REVIEW

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Mechanical nasal alar dilators*

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SUMMARY

- *Most studies on nasal dilators have used Breathe Right or Nozovent. Both devices dilate the nasal valves, reduce nasal resistance, and improve nasal airflow.*
- *The use of dilators improves airflow most on inspiration, as the valve is stabilised and prevented from collapse.*
- *The response varies greatly between individuals, and can be impressive.*
- *The effect of nasal dilators may be lower in non-Caucasians.*
- *During exercise, nasal dilators delay the onset of oronasal breathing, and can have only small effects on performance thereafter.*
- *Nozovent and Breathe Right can reduce snoring, and improve otherwise obstructed breathing during sleep in selected patients. It is a challenge to find those patients, and one way could be to perform polysomnography with and without nasal dilator.*

Key words: nasal valve, exercise, snoring, breathe right, nozovent

INTRODUCTION

Air passing in through the nose is prepared to suit the lungs: filtered from particles, tempered and humidified. It also presents potentially noxious agents to the immunologic defence system of the nasal mucosa, and molecules are delivered to the olfactory receptors to give a sensation of smell [(1)]. Nasally inhaled air also transports nitric oxide from the maxillary sinuses to the lungs, where it reduces vascular resistance, and increases oxygenation [(2)]. Nasal expiration, compared with oral, reduces the loss of water [(3)]. Nasal congestion may force the subject into mouth breathing, which lacks these functions, and which facilitates snoring because respiratory nasal reflexes are bypassed, and the oropharyngeal patency is reduced as a consequence of the infero-posterior movement of the mandible [(1)].

The nasal valve is the narrowest passage of the nasal cavity, which contributes to approximately half the airflow resistance of the respiratory tract during resting breathing [(4)]. As even small changes in diameter induce significant changes in airflow (Poiseuille´s Equation), several devices have been constructed in order to widen this passage, and to prevent collapse of the valve on inspiration. Most published studies have used Breathe Right, an external, or Nozovent, an internal device, but there are occasional reports on other products like "the Improved Mechanical Therapeutic Nasal Dilator" [(5)], "Airplus" [(6)], Respir+ [(7)], the Francis alar dilator [(8)], the Ognibene dilator [(9)], and the Side Strip (10). There is even a paper on how to bend your own nasal dilator from a plastic-coated paper clip [(11)].

Breathe Right®, invented by Bruce Johnson, is an adhesive band with 2 parallel plastic strips, which acts as a spring when placed on the skin on the dorsum of the nose from one nasal alar crease to the other. It is for once-only use, and it comes in 2-3 sizes (on different markets) [(12)].

Nozovent®, invented by Björn Petruson, is a silicone device, which acts as a spring from the outside when bent and put into position from one nasal vestibule to the other. It comes in 3 sizes. After some 3 months of daily use it loses in springiness, and has to be replaced [(13)].

ABBREVIATIONS

antRM = anterior rhinomanometry; AHI = apnea-hypopnea index; AI = apnea index; AR = acoustic rhinometry; AUC = area under curve; BR = Breathe Right; BMI = body mass index; CAPS = cyclic alternating pattern; CPAP = continuous positive airway pressure; f = female; FVL = flow-volume loop; HR = heart rate; IGF-1 = insulin-like growth factor 1; m = male; MCA = minimal cross-sectional area; Noz = Nozovent; nPIF = nasal Peak Inspiratory Flow; $nPIF^{50}$ = nPIF at 50% of vital capacity; nPEF = nasal Peak Expiratory Flow; NR = nasal resistance to airflow; NS = non-significant; OSAS = obstructive sleep apnea syndrome; postRM = posterior rhinomanometry; RDI = Respiratory disturbance index; RPE = rate of perceived exertion; RPMBE = rate of perceived magnitude of breathing effort; SI = snoring index; TMCA = total MCA; UARS = upper airway resistance syndrome; VAS = visual analogue scale; VO_2 = oxygen consumption

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Table 1. Studies presenting physical nasal measurements.

author	subjects N	subjects, type	nasal problem	device	placebo type	method	mean significant differences
Roithmann [4]	23 f, 43 m	normal	no	BR	no	AR; MCA 1, MCA 2, cm^2	0.07(9%), 0.21(30%)
						plethysmograph; NR, Pa/(cm3/s)	-0.06(-24%)
	10 f, 7 m	postrhinoplasty, obstructed sides	obstructed			AR; MCA, cm^2	0.3(88%)
						plethysmograph; NR, Pa/(cm3/s)	-0.42(62%)
Ochi [27]	33 f, 27 m	Japanese volunteers	no	BR	no	antRM; NR at 150 Pa, kPa/L/s	-0.03(-14%)
Roithmann [17]	15 f, 26 m	healthy	no	BR	no	AR; MCA, cm^2	0.12(19%)
						plethysmograph; NR, Pa/(cm3/s)	-0.06(-23%)
	8 f, 20 m	anterior septal deviation	obstructed			AR; MCA, cm^2	0.24(77%)
						plethysmograph; NR, Pa/(cm3/s)	-0.4(-51%)
	9 f, 20 m	mucosal congestion	obstructed			AR; MCA, cm^2	0.11(25%)
						plethysmograph; NR, Pa/(cm3/s)	-0.22(-24%)
Pickering [84]	25 f, 22 m	Caucasian children, 5-16 yrs	no	BR	no	FVL; nPIF, $nPIF_{50}$	12%, 31%
Wong [86]	33 f, 14 m	volunteers	some obstructed	BR	no	"Airflow Pertubation Device"; NR	-9%
Burres [19]	20 f, 8 m	healthy Asian	no	BR	no	AR; MCA, cm^2	0.08(14%)
	24 f, 18 m	healthy "western style" noses	no				0.18(34%)
Griffin [15]	8 f, 10 m	healthy Black athletes	no	BR	placebo strips, technician	AR; TMCA, cm^2	0.20
	12 f, 23 m	healthy Caucasian athletes	no				0.36
Peltonen [23]	12 f, 15 m	healthy, decongested	no	BR	no	AR; TMCA, cm^2	0.33(24%)
						postRM; NR at 200 Pa, Pa/(cm^3/s)	-0.02(-22%)
				Noz	no	AR; TMCA, cm^2	0.11(8%)
						postRM; NR at 200 Pa, Pa/(cm^3/s)	-0.03(-30%)
Gosepath [20]	26	sleep related breathing disorder	obstruction	BR	no	AR; MCA 1, MCA 2, cm^2	0.1(8%), 0.3(16%)
						antRM; air flow at 150 Pa, cm^3/s	43(6%) NS
		same, decongested				AR; MCA 1, MCA 2, cm^2	0.1(8%), 0.5(23%)
						antRM; air flow at 150 Pa, cm^3/s	138(17%)
Ho [25]	10 f, 15 m	healthy students	6 obstructed	BR	no	AR; MCA, TMCA, cm^2	0.10(17%), 0.19(16%)
Di Somma [55]	13 f, 7 m	healthy Caucasian	no	BR	no	spirometry; nPIF	12%
Gosepath [14]	6 f, 14 m	Caucasian patients	no	BR	no	AR; MCA 1, MCA 2, cm^2	0.1(9%), 0.61(35%)
		same, decongested					0.11(10%), 0.77(38%)
		same patients				antRM, airflow	17%
		same, decongested					27%
Kirkness [32]	10 f, 10 m	healthy Caucasian	no	BR	placebo strips, technician	postRM; NR at 0.4L/s, cmH_2O/L/s	insp. -0.57(-22%), exp. -0.65(-23%)
		same, decongested					insp. -0.42(-31%), exp. -0.39(-31%)
Portugal [16]	20 m	10 Caucasian, 10 Black	no	BR	no	AR; MCA, cm^2	21%
						antRM, NR	-27% in the caucasian group
Bahammam [21]	6 f, 12 m	snoring, daytime sleepiness, some obese		BR	placebo strips	AR; TCA, cm^2	0.38(40%)
Djupesland [40]	5 f, 13 m	heavy snorers, no severe OSAS	night obstruction	BR	placebo strips	supine AR; TMCA, cm2	0.39(54%)
Gehring [33]	9 f, 6 m	Caucasian	no	BR	no	postRM; NR at 0.4L/s, cmH_2O/L/s	insp. -1.52(-50%), exp. 1.42(48%)
Latte [10]	10 f, 2 m	healthy	no	BR	no	AR; TMCA AUC, cm^2	3.6
				SideStrip			0.95
Faria [87]	6 f, 6 m	healthy	no	BR	no	spirometry; expiratory parameters	no
Pevernagie [26]	1 f, 11 m	nonobese snoring chronic rhinitis	obstruction	BR	placebo strips	antRM; NR at 150 Pa, Pa/(cm^3/s)	-0.17(-19%) NS
Ng [18]	2 f, 9 m	healthy		BR	no	AR; MCA 1, cm^2	0.5(42%)
		same, decongested					0.39(27%)
Ognibene [22]	10	students		BR	placebo strips	AR; CA, cm^2	0.1(17%)
Shaida [8]	3 f, 7 m	healthy	no	BR	no	AR; TMCA, cm^2	0.18(14%)
		same, decongested				AR; TMCA, cm^2	0.28(15%)
		same healthy		Francis	no	spirometry; nPIF	25%
		same, decongested					30%
Vermoen [88]	5 f, 5 m	cardiopulmonary healthy	no	BR	no	plethysmograph; FIV_1, L	0.26(10%)
Seto-Poon [31]	5 f, 4 m	healthy	no	BR	no	postRM; NR at 0.4L/s, kPa/L/s	insp. -0.11(-31%)
Tong [61]	9 m	healthy, active students		BR	placebo strips	nPIF, L/s	0.63(18%)
Tong [62]	8 m	healthy, active students		BR	no	nPIF, L/s	0.7(23%)
Metes [41]	26 f, 46 m	patients		Noz	no	supine postRM ; NR, Pa/(cm3/s)	-0.099(-60%) -no significance test
Lorino [24]	7 f, 8 m	healthy	no	Noz	no	postRM; NR at 0.5L/s, cmH_2O/L/s	-0.84(-45%),
				Respir+			-0.26(-14%)
Lorino [7]	8 f, 9 m	healthy	no	Noz	no	postRM; NR at 0.5L/s, cmH_2O/L/s	-0.63(-35%)
		same, decongested					-0.55(-47%)
Petruson [13]	16	ENT staff	no	Noz	no	postRM; air flow at 150 Pa, L/s	0.16(24%) -no significance test
Lorino [34]	12 f, 3 m	healthy	no	Noz	no	postRM; NR at 0.5L/s, cmH_2O/L/s	-1.1(44%)
Petruson [28]	10 m	healthy	no	Noz	no	postRM; air flow at 150 Pa, L/s	0.20(29%)
Meissner [56]	4 f, 4 m	normal Caucasian, "variable" nasal FVL	no	Noz	no	FVL; $nPIF_{50}$, L/s	1.32(86%)
	6 f, 3 m	4 Caucasian, 4 black, 1 Asian: "fixed" nasal FVL					0.29(15%) NS
Höijer [29]	4 f, 7 m	snoring, apneas	not when awake	Noz	no	postRM; air flow at 150 Pa, L/s	0.12(17%)
Hoffstein [42]	7	obese snorers, suspected OSAS	no	Noz	no	RM; NR, cmH_2O/L/s	-0.68(-42%)
Tasca [9]	38 f, 55 m	valvular stenosis, decongested	all obstructed	Ognibene	no	AR; TMCA, cm^2	0.61(75%) -no significance test
						RM; NR, Pa/(cm^3/s)	-0.06(-29%) -no significance test
Kerr [30]	10 m	obese OSAS	6 obstructed	"stent"		postRM; NR at 0.4L/s, cmH_2O/L/s	-73%

Table 2. Studies on exercise.

author	subjects N	subjects, type	exercise, type	load	device	placebo type	method	mean sign. difference
Macfarlane [58]	30 m	Chinese student athletes	field running	20m shuttle run=peak aerobic	BR	placebo strips	peak speed, km/h	3%
Griffin [15]	10 f, 20 m	Black and White, healthy	cycle ergometer	100W 10 min, 150W 5 min	BR	placebo strips	HR, beats/min	NS, -5(-3%)
							VO2, L/min	-0.14(-10%), -0.18(-9%)
							ventilation, L/min	-4(-9%), -6.5(-11%)
							RPE, Borg scale	-0.6(-5%), -0.9(-6%)
Overend [36]	20 m	active, with mouthguards	treadmill	4.83km/h+0.32km/h/(15s)	BR	no	HR, beats/min	NS
							exercise time	NS
							running speed	NS
Thomas [64]	5 f, 10 m	athletes	cycle ergometer	30s anaerobic sprint	BR	placebo strips	peak power output, W	NS
							anaerobic capacity, W	NS
Trocchio [63]	16 m	college athletes	cycle ergometer	+30W/min to maxVO_2	BR	no	VO_2max, and time until	NS
							max work rate	NS
							respiratory exchange ratio	NS
							time until anaerobic	NS
Gehring [33]	9 f, 6 m	healthy Caucasians	cycle ergometer	50W +30W/(2 min) to end	BR	no	work of nasal breathing	NS
O'Kroy [37]	10 f, 5 m	"easier" with BR at rest	cycle ergometer	20/30W+20/30W/min to end	BR	placebo strips	HR, beats/min	NS
							VO_2 at 70%, and max	NS
							max work rate	NS
							RPE, Borg scale	NS
O'Kroy [39]	11 f, 3 m	untrained college students	cycle ergometer	20/30W+20/30W/min to end	BR	placebo strips	work of breathing	NS
							VO_2 at 70%, and max	NS
							max work rate	NS
Bourdin [38]	10 m	elite endurance triathletes	field running	at 80% of max aerobic	BR	no	HR, beats/min	NS
							RPE, Borg scale	NS
					nasal clamp		HR, beats/min	NS
							RPE, Borg scale	NS
Baker [52]	7 f, 3 m	healthy, trained/active	cycle ergometer	50(?)W+50W(?)/(2min)	BR and adhesive tape	suture strip and adhesive tape	HR, beats/min VO_2	NS
							ventilation, L/min	NS
Petruson [28]	10 m	healthy	cycle ergometer	70 or 90W+10 or 20W/min to end	Nozovent	no	nasal breathing, max load, W	24(12%)
							systolic BP increase, mmHg	-13(-15%)
							HR increase, beats/min	NS
Seto-Poon [31]	5 f, 4 m	healthy	cycle ergometer	30W+10W/min until oral breathing	BR	no	exercise duration, s	20(13%)
							peak nasal airflow, L/s	0.18(14%)
Tong [61]	9 m	healthy, active students	treadmill	70% of VO_2max to end, mouth closed	BR	placebo strips	exercise duration, min	13.5(22%)
							HR, beats/min VO_2	NS
							RPMBE at end, Borg scale	-6.7
Case [65]	9 m	college students	treadmill	1min intervals at VO_2max pace to end	BR	placebo strips	HR, beats/min	NS
							VO_2max	NS
							max ventilation, L/min	NS
							no of trials	NS
Tong [62]	8 m	healthy, active students	cycle ergometer	30x20s at 160% of VO_2max pace	BR	no	power output, W	17(5%)
							RPE, Borg scale	-0.8(-5%)
							VO_2	NS

There is a wide-spread use of these mechanical nasal dilators among snorers, and the strips went even more popular after the use by athletes in the Olympic Games in Atlanta in 1996. The aim of this paper is to present the published papers, and to evaluate the effects of nasal dilators when used in different conditions. All the differences quoted below were reported as statistically significant unless stated otherwise.

METHOD

The paper is based on Pubmed searches up to April 9th 2006: *nasal dilator* (first 10 results), *nasal dilator* AND *human, nasal dilation* AND *human* NOT *pneumosinus, nasal valve* AND *dilation, nasal valve dilator, nasal valve dilation, nasal dilatator* AND *human, nasal dilatation* AND *human* NOT *pneumosinus, nasal valve* AND *dilatation, nasal valve dilatator, nasal valve dilatation, nozovent*, and *breathe right*. Some additional refer-

Table 3. Studies on snoring and obstructive breathing during sleep.

author	subjects N	subjects, type	BMI	nasal obstruction	device	placebo type	time	practise	polysomnography	parameters with sign. diff.	mean sign. difference	% responders
Ulfberg [50]	18 f, 17 m	heavy snoring, AI<5	27(20-41)		BR	no	2 weeks	no	before	mouth dryness		40
										Epworth Sleepiness Scale		66
										partner scores, snoring		52
Gosepath [20]	26	OSAS, RDI>10, normal to obese		all	BR	no	2 nights	no	yes	RDI, events/h	-5(-17%)	38
Scharf [49]	10 f, 10 m	mild snoring			BR	no	2 weeks	no	no	Stanford Sleepiness Scale		90
										sleep quality, subjective		90
										partner scores, snoring loudness		75
Djupesland [40]	5 f, 13 m	heavy snoring, AHI<26	26(21-33)	at night	BR	placebo strips	2 nights	1 week	yes	AHI, events/h	3.5 (increase!)	
Bahammam [21]	6 f, 12 m	Upper Airway Resistance Sy.	29(21-46)		BR	placebo strips	2 nights	no	yes	stage 1 sleep, %	-1.5	
				chronic rhinitis								
Pevernagie [26]	1 f, 11 m		25(21-29)		BR	placebo strips	2 nights	no	yes	SI; snores/h	-85(-33%)	83
McLean [47]	1 f, 9 m	OSAS, normal retroglossal airway	27(23-37)	all	BR+decongestion	placebo strips	2 nights	no	yes	AHI, events/h	-12	
										oral breathing fraction, %	-31	
Liistro [44]	1 f, 9 m	non-OSAS	30	in 50%, by RM	BR	no	2 nights	no	yes	none		
Scharf [43]	9	loud snoring, AHI<5		no	BR	no	2 nights	no	yes	CAPS rate of NREM, %	-9.5	
Löth [72]	42 m	snorers, AHI 9(2-45)	26(20-39)		Nozovent	no	1 month	no	once	morning tiredness		41 -no significance test
Löth [51]	42 m	snorers, AHI 9(2-45)	26(20-39)		Nozovent	no	1 month	no	once	Nottingham Health Profile	-4(31%)	
Schönhofer [46]	7 f, 31 m	OSAS, AHI>20, daytime tired			Nozovent	no	2 nights	no	yes	CPAP pressure, cm H_2O	-0.6(-7%)	
	20	>9cm H_2O CPAP pressure								>1cm H_2O reduction		
Schönhofer [45]	4 f, 22 m	OSAS, AHI>10	32		Nozovent	no	2 nights	1 month	yes	Epworth Sleepiness Scale	-1.0(-11%)	50
										AHI reduction by >50%, to <10		19 -no significance test
Shinkawa [57]	6 f, 12 m	Japanese snorers, 3 apnoic			Nozovent	no	8 nights	no	no	partner scores, snoring		50 -no significance test
Petruson [71]	3 f, 14 m	snorers		no	Nozovent	no	10 nights	no	no	mouth dryness		reduced (statistics not specified)
										partner scores, snoring		reduced (statistics not specified)
Hoffstein [42]	6 f, 9 m	snoring, suspicion of apneas	36(23-59)	no	Nozovent	no	1 night	no	yes	Slow Wave Sleep: SI; snores/h	-5.3(-56%)	
								10				
Höijer [29]	4 f, 7 m	snoring, some apnoic		no	Nozovent	no	2 nights	nights	yes	AI, events/h	-12(-64%)	
										minSaO_2, %	6(8%)	
Kerr [30]	10 m	OSAS	32(26-39)	in 6 patients	"stents"+decongestion	saline	2 nights	no	yes	heart rate, beats/min	-3.2(-5%)	
										arousals/h	-8.7(-17%)	
Metes [41]	10	heavy snorers			Nozovent	no	1 night	no	yes	none	reduced (statistics	
Petruson [70]	2 f, 8 m	snorers		no	Nozovent	no	10 nights	1 week	no	partner scores, snoring	on score sums)	

ences were found in the retrieved papers. Only original papers in English were included.

STUDY METHODS

Many studies have been made on patients, and on healthy subjects of different races, at rest and during exercise, and before and after local decongestion. Subjective scoring as well as objective measurements of static nasal minimal cross-sectional areas (=MCA) during breath-holding using acoustic rhinometry [4,8,9,14-23], and dynamic nasal airflow and resistance using anterior [14,16,20,24-27], or posterior [7,13,23,24,28-34] rhinomanometry are common evaluation methods. Difficulties to compare results will hopefully be reduced with modern standardised protocols [35]. Papers on physical measurements are summarised in Table 1. In studies such as these, where collapse of the nasal valve on inspiration is often part of the problem, inspiratory nasal parameters give the most relevant information. Some exercise studies have used heart rate [15,28,36-38], and oxygen consumption [15,37,39] as endpoints, which are important factors for athletes. Papers on exercise are summarised in Table 2. Only one study on snoring used acoustic rhinometry in the recumbent position rather than the upright [40], and another used rhinomanometry [41]. Polysomnography can be used to evaluate snoring and apnea objectively [20,21,26,29,30,40-47], with endpoints like arousal-index (from electroencephalography), apnea-hypopnea index (AHI= the number of apneas, and hypopneas per hour of sleep, measured from oxygen saturation curves), and different snoring indices. Papers on snoring are summarised in Table 3. Power calculations were very seldom presented.

Unfortunately, even though they are categorical data, VAS scores are most often misused as continuous data in statistic calculations in these studies as well as in other studies on nasal congestion [48]. However, there are a few properly performed analyses on subjective scores from questionnaires on patients' perception of different parameters of sleep, and bed partners' scores [49, 50], Epworth Sleepiness Scale [45, 50], Stanford Sleepiness Scale [49], and Nottingham Health Profile [51].

There is an obvious problem to produce placebo-controlled studies on Nozovent, but some studies on Breathe Right have been "blinded", *i.e.* used placebo strips without the plastic springs. To cover Breathe Right and placebo "suture strips" with adhesive tape [52] cannot be recommended, as it may disturb the results. In order to have the subjects truly blinded, they have to close their eyes, and let someone else apply the strips. Otherwise they may perceive the difference between the different types of strips, and you cannot count on the subjects being ignorant of the nature of the device. This is especially important when subjective endpoints are used. The person placing the strips cannot possibly be blinded, as you can feel what type of device you are handling. The use of placebo devices is none the less valuable, as the nasal mucosa may react promptly to manipulation of the nose, and even to minor psychological events [53]. On the other hand, if the device has a relevant effect for more than the first minutes of adaptation, it would not matter if that effect were partially caused by sensory, or psychological mechanisms.

HEALTHY SUBJECTS (see Table 1)

The springiness of Breathe Right was not changed after 8 hours, and it exerted the same forces on noses of varying width, at least within Caucasian limits. However, the resulting displacements of the outside lateral wall varied greatly between individuals due to differences in wall compliance [54].

In the published papers Breathe Right increased MCA by 9-42%, in decongested noses by 10-38%. The devices reduced nasal resistance by 22-50% (Breathe Right), and 35-45% (Nozovent), and increased nasal airflow by 10-23% (Breathe Right), 29% (Nozovent) (Table 1). In the one study which compares Breathe Right with Nozovent decongested noses improved in MCA with both devices -- Breathe Right dilating the most -- but the reductions in nasal resistance were not different between the two [23].

In tidal breathing with Breathe Right 7/20 were responders, defined as subjects with a significant decrease in inspiratory nasal resistance, and during hyperpnea 8/17 were responders [32]. As Breathe Right increased nasal peak inspiratory flow (=nPIF) but not expiratory (=nPEF), Di Somma *et al.* conclude that it stabilised the nasal valve, and thus prevented collapse on inspiration, rather than just dilating the narrow passage [55].

In a study by Lorino *et al.*, Nozovent and local decongestion both reduced mean nasal resistance [24]. In a similar study of theirs, the effects were not totally additive, which was interpreted as due to a slight expanding effect of the device on the turbinates, and/or a slight decongestive effect in the valve region [7]. Neither of the studies showed any correlation between the effects by Nozovent and decongestion.

When they analysed nasal respiratory flow volume loops (=FVL), Meissner *et al.* found 2 patterns of extrathoracic obstruction; a "fixed" pattern, in which the resistance was constant during both phases of the respiratory cycle, and a "variable" pattern. As the oral FVL all were normal, the conclusion was that these obstructions were attributable to the nasal passages. Nozovent improved inspiratory airflow only, and this improvement was confined to cases with "variable" patterns. The fact that their flow limitation was seen exclusively on inspiration suggests that a collapsible segment was responsible, and the improvement by the dilator implicates that the site was identified [56].

In conclusion, both Breathe Right and Nozovent dilate the nasal valves, reduce nasal resistance, and improve nasal airflow. Airflow is most improved on inspiration, as the valve is stabilised and prevented from collapse. The response varies greatly between individuals, and can be impressive.

Racial aspects

Breathe Right increased MCA more in Caucasian athletes than in Black [15]. Portugal *et al.* studied the use of Breathe Right in a group of Black and Caucasian students, and MCA increased irrespective of race. However, the group of Blacks had lower nasal resistance at rest, and the dilator reduced mean inspiratory nasal resistance in the Caucasians. All but one "felt subjective improvement in nasal breathing" when using the device, but no placebo strips were used [16].

A group of healthy Asian adults improved less in MCA with Breathe Right than did a group with typical Western style noses [19]. In students with Oriental noses, it increased MCA by 17% [25], and in Japanese adults it decreased nasal resistance by 14% [27]. The bed partners of 15/18 Japanese snorers scored improved snoring with Nozovent [57](no significance test). In the study by Meissner *et al.,* all 5 non-Caucasians belonged to the group with "fixed" nasal FVL patterns, who did not improve by Nozovent [56].

These studies suggest that the potential of nasal dilators may be lower in non-Caucasians, but one of the few positive exercise studies was performed on Chinese students [58].

Exercise (see Tables 1 and 2)

Most subjects automatically switch from nasal to oronasal breathing at a certain workload, but a substantial portion of total airflow remains via the nasal route in oronasal breathing: 40-57% depending on workload [59]. The nasal component may be of increased importance in contact sports, where protective headgear like chinstraps and mouth guards restrict the oral airway [16]. Nasal muscles dilate the valve during exercise, and therefore the additive effect of mechanical dilators would be less than at rest. Training of these muscles [60] may improve nasal breathing.

However, both Breathe Right and Nozovent can prolong the use of exclusive nasal breathing with increasing workload: Breathe Right increased the capacity to sustain moderate exercise with exclusive nasal breathing, while cardiorespiratory parameters were similar to placebo [61], and the switch to oronasal breathing was delayed [31]. In the one study on Nozovent during exercise, maximum load with nasal breathing increased. The increase in systolic blood pressure was lower with the device, but the heart rate was not affected [28].

When the workload has forced subjects into oral, or oronasal breathing, improvement of the nasal airway gives small measurable effects on performance [58,62], or none at all [36,37,39,63-65]. Maximum oxygen consumption, which has been measured in several of these studies, varies between individuals depending on genetic factors, training, and type of exercise performed, and cannot be expected to change with nasal dilation. Submaximal oxygen consumption, however, shows the economy at a given intensity of exercise, and was reduced, as was heart rate, while ventilation was increased with Breathe Right in one study where placebo strips were used, and a technician placed all devices [15], whereas others have not shown any improvement versus placebo [37,39,61]. Heart rate during exercise was not even different with Breathe Right compared with a nasal clamp [38], or compared with placebo in subjects who perceived that it was easier to breathe through the nose with the dilator at rest [37].

Before exercise, nasal resistance was reduced in 11/15 subjects, who were considered to be responders. During exclusive nasal breathing and progressive work rate on a cycle ergometer, this subgroup showed increased ventilation with Breathe Right on all work rates, significant in several, decreased nasal resistance at peak airflow, and reduced work of nasal breathing [33]. The work of breathing was not reduced in a comparable, placebo-controlled study, however, in which oronasal breathing was allowed until exhaustion [39].

Soft plastic maxillary mouthguards, reported to give breathing difficulties, were used in a Breathe Right study, which did not show any effect on heart rate, exercise time or running speed. This was not surprising, as healthy, untrained young humans are not usually limited by pulmonary ventilation during exercise [36].

In field tests on 30 Chinese male adolescent athletes, Breathe Right improved peak aerobic running speeds by 3% compared with placebo. The authors argue that field tests, and the use of athletes, give results with lower intra-individual variation, which may explain why they found this small but significant difference. There was no improvement during the anaerobic tests [58]. Neither was there any difference in anaerobic capacity in an ergometer test [64].

Nasal dilators delay the onset of oronasal breathing, and can have small effects on performance thereafter. Nasal breathing is of increased importance to patients such as asthmatics, especially during exercise and during outdoor activity in very low temperatures. It is also beneficial in athletes, who would perceive less dryness in the mouth and pharynx, and lose less water, which is of great interest in many sports.

Psychophysical effects

An unspecified nasal dilator improved smell thresholds and quality identifications [66]. Breathe Right compared with placebo made subjects perceive foods as more intense, and less pleasant [67].

PATIENTS

A comparatively large Pakistani population (100 patients) with various causes of nasal congestion was offered Nozovent [68]. After at least 3 months of follow-up 80% of patients reported 75-100% relief of problems. The best results were obtained in patients with posttraumatic alar collapse. Even though this was an open study with a subjective endpoint, it indicates a possible usefulness of the device.

Snoring (see Tables 1 and 3)

Normal nose-breathing subjects may encounter difficulties to breathe through the nose when they go to bed, due to physio-

logical congestion of the venous sinusoids in the mucosa of the nasal turbinates [69]. The corporo-nasal reflex, which gives a dilation of the contralateral nasal passage when the subject lies down in the lateral position, and the nasal cycle also influence the degree of nasal patency [1]. Thus, measurements of nasal airflow in a sitting subject may be a blunt tool to predict the function at different positions during sleep. Supine measurements resulted in a 54% increase of MCA with Breathe Right versus placebo [40], and a 60% decrease of nasal resistance with Nozovent (no significance test) [41]. Many snoring studies use the same standardised polysomnographic parameters, but the one power calculation presented concerned MCA [40], and in many studies the properties of the study groups are poorly described. Some studies include very few subjects, and the devices were worn for one night or less, which may explain their failure to detect any convincing, clinically relevant objective differences [21,26,30,40-44].

In his snoring studies on Nozovent, Petruson evaluated subjective scores given by bed partners, which improved on 5 nights with the device compared with 5 nights without [70], and the snorers reported less dryness in the mouth in the morning as well [71] (statistics not specified). Polysomnography was used after 10 practise nights with Nozovent in snorers, some with apneas. Even though patients with nasal problems were excluded, Nozovent increased nasal airflow. All patients but one had a decrease in apnea index (=AI), and there was also an increase in minimum oxygen saturation with the device [29]. The use of Nozovent in heavily snoring men was 88% after 1 month, 60% after 6 months [72], and 21% after 5 years [73]. The group of men reported less morning tiredness, and their sleeping partners scored snoring to be reduced with the device [72]. At 1 month the total score, and the energy section of the Nottingham Health Profile questionnaire had improved [51], which the vitality section of the Psychological General Well-Being questionnaire had not. These are validated quality-of-life questionnaires, and correlations between them and a simple VAS value for drowsiness were not impressive [74]. At 1 month, there was also an increase in serum levels of insulin-like growth factor 1 (=IGF-1) in the group of men who "snored less and experienced less tiredness in the morning". Increased levels of IGF-1 have also been found in continuous positive airway pressure (=CPAP) treatments of sleep apnea, and after adenotonsillectomy, and are probably caused by the increased secretion of growth hormone induced by more deep sleep [75].

A correct interpretation of subjective scores with Breathe Right using Stanford Sleepiness Scale, and post-sleep questionnaires including assessment by the bed partners, showed improvement in a 2-week study of mild snorers [49]. A larger group of heavy, non-apnoic snorers improved scores on snoring intensity, mouth dryness, and Epworth Sleepiness Scale after using Breathe Right for 2 weeks [50].

Respiratory disturbance index (RDI=AI+HI+index of obstructive snoring >10s) improved with Breathe Right in apnoic snorers with a history of nasal obstruction [20]. A very similar study resulted in 4/21 responders in AHI after 1 month's use of Nozovent, even though 14/15 bed partners reported reduction of snoring to different degrees. Responders were defined as those improving in AHI by >50%, to <10 events/h. The authors concluded that the use of the dilator might in fact satisfy the bed partner, and thereby in many cases delay the initiation of adequate treatment for sleep apnea [45]. However, their finding that four patients were actually responders indicates that the challenge to find the right patients should be addressed. The frequency of nasal obstruction in their study group was unfortunately not reported, and the body mass index (=BMI) indicated a high proportion of obesity.

A selected group of obese patients with obstructive sleep apnea syndrome (=OSAS), nasal obstruction, and normal retroglossal airways were treated with nasal decongestion and Breathe Right at the same time. Compared with placebo spray and -strips, they showed a marked reduction of recumbent nasal resistance, and mouth breathing was reduced by 30%. Their sleep architectures were also improved, but the mean reduction in AHI was just 12 events/h, which suggests that nasal congestion in itself may have disturbed sleep architecture [47].

Lorino et al. stress that the use of nasal prongs in measurements of nasal pressure during polysomnography may increase the nasal airway resistance significantly. In their study, Nozovent tended to slightly overcorrect this effect [34].

A positive contribution by Nozovent was demonstrated in the use of CPAP treatment of OSAS patients. It reduced the pressure needed by a clinically relevant level of >1 cm H_2O in 50% of patients, who required a pressure above 9 cm H_2O [46].

After the American Academy of Sleep Medicine concluded in 2003 that the scientific evidence was limited, however indicating that snoring may be reduced [76], additional studies indicate that Nozovent and Breathe Right can also improve obstructed breathing during sleep in selected patients [45,47]. It is a challenge to find those patients, and the perfect study that shows how this can be done is yet to be presented. As the conditions include many different physical factors like BMI, pharyngeal or nasal obstruction, and mandibular pathology, which may all be present in the same individual, it is hard to predict what impact an intervention against any one of them might have. Polysomnography with and without nasal dilator could be a useful tool, as suggested by Gosepath *et al.* [20].

Insomnia

"Chronic sleep maintenance insomnia" is related to sleep-disordered breathing, but it may be hard to persuade patients to commence treatment like CPAP. Breathe Right has been tried successfully as a means to motivate patients to pursue comprehensive therapies for their breathing disorder [77].

Nocturnal asthma

Petruson and Theman studied 15 patients who suffered from nocturnal asthma. Nozovent used every other night during a period of 10 nights decreased the number of nights that 6/10

patients reported to have woken up due to asthma. The nocturnal use of asthma medication was also reduced [78].

Post-rhinoplasty nasal obstruction

Obstructed nasal cavities in patients who had been subject to rhinoplasty showed a single MCA, with a mean value smaller than normal, which was markedly increased by Breathe Right, "giving immediate relief" (statistical significance of VAS improvement unknown), while nasal resistance decreased by 62% [4].

Septal deviation

Breathe Right increased MCA, and reduced nasal resistance in patients who had anterior septal deviation exceeding 50%, and nasal resistance >0.4 $Pa/cm^3/s$ [17]. As the effect on MCA, and on nasal resistance by the Ognibene internal dilator was comparable to that of operation in decongested patients with valvular stenosis due to septal deviation, Tasca *et al.* suggest that it should be performed as a preoperative diagnostic [9].

Corneal disease

In the treatment of corneal ulcers due to neurotrophic keratopathy, Magone *et al.* used Breathe Right applied vertically across the eyelids to avoid surgical tarsorrhaphy [79].

Cancer

Oncological patients with dyspnea due to cachexia felt relief with Breathe Right, and 7 out of 9 patients wanted to continue to wear it after a 12-hour test period [80].

PREGNANCY

Pregnancy rhinitis is a common cause of nasal congestion during pregnancy. The congestion can be longstanding, and can possibly have negative effects on the fetus. Symptomatic treatment is often needed, as there is no known cure but delivery [81]. In a study on patients with "pregnancy-related nocturnal nasal congestion", 12 women who used Breathe Right for 3 nights improved subjective nasal breathing more than did 12 women who used placebo devices. However, the nasal condition was not defined, and the devices were not used in a crossover fashion [82]. Breathe Right had higher satisfaction rate than placebo in a study on 150 women during labour (however, categorical data "no", "mild", "moderate", and "full" were handled as continuous in statistics) [83]. There is no study that proves nasal dilators to be effective in pregnancy rhinitis, but as the side effects are limited, they are well suited for pregnants to try.

CHILDREN

The symptoms of rhinitis are more severe in young children than in older children or adults, because they have smaller nasal passages in absolute terms. Breathe Right improved nPIF, and $nPIF_{50}$ in children [84]. Newborn infants are the most vulnerable to nasal congestion, as they are obligatory nose breathers, not only when feeding. In a crossover study on 20 infants aged 2-4 months, a cutdown version of Breathe Right reduced the frequency of obstructive apnea-/hypopneas by more than 50%. Infants with higher frequencies of events showed the greatest improvement [85]. These results suggest a possible way to reduce the risk for sudden infant death syndrome. The risk of placing a small foreign body on an infant should also be considered, as it could find its way to the mouth and obstruct the airway.

NEGATIVE PROPERTIES

Negative effects of nasal dilators are scarcely reported. Breathe Right tape glue may *irritate* the skin on the dorsum of the nose, and the pressure of Nozovent may irritate the skin in the nasal vestibule, especially if too big a size is used. One snorer out of 18 who used Breathe Right for two nights reported skin irritation [40].

Discomfort may be one reason to stop using the device. That was reported in 1/11 of Caucasian [29], and 3/18 Japanese snorers [57]. Nozovent did not give sleep disturbance during one night in any of 38 OSAS patients with CPAP [46].

Both devices are cosmetically *unattractive*, but Breathe Right may be more socially acceptable, especially the transparent version. Because of the appearance, 5/26 Japanese snorers did not want to use Nozovent [57]. Pakistani women had problems of this kind versus Nozovent in 10 cases out of 40, whereas all 60 men were satisfied [68].

Both devices may *fall off*, most easily Nozovent. In 2/10 Caucasian snorers it fell off during the night [70], another report was 3/26 [45]. In Petruson's overall experience, Nozovent falls off in 1 out of 5 nights, and he recommends the use of a plaster to attach the connecting bar to the underlying skin if a better fixation is needed [70]. Even though positive effects of Nozovent were registered on polysomnography, only 4/11 snorers wanted to continue using it [29]. This may partly be explained by the fact that they had no nasal problems, and they may not themselves have experienced their snoring as a problem. Nozovent fell off during the night in 5/18 Japanese snorers [57]. Breathe Right fell off on one occasion in 18 snorers, who used it for 2 nights [40]. In 6/20 snorers, Breathe Right had lifted off at the ends by morning at least once in 1 week, but the skin had not been cleaned with alcohol before the strips were applied [49].

Being once-use only, Breathe Right is more *expensive* for regular use than is Nozovent, which can be used for months.

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