

A Clinical Study
in Japanese
on
the Nasal Dilator
Nozovent

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Introduction

The importance of the nasal valve area in the nasal airflow has recently been reported. Nozovent is a device to dilate the nasal valve area developed by Petruson et al. in Sweden. It is reported to be useful against snoring and sleep apnea, and has been placed in the market primarily in the Scandinavian countries. The device has been developed to fit in the nasal cavity and external nose of Caucasian noses, and the effect has been confirmed. It has not been studied, however, if the device is useful to dilate nasal valve areas of the Orientals who possess different external nose structure. By the courtesy of Petruson we have had an opportunity of obtaining Nozovent. The effect was studied against the Japanese according to the test methods of Petruson, and the results are herein reported.

Nozovent

The cross-sectional area of nasal cavity at distances from the nasal orifice measured by Rhinometry are shown in the Figure 1. The narrowest part in the nasal cavity is at 2-3 cm deep from the nasal orifice, and Nozovent is designed to dilate the narrowest nasal valve area.

Nozovent is made of a medical grade plastic (Figure 2), and two pieces are packed in a packing unit. In Scandinavian countries two sizes of L and M are sold, and the size M was used in the present tests. The oval two end tabs have a long diameter of 23 mm and a short diameter of 9.5 mm, and the two oval tabs are connected with a bar of 48 mm long. The two end tabs are pressed against the skin in the lateral walls of the nasal vestibules to dilate the nasal valve, and the outside of the end tabs are covered with knobs to prevent Nozovent from falling out by slipping.

Figure 3 shows a Nozovent worn in position. The picture shows a Japanese nose having a wide nasal valve area and the nasal valve is dilated when Nozovent is worn. The device is designed to most properly dilate leptorrhine nasal valve such as those of Caucasian.

Test subjects

Clinical test plans were explained to 15 inpatient subjects who were reported by nurses to snore. The subjects practised to put on Nozovent, and, out of the 15 subjects, ten subjects agreed to participate in the test. Nozovent and the usage were also introduced to 11 outpatients who visited the hospital to consult about their snoring. The subjects practised to wear Nozovent, and the test plans were explained to the subjects and the family. Eight agreed to participate in the tests. Further, two in the inpatients and one in the outpatients had sleep apnea. The subjects consisted of 12 males and 6 females between 20 and 60 years old with an average of 48 years old.

Test methods

Usage of Nozovent were explained to the subjects by making use of Nozovent samples, and the subjects were trained to correctly wear the device. Clinical tests were then conducted according to the schedule shown in Figure 4 for a total of eight nights, to sleep every second night with Nozovent; i.e., four nights with Nozovent and four nights without.

Snoring score

The effect of Nozovent was tested by scoring the degree of snoring in the following four scales; 3 points for severe snoring, and 0 point for nights without snoring. That is:-

Point

- | | |
|---|--|
| 3 | Severe snoring where sleeping partners could not sleep. |
| 2 | Moderate snoring where sleeping partners were disturbed by snoring but managed to sleep. |
| 1 | Slight snoring, audible in the stillness. |
| 0 | No snoring. |

Total scores of the four days with Nozovent and those without were obtained, and differences in the total scores were obtained by subtracting the total with Nozovent from the total without. The effect of Nozovent was judged from the differences; i.e., significant improvement when the difference is greater than 5 points, good improvement when it is 3-5 points, fair improvement when it is less than 3 points, and no change in case of zero point.

Results

The results of the 18 subjects are shown in Figure 5, including 3 subjects who discontinued the test for having not been able to wear Nozovent for 4 days. In the outpatient group, 5 showed significant improvement, 2 good improvement, and one fair improvement, and the rate of improvement was 87.5%. On the other hand, out of the 10 inpatients, 4 showed significant improvement, 2 good improvement, one fair improvement, and 3 dropped out for discomfort in wearing. In the three subjects with sleep apnea, 2 showed significant improvement, and one showed good improvement. Nozovent was claimed to present discomfort, and there were 3 cases claimed of insomnia and they discontinued the use in 1 to 2 days. Two cases out of the three were in the inpatients, who were not aware of their snoring. Five cases were counted where Nozovent fell out during the sleep.

Some of the representative cases are presented as follows:-

Case 1: A male outpatient of 56 years old whose wife suffered from his snoring and was not able to sleep in the same room. Examination revealed deviated nasal septum to the right, but an X-ray examination did not show abnormality in the paranasal cavity. Test plans with Nozovent were explained to the couple, and participation was positively accepted. Out of the 8 test days each of the four days without Nozovent scored 3 points which meant severe snoring, whereas one day scored 0 and three days were with slight snoring with Nozovent. The use of Nozovent showed significant improvement, and the couple wished to continue the use of Nozovent after the tests.

Case 2: A female outpatient of 27 years old who wished to control her snoring during a trip. Test plans with Nozovent were introduced, and her mother was asked to make observation. The subject however claimed strong discomfort in wearing Nozovent, while the result showed only slight improvement. Further, Nozovent was reported to fall out quite often. Also, for reason of appearance, the subject did not wish to continue the use of Nozovent after the tests.

Case 3: A male inpatient of 46 years old to remove laryngeal polyp under general anesthesia. Received complaints from patients in the same room for his severe snoring. The subject however did not admit his snoring, said to have good sleep, and did not wish to participate in the Nozovent test plans.

Case 4: A male inpatient of 65 years old, suspected to have laryngeal cancer. Closely examined by laryngomicrosurgery. Reported by a nurse to have snoring. Explained the test plans with Nozovent, and received consent. Scored 8 points (daily average of 2 points) and had moderate snoring on the days without Nozovent, but scored nil on the days with Nozovent and recorded no snoring. The subject admitted of better sleeping with Nozovent, and wished to continue the use after the tests.

Case 5: A corpulent male outpatient of 40 year old who visited hospital to consult about his snoring. The wife indicated his having sleep apnea. Explained the test plans with Nozovent, and received consent. No abnormality observed in the X-ray examination at the paranasal cavity. Recorded 10 scores during the days without Nozovent, and the wife was able to sleep during 2 nights and was not during 2 nights. The score was seen to decrease to a total of 4 points during 4 days with Nozovent. During 2 nights with Nozovent the wife was awoken by his snoring, and found Nozovent was fallen out of the nose.

Total snoring scores of each of the 15 subjects in four days each are shown in Figure 6. Total scores of the 15 subjects in the four days without Nozovent were 155 points which are in average 2.6 points per person per night. The total with Nozovent were 52 points which are in average 0.9 point per person per night, and showed apparent control on the snoring. That is, the results indicated that snoring of the majority of the subjects improved from a severe level where the sleeping partners could not sleep, to a slight level where it was heard only in stillness.

Out of the 15 subjects 9 wished to continue the use of Nozovent after the tests, and the device was given to them free of charge. Five subjects, including those Nozovent was effective, did not wish to continue the use of the device. They were subjects who did not care much of their snoring or who did not admit to be a snorer.

There were 5 inpatients who did not wish to participate in the tests, and they were 4 females and 1 male. Three out of the five did not wish as they were little conscious of their snoring, and two for the reason of appearance. There were also 3 outpatients who came to consult about the snoring, but, after having heard of the test plans, did not wish to participate. The 3 were all females who did not wish because of the discomfort and appearance when worn.

Discussion

The nasal valve area is the narrowest passage in the respiratory tract according to Bachman et al., causing more than 50% of the total resistance to nasal respiration. Further, as a result of Acoustic Rhinometry studies by Lenders et al. and Hansen et al., who cooperated in the present studies, the cross sectional area of the nasal valve is 0.7 - 1.0 cm² and is the narrowest in the respiratory tract. Petruson et al. developed a device Nozovent to dilate the both nostrils, and the nasal airflow was reported to have increased by 24%.

Petruson calculated that, when the cross sectional area of the nasal valve increased from 1 cm² to 1.4 cm², the nasal pressure decreased from 8 cm H₂O to 4 cm H₂O. It is therefore calculated that one may inhale the air with a half negative pressure when the nasal valve is dilated by Nozovent. That is, where snoring is generated by the vibration of soft palate and pharynx, it is expected that the snoring is reduced as the negative pressure is reduced.

The results are based on studies with Scandinavian whose external nasal structure is different from Japanese. It is therefore considered important to study effect of Nozovent with Japanese who possess structural differences in the nasal valve area and the external nose, particularly in the nasal ala. Studies were therefore conducted under cooperation from Petruson to evaluate the effectiveness of Nozovent to Japanese against snoring.

There were 8 subjects who did not wish to participate in the tests, and three discontinued the tests. The primary reasons for non-participation or discontinuation were either lack of consciousness against snoring or disagreement of wearing for an appearance reason. Similar responses have been reported by Petruson.

It is observed however that snoring can be reduced at a high success rate once Nozovent is worn. The device was also seen to be effective against the three sleep apnea patients.

Nozovent provides a unique method in non-surgical treatment of snoring, and the effectiveness is a result of dilation of nasal valve area which provides the highest airway pressure in the nasal cavity. The principle is medically logical, and is equally applicable to nasal valves of Caucasian as well as Japanese who have different structures in the external noses. There were 5 cases out of 18 (27%) who experienced the falling out of Nozovent during the sleep, and the rate was considered rather high. This may have been attributable to Nozovent having been developed to suit Caucasian noses, and may suggest it necessary to modify its size and shape according to the structure of Japanese nasal ala. It is considered such alternation could result to prevent falling out of Nozovent, reduce discomfort in wearing, and lead us to develop a safe and effective way of controlling the snoring. Studies may then be developed, as have been conducted by Petruson, to evaluate the usefulness against sleep apnea in Japanese (Orient) and to make the use of Nozovent to increase the pulmonary function in various sports by utilizing Acoustic Rhinometry.

**** RHINOMETRY AREA / DISTANCE - CURVES ****

F i g u r e 1

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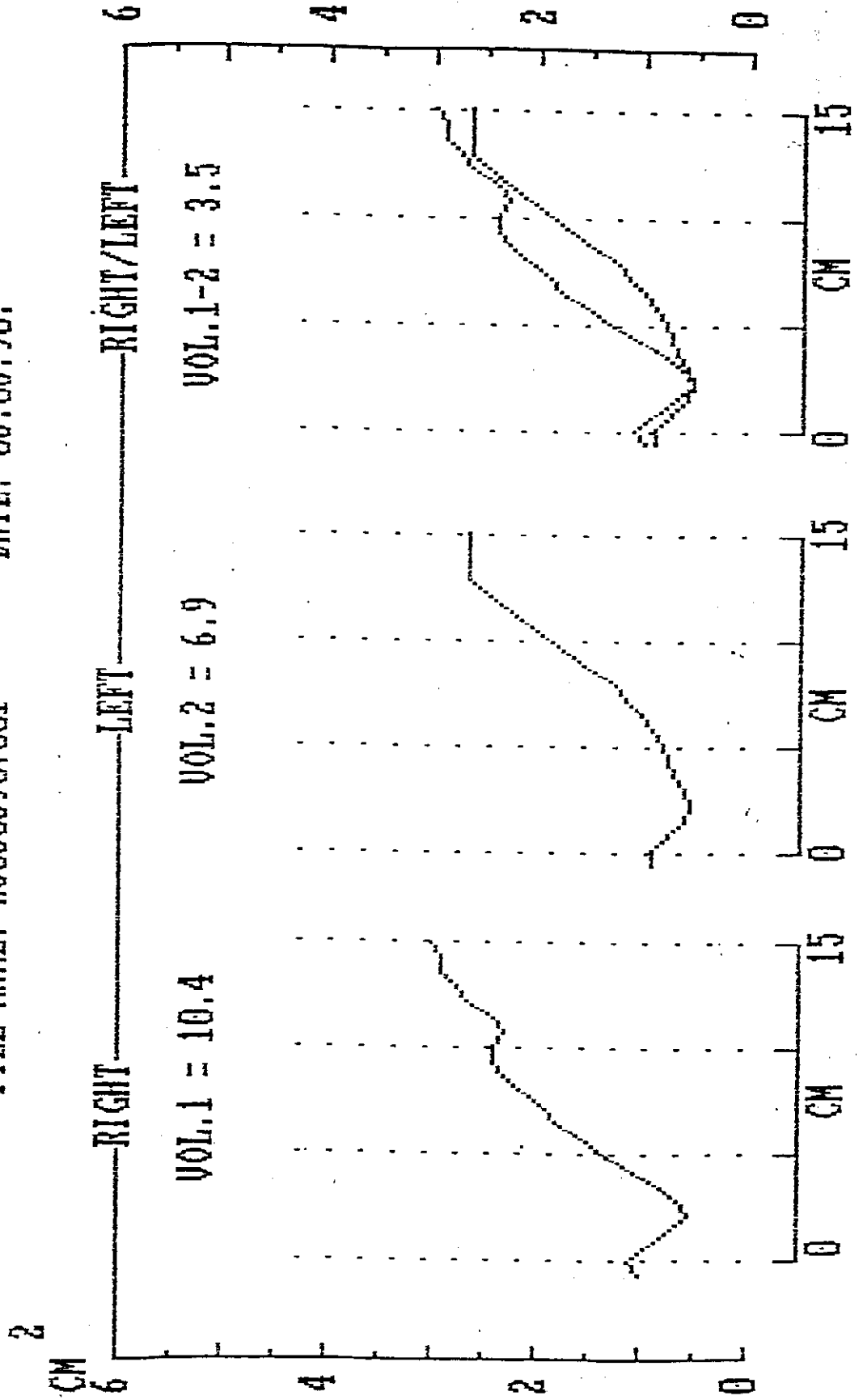


Figure 2

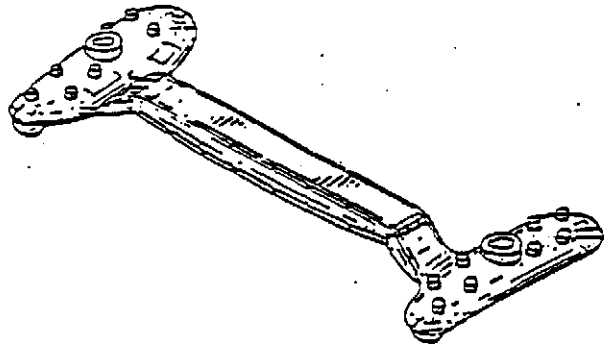


Figure 3



Figure 4 Schedule of study

First day	without Nozovent
2nd day	with Nozovent
3rd day	without Nozovent
4th day	with Nozovent
5th day	without Nozovent
6th day	with Nozovent
7th day	without Nozovent
8th day	with Nozovent
9th day	Wish to use continuously or not

Figure 5 Summary of clinical effects of Nozovent

Out- or In-Patient	No. of cases	Clinical effect				Efficacy rate
		Excellent	Good	Fair	No change	
Out-patient	8	5	2	1	0	87.5%
In-patient	10	4	2	1	3	60.0%
Total	18	9	4	2	3*	72.2%

* : Drop-out for discomfort

Figure 6

