Efficacy of PUREZONE™, a Novel Local High Efficiency Particulate Air Filtration Pillow Device, in Patients With Perennial Allergic Rhinoconjunctivitis: A Double-Blind, Placebo-Controlled Randomized Clinical Trial

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ABSTRACT

Rationale: To assess the efficacy of a novel HEPA filtration pillow device (PUREZONE™) versus placebo for reducing symptoms in adults with perennial allergic rhinoconjunctivitis.

Methods: In a crossover randomized clinical trial, symptomatic adults (N=35) with a >1-year history of perennial allergic rhinoconjunctivitis and a positive skin prick test (dust mite, cat, or dog) received PUREZONE™ and placebo (identical pillow device lacking airflow to the breathing zone) during 2-week intervals separated by a 1-week washout. Total Symptom Scores were assessed daily upon awakening and before going to bed. The Nocturnal Rhinoconjunctivitis Quality of Life Questionnaire was completed weekly. Breathing zone particle counts and mean changes in Total Symptom Scores and Nocturnal Rhinoconjunctivitis Quality of Life Questionnaire were assessed.

Results: PUREZONE significantly improved nocturnal symptoms versus placebo based on reductions in instantaneous Total Symptom Scores Upon-Awakening (-3.44 vs -2.32; P<0.001) and reflective Total Symptom Scores Overnight (-1.95 vs -1.32; P<0.001) from baseline; this finding was supported by large instantaneous Symptom Component Reductions Upon-Awakening in Congestion (-0.71 vs -0.40; P<0.001) and Itchy/ Watery Eyes (-0.75 vs -0.36; P<0.001). Onset of action was noted the first night of use. Daytime Total Symptom Scores were similar between groups. Nocturnal Rhinoconjunctivitis Quality of Life Questionnaire reductions from baseline were greater for PUREZONE than placebo (-1.02 vs -0.57; P=0.005). PUREZONE reduced breathing zone particle counts by >99.99% versus placebo.

Conclusion: The results suggest that PUREZONE is an efficacious avoidance measure for reducing nocturnal nasal and ocular symptoms and improving nocturnal quality of life and sleep in perennial allergic rhinoconjunctivitis patients.

INTRODUCTION

Despite the lack of conclusive clinical evidence supporting symptom reductions[1-4], dust mite encasements and HEPA room air filtration are often recommended as a therapy for persons suffering from allergic rhinoconjunctivitis symptoms. Both therapies have been shown to reduce airborne levels of dust mite and pet allergens in the bedroom, but neither therapy has demonstrated significant symptom reductions vs. placebo in randomized clinical trials; the outcomes suggest that these measures do not prevent individuals from being exposed to significant quantities of inhalant allergens.

Therefore, we sought to determine if the localized delivery of HEPA filtered air to a sleeping person's breathing zone would reduce inhalant allergen levels sufficiently to result in perennial allergic rhinoconjunctivitis symptom reductions and improvements in quality of life. We present the primary results of a randomized double blind clinical trial evaluating the efficacy of a localized HEPA filtration pillow (PUREZONE™) tested on individuals suffering from dust mite, dog, or cat inhalant allergens. Individuals used the PUREZONE™ pillow nightly to reduce their inhalant allergen exposure while sleeping.

PRIMARY OBJECTIVES

- Assess within-patient reductions in instantaneous total symptom scores vs placebo, upon awakening
- Assess within-patient improvements in nocturnal rhinoconjunctivitis quality of life questionnaire scores vs placebo

PUREZONE™ PILLOW

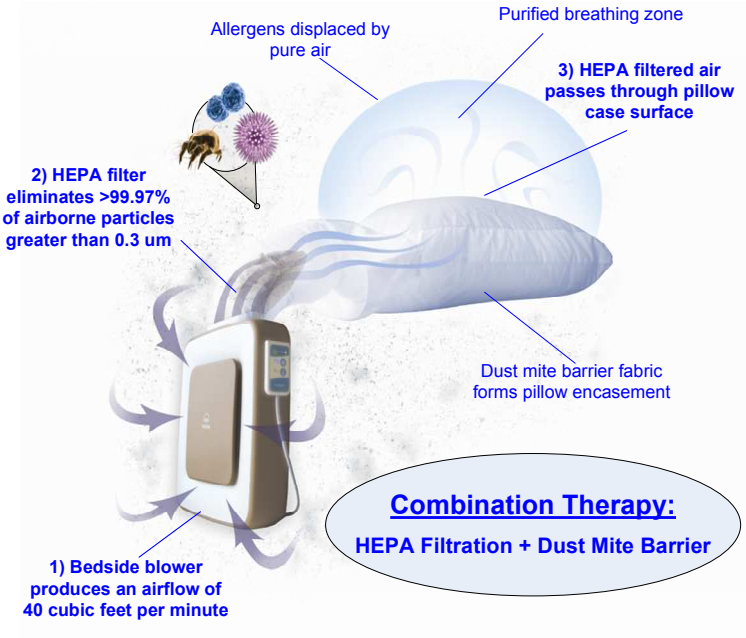

Figure 1. Active and Placebo Treatments (Active Shown Above): The active and placebo treatment were identical devices, with the exception that the placebo device delivered un-filtered air to the breathing zone.

METHODS

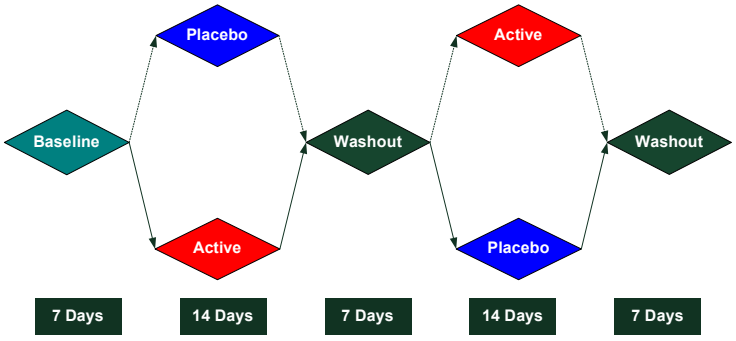

Figure 2. ***Cross-over study design***: 35 patients were randomized to placebo-then-active or active-then-placebo treatments, so each patient served as his or her own control. Treatment periods were separated by a 1-week washout period. Patients assessed nasal and ocular symptoms daily upon-awakening and before going to bed on a 3-point severity scale: 0=none; 1=mild; 2=moderate; and 3=severe. Quality of life was assessed weekly via the nocturnal rhinoconjunctivitis quality of life questionnaire. In the second treatment period, in-home sampling assessed bedroom allergen levels and treatment reductions in inhalant particulate exposure; for the former bedroom dust samples were collected for MARIA™ analysis (Indoor Biotechnologies, Charlottesville, VA) and for the latter particle counts were performed in the breathing zone of the assigned treatment.

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3) Reisman R. Do Air Cleaners Make a Difference in Treating Allergic Diseases in Homes? Annals of Allergy Asthma and Immunology 2001; 87:41-43
4) Wallace et al. The Diagnosis and Management of Rhinitis: an Updated Practice Parameter. J Allergy Clin Immunol 2008; 122: S1-84
5) Chapman M. Indoor Allergens. Pediatric Allergy Principles and Practice, Chapter 25.

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RESULTS

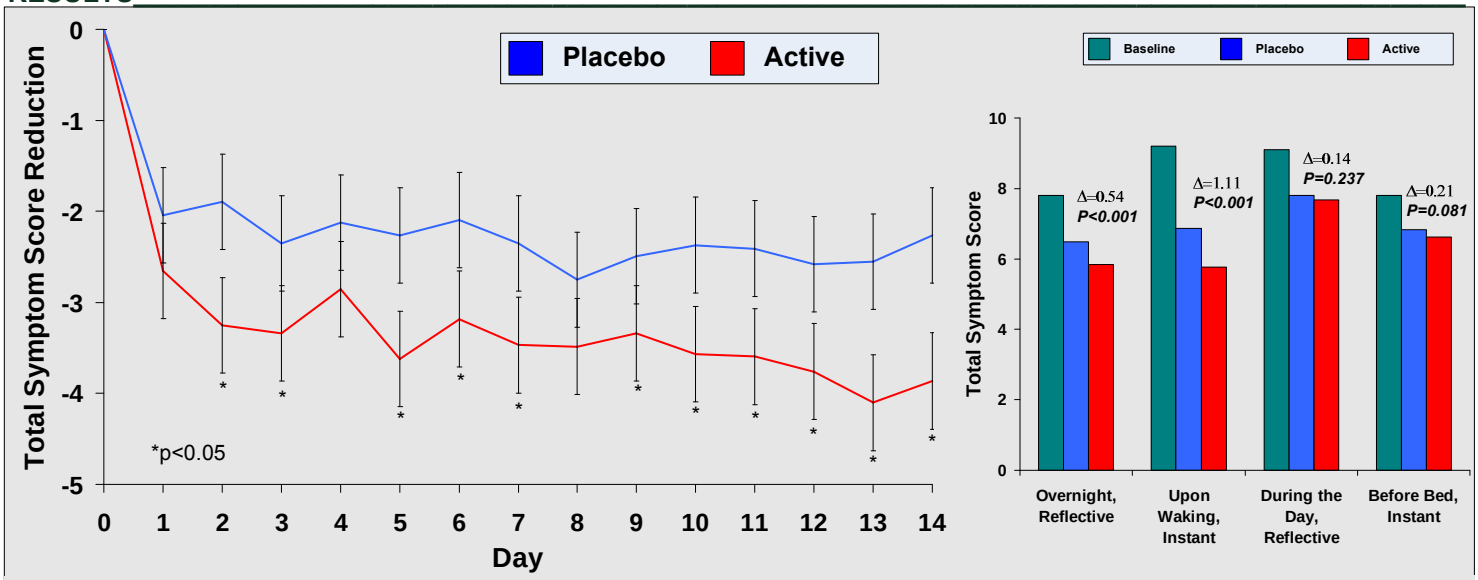

Figure 3. Onset of Action and Maintenance of Benefit: Mean Total Symptom Score** reductions from baseline and standard deviation bands for the placebo and active treatments by day, for the instantaneous upon-waking assessment.

Figure 5. Total Symptom Scores (15-point):** Treatment means for instantaneous and reflective measures.

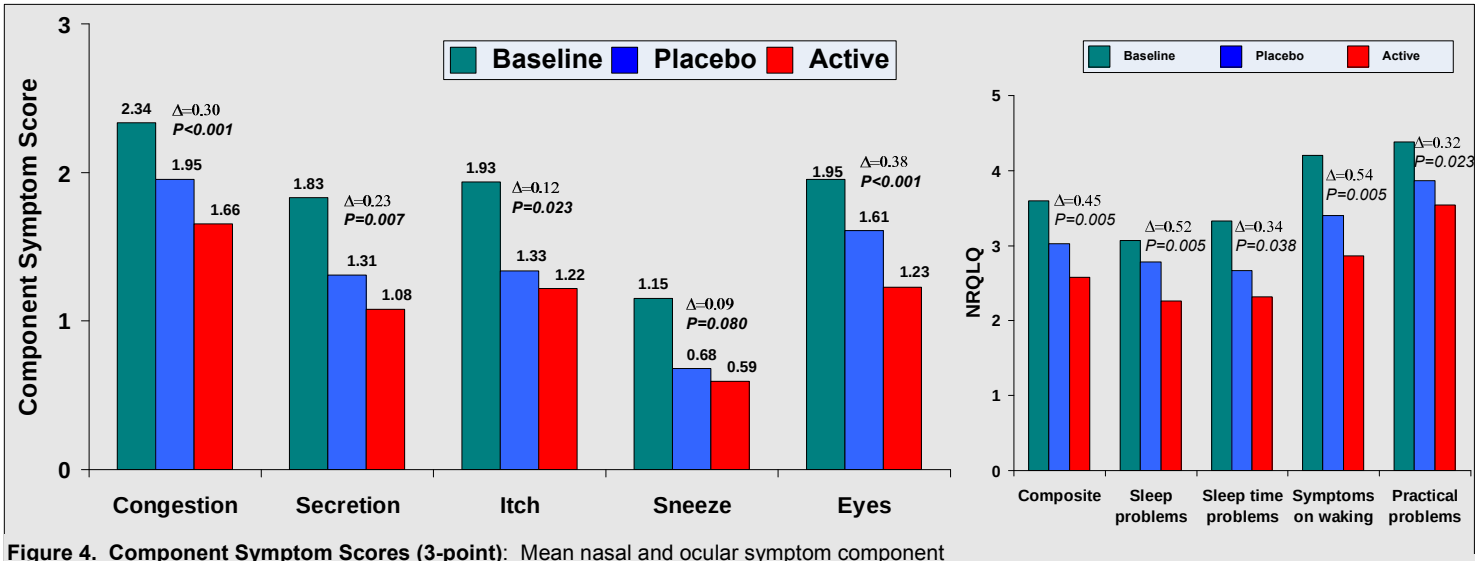

Figure 4. Component Symptom Scores (3-point): Mean nasal and ocular symptom component reductions for the instantaneous upon-waking assessment.

***Total Symptom Score=15-point summation of congestion, itch, sneeze, secretion, and eye symptoms [3-point scale each] Δ=Active – Placebo P=Contrast significance of active vs placebo means*

Figure 6. Nocturnal Rhinoconjunctivitis Quality of Life Questionnaire (6-point): Treatment means for weekly assessment.

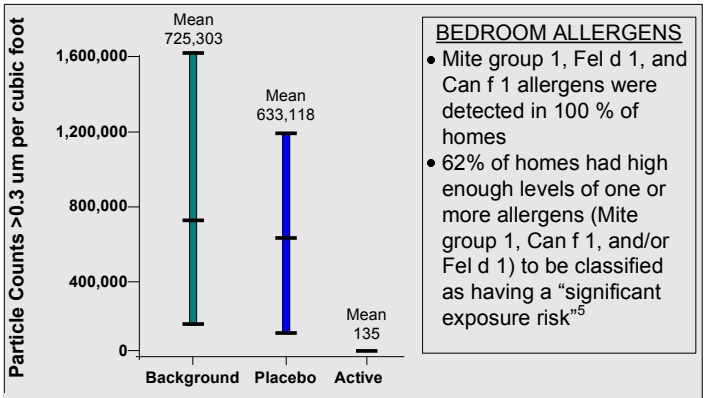

Figure 7. Breathing Zone Particle Counts: Mean and range of particles >0.3 um per cubic foot.

BEDROOM ALLERGENS

- Mite group 1, Fel d 1, and Can f 1 allergens were detected in 100 % of homes
- 62% of homes had high enough levels of one or more allergens (Mite group 1, Can f 1, and/or Fel d 1) to be classified as having a "significant exposure risk"[5]

Figure 8. MARIA™ Allergen Analysis

CONCLUSIONS

- The study results show PUREZONE™ Pillow to be the first HEPA air filtration device proven efficacious for reducing nasal and ocular symptoms and for improving quality of life in patients with perennial allergic rhinoconjunctivitis, when evaluated in a randomized double blind clinical trial.
- Total Symptom Score reductions were statistically significant vs placebo for the periods of overnight and upon-awakening (Figure 5), with onset of action occurring within 2 days and persisting throughout the treatment period (Figure 3).
- Symptom component reductions vs placebo were greatest for congestion and eyes (Figure 4).
- Quality of life improvements were statistically significant vs placebo, with the greatest improvements for sleep problems and symptoms on waking (Figure 6).
- Clinical efficacy was most likely the result of significant reductions in patient overnight inhalant allergen exposure, evidenced by the large reductions in breathing zone particle counts vs placebo (>99.99% Figure 7).