Reduction of Allergy Symptoms by Molekule's PECO AIR Purification

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Abstract:

Exposure to airborne allergens and pollutants is linked to symptom severity for allergic rhinitis and other respiratory problems. In this study a novel method of PECO (Photo ElectroChemical Oxidation) air purification developed by Molekule is used to destroy indoor air pollutants in the environment of study participants. The overall reduction in symptoms for allergy sufferers was significant; With the use of Molekule's technology, Total Symptom Scores (TSS) of allergy sufferers dropped to the normal range (equivalent to the score of non allergy sufferers) within 1 week following initiation of treatment. After initiation of treatment, there was no difference in TSS between allergy and non-allergy sufferers. This improvement in TSS was consistent over the 4 week course of treatment. Results point to the potential for Molekule to immediately improve allergy sufferers quality of life.

I. Introduction

Exposure to airborne allergens and pollutants has been linked to the exacerbation of allergic rhinitis, asthma, and other respiratory problems. Allergic rhinitis, in particular, is a significant and growing medical problem in the United States. It is estimated that rhinitis including allergic and nonallergic may affect around 70-80 million people every year in the United States alone (1,Settipane). Poorly controlled exposure to allergens adversely affects people's routine activities and overall quality of life (2,D'Alonzo). Multiple allergens have been implicated in worsening symptoms including, microbes, pollen, dander, dust and other airborne pollutants (3,Sublett).

While measures can be taken to reduce exposure to food and surface allergens, current methods of mitigating airborne allergens are unable to keep up with the rate of airborne allergen accumulation indoors. The US EPA states that the "Indoor air can be up to 5 times more polluted

than the air outdoors." These pollutants are microscopic and include material such as mold, bacteria, viruses, and volatile organic compounds.

Current methods to deal with indoor air pollutants rely on filters to trap and remove these irritants. However, biological contaminants including, mold, bacteria, and viruses, survive on filters, can multiply there, and get released back into the air. Other pollutants like volatile organic compounds are too small to be caught by filters, and continue to concentrate indoors.

Molekule uses photo electrochemical oxidation (PECO) to not just filter pollutants, but completely eliminate them. Mold, bacteria, viruses, and volatile organic compounds are broken down into safe to breathe molecules like trace amounts of water and CO2. Multiple third party independent laboratories have studied the efficacy of this technology and results have been published in peer-reviewed journals.

II. Methods

In order to measure the real world impact of Molekule's new air purification technology, 28 beta devices were given to volunteering participants with and without allergies for a 4-week trial period. Participants reported their symptoms in baseline and weekly self-reported surveys. The reported data was retrospectively evaluated from March 2015 to April 2016.

Total nasal symptom scores (TNSS) and total ocular symptom (TOSS) values score were obtained as a baseline via survey monkey, a web based survey tool, and were continuously reported over the following 4 weeks. TNSS consisted of measuring nasal congestion, runny nose, nasal itchiness, and sneezing. TOSS consisted of measuring eye itchiness, eye wateriness, and eye redness. Both were graded on a scale of 0-3 where 0 represented no symptoms, 1 - mild symptoms, 2 – moderate symptoms, 3 – severe symptoms. Both male and female subjects were recruited to participate.

Based on symptom reporting, participants were separated into those suffering from allergies and those not suffering from allergies. Allergy sufferers were defined as participants reporting 8 or more total symptom score, TSS (a total of TNSS and TOSS), out of a maximum of 21 (if participants reported severe symptoms for all existing symptoms). A total of 22 participants were categorized as having allergies and a total of 6 participants without allergies.

Instructions were given with the device that participants use the device at a minimum of 12 hours per day. They were also instructed to keep the unit close to the bed at night. During the study duration participants were advised to continue their normal medications for allergic symptoms and any other general medical condition, and to continue their usual routine for managing allergies.

III. Statistical Analysis

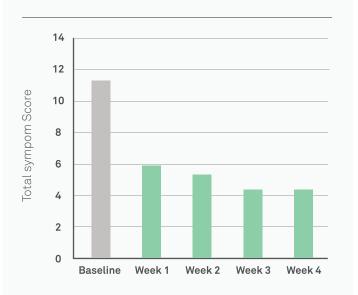
The primary endpoint was to determine weekly and overall decreases in TSS, TNSS and TOSS comparing subjects with and without allergies. Further analysis was conducted in order to determine statistical significance of TSS scores. TSS scores were compared among patients with and without allergies at baseline and each time point using the

Wilcoxon rank sum test. All tests were two-sided and an α (type I) error <0.05 was considered to be statistically significant.

IV. Results

The overall reduction of total symptoms for allergy sufferers was significant, see Figure 1.

Figure 1
Improvement in mean Total Symptom Scores of 22
Allergy Sufferers



Improvement in baseline from mean total symptom score including - nasal congestion, nasal itchiness, runny nose, sneezing, eye itchiness, eye redness, and eye secretiions for 22 allergy sufferers over a 28 day trial period

The baseline TSS among participants with allergies was significantly higher than participants without allergies (Table 1; median TSS 11 vs. 5, respectively; p<0.001). Following initiation of using the Molekule beta device, the difference in TSS between patients with and without allergies resolved by 1 week, with median 1-week, 2-week, 3-week, and 4-week TSS scores of 5 vs. 4, 6 vs. 4, 5 vs. 5, and 5 vs. 5, respectively (p>0.05). Consistent with these findings, the change in TSS from baseline (Δ TSS) among allergy sufferers was significantly different compared with non-allergy sufferers by 1 week following treatment (Table 1; median Δ TSS -7 vs. 0, respectively; p=0.004), and the Δ TSS remained significantly improved at 2-weeks, 3-weeks

and 4-weeks following initiation of treatment. Among baseline allergy sufferers, following the improvement of allergy symptoms as measured by ΔTSS , the benefit was consistent and did not significantly change over the next 3 weeks (p>0.05). Table 2 demonstrates the reduction in TNSS and TOSS for allergy sufferers.

 Table 1

 Baseline TSS changes over time in allergy and non-allergy sufferers

	All Patients	Baseline Allergies		
TSS	Median (rang)	Yes	No	p-value
Baseline	9 (2,19)	11 (8,19)	5 (2,6)	<0.001
1 week	5 (1,13)	5 (1,13)	4 (1,6)	0.195
2 weeks	5 (2,11)	6 (2,11)	4 (3,7)	0.365
3 weeks	5 (1,10)	5 (1,10)	5 (2,9)	0.892
4 weeks	5 (1,10)	5 (1,10)	5 (4,8)	0.447
ΔTSS at 1 week	-6 (-10,2)	-7 (-10,2)	0 (-3,0)	0.004
ΔTSS at 2 weeks	-5 (-12,3)	-6 (-12,2)	-1 (-3,3)	0.003
ΔTSS at 3 weeks	-5 (-17,7)	-7 (-17,7)	1 (-4,7)	0.007
ΔTSS at 4 weeks	-3 (-18,6)	-7 (-18,-1)	0 (-1,6)	<0.001

Figure 2
Changes in Mean TSS over time

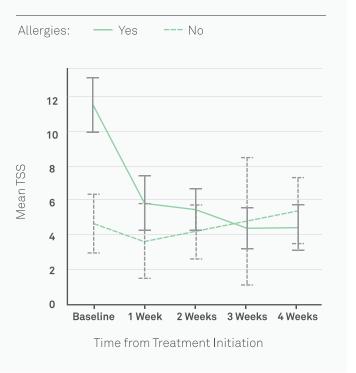


 Table 2

 Baseline TNSS and TOSS changes over time in allergy and non-allergy sufferers

	All Patients	Baseline Allergies		
TNSS	Median (range)	Yes	No	p-value
Baseline	6 (2,12)	7 (2,19)	5 (2,6)	0.052
1 week	3 (1,8)	5 (1,13)	4 (1,6)	0.932
2 weeks	4 (1,9)	6 (2,11)	4 (3,7)	0.604
3 weeks	3 (1,7)	5 (1,10)	5 (2,9)	0.192
4 weeks	3 (1,7)	5 (1,10)	5 (4,8)	0.110
ΔTNSS at 1 week	-4 (-6,2)	-7 (-10,2)	0 (-3,0)	0.018
ΔTNSS at 2 weeks	-4 (-8,3)	-6 (-12,2)	-1 (-3,3)	0.045
ΔTNSS at 3 weeks	-4 (-10,0)	-7 (-17,7)	1 (-4,7)	0.035
ΔTNSS at 4 weeks	-3 (-11,6)	-4 (-11,-1)	0 (-1,6)	0.010
TOSS				
TOSS Baseline	4 (0,8)	4 (0,8)	1 (0,3)	<0.001
	4 (0,8) 2 (0,6)	4 (0,8) 2 (0,6)	1 (0,3) 1 (0,2)	<0.001 0.097
Baseline				
Baseline 1 week	2 (0,6)	2 (0,6)	1 (0,2)	0.097
Baseline 1 week 2 weeks	2 (0,6) 1 (0,6)	2 (0,6)	1 (0,2) 0 (0,4)	0.097 0.395
Baseline 1 week 2 weeks 3 weeks	2 (0,6) 1 (0,6) 1 (0,5)	2 (0,6) 2 (0,6) 1 (0,5)	1 (0,2) 0 (0,4) 2 (0,4)	0.097 0.395 0.668
Baseline 1 week 2 weeks 3 weeks 4 weeks	2 (0,6) 1 (0,6) 1 (0,5) 1 (0,5)	2 (0,6) 2 (0,6) 1 (0,5) 1 (0,5)	1 (0,2) 0 (0,4) 2 (0,4) 1 (0,3)	0.097 0.395 0.668 0.717
Baseline 1 week 2 weeks 3 weeks 4 weeks ΔTOSS at 1 week	2 (0,6) 1 (0,6) 1 (0,5) 1 (0,5) -2 (-5,2)	2 (0,6) 2 (0,6) 1 (0,5) 1 (0,5) -3 (-5,2)	1 (0,2) 0 (0,4) 2 (0,4) 1 (0,3) -1 (-2,1)	0.097 0.395 0.668 0.717 0.026

V. Discussion

Home air purification systems have been used for many years to decrease allergic symptoms and to improve the quality of indoor air. Unfortunately, data has not conclusively shown a clinical benefit to the use of existing air purification technology and the degree of purification has been uncertain (3, Sublett).

Molekule's novel air purification technology using PECO allows for the breakdown of organic material, including volatile organic compounds, and conversion to harmless byproducts including carbon dioxide and water. The importance of this technology may reside in its ability to destroy microbes including bacteria, viruses and fungi more effectively and rapidly than any existing technology. The link between fungal exposure and allergies has been well established and may be an under-recognized health hazard (4, Hamilos).

With the use of Molekule's technology, TSS scores from allergy sufferers dropped to the normal range (equivalent to the score of non allergy sufferers) within 1 week following initiation of treatment. After initiation of treatment, there was no difference in TSS between allergy and non-allergy sufferers. This improvement in TSS was consistent over the 4 week course of treatment. Reductions were seen in both nasal and ocular allergy symptoms for allergy sufferers as well.

Future studies will look to expand to a larger cohort of test subjects to further validate the results and understand the impact on symptoms over a longer evaluation period. Molekule will continue to study the use of its technology to benefit people with allergic symptoms and plan to continue to work with an exceptional team of doctors to achieve this. Results of this initial beta study point to the potential for Molekule to immediately improve the quality of life for those who suffer from allergies.

VI. Acknowledgments

We would like to thank Dr. Tobin Strom for his help in the statistical analysis of our beta trial results. We would also like to thank our participants for their feedback.

VII. References

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