Superior comfort and sealing performance - F&P Brevida™ nasal pillows mask

Published: Dec 2016

1.0 Introduction

Obstructive sleep apnea (OSA) is a common breathing disorder affecting around 3 to 7% of men and 2 to 5% of women in the general population[1] and is characterized by periodic collapse of the upper airway during sleep[2]. The standard treatment for OSA is continuous positive airway pressure (CPAP), which consists of pressurized air applied to the nose via an interface.

Despite the effectiveness of CPAP in alleviating upper airway obstruction, acceptance of and adherence to therapy is often sub-optimal[3]. Reasons for the low compliance include nocturnal awakenings[4], incorrect therapeutic pressure, and discomfort primarily due to poor interface fit[5]. Poor interface fit can result in facial abrasion, leak causing fluctuations in therapeutic pressure, and irritation of the eyes. Fisher & Paykel Healthcare (Auckland, New Zealand) has designed a new nasal pillows mask – the F&P Brevida (Figure 1).

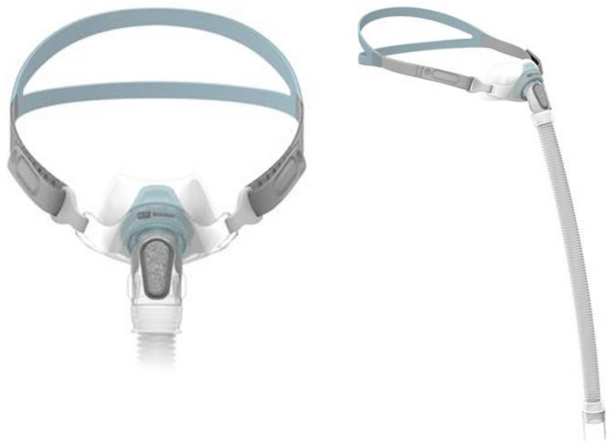


Figure 1 The F&P Brevida nasal pillows mask.

The primary aim of this study was to evaluate how participants viewed the performance, comfort, and ease of use of the F&P Brevida nasal pillows mask in a home environment and to understand the user's view on general comfort, overall experience, and their level of satisfaction.

2.0 Method

2.1 Participant selection

Thirty-eight participants with OSA, established on PAP therapy, were recruited into this study by Ohio Sleep Medicine Institute (Columbus, Ohio, USA). All participants provided written informed consent, and the study was approved by IntegReview IRB. Participant inclusion criteria were: age > 18 years, a diagnosis of OSA by a practicing physician, AHI ≥ 5/hr from the diagnostic night, prescribed a PAP therapy (bi-level or CPAP or automatic positive airway pressure (APAP)) for OSA and an existing nasal pillows mask user.

2.2 Study design

This investigation was an open-label (investigators are un-blinded and informed of intended treatment device), single-arm study. The intended treatment with the F&P Brevida mask was not randomized. During the first visit to Ohio Sleep Medicine Institute (OSMI), following informed consent, participants (excluding those on bi-level therapy) used an F&P ICON+ Premo/Auto-CPAP device for 14 ± 4 days using their usual nasal pillows mask to provide baseline data.

During the second visit, the participants' treatment compliance and leak baseline data was downloaded from their PAP devices. Each participant was then fitted and issued with the F&P Brevida mask. The initial impression of the mask was captured by means of a questionnaire. The participants used this mask in home, according to their normal PAP prescription, for 14 ± 4 days.

During visit three, the participants returned the F&P Brevida mask. Compliance and leak data were downloaded from their PAP devices. Each participant also underwent a short interview and completed a questionnaire about their experience with the F&P Brevida mask. Participants who preferred the F&P Brevida to their usual mask were asked if they would like to continue using the F&P Brevida mask in-home for an additional 3 months to determine as to whether or not longer-term participant satisfaction was evident.

For those participants who chose to continue to use the F&P Brevida mask for 3 months, follow-up phone calls were made after visit three at 1 month (± 5 days), and also at +2 months (± 5 days).

During visit four (3-month visit), participants returned the F&P Brevida mask. They were asked to also complete a questionnaire.

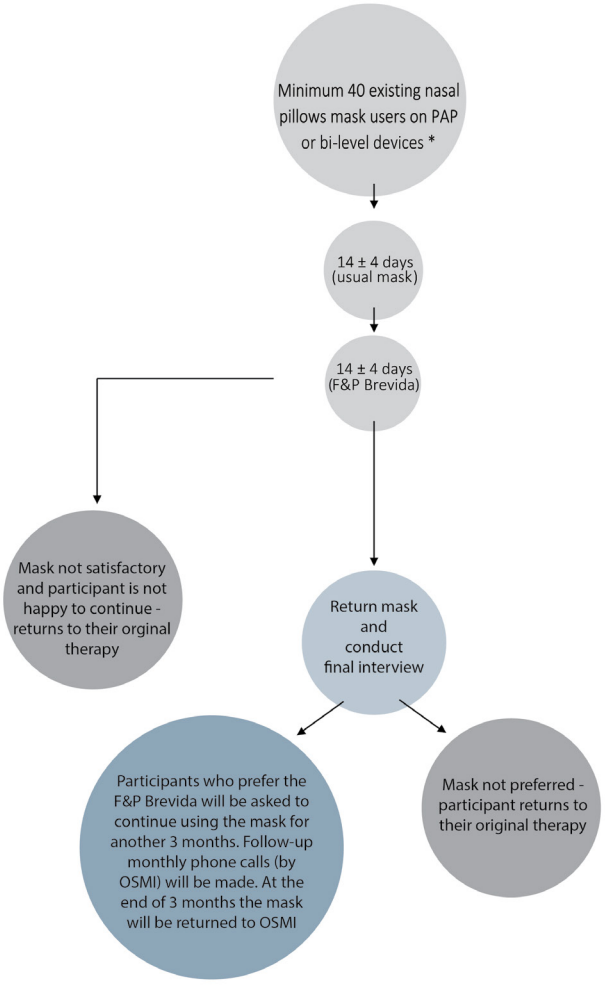


Figure 2: Flow chart of study protocol

2.3 Measurements

The study evaluated the following:

- The general demographic of participants (age, ethnicity, length of time on therapy, current CPAP settings and previous mask and size used)
- The participants' rating of the F&P Brevida in relation to comfort, seal performance (leak), ease of use and noise/air draft performance
- The participants' rating of the F&P Brevida in terms of overall fitting and removal of the mask
- The participants' comparison of the F&P Brevida to their usual mask in relation to overall fitting of the mask, assembly/disassembly, and preference of mask for ongoing use with PAP therapy.

Other measurements that were recorded during the study were: the participants' AHI, average leak as measured by the CPAP device and average time on therapy.

3.0 Results

Thirty-eight participants completed the clinical investigation. (*42 patients were recruited initially, but 4 participants subsequently withdrew for various reasons.)

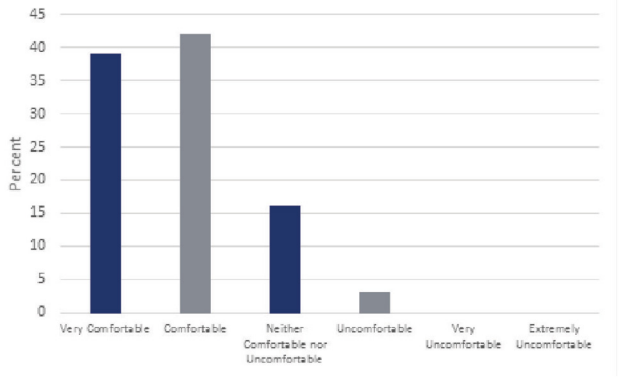
3.1 Participant demographics

N	38
Male/Female	22/16
Ethnicity	37 Caucasian, 1 African-American
Time on CPAP	One to six years: 26 participants Greater than six years: 12 participants

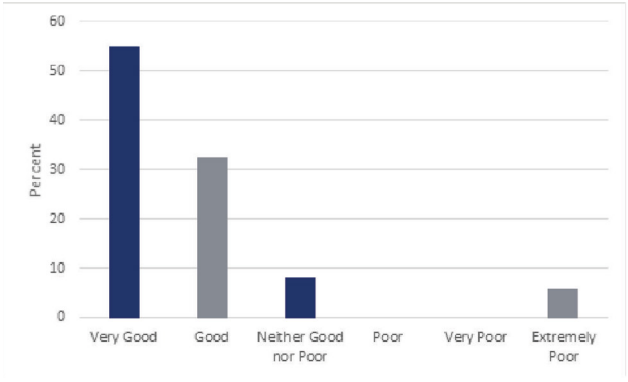
3.2 Participants' ratings of the F&P Brevida nasal pillows mask

The ratings used in the survey were based on a six-point Likert scale. A total of 39% and 42% of the participants rated the F&P Brevida to be "very comfortable" and "comfortable" respectively in terms of comfort of the mask (refer to graphs below); 55% and 32% rated it to be "very good" and "good" respectively for sealing performance; 39 % and 42% rated it to be "very easy" and "easy" respectively in terms of fitting.

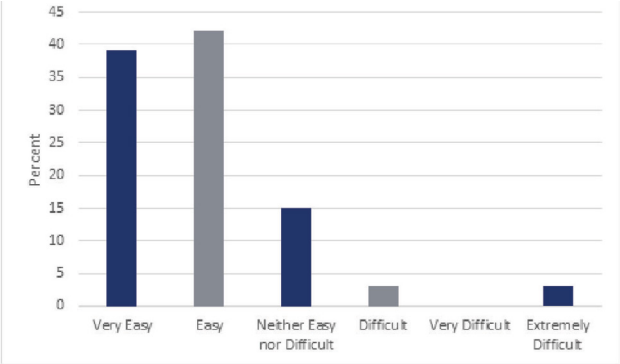
Participants' ratings of the F&P Brevida in regard to comfort of the mask



Participants' ratings of the F&P Brevida in regard to sealing performance of the mask



Participants' ratings of the F&P Brevida in regard to fitting of the mask of the mask



A total of 82% participants commented where relevant that the noise didn't disturb them or their bed partners during use of the F&P Brevida and 97% of participants commented that the draft didn't disturb them or their bed partner.

The assembly and disassembly of the F&P Brevida mask was assessed to determine its usability during maintenance activities. At least 79% of the participants found disconnecting and connecting the following parts of the F&P Brevida to be "very easy" or "easy". (See Figure 3 for part references.)

- Removing the headgear from the mask frame (D–B): 92%
- Connecting the swivel to the mask breathing tube (F–H): 95%
- Attaching the diffuser to the elbow (G–E): 86%
- Connecting the seal (A–B): 79%
- Removing the swivel from the mask breathing tube (F–H): 89%
- Removing the diffuser from the elbow (G–E): 90%
- Removing the seal from the mask frame (A–B): 84%
- Attaching headgear: 92%

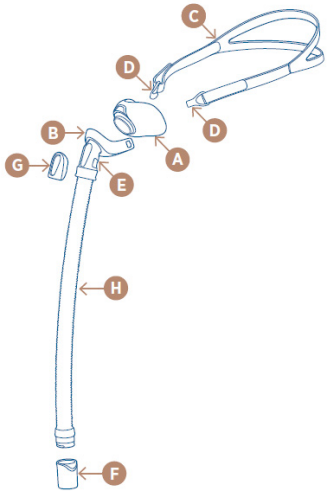


Figure 3: The F&P Brevida nasal pillows mask parts

3.3 Comparison of the F&P Brevida with each participant's usual mask

After 14 ± 4 days' in-home use of the F&P Brevida mask, participants were asked to compare their experience with that of their usual mask. The ratings used in the survey were based on a three-point Likert scale.

At least 50% of the participants indicated that they had a superior experience using the F&P Brevida mask in comparison with their usual mask in the categories below:

- The F&P Brevida mask noise was quieter than the participant's usual mask (82%).
- The F&P Brevida had less draft than the participant's usual mask (79%).
- The F&P Brevida was more comfortable on the nose than the participant's usual mask (66%).
- The F&P Brevida headgear was more comfortable than the participant's usual mask (50%).
- The F&P Brevida headgear was more stable than the participant's usual mask (58%).

Subjective feedback from participants was collected and individual comments such as the following were used to convey their level of satisfaction of the F&P Brevida nasal pillows mask:

I especially liked the comfort of the nasal pillows, the softness of the straps and the quietness of its operation.

Comfort and stability of the seal is the main factor.

3.4 Participants' preference

When given the choice of the primary mask to use going forward, 29 participants preferred to continue using the F&P Brevida mask and 28 consented to continue using the F&P Brevida in home for an additional 3 months (74% of trial participants).

Discussion

4.0 Discussion

Having a mask design that focuses on improving the current state of comfort, ease of use, and satisfaction during use is an important factor in achieving the patients' acceptance of CPAP therapy. To continually strive to increase the level of patient comfort, usability, and satisfaction with masks is a challenge, especially with nasal pillows masks.

A study by Bachour et al[6] reported that patients who switch their mask from their initial mask are seven times more likely to abandon PAP therapy within 1 year. This study shows the importance of initial impression and performance of a mask on therapy adherence. The F&P Brevida is a mask designed to have features that ensures a positive initial experience and therefore promote mask

adherence by preventing mask switching.

Current commonly reported complaints about nasal pillows masks include local allergic reactions and discomfort, air leaks, and mask dislodgement[7]. Most participants considered the F&P Brevida to be quieter. The participants also appreciated features such as ease of fitting and adjustment, comfort of the mask, stability of the headgear and sealing performance. This could have been attributed to several innovative key design features as discussed below.

Improving mask leak is essential for patient comfort as this has previously been reported to be a problem in 63% of OSA patients[8]. The feedback from the final interviews suggests that there was an improvement in the sealing performance of the F&P Brevida mask with 82% of patients reporting that the F&P Brevida was quieter in comparison with their usual mask. The participants (79%) also reported a lower amount of draft compared to their usual mask. Maintaining an effective seal during use is an integral part of the mask design process and important in determining whether or not a mask provides the best chance of therapy success. The F&P Brevida mask has been designed to seal in and around the nose, acting as a double seal, and this allows for more pressure/air distribution. This double seal also offers the benefit of stability to people who move around considerably in their sleep. The F&P Brevida was reported to be more comfortable (66%) or the same (21%) on the nose than the participant's usual mask. Design development in this area has been aimed to minimize irritation and discomfort of the seal in and around the nose.

Stability of the headgear on the head overnight is important to ensure compliance. The F&P Brevida mask has adjustable headgear which meets the participants' preference for minimal headgear without jeopardizing stability. Participants rated the F&P Brevida headgear to be more stable (58%) or the same level of stability (32%) as their usual mask's headgear. They also rated the comfort of the headgear as more comfortable (50%) or at the same level of comfort (42%) in comparison with their usual mask.

These results are reflected in the participants' mask preference. When given the choice, 74% of trial participants preferred to continue to use the F&P Brevida mask as their primary mask in-home for an additional 3 months. A mask that is more stable and more comfortable for the patient to wear could contribute significantly to increasing patient compliance levels.

A major limitation of the study, however, was that it was not blinded to the type of mask. Therefore, bias on the part of investigators, or even participants, cannot be eliminated completely.

In conclusion, this study has shown that the F&P Brevida mask can improve the satisfaction of current nasal pillow mask users. For patients using PAP therapy, the F&P Brevida may offer a good chance of ongoing therapy adherence. Given the potential cost of untreated OSA to healthcare systems, it is important that enhancements to current mask features and technologies continue to ensure the best-possible care can be provided to those who suffer from OSA and that adherence to CPAP therapy is improved on an ongoing basis.

Acknowledgment: This study was sponsored by Fisher & Paykel Healthcare Ltd, Auckland, New Zealand. Fisher & Paykel Healthcare Ltd would like to thank the staff of the Ohio Sleep Medicine Institute, for their assistance with patient appointments.

References

1. Al Lawati N et al. Epidemiology, Risk Factors, and Consequences of Obstructive Sleep Apnea and Short Sleep Duration. Prog Cardiovasc Dis 2009; 51(4):285–293.
2. Dempsey, et al. Pathophysiology of Sleep Apnea. Physiological Reviews 2010; 90:47–112.
3. Weaver TE, Faan RN & Sawyer AM. Adherence to Continuous Positive Airway Pressure Treatment for Obstructive Sleep Apnea: Implications for Future Interventions. Indian J Med Res 2010; 131:245–258.
4. Hoffstein V, et al. Treatment of obstructive sleep apnea with nasal continuous positive airway pressure: patient compliance, perception of benefits and side effects. ATS 1992; 145(4):841–845.
5. Pelletier-Fleury N, Rakotonanahary D & Fleury B. The age and other factors in the evaluation of compliance with nasal continuous positive airway pressure for obstructive sleep apnea syndrome. A Cox's proportional hazard analysis. Sleep Medicine 2001; 2(3):225–232.
6. Bachour A, Vitikainen P & Maasilta P. Rates of initial acceptance of PAP masks and outcomes of mask switching. Sleep and Breathing 2016; 20:733–738.
7. Bachour A & Vitikainen Maasilta P. CPAP interface: satisfaction and side effects. Sleep and Breathing 2013; 17:667-672.
8. Engleman HM et al. Self-reported use of CPAP and benefits of CPAP therapy. Chest 1996; 109:1470–1476.

Fisher & Paykel HEALTHCARE