulative wear time and average maximum duration of use during a 24-hour period were also correlated to the Comfort subdomain, with those individuals perceiving the device to be more comfortable having longer cumulative and average maximum durations of wear. Finally, the Challenge subdomain of the WNDTS appeared to relate significantly to the total cumulative duration of wear over the seven-day trials for both devices. Collectively, these data suggest that the INDS is perceived to be well-tolerated not only for short periods of wear (ie, 24 hours), but for longer durations (ie, seven days) and these perceptions are significantly improved from those reported for the END.

The strong correlations observed for the WNDTS fit within the context of the present study. That is, a device that demonstrates efficacy in improving nasal airflow and has greater overall tolerability and comfort would naturally be used more frequently and to a greater cumulative degree. These findings indicate strong construct validity for the WNDTS and suggest, albeit in a preliminary fashion, that this is a valid tool for the assessment of nasal dilation device tolerance.

Application of the WNDTS demonstrated the INDS to be significantly more comfortable and less challenging to use than the END. The overall tolerance of the INDS was found to be significantly greater than the END. These findings fit well with the observed greater cumulative wear time and average 24-hour wear time for the INDS device. Paired with the aforementioned significantly greater reduction in nasal

airflow, the INDS device appears to be superior to an END, both in perceived tolerability and objective utility. These findings reflect that despite an equivalent subjective improvement in nasal airflow, improved comfort and tolerability result in significantly greater device utility.

A few concerns potentially limit the results of this study. The first limitation is the short evaluation period. Although it is difficult to predict long-term surface-stent interactions, there were no complications or adverse events noted during the study. Furthermore, the durability of the INDS lends itself well to easy cleaning and thus limited bacterial colonization; the comfort and ease of use limits potential irritation to the nasal mucosa. Thus, in spite of no long-term data, it seems plausible that a comfortable and easily maintainable device should portend long-term utility.

The second limitation to this study is the absence of scaled quantification of patients' subjective nasal obstruction relief with the use of the devices. Subjective nasal obstruction is a complex issue with many interrelated factors. Therefore, it was feared that prompting participants to quantify their perceived improvement in nasal airflow and comparing this improvement among devices would yield inconsistent results. Furthermore, great difficulty was anticipated in the determination of the reliability and validity of these responses with linear or curvilinear scales. Thus, we elected to focus on factors that determine the utility of the devices (ie, comfort and challenge) and forgo the quantification of patients' subjective experience of nasal obstruction.

Finally, the issue of bias requires discussion. Multiple measures were used to reduce the influence of bias. Participants were randomized and provided with a dilator-free "washout" period when undergoing rhinometry. The nasal device tested was randomized and crossed-over to minimize pre-exposure effects and control the influence of individual patient variability. The use of an independent study administrator and rhinometry technician, with the blinding of the research team, provided an additional means of minimizing bias. In spite of these measures, there were no placebo control groups for either device. Although it would be feasible to create control devices, it would be impractical to use a nonfunctioning internal nasal dilation stent as it may be more obstructive than baseline.

CONCLUSION

Based on data gathered in the present study, the novel Western Nasal Dilation Tolerance Scale (WNDTS) has preliminarily established itself as a valid assessment tool in evaluating perceived device comfort and challenge. Nasal dilation devices have been shown to subjectively and objectively improve nasal airflow among adults with symptoms of nasal obstruction. The innovative internal nasal dilation stent has proven itself to improve nasal airflow to a significantly greater degree than an external nasal dilator. This novel device has also shown greater patient comfort and less perceived challenge associated with its use. Thus, the internal nasal dilation stent is a valuable adjunct in the treatment of nasal obstruction. Although additional research with this clinical population is warranted, the present data provide an initial step to understand multifactorial considerations of nasal obstruction and direct patient perceptions of treatment options.

AUTHOR INFORMATION

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AUTHOR CONTRIBUTIONS

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FINANCIAL DISCLOSURE

Corey C. Moore holds patent to device described.

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APPENDIX 1

Patient code/name_____ Device code/name_____

Date of completion_____

Western Nasal Dilation Tolerance Scale

Please answer the following ten questions by circling the number that best represents your opinion. Please use the definition for each value as listed below:

1 = Never
2 = Very rarely
3 = About half of the time
4 = Very frequently
5 = Always

When wearing the device, I

1. find it difficult to become comfortable. 1 2 3 4 5
2. find it distracting. 1 2 3 4 5
3. find it hard to sleep or relax. 1 2 3 4 5
4. find it upsetting to wear. 1 2 3 4 5
5. find it painful. 1 2 3 4 5
6. find it hard to get use to. 1 2 3 4 5

Regarding use and placement of the device, I find that it is

1. difficult to put on. 1 2 3 4 5
2. time consuming to place. 1 2 3 4 5
3. worrisome to me to see it in place. 1 2 3 4 5
4. difficult to use as recommended. 1 2 3 4 5

Scoring Procedure for the Western Nasal Dilation Tolerance Scale

This measurement tool is designed to have two subdomains of assessment. The first is termed "Patient Comfort" and the second is termed "Patient Challenge." Patient Comfort is composed of the first six questions (1-6) with Patient Challenge comprising questions 7-10. A total score that reflects both subdomains is also calculated. Regardless of whether a single subdomain of the tool or the tool in its entirety is used, the scoring procedure is designed to show that higher scores will reflect a less favorable outcome for the area(s) of questioning. The scoring measure used is consistent with that used in the Voice-Related Quality of Life (V-RQOL) instrument reported by Hogikyan et al from the University of Michigan. The scoring procedure involves the following steps.

Patient Comfort (Questions 1-6):

$$100 - \left[\left(\frac{\text{Raw Score} - \text{Number of Question}(6)}{\text{Highest Possible Score}(24)^*}\right) \times 100\right]$$

$$\text{OR } 100 - \left[\left(\text{Raw Score} - 6/24\right) \times 100\right]$$

Patient Challenge (Questions 7-10):

$$100 - \left[\left(\frac{\text{Raw Score} - \text{Number of Question}(4)}{\text{Highest Possible Score}(16)^*}\right) \times 100\right]$$

$$\text{OR } 100 - \left[\left(\text{Raw Score} - 6/16\right) \times 100\right]$$

Total Score (Questions 1-10):

$$100 - \left[\left(\frac{\text{Raw Score} - \text{Number of Question}(10)}{\text{Highest Possible Score}(40)^*}\right) \times 100\right]$$

$$\text{OR } 100 - \left[\left(\text{Raw Score} - 10/40\right) \times 100\right]$$

*Basis of denominator is constructed on total possible score less number of questions in subdomain or total measures