
Efficacy of a novel air filtration pillow for avoidance of perennial allergens in symptomatic adults

Allan Stillerman, MD*; Christopher Nachtsheim, PhD†; William Li, PhD†; Mark Albrecht, BSME‡; and Joshua Waldman, MBA‡

Background: Nighttime allergen exposures are a primary contributor to the development of allergic and asthmatic morbidities. Disease management guidelines recommend the use of environmental control measures to reduce these exposures, but clinically relevant reductions are difficult to achieve because most measures control only 1 allergen source among many in the bedroom environment.

Objective: To determine whether a novel localized approach to nighttime allergen avoidance provides effective exposure reductions and clinical benefits.

Methods: Thirty-five adults with perennial allergic rhinoconjunctivitis (dog, cat, or dust mite sensitivity) were randomized to receive PureZone, a combination therapy involving localized air filtration and pillow encasement, or placebo in a crossover trial with two 2-week treatment periods separated by a 1-week washout. Nasal and ocular allergy symptoms, quality of life, and breathing zone particulate exposure were assessed. Bedroom allergen dust samples were collected in the sleeping environment.

Results: Reductions (>99.99%) in allergen-sized particulate ($\geq 0.3 \mu\text{m}$) in the breathing zone led to significant improvements in nocturnal nasal and ocular allergy symptoms ($P < .001$) and quality of life ($P = .02$) for the active vs placebo device. Significant nocturnal symptom reductions vs placebo occurred the second night of use and were maintained for the duration of treatment; these reductions improved sleep problems in particular ($P = .02$). Allergens were detected in 100% of bedrooms, of which 44% had levels that exceeded sensitizing thresholds.

Conclusions: The combination therapy of pillow encasement and localized air filtration provided effective nighttime allergen exposure reductions and clinical benefits without the use of adjunctive therapy.

Ann Allergy Asthma Immunol. 2010;104:440–449.

INTRODUCTION

Indoor allergen exposures are a primary contributor to allergic and asthmatic morbidities. The risks of such exposures are often greatest overnight because of the potency of allergen sources in the bedroom^{1–5} and the amount of time a person sleeps. Consistent nighttime exposures intensify allergic and asthmatic symptoms, which leads to long-term sleep

disturbances and compromised quality of life.^{6–8} Disease management guidelines^{9,10} emphasize the importance of reducing nighttime exposures through the use of environmental control measures, but clinically relevant reductions can be difficult to achieve given the number of allergen sources in the bedroom and the problems with patient compliance.

Bedroom environments rarely have a single identifiable allergen source or reservoir. As such, isolated use of whole-room high-efficiency particulate air (HEPA) filtration or dust mite encasement offers minimal clinical benefit.^{11–14} In contrast, multifaceted approaches have shown promise in efficacy studies.^{15–17} However, patient compliance is poor for simple measures such as encasement and is rare when the family pet is involved.^{18–20}

Personal air filtration (PAF) systems have been developed that use HEPA filtration to create allergen-free breathing zones in whole-room environments that are otherwise allergen rich. Traditional designs of such PAF systems use rigid air delivery manifolds, mounted near the headboard of the bed, to distribute HEPA-filtered air toward a sleeping person's breathing zone.^{21–25} However, such designs are limited in their ability to protect the patient from dust mite allergen within the pillow or to prevent allergen recontamination of the airstream because the airstream travels a considerable distance before reaching the patient's breathing zone. Despite

* **Affiliations:** *Clinical Research Institute Inc of Minneapolis, Minneapolis, Minnesota; † Carlson School of Management, University of Minnesota, Minneapolis, Minnesota; and ‡ PureZone Technologies LLC, Eden Prairie, Minnesota.

Disclosures: Dr Stillerman is a consultant for PureZone Technologies LLC and Messrs Albrecht and Waldman are employees of PureZone Technologies LLC.

Funding Sources: This study was supported by PureZone Technologies LLC.

Received for publication November 13, 2009; Received in revised form February 24, 2010; Accepted for publication March 5, 2010.

© 2010 American College of Allergy, Asthma & Immunology.

Published by Elsevier Inc. All rights reserved.

doi:10.1016/j.anai.2010.03.006

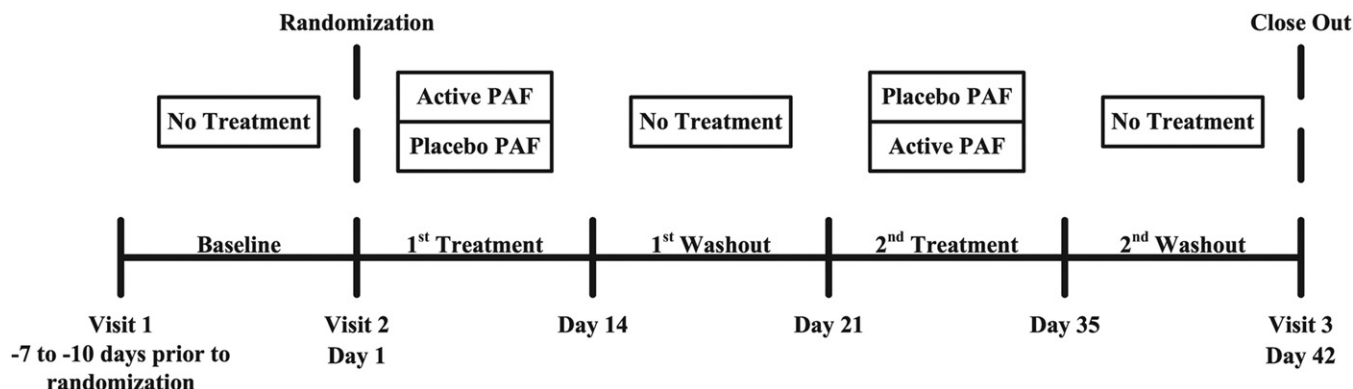


Figure 1. Crossover study design. PAF indicates personal air filtration.

these limitations, allergen reductions provided by traditional PAF systems have shown clinical benefits in efficacy studies of asthmatic populations.^{21–24}

To improve on traditional designs, a new PAF system (PureZone; PureZone Technologies LLC) was developed that uses a pillow coverlet air distribution manifold that combines pillow encasement and localized air delivery through the surface of the coverlet. These features serve to protect the user from dust mite allergens in the pillow and to minimize the distance between the air delivery point and a person's nose and mouth. We studied the efficacy of this unique PAF system in a randomized, placebo-controlled clinical trial of adults with perennial allergic rhinoconjunctivitis (PARC). The primary efficacy end points were symptom and quality of life based because treatment for PARC primarily focuses on managing these outcomes.

METHODS

Study Population

Eligible patients were adults with a more than 1-year history of PARC and sensitivity to dust mite, dog, or cat

allergen. Patients with a relevant seasonal allergy were excluded. Patients agreed to sleep in their bedroom, not to modify their bedroom environment, and not to be away from home for more than 2 days during any treatment period. Patients were excluded if they had asthma, except mild intermittent asthma. Other exclusion criteria were pregnancy, rhinitis medicamentosa, severe nasal obstruction, upper respiratory tract infection, rhinosinusitis, use of nasal continuous positive airway pressure devices, and ocular or nasal allergy medication use in predetermined periods before screening.

During screening, a physical examination and medical tests were performed. Qualifying patients were given diaries, and they returned the following week for randomization; those who demonstrated at least 1 nocturnal nasal symptom (moderate to severe) and at least 80% diary compliance were randomized. The study protocol was approved by Western Institutional Review Board (Olympia, Washington), and participants provided written informed consent. The Clinical Research Institute Inc of Minneapolis performed the study during the spring and summer of 2008.

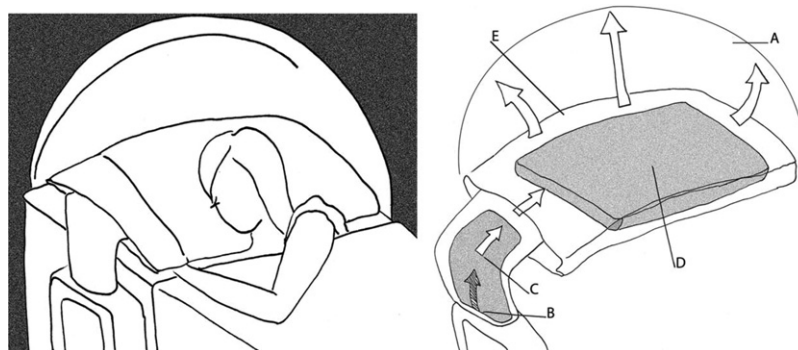


Figure 2. A, PureZone system in use. B, PureZone system diagram depicting the clean air breathing zone (a), which is created by pressurizing room air (b); removing allergens through high-efficiency particulate air filtration (c); conveying the clean airflow toward the breathing zone through an upper chamber in the pillowcase over the existing pillow, which is encapsulated in a lower chamber dust mite barrier (d); and providing clean airflow to the breathing zone through the top pillowcase surface (e).

Study Design

This study was a randomized, double-blind, placebo-controlled, crossover trial (Fig 1). Patients were assigned to placebo-then-active or active-then-placebo treatments. An indexed list of enrollment numbers and matching PAF devices in sealed envelopes was used to blind the researchers. Active PAF treatment consisted of a pillow coverlet that encased the pillow in a dust mite barrier fabric ($<1\text{-}\mu\text{m}$ pore size) and accepted a HEPA-filtered (Technostat 500 g/m; Hollingsworth & Vose, Kentmere, England) airstream from a bedside blower (Fig 2). Active treatment created a breathing zone of filtered air around the patient's head. Placebo PAF treatment was identical in construction, look, and feel to active treatment except that the HEPA filter was blocked by an internal air-impermeable barrier that vented the airflow around the periphery of the HEPA filter. Although placebo PAF treatment did not create a purified breathing zone, it did serve as a pillow dust mite barrier.

Patients were assigned on a rolling basis to the following periods: 1-week run-in, 2-week treatment, 1-week washout, 2-week treatment, and 1-week washout. During treatment periods, patients slept on the assigned PAF device. During washout and run-in periods, patients slept in their bedrooms without a PAF treatment device and using their own pillow. Allergy medications and ocular preparations were prohibited, along with contact lens use overnight.

During the second treatment period, staff performed in-home visits to collect a single dust sample from each bedroom and to measure breathing zone particle counts with the current PAF treatment device. Dust samples were collected using a 10.0-A vacuum fitted with a DUSTREAM Collector (INDOOR Biotechnologies Inc, Charlottesville, Virginia). A 36×76 -inch floor area adjacent to the bed, with one-eighth of the area under the bed, was vacuumed for 5 minutes or until the collector was half full of dust. If after 5 minutes the collector was less than half full, the patient's bedding was vacuumed to complete the sample. Breathing zone particle counts were measured using a laser particle counter (Particle Measuring Systems, Boulder, Colorado) held 6 inches above the center of the treatment device. Three samples were taken with the assigned PAF treatment device turned off, followed by 3 samples with the PAF treatment device turned on. Patients were compliant if they completed at least 80% of the diary forms and slept on the PAF treatment device at least 12 of the 14 nights during both treatment periods.

Assessments

Patients were assessed at the clinic by licensed medical physicians and study coordinators. In-home environmental assessments were performed by engineering staff from PureZone Technologies LLC. Skin prick tests were performed during screening against a battery of relevant seasonal and perennial allergens for patients without documented results in the past 2 years. Urine samples were collected from women of childbearing potential during the closeout visit to confirm nonpregnancy during the trial.

Table 1. Patient Demographics, Baseline Symptoms, Bedroom Allergen Exposures, and Bedroom Allergen Sources

	All patients (n = 35)	Patients with moderate to severe nasal symptoms (n = 26)
Age, y		
Mean (SD)	39.1 (11.9)	39.1 (12.5)
Range	21–61	21–61
Sex, No. (%)		
Female	22 (63)	18 (69)
Male	13 (37)	8 (31)
Having mild intermittent asthma, No. (%)	9 (26)	5 (19)
Symptoms (1-week period), mean (SD)		
TSS		
On waking, instant	9.2 (3.2)	10.6 (2.3)
Daytime, reflective	9.1 (3.5)	10.4 (2.7)
Before bed, instant	7.8 (3.4)	9.1 (2.9)
Overnight, reflective	7.8 (3.4)	9.1 (3.0)
NRQLQ score		
Sleep problems	2.71 (1.48)	3.07 (1.37)
Sleep time problems	2.85 (1.43)	3.33 (1.26)
Symptoms on waking	3.71 (1.56)	4.20 (1.30)
Practical problems	3.87 (1.59)	4.38 (1.41)
Composite	3.16 (1.36)	3.60 (1.19)
Dust mite allergen, No. (%)		
Sensitized	31 (89)	22 (85)
Sensitized and having significant exposures ^a	4 (11)	4 (15)
Dog allergen, No. (%)		
Sensitized	16 (46)	9 (35)
Sensitized and having significant exposures ^b	10 (29)	6 (23)
Sensitized and having a dog in the home	5 (14)	3 (12)
Dog allowed in bedroom	5 (100)	3 (100)
Cat allergen, No. (%)		
Sensitized	20 (57)	15 (58)
Sensitized and having significant exposures ^c	4 (11)	3 (12)
Sensitized and having a cat in the home	5 (14)	4 (15)
Cat allowed in bedroom	5 (100)	4 (100)
Dust mite, dog, and cat allergen Sensitized and having significant exposures to ≥ 1 allergens, No. (%) ^d	15 (43)	10 (38)
Other animal exposures		
Bird, No. (%)	1 (3)	1 (4)

Abbreviations: NRQLQ, Nocturnal Rhinoconjunctivitis Quality of Life Questionnaire; TSS, Total Symptom Score.

^a Sum of Der p 1 and Der f 1 greater than $2.0 \mu\text{g/g}$ of dust.

^b Can f 1 greater than $2.0 \mu\text{g/g}$ of dust.

^c Fel d 1 greater than $1.0 \mu\text{g/g}$ of dust.

^d Positive if the patient was sensitized to a specific allergen having levels greater than those in the previous 3 footnotes.

Patients recorded their symptom severity in their diary on waking and before going to bed. Symptom severity assessments included reflective (assessing the preceding 12 hours: “daytime” and “overnight”) and instantaneous (assessing current status: “before bed” and “on waking”) questions. Symptom severity was assessed using a 4-point scale (0 = none, 1 = mild, 2 = moderate, and 3 = severe) for the 4 nasal components (congestion, rhinorrhea, itching, and sneezing) and for the ocular component (itching/watering). Instantaneous and reflective Total Symptom Scores (TSSs) were calculated by summing the nasal and ocular symptom components, resulting in a possible score of 0 to 15. Instantaneous and reflective Total Nasal Symptom Scores (TNSSs) were calculated by summing the nasal components, resulting in a possible score of 0 to 12. Patients with a baseline average score of at least 2 on waking or overnight for 1 or more of the 4 nasal components were eligible for randomization. Patients with a baseline average TNSS of at least 6 on waking were considered to be affected by “moderate to severe nasal symptoms” and were separate out for additional analyses.

Quality-of-life scores were recorded weekly using the Nocturnal Rhinoconjunctivitis Quality of Life Questionnaire (NRQLQ).²⁶ Question 16 was omitted from the questionnaire owing to the prohibition of allergy medication.

Dust samples were analyzed by INDOOR Biotechnologies using the multiplex array for indoor allergens²⁷ to determine bedroom concentrations of the following allergens: Der p 1, Der f 1, Can f 1, and Fel d 1. Allergen exposures were assessed as significant if analyzed dust samples exceeded the following thresholds^{1,2}: 2 $\mu\text{g/g}$ for the sum of Der p 1 and Der f 1, 1 $\mu\text{g/g}$ for Fel d 1, and 2 $\mu\text{g/g}$ for Can f 1.

Statistical Analysis

Efficacy analyses were performed on data from compliant patients only. Coprimary efficacy end points included the mean change from baseline (defined as the mean of values during the 1-week run-in period) between the active and placebo treatment periods for TSS on waking and NRQLQ composite score. Secondary efficacy end points included the mean change from baseline between the active and placebo treatment periods for TSS and TNSS (all measures), nasal and ocular symptom component scores (on waking), and NRQLQ component scores. In addition, onset of morning symptom relief was assessed by comparing the daily mean change from baseline in TSS on waking between the active and placebo treatment periods.

For the analysis, a first-order autoregressive analysis of covariance model was used, with baseline symptoms as a covariate, patient as a random effect, and treatment, period (day or week), treatment $\times$ period interaction, and treatment $\times$ day or week interaction as fixed effects. Reported means are the maximum likelihood variable estimates. All tests of significance were 1-tailed, and $P < .05$ was considered significant. The analysis was conducted using a statistical software program (SAS version 9.1.3; SAS Institute Inc, Cary, North Carolina).

RESULTS

Study Population

Of 48 patients screened, 38 were randomized; 3 patients were dropped from the study because of noncompliance, resulting in an entire study population of 35 individuals. Twenty-six of

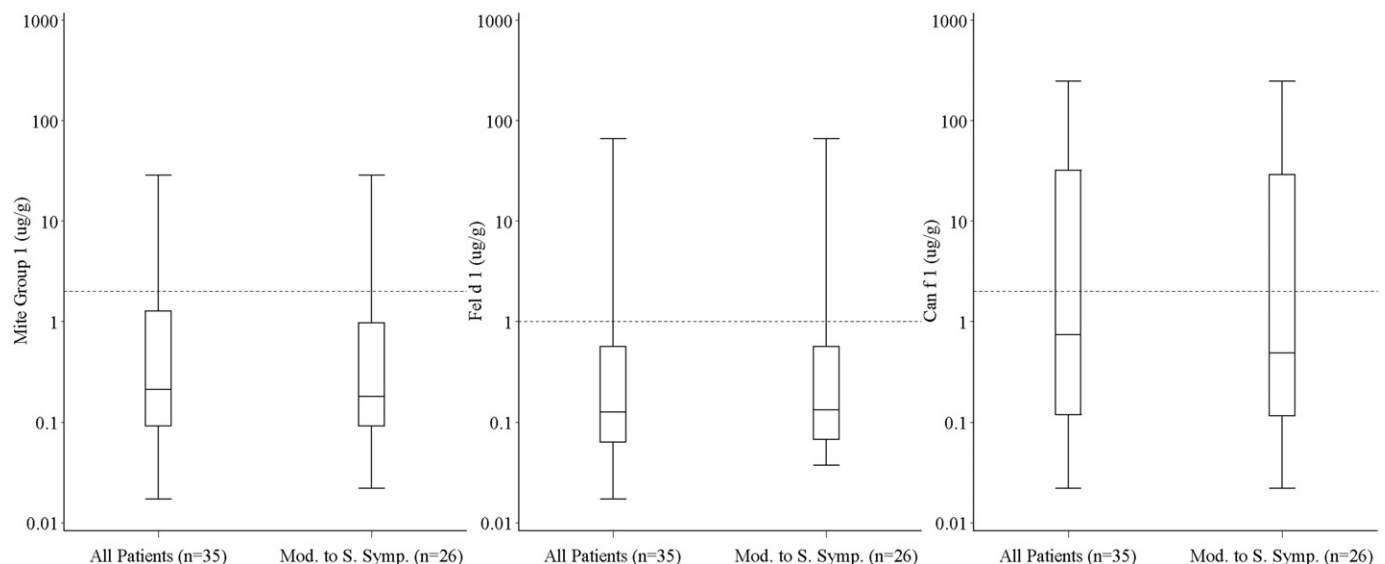


Figure 3. Distributions of mite group, Fel d 1, and Can f 1 concentrations in bedrooms for all patients and the subgroup of patients with moderate to severe nasal symptoms (Mod. to S. Symp.). Box plots represent the 0, 25th, 50th, 75th, and 100th percentiles. The dotted lines represent the thresholds for significant exposures ($>2 \mu\text{g/g}$ for the mite group, $>2 \mu\text{g/g}$ for Can f 1, and $>1 \mu\text{g/g}$ for Fel d 1).

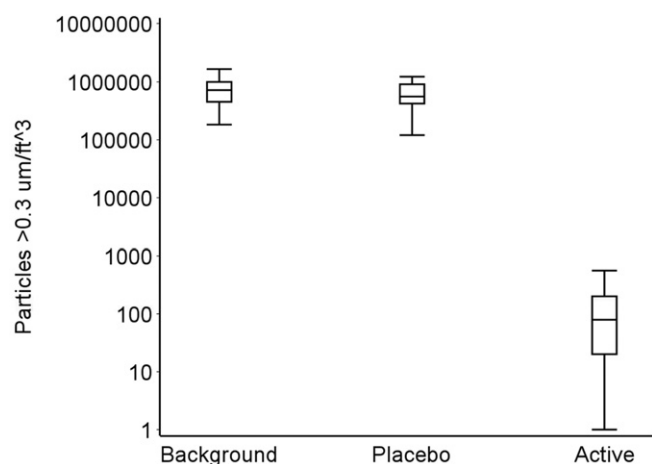


Figure 4. Bedroom breathing zone particle counts for the personal air filtration system used during the second treatment period. Background counts were performed in the personal air filtration system breathing zone when the device was turned off. Box plots represent the 0, 25th, 50th, 75th, and 100th percentiles on a logarithmic scale.

those individuals were classified as having moderate to severe nasal symptoms. The study enrolled a higher percentage of women (63%) than men (37%), and patients ranged from 21 to 61 years of age (Table 1). Coprimary efficacy baseline values of TSSs on waking and overnight were higher for patients with moderate to severe nasal symptoms than for the entire patient population by 1.4 and 1.3 points, respectively;

similar trends were seen in the NRQLQ components for these populations.

Forty-three percent of patients had significant exposures to at least 1 sensitizing allergen based on allergen concentrations in vacuum dust samples. Allergen concentrations were similar for the entire population and the subpopulation with moderate to severe nasal symptoms, implying that baseline symptom severity was unrelated to measured allergen dust concentrations (Fig 3).

Breathing Zone Filtration Efficiency

Particle counting showed that active and placebo devices reduced breathing zone particles measuring at least 0.3 μm from a median background level of 712,680/cu ft to median levels of 80/ and 548,050/cu ft, respectively (Fig 4). This reduction corresponded to median breathing zone filtration efficiencies of 99.99% and 7.30% for the active and placebo PAF treatments, respectively. Breathing zone air quality was not significantly improved relative to background air quality with the placebo PAF treatment.

Effect on Rhinoconjunctivitis Symptoms

For the mean change from baseline in TSS on waking and overnight, active PAF treatment produced significant symptom reductions vs placebo for all the patients (Fig 5), with TSS reductions of -1.11 ($P < .001$) on waking and -0.84 ($P < .001$) overnight; the resulting numbers needed to treat are

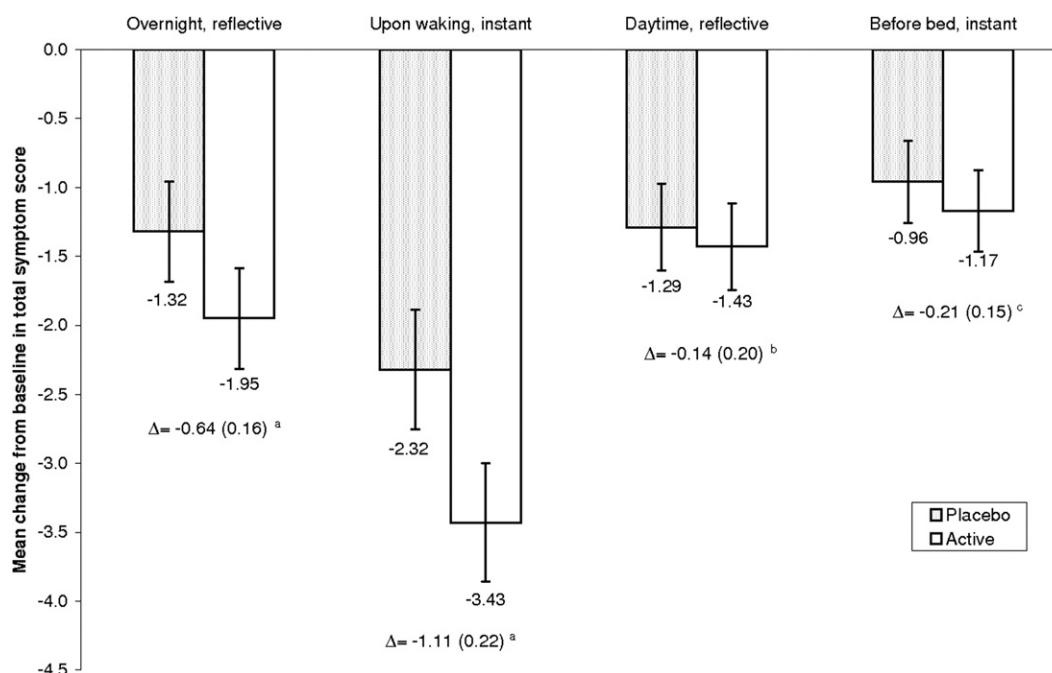


Figure 5. Mean change from baseline in Total Symptom Scores during both treatment periods and mean (SE) within-patient contrast (Δ) between active and placebo treatments for all 35 patients. Error bars represent SE. ^a $P < .001$. ^b $P = .24$. ^c $P = .08$.

0.9 and 1.2 patients, respectively. Active vs placebo symptom reductions were marginally significant for TSS before bed (-0.21 , $P = .08$). Differences were not significant between active and placebo PAF treatments for daytime TSS ($P = .24$).

In terms of individual symptom components, the greatest differences between the active and placebo PAF treatments were found on waking, with large contrasts for all patients of -0.30 for congestion and -0.38 for itching/watering eyes ($P < .001$ for both) (Table 2). Treatment differences were greater for patients with moderate to severe nasal symptoms (-0.34 for congestion and -0.48 for itching/watering eyes). Other significant treatment differences on waking were reported for the components of rhinorrhea and nasal itching.

For onset of action on waking, significant differences in TSS reductions between the active and placebo treatments occurred the second night of use for all patients (Fig 6). Those differences were consistent and were maintained throughout the 2-week treatment period, with a trend of increasing separation across time.

Effect on NRQLQ Components

Improvements in quality of life were significant for active PAF treatment, with differences in mean NRQLQ composite scores from baseline vs placebo of -0.32 ($P = .02$) for all patients and -0.45 ($P = .005$) for patients with moderate to severe nasal symptoms (Table 3). For all patients, mean differences in NRQLQ component scores for active PAF treatment vs placebo were significant for the components of sleep problems ($P = .02$), symptoms on waking ($P = .01$), and practical problems ($P = .02$); improvements in sleep time problems were not significant. For patients with moderate to severe nasal symptoms, mean differences in NRQLQ component scores for active PAF treatment vs placebo were significant for all the components, with sleep problems (-0.52 ; $P = .005$) and symptoms on waking (-0.54 ; $P = .005$) showing differences greater than -0.5 .

DISCUSSION

This randomized clinical trial of a novel allergen avoidance therapy showed the PAF system to be of clinical benefit for

Table 2. Mean Change From Baseline in Symptom Components on Waking for the Placebo and Active Treatments and Treatment Contrasts

	All patients (n = 35)		Patients with moderate to severe nasal symptoms (n = 26)	
	Placebo	Active	Placebo	Active
Nasal symptoms				
Congestion				
Change, mean (SE)	-0.38 (0.10)	-0.68 (0.10)	-0.44 (0.13)	-0.78 (0.13)
Difference, mean (SE)		-0.30 (0.09)		-0.34 (0.11)
P value		$<.001$		$<.001$
Itching				
Change, mean (SE)	-0.60 (0.11)	-0.71 (0.11)	-0.75 (0.14)	-0.88 (0.14)
Difference, mean (SE)		-0.11 (0.06)		-0.13 (0.07)
P value		.02		.04
Rhinorrhea				
Change, mean (SE)	-0.52 (0.12)	-0.75 (0.12)	-0.69 (0.16)	-0.98 (0.16)
Difference, mean (SE)		-0.23 (0.09)		-0.29 (0.10)
P value		.007		.003
Sneezing				
Change, mean (SE)	-0.47 (0.09)	-0.56 (0.09)	-0.62 (0.12)	-0.70 (0.12)
Difference, mean (SE)		-0.09 (0.06)		-0.08 (0.08)
P value		.08		.15
Total Nasal Symptom Score				
Change, mean (SE)	-1.97 (0.36)	-2.71 (0.36)	-2.51 (0.45)	-3.36 (0.45)
Difference, mean (SE)		-0.74 (0.17)		-0.85 (0.21)
P value		$<.001$		$<.001$
Ocular symptoms				
Ocular itching/watering				
Change, mean (SE)	-0.35 (0.11)	-0.73 (0.11)	-0.31 (0.14)	-0.79 (0.14)
Difference, mean (SE)		-0.38 (0.11)		-0.48 (0.14)
P value		$<.001$		$<.001$
Total Symptom Score				
Change, mean (SE)	-2.32 (0.43)	-3.43 (0.43)	-2.84 (0.54)	-4.15 (0.54)
Difference, mean (SE)		-1.11 (0.22)		-1.31 (0.28)
P value		$<.001$		$<.001$

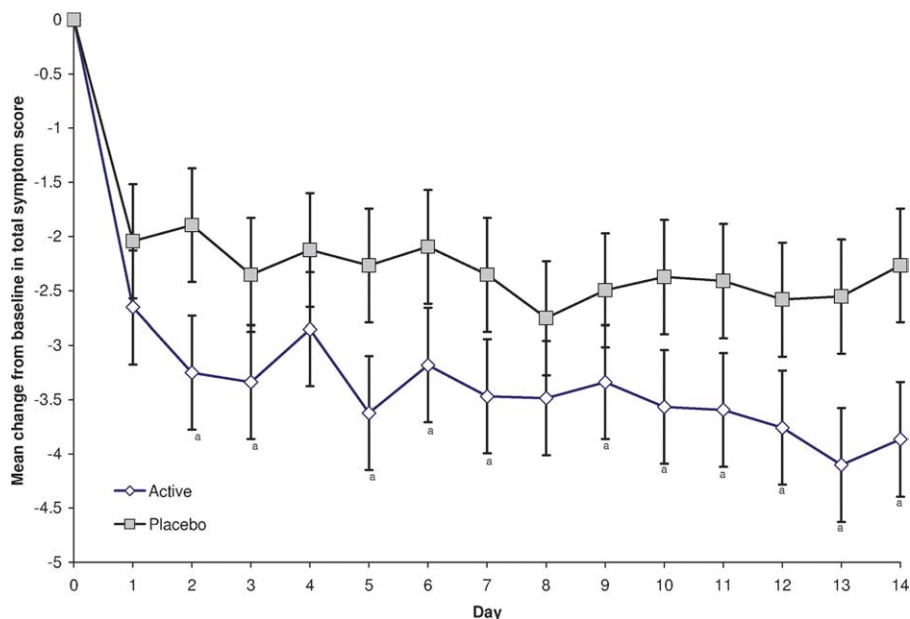


Figure 6. Mean change from baseline in Total Symptom Scores on waking by treatment period day for the placebo and active treatment periods for all 35 patients; significant contrasts by day are identified. Error bars represent SE. ^a*P* < .05.

patients with PARC. Improvements in nasal and ocular symptoms overnight and in the morning led to substantial reductions in sleep disturbance, which have been shown to directly affect daytime fatigue and cognitive function.²⁸ This is the

first trial, to our knowledge, supporting the use of a novel PAF system combining pillow encasement and localized filtration as stand-alone combination therapy for nighttime allergen avoidance in adults with PARC.

Table 3. Mean Change From Baseline in Quality-of-Life Components for the Placebo and Active Treatments and Treatment Contrasts

	All patients (n = 35)		Patients with moderate to severe nasal symptoms (n = 26)	
	Placebo	Active	Placebo	Active
NRQLQ component scores				
Sleep problems				
Change, mean (SE)	−0.36 (0.18)	−0.71 (0.18)	−0.29 (0.22)	−0.81 (0.22)
Difference, mean (SE)		−0.35 (0.16)		−0.52 (0.19)
<i>P</i> value		.02		.005
Sleep time problems				
Change, mean (SE)	−0.59 (0.20)	−0.81 (0.20)	−0.67 (0.26)	−1.01 (0.26)
Difference, mean (SE)		−0.22 (0.16)		−0.34 (0.19)
<i>P</i> value		.09		.04
Symptoms on waking				
Change, mean (SE)	−0.69 (0.22)	−1.10 (0.22)	−0.80 (0.28)	−1.34 (0.28)
Difference, mean (SE)		−0.41 (0.18)		−0.54 (0.21)
<i>P</i> value		.01		.005
Practical problems				
Change, mean (SE)	−0.48 (0.18)	−0.78 (0.18)	−0.51 (0.23)	−0.84 (0.23)
Difference, mean (SE)		−0.30 (0.14)		−0.32 (0.16)
<i>P</i> value		.02		.02
NRQLQ composite score				
Change, mean (SE)	−0.54 (0.18)	−0.86 (0.18)	−0.57 (0.22)	−1.02 (0.22)
Difference, mean (SE)		−0.32 (0.15)		−0.45 (0.17)
<i>P</i> value		.02		.005

Abbreviation: NRQLQ, Nocturnal Rhinoconjunctivitis Quality of Life Questionnaire.

We believed that it was important to ascertain whether overnight reductions in allergen exposure could be achieved with the PAF system and if those reductions would be of any benefit given that the patient would face other exposures during the daytime. With active treatment, particle counting demonstrated overnight elimination of airborne particulates measuring at least 0.3 μm in the breathing zone. Based on the size distribution²⁹ of airborne animal dander (2–15 μm) and dust mite feces (10–40 μm), these reductions in particulate exposure likely translated to reductions in overnight allergen exposure.

Clinical benefits also support apparent reductions in inhaled allergen exposure. Participants reported significant improvements vs placebo in nocturnal symptoms overnight and on waking. The clinical relevance of such improvements is supported by the circadian variability of PARC symptoms wherein symptom severity builds overnight and peaks on waking.³⁰ As such, elevated nocturnal symptoms often lead to increased nasal airway resistance, which contributes to rhinitis-related sleep disorders.³¹ Furthermore, 96% of adults with symptoms on waking report adverse psychological effects, including increased fatigue, irritability, and frustration, along with less energy, motivation, alertness, and ability to concentrate.³² Thus, the significant reductions in nocturnal symptoms seem to be clinically relevant.

Improvements in quality of life provide further support for the clinical relevance of these symptom reductions. Significant improvements vs placebo were demonstrated for most NRQLQ components, but the magnitude of improvement was less than the suggested clinically relevant difference of 0.5.³³ However, the present study population, on average, had less severe symptoms than did those of most PARC studies,²⁸ which typically require individuals with moderate to severe nasal symptoms. Thus, the entire study population was not expected to demonstrate similar magnitudes of improvement. A secondary analysis performed on 26 individuals with moderate to severe nasal symptoms revealed significant improvements near or above the clinically relevant difference for the NRQLQ composite score and the NRQLQ components of sleep problems and symptoms on waking.

Previous studies of whole-room avoidance measures underscore the difficulty of controlling pet dander and dust mite exposures that are ubiquitous in the bedroom environment. Homes with a dog or cat have 100 times the allergen exposure of homes without these pets.³⁴ Avoidance measures short of pet removal are often of minimal benefit given the potency of allergen emission from the animal and reservoirs.^{35,36} Similarly, 46.2% of US homes have sensitizing levels of dust mite allergen.¹ Encasements typically reduce allergen concentrations by more than 50%, but reductions of this magnitude generally do not result in clinical benefits.^{11,37,38} Effective avoidance requires targeting multiple allergen sources in the bedroom, but the required expenses and difficult lifestyle choices can lead to problems with patient compliance.

The present study differed from whole-room avoidance approaches in that (1) we focused on controlling indoor

allergen exposures in a localized breathing zone without any additional modifications to the bedroom environment and (2) we sought to reduce allergen exposures beyond what had been deemed ineffective in whole-room avoidance studies. This study was similar to those of other PAF systems in that HEPA filtration was used to create an allergen-free breathing zone over the bed. However, as illustrated in the “Introduction,” considerable differences exist in the design of the PAF device we studied relative to that of previous PAF systems.

The efficacy data from this and other PAF systems have been encouraging.^{21–24} Previous studies of PAF systems for nighttime allergen avoidance have demonstrated compelling outcomes for patients with asthma, including reduced symptoms, improved quality of life, and reduced bronchial inflammation. The present study demonstrates the benefits of the PureZone PAF system for patients with PARC, benefits that were comparable overnight and on waking with those reported for commonly used intranasal corticosteroids^{39–43} and antihistamines.^{44–48} In terms of affordability, the average selling price of the PureZone PAF system is \$339, which includes a 6-month filter. Replacement filters cost \$100 a year. These costs are less than those for most multifaceted nighttime allergen avoidance strategies ($\geq$ \$800)⁴⁹ and are similar to the yearly treatment costs for common intranasal corticosteroids (\$420–\$450).⁵⁰ These factors, in combination, suggest that PAF systems are cost-effective therapies.

A limiting factor in this study was the inability to detect statistical relationships between measured allergen exposures (dust samples) and either baseline symptom severity or the clinical benefits of the PAF treatment. Furthermore, detected allergen concentrations were less than those reported in the general US housing stock.^{1,2} These results suggest that patient exposures may not have been accurately represented by allergen concentrations found in dust samples, particularly because all the patients were experiencing symptoms and had no relevant allergic sensitizations other than dog, cat, or dust mite allergen. In addition, reductions in overnight nonallergenic particulate exposure may have contributed to treatment effects for individuals with nonallergic rhinoconjunctivitis.

Nonetheless, this study demonstrates the efficacy of a unique PAF system that combines pillow encasement and localized filtration as stand-alone combination therapy for nighttime allergen avoidance in adults with PARC. Particle counting showed that the PAF system was effective for eliminating the most difficult-to-avoid allergens (pet dander and dust mite) in the breathing zone, which led to significant improvements in nasal and ocular symptoms, quality of life, and quality of sleep. Nighttime allergen avoidance options that deliver effective symptom relief while minimizing the need for difficult lifestyle choices may be of benefit to patients and physicians.

ACKNOWLEDGMENTS

We thank Nicole Tierney, Clinical Research Institute Inc of Minneapolis, for coordinating data collection and patient follow-up; Harold Kaiser, MD, Clinical Research Institute

Inc of Minneapolis, for his sage advice during study development and regarding its publication; and Mary Anne Elder, RN, MS, FNP-C, AE-C, Clinical Research Institute Inc of Minneapolis, for her astute recommendations regarding study design and implementation.

REFERENCES

- Arbes SJ, Cohn RD, Yin M, et al. House dust mite allergen in US beds: results from the First National Survey of Lead and Allergens in Housing. *J Allergy Clin Immunol*. 2003;111:408–414.
- Arbes SJ, Cohn RD, Yin M, et al. Dog allergen (Can f 1) and cat allergen (Fel d 1) in US homes: results from the National Survey of Lead and Allergens in Housing. *J Allergy Clin Immunol*. 2004;114:111–117.
- Cohn RD, Arbes SJ, Jaramillo R, Reid LH, Zeldin DC. National prevalence and exposure risk for cockroach allergen in U.S. households. *Environ Health Perspect*. 2006;114:522–526.
- Salo PM, Yin M, Arbes SJ, et al. Dustborne *Alternaria alternata* antigens in US homes: results from the National Survey of Lead and Allergens in Housing. *J Allergy Clin Immunol*. 2005;116:623–629.
- Custovic A. The effectiveness of measures to change the indoor environment in the treatment of allergic rhinitis and asthma: ARIA update (in collaboration with GA(2)LEN). *Allergy*. 2005;60:1112–1115.
- Salo PM, Arbes SJ, Crockett PW, et al. Exposure to multiple indoor allergens in US homes and its relationship to asthma. *J Allergy Clin Immunol*. 2008;121:678–684.
- Rosenstreich DL, Eggleston P, Kattan M, et al. The role of cockroach allergy and exposure to cockroach allergen in causing morbidity among inner-city children with asthma. *N Engl J Med*. 1997;336:1356–1363.
- Sporik R, Holgate ST, Platts-Mills TA, Cogswell JJ. Exposure to house-dust mite allergen (Der p 1) and the development of asthma in childhood: a prospective study. *N Engl J Med*. 1990;323:502–507.
- NHLBI Guidelines for the Diagnosis and Treatment of Asthma. <http://www.nhlbi.nih.gov/guidelines/asthma/>. Accessed April 21, 2009.
- Wallace DV, Dykewicz MS, Bernstein DI, et al. The diagnosis and management of rhinitis: an updated practice parameter. *J Allergy Clin Immunol*. 2008;122(suppl):S1–S84.
- Sheikh A, Hurwitz B. House dust mite avoidance measures for perennial allergic rhinitis. *Cochrane Database Syst Rev*. 2001;4:CD001563.
- Reisman RE. Do air cleaners make a difference in treating allergic disease in homes? *Ann Allergy Asthma Immunol*. 2001;87(suppl 3):41–43.
- Wood RA. Air filtration devices in the control of indoor allergens. *Curr Allergy Asthma Rep*. 2002;2:397–400.
- McDonald E, Cook D, Newman T, et al. Effect of air filtration systems on asthma: a systematic review of randomized trials. *Chest*. 2002;122:1535–1542.
- Björnsdóttir US, Jakóbinudóttir S, Runarsdóttir V, Juliusson S. The effect of reducing levels of cat allergen (Fel d 1) on clinical symptoms in patients with cat allergy. *Ann Allergy Asthma Immunol*. 2003;91:189–194.
- Morgan WJ, Crain EF, Gruchalla RS, et al. Results of a home-based environmental intervention among urban children with asthma. *N Engl J Med*. 2004;351:1068–1080.
- Platts-Mills TA, Vaughan JW, Carter MC, Woodfolk JA. The role of intervention in established allergy: avoidance of indoor allergens in the treatment of chronic allergic disease. *J Allergy Clin Immunol*. 2000;106:787–804.
- Busse PJ, Wang JJ, Halm EA. Allergen sensitization evaluation and allergen avoidance education in an inner-city adult cohort with persistent asthma. *J Allergy Clin Immunol*. 2005;116:146–152.
- Schönberger HJAM, Maas T, Dompeling E, et al. Compliance of asthmatic families with a primary prevention programme of asthma and effectiveness of measures to reduce inhalant allergens: a randomized trial. *Clin Exp Allergy*. 2004;34:1024–1031.
- de Blay F, Fourgaut G, Hedelin G, et al. Medical Indoor Environment Counselor (MIEC): role in compliance with advice on mite allergen avoidance and on mite allergen exposure. *Allergy*. 2003;58:27–33.
- Zwemer RJ, Karibo J. Use of laminar control device as adjunct to standard environmental control measures in symptomatic asthmatic children. *Ann Allergy*. 1973;31:284–290.
- Villaveces JW, Rosengren H, Evans J. Use of laminar air flow portable filter in asthmatic children. *Ann Allergy*. 1977;38:400–404.
- Pedroletti C, Millinger E, Dahlén B, Söderman P, Zetterström O. Clinical effects of purified air administered to the breathing zone in allergic asthma: a double-blind randomized cross-over trial. *Respir Med*. 2009;103:1313–1319.
- Verrall B, Muir DC, Wilson WM, et al. Laminar flow air cleaner bed attachment: a controlled trial. *Ann Allergy*. 1988;61:117–122.
- Morris RJ, Helm TJ, Schmid W, Hacker D. A novel air filtration delivery system improves seasonal allergic rhinitis. *Allergy Asthma Proc*. 2006;27:63–67.
- Juniper EF, Rohrbach T, Meltzer EO. A questionnaire to measure quality of life in adults with nocturnal allergic rhinoconjunctivitis. *J Allergy Clin Immunol*. 2003;111:484–490.
- King E, Vailes LD, Tsay A, Satinover SM, Chapman MD. Simultaneous detection of total and allergen-specific IgE by using purified allergens in a fluorescent multiplex array. *J Allergy Clin Immunol*. 2007;120:1126–1131.
- Juniper EF, Ståhl E, Doty RL, et al. Clinical outcomes and adverse effect monitoring in allergic rhinitis. *J Allergy Clin Immunol*. 2005;115(suppl 1):S390–S413.
- Erwin EA, Woodfolk JA, Custis N, Platts-Mills TAE. Animal danders. *Immunol Allergy Clin North Am*. 2003;23:469–481.
- Storms WW. Pharmacologic approaches to daytime and nighttime symptoms of allergic rhinitis. *J Allergy Clin Immunol*. 2004;114(suppl):S146–S153.
- Craig TJ, Teets S, Lehman EB, Chinchilli VM, Zwillich C. Nasal congestion secondary to allergic rhinitis as a cause of sleep disturbance and daytime fatigue and the response to topical nasal corticosteroids. *J Allergy Clin Immunol*. 1998;101:633–637.
- Nathan RA. The burden of allergic rhinitis. *Allergy Asthma Proc*. 2007;28:3–9.
- Mintz M, Garcia J, Diener P, et al. Triamcinolone acetate aqueous nasal spray improves nocturnal rhinitis-related quality of life in patients treated in a primary care setting: the Quality of Sleep in Allergic Rhinitis study. *Ann Allergy Asthma Immunol*. 2004;92:255–261.
- Eggleston PA. Control of environmental allergens as a therapeutic approach. *Immunol Allergy Clin North Am*. 2003;23:533–547, viii–ix.
- Avner DB, Perzanowski MS, Platts-Mills TA, Woodfolk JA. Evaluation of different techniques for washing cats: quantitation of allergen removed from the cat and the effect on airborne Fel d 1. *J Allergy Clin Immunol*. 1997;100:307–312.
- Wood RA, Johnson EF, Van Natta ML, Chen PH, Eggleston PA. A placebo-controlled trial of a HEPA air cleaner in the treatment of cat allergy. *Am J Respir Crit Care Med*. 1998;158:115–120.
- Terreehorst I, Hak E, Oosting AJ, et al. Evaluation of impermeable covers for bedding in patients with allergic rhinitis. *N Engl J Med*. 2003;349:237–246.
- Götzsche PC, Johansen HK. House dust mite control measures for asthma. *Cochrane Database Syst Rev*. 2008;2:CD001187.
- Nathan RA, Berger W, Yang W, et al. Effect of once-daily fluticasone furoate nasal spray on nasal symptoms in adults and adolescents with perennial allergic rhinitis. *Ann Allergy Asthma Immunol*. 2008;100:497–505.
- Stern MA, Wade AG, Ridout SM, Cambell LM. Nasal budesonide offers superior symptom relief in perennial allergic rhinitis in comparison to nasal azelastine. *Ann Allergy Asthma Immunol*. 1998;81:354–358.
- Hughes K, Glass C, Ripchinski M, et al. Efficacy of the topical nasal steroid budesonide on improving sleep and daytime somnolence in patients with perennial allergic rhinitis. *Allergy*. 2003;58:380–385.
- Day J, Carrillo T. Comparison of the efficacy of budesonide and fluticasone propionate aqueous nasal spray for once daily treatment of perennial allergic rhinitis. *J Allergy Clin Immunol*. 1998;102(pt 1):902–908.

-
-
43. Bende M, Carrillo T, Vóna I, da Castel-Branco MG, Arheden L. A randomized comparison of the effects of budesonide and mometasone furoate aqueous nasal sprays on nasal peak flow rate and symptoms in perennial allergic rhinitis. *Ann Allergy Asthma Immunol.* 2002;88: 617–623.
 44. Davies R. Efficacy and tolerability comparison of ebastine 10 and 20mg with loratadine 10mg: a double-blind, randomised study in patients with perennial allergic rhinitis. *Clin Drug Investig.* 1998;16:413–420.
 45. Philip G, Williams-Herman D, Patel P, et al. Efficacy of montelukast for treating perennial allergic rhinitis. *Allergy Asthma Proc.* 2007;28: 296–304.
 46. Kim K, Sussman G, Hébert J, et al. Desloratadine therapy for symptoms associated with perennial allergic rhinitis. *Ann Allergy Asthma Immunol.* 2006;96:460–465.
 47. Fantin S, Maspero J, Bisbal C, et al. A 12-week placebo-controlled study of rupatadine 10 mg once daily compared with cetirizine 10 mg once daily, in the treatment of persistent allergic rhinitis. *Allergy.* 2008;63: 924–931.
 48. Walter Canonica G, Bousquet J, Van Hammée G, et al. Levocetirizine improves health-related quality of life and health status in persistent allergic rhinitis. *Respir Med.* 2006;100:1706–1715.
 49. Mission Allergy product catalog. <http://www.missionallergy.com/>. Accessed December 15, 2009.
 50. Garris C, Shah M, D’Souza A, Stanford R. Comparison of corticosteroid nasal sprays in relation to concomitant use and cost of other prescription medications to treat allergic rhinitis symptoms: retrospective cohort analysis of pharmacy claims data. *Clin Drug Investig.* 2009;29:515–526.

Requests for reprints should be addressed to:
Allan Stillerman, MD
Clinical Research Institute Inc of Minneapolis
825 Nicollet Mall
Ste 1135 Minneapolis, MN 55402
E-mail: as@allergy-asthma-docs.com