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Background

Obstructive sleep apnea (OSA) is a chronic syndrome that is estimated to affect up to 7 percent of the adult population.⁽¹⁾ Patients with OSA experience intermittent loss of upper-airway muscle tone during sleep, resulting in either partial or total obstruction of the upper airway. Loud snoring and excessive daytime sleepiness are the two most common symptoms of OSA. Airway obstruction leads to hypoxemia and hypercarbia, which can cause activation of the sympathetic nervous system and arousal from sleep.⁽²⁾ The excessive daytime sleepiness will commonly have a negative impact on daytime activities.⁽³⁾ OSA is also associated with cardiovascular sequelae.⁽⁴⁾ Patients with OSA are likely to be obese, have high blood pressure, experience more depression, and be involved in more traffic accidents.^(5,6)

Continuous positive airway pressure (CPAP) is prescribed to treat OSA.⁽⁷⁾ A CPAP therapy system consists of a blower to generate pressure, a humidification system to help make the air more comfortable to breathe, and a mask. The mask is the interface between the patient and the therapy device. There are three general styles of masks: one that covers the nose (nasal mask), one that seals at or in the nares (nasal cannula or pillows), and one that delivers therapy through the mouth and nose (full face mask).⁽⁸⁾

The style of mask best suited for a patient can be influenced by patient and clinician preference, facial anatomy, and therapy pressure.⁽⁹⁾ The overall configuration of the mask may affect mask performance and patient preference. Mask-related issues such as air leaks, discomfort, and negative perceptions about its appearance may present barriers to adherence to therapy.⁽¹⁰⁾



This study was undertaken to compare subjective patient ratings of the new DreamWear Full face mask to other full face masks currently available. The primary aims of the study were:

- To determine patient preference for the DreamWear Full face mask in relation to other full face masks
- To determine whether attributes of the DreamWear Full face mask, including mask fit, seal, comfort, and usability, are rated more highly than those of the other full face masks

Methods

This was a multicenter, open-label trial. The study was approved by an Independent Ethics Committee, and all participants gave written, informed consent. Recruited between August and November of 2017, participants completed baseline study procedures either through the mail or in person at an independent sleep center. Surveys related to the DreamWear Full face mask were conducted over the telephone.

To be eligible, participants were required to have been previously diagnosed with OSA and to have undergone a successful CPAP titration. Additionally, they had to be using one of the following full face masks: AirFit F20 or AirTouch F20, ResMed (San Diego, California); Simplus, Fisher & Paykel Healthcare (Irvine, California); or Amara View, Philips Respironics (Murrysville, Pennsylvania). Participants were required to report using therapy at least 4 days a week. Those who had known allergies to silicone, who were not medically stable, who were not likely to comply with or fulfill the requirements of the study procedures, or who had contraindications for using a full face mask, were excluded.

Data analysis

Demographic and baseline variables are presented with descriptive statistics. Using a 0-10 scale, participants rated various attributes of their prescribed mask at the beginning of the trial. These same attributes were then evaluated for the DreamWear Full face mask after 10 and 30 days of use. Attribute ratings were compared between the study intervals using Mixed Models with repeated measures. If the overall interval effect was significant, the rating was compared to the prescribed-mask rating collected at the beginning of the trial, but the 10- and 30-day ratings were not compared to each other. The p-values of the post hoc comparisons were adjusted using the Sidak method.

Categorical questions were analyzed with a one-sample binomial test that compared the observed proportion to a 50/50 split. For categorical questions that had more than two alternative responses (e.g., “Prescribed mask” / “Trial mask” / “Both masks equal”), options such as “Your current/prescribed mask” and “Both masks are equal” were combined into one category and compared to the trial mask for the significance testing. To account for multiple comparisons conducted at the 10- and 30-day intervals, the p-values were adjusted using the Sidak method.

Participants were excluded from the analysis of a given endpoint if they did not contribute a rating for their prescribed mask and at least one of the 10- and 30-day trial intervals. All statistical tests were considered significant at $p < 0.05$, and the analyses were conducted using SAS® software.

Results

Gender and age data are presented in Table 1 and race information is displayed in Table 2. A majority of the participants (75%) were Caucasian. The Amara View mask was prescribed for 30% of the participants, and 42% of them used one of four different masks made by ResMed (Table 3). Just under 80% of the participants used CPAP, while approximately 20% used bi-level therapy (Table 4).

Gender	N	Age
Female	31 (33%)	63 ± 10.1
Male	62 (67%)	58 ± 14.4

Table 1: Gender and age characteristics

Race	
Caucasian	75%
Latino/Hispanic	17%
African American	3%
American Indian	2%
Multiple races indicated	2%

Table 2: Race characteristics

Prescribed mask	N	% of patients
AirFit F10 and AirFit F10 for Her	25	27%
AirFit F20 and AirTouch F20	14	15%
Amara View	28	30%
Simplus	26	28%

Table 3: Participant prescribed mask information

Therapy type	% of patients
CPAP	42%
Auto CPAP	37%
Bi-level/BiPAP	9%
Auto bi-level/BiPAP	11%
Don't know	2%

Table 4: Participant therapy summary

Of the study's 93 participants, 29 were recruited from an independent sleep center and 64 were recruited remotely. The participants from the sleep center had a baseline visit there and were provided the mask by study staff. The baseline visit was conducted by telephone for the remote participants and they were subsequently mailed their study mask.

Mask preference survey results (Table 5) show that the DreamWear Full face mask was chosen significantly more often than the prescribed masks when considering these factors:

- Accommodating the use of eyeglasses for those wearing them with their mask
- Lack of obtrusiveness (less of a feeling that there is something on the face)
- Freedom of movement while sleeping
- Less intimidating appearance
- Allowing closeness to a bed partner

Most participants reported no discomfort on the nose or nostrils but a subset of participants reported it with the full face mask. However, the discomfort did not reach a level where the participant abandoned mask use.

A significant majority of participants indicated that it was not necessary to choose a sleeping position with the DreamWear Full face mask.



Mask preference questions (30 days)

	N	% preferring DreamWear Full mask	% preferring prescribed mask, both masks, or neither mask	p-value
Which mask do you prefer to wear your eyeglasses with? (N=36 wearing eyeglasses with mask)	69	86.1	13.9	<0.0002
Which mask comes closest to making you feel like you have nothing on your face?	85	81.2	18.8	<0.0002
Which mask do you feel provides you more freedom of movement when you sleep?	85	76.5	23.5	<0.0002
Which mask is least intimidating?	85	74.1	25.9	<0.0002
Which mask enables you to get closer to your bed partner?	64	67.2	32.8	0.016
Which mask does your bed partner prefer?	64	48.4	51.6	0.99
Which mask allows you to sleep on your stomach?	42	23.8	76.2	0.002
Did you experience any discomfort in your nostrils or on your nose? (Yes=22) With which mask?	22	90.9	9.1	0.0002
		No	Yes	p-value
Did you feel it necessary to choose a sleep position with the DreamWear mask?	85	80.0	20.0	<0.002

Table 5: Mask preference results



Table 6 summarizes the results of the mask attributes survey. Several aspects of the design of the mask were rated more highly for the DreamWear Full face mask than the prescribed masks. Its ratings were significantly higher at 10 and 30 days for visual appeal, fit of the headgear, mask comfort, and bed partner's satisfaction with the exhalation of air from the mask. Both intervals saw the DreamWear Full face mask do markedly better for overall fit of the mask cushion and how well the mask stayed in place. Ratings for mask noise tended to favor the DreamWear Full face mask on the 10-day survey and were significantly higher on the 30-day survey.

Although the remaining 10- and 30-day mean scores tended to be higher for the DreamWear Full face mask, there were no significant differences in the mask ratings for ease of use, maintaining a seal, quality of sleep, and likelihood of recommending the mask to others.

Mask attributes survey questions	Prescribed mask Mean ± SD	10-day DreamWear Mean ± SD	30-day DreamWear Mean ± SD	10-day p-value	30-day p-value
How satisfied are you with the visual appeal of the mask?	7.2 ± 2.9	8.9 ± 1.4	8.8 ± 1.7	<0.0001	<0.0001
How satisfied are you with the overall fit of the mask's headgear?	7.5 ± 2.2	8.9 ± 1.5	8.8 ± 1.8	<0.0001	<0.0001
How satisfied are you with the exhalation of air from the mask?	7.9 ± 2.1	8.7 ± 1.8	8.5 ± 2.4	0.016	0.097
How satisfied is your bed partner with the exhalation of air from the mask?	7.5 ± 2.5	8.5 ± 2.5	8.6 ± 2.2	0.026	0.010
How satisfied are you with the comfort of the mask?	7.5 ± 2.2	8.8 ± 1.7	8.6 ± 1.9	<0.0001	0.001
How satisfied are you with the noise level of the mask?	7.7 ± 2.2	8.4 ± 2.3	8.6 ± 2.2	0.053	0.018
How satisfied are you with the ease of use of the mask?	8.2 ± 2.0	8.7 ± 1.8	8.5 ± 2.0	0.231	0.675
How satisfied are you with the overall fit of the mask cushion?	7.5 ± 2.1	8.4 ± 2.0	8.4 ± 2.1	0.008	0.012
How satisfied are you with how well the mask stays in place while you're sleeping?	7.0 ± 2.4	8.2 ± 2.1	8.2 ± 2.3	0.001	0.001
Would you recommend your mask to others?	7.7 ± 2.2	7.8 ± 2.3	8.2 ± 2.3	0.997	0.286
How would you rate your overall satisfaction with the mask?	7.8 ± 2.0	8.2 ± 2.1	8.2 ± 2.3	0.223	0.305
How satisfied is your bed partner with the mask?	8.0 ± 2.4	7.9 ± 2.7	8.5 ± 2.0	0.995	0.258
How satisfied are you with the quality of sleep you receive while wearing the mask?	8.0 ± 2.0	8.0 ± 2.5	8.0 ± 2.5	0.993	0.999
How satisfied are you with how well the mask maintains a seal during use?	6.8 ± 2.2	7.6 ± 2.6	7.5 ± 2.7	0.059	0.112

Table 6: Mask attributes survey results

Discussion

In this group of experienced full face mask users, survey results confirm that the DreamWear Full face mask design was viewed more favorably than the participants' prescribed masks with respect to visual appeal, fit of the headgear, mask comfort and stability, overall fit of the mask cushion, and the bed partner's satisfaction with exhalation of air from the mask over a period of 30 days of use. Consistent with those findings, the DreamWear Full face mask was preferred more frequently than the prescribed masks in the areas of accommodating the use of eyeglasses (for those wearing them with their mask), lack of obtrusiveness (less of a feeling that there is something on the face), freedom of movement while sleeping, less intimidating appearance, and allowing closeness to a bed partner. In a subset of participants, the DreamWear Full face mask was more frequently associated with discomfort on the nose or in the nostrils than were the prescribed masks.

Feeling uncomfortable with wearing a CPAP, discomfort from pressure of the mask,⁽¹¹⁾ and aversion to wearing unattractive headgear to bed have been identified as reasons for nonadherence.⁽¹²⁾ With favorable ratings for the visual appeal of the mask and the fit of the headgear, the design of the DreamWear Full face mask may help address these issues.

Participants gave the DreamWear Full face mask better ratings for appearance and exhalation airflow than those of their prescribed masks. They found the DreamWear Full face mask to be less obtrusive and intimidating, and it was rated more highly with respect to allowing closeness to a bed partner. That aspect, combined with the favorable ratings for appearance,

exhalation airflow, and relative lack of intimidation in wearing the mask, could minimize the impact on intimacy that treatment may have. Intimacy is a significant issue for patients with sleep-disordered breathing.^(13, 14)

Additionally, the DreamWear Full face mask design was found to be more accommodating for participants who wanted to wear their eyeglasses while wearing their mask. This feature may be less disruptive to bedtime routines that include reading or watching television.

Conclusion

In this study group, the DreamWear Full face mask received higher ratings than the participants' prescribed masks when evaluating several mask attributes. By having more visual appeal and being less obtrusive and intimidating, the DreamWear Full face mask overcomes common issues with mask products and is a viable option for patients using a full face mask.

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