F&P Evora™ Nasal - Prepared by Fisher & Paykel Healthcare

Abstract

This whitepaper outlines two Fisher & Paykel Healthcare (F&P) sponsored clinical investigations that assessed the performance, ease of use, and comfort of the new F&P Evora Nasal PAP mask in regular positive airway pressure (PAP) users with obstructive sleep apnea (OSA) (n = 45) and mask-fitting subject-matter experts (SMEs) (n = 21). The Evora Nasal is a compact nasal mask that features CapFit™ headgear and the next generation of Dynamic Support. With the new CapFit headgear, 93% of OSA participants thought that fitting the Evora Nasal was similar to putting on a baseball cap[1] and 98% found it simple to put on and take off in the dark.[2] Mask-fitting SMEs confirmed the Evora Nasal's ease of use, with 95% rating its fitting as simple.[3] These results place the Evora Nasal as a strong new player in the nasal mask category for PAP therapy.

1.0 Introduction

OSA is a sleep disorder characterized by repeated collapse or partial collapse of the upper airway (apnea or hypopnea respectively), leading to multiple arousals throughout the night.[4] When left untreated, this condition leads to significant dysfunction during the daytime, neurological impairment, and comorbidities including hypertension[5] and vascular disease.[6] OSA poses a significant health burden to society, predicted to affect approximately one billion people globally.[7] Obesity and ageing are two key predictive factors for OSA;[8–10] with the current obesity epidemic and ageing population, the affected population will only continue to increase worldwide. Since its introduction almost 40 years ago,[11] PAP has been the gold-standard treatment for OSA, reducing the nightly apnea/hypopnea events (measured as AHI) effectively and thereby improving the related symptoms. Despite this, adherence to PAP therapy remains a significant barrier to effective treatment in this patient population.[12–14]

At F&P, we know that adjusting to PAP therapy can be challenging. Our aim is to improve adherence by designing masks that provide effective therapy, are easy to use and comfortable to wear. F&P has recently designed a new compact nasal mask, the Evora Nasal (Figure 1).

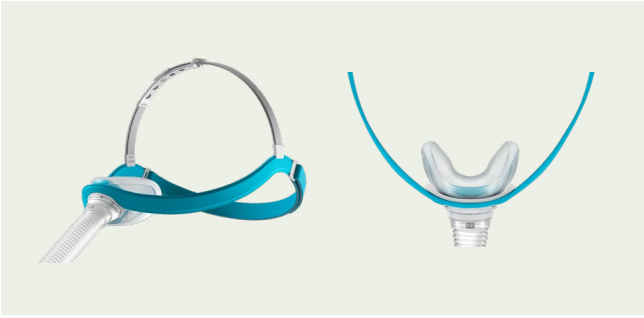

***Figure 1**. The Evora Nasal compact nasal mask featuring CapFit headgear with a floating seal and stability wings.*

The aim of this investigation was to evaluate the performance, comfort, and ease of use of the F&P Evora Nasal across 45 participants diagnosed with OSA who were existing nasal, sub-nasal, or nasal pillows mask users. Previous studies have shown that having a positive experience with aspects like ease of use during the initial consultation and introduction to a mask is crucial for long-term adherence[15,16] For this reason, feedback was gathered from sleep technicians and respiratory therapists on the usability aspects of the F&P Evora Nasal.

2.0 Method

2.1 Participant selection

Forty-five participants diagnosed with OSA using PAP therapy (APAP, CPAP, or Bi-level) were recruited into the clinical investigation. This included users of three different nasal mask categories: nasal, sub-nasal, and nasal pillows. Participants were recruited at the study site, Clayton Sleep Institute based in St. Louis, Missouri, USA, from their internal database of participants. The participant population consisted of 36% females, and an ethnicity make-up of 71% Caucasian and 29% Hispanic/African American/Asian or Polynesian descent. The investigation obtained ethics approval by IntegReview IRB (Austin, Texas) via an expedited review process prior to enrolling participants into the investigation.

The inclusion criteria for this investigation were:

- Diagnosis of OSA by a physician
- Aged ≥ 22 years
- Weight ≥ 66 lb (approximately 30 kg)
- Prescribed PAP or Bi-level therapy
- Existing nasal, sub-nasal, or nasal pillows user (for at least 3 months prior to investigation start date)
- Fluent in written and spoken English
- A PAP therapy device that has data efficacy recording capabilities

The exclusion criteria for this investigation were:

- Inability to provide informed consent
- Participant is pregnant or think they may be pregnant
- PAP intolerant, anatomical, or physiological conditions making PAP therapy inappropriate
- IPAP pressure ≥ 25 cmH_2O
- PAP therapy device used for delivery of medicines (excluding oxygen)

In a concurrent investigation, 21 mask-fitting SMEs were recruited to provide feedback on the ease of use of the F&P Evora Nasal. These participants, referred to herein as SMEs, were trained sleep technicians or respiratory therapists. SMEs were recruited from Clayton Sleep Institute (n = 15) and IV & Respiratory Care, St. Louis, USA (n = 6).

2.2 Study design

The clinical investigation on OSA participants was a prospective, non-randomized, non-blinded study. This investigation was funded and sponsored by F&P, the principal investigator was independent to F&P. Figure 2 shows the investigation timeline. During the first visit, informed consent was obtained and participant demographic and treatment information was recorded. The second visit took place 7 ± 3 days after the first visit, during which time each participant's baseline data was downloaded and an Evora Nasal mask was issued and fitted by a mask-fitting SME from Clayton Sleep Institute. Participants' initial feedback was gathered via a questionnaire and participants were issued a sleep diary to keep track of their daily progress with the mask. A follow-up phone call was made 3 ± 1 days after the second visit and feedback was recorded. Visit 3 was 14 ± 3 days later; this was an exit interview where a questionnaire evaluated each participant's feedback.

In the investigation on mask-fitting SMEs, participants were given a short demonstration and explanation of the Evora Nasal mask by an F&P employee and were then asked to fit the mask as they normally would on a patient, as well as to clean, assemble, and disassemble the mask. They then completed a questionnaire to provide feedback on their experience with the F&P Evora Nasal.

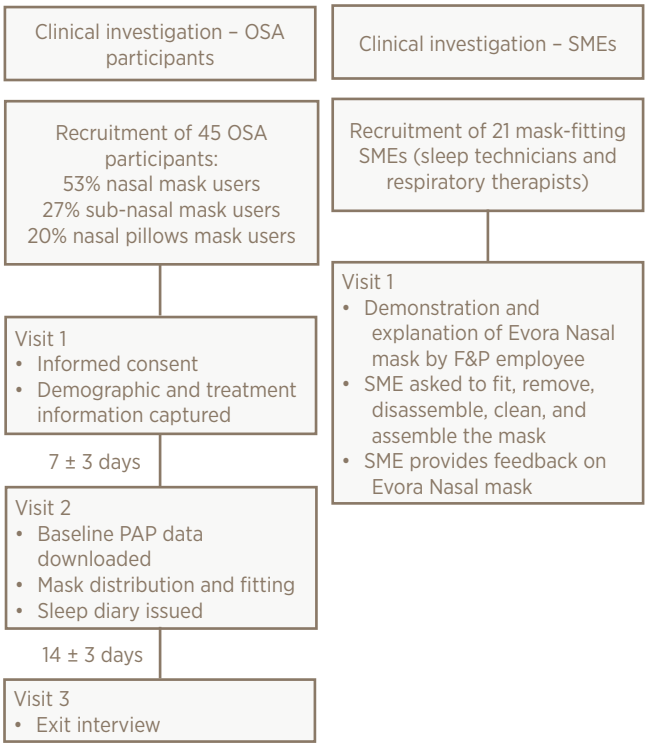

***Figure 2**. Timeline for the clinical investigations on the Evora Nasal mask.*

2.3 Measurements

The two-week in-home clinical investigation on OSA participants assessed the following measurements:

- Demographic information, including age, gender, ethnicity, PAP device settings, existing mask, sleeping position
- Participants' rating of the Evora Nasal in terms of comfort, seal performance, ease of use, and field of view
- Participants' rating of the Evora Nasal in terms of fitting and removal of the mask
- Participants' comparison of the Evora Nasal to their usual mask in terms of comfort, stability, and seal performance
- Participants' preference between the Evora Nasal and their current mask

The clinical investigation on SMEs evaluated their experience with fitting the mask, removing the mask, disassembly and reassembly of the mask, and cleaning the mask.

3.0 Results

Forty-five OSA participants completed the two-week in-home trial with the Evora Nasal; this included users of nasal (53%), sub-nasal (27%), and nasal pillows (20%) masks. Twenty-one mask-fitting SMEs trialed fitting and assembly of the mask. Feedback was gathered from each of these groups using questionnaires with a five-point Likert scale. There was no participant dropout in either investigation, however some OSA participants were later excluded due to protocol violations affecting the investigation integrity.

3.1 Simplicity for patients and sleep technicians

The small and intuitive design of the Evora Nasal resulted in strong outcomes for simplicity of use. Fitting and removal of the mask was rated as simple ("very simple" or "simple") by 93%[17] (Figure 3A) and 95%[18] of participants respectively. In line with its streamlined CapFit design, 93% of participants thought that fitting the Evora Nasal was similar to putting on a baseball cap.[1] This simple fitting technique also meant that 98% of participants found it simple to put on and take off the mask in the dark.[2] Overall, 90.9% of participants felt that the Evora Nasal mask's simplicity of use was "very simple", "simple", or "neutral" (Figure 3B).[19]

Simplicity outcomes

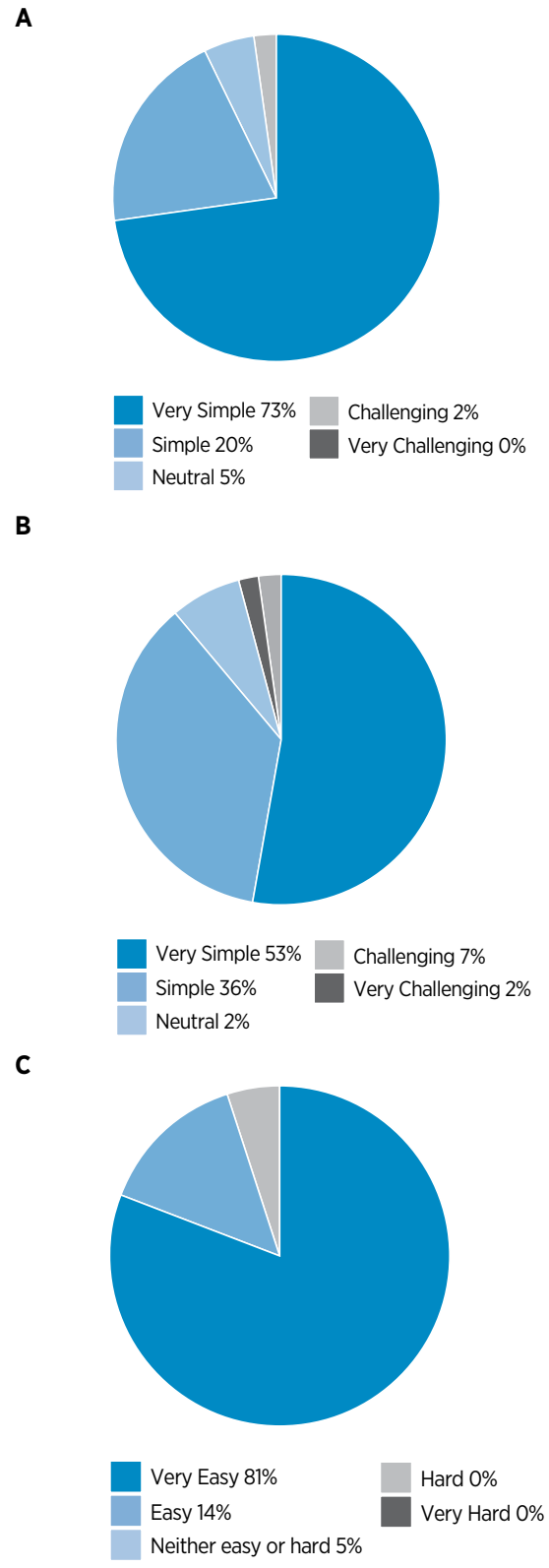

***Figure 3**. Simplicity outcomes of F&P Evora Nasal mask: (**A**) Simplicity of mask fitting (participants). (**B**) Overall simplicity of use. (**C**) Mask-fitting (SMEs).*

3.2 Participant satisfaction

The Evora Nasal provided the intended effective treatment for OSA.[22] Participants showed a high level of satisfaction with the Evora Nasal, rating comfort highly across its novel features. A total of 86% of participants rated the comfort of the Evora Nasal seal as either comfortable ("very comfortable" or "comfortable") or average (Figure 4A).[23] The compact size of the nasal seal and absence of a stability bar meant that participants also had a clear field of view; 86% of participants rated their vision as either "completely unobstructed" or "unobstructed" while wearing the Evora Nasal.[24] The CapFit headgear with AirEdge technology was well received in terms of comfort, with 96% rating the headgear as comfortable ("very comfortable" or "comfortable") or average (Figure 4B).[25]

Comfort outcomes

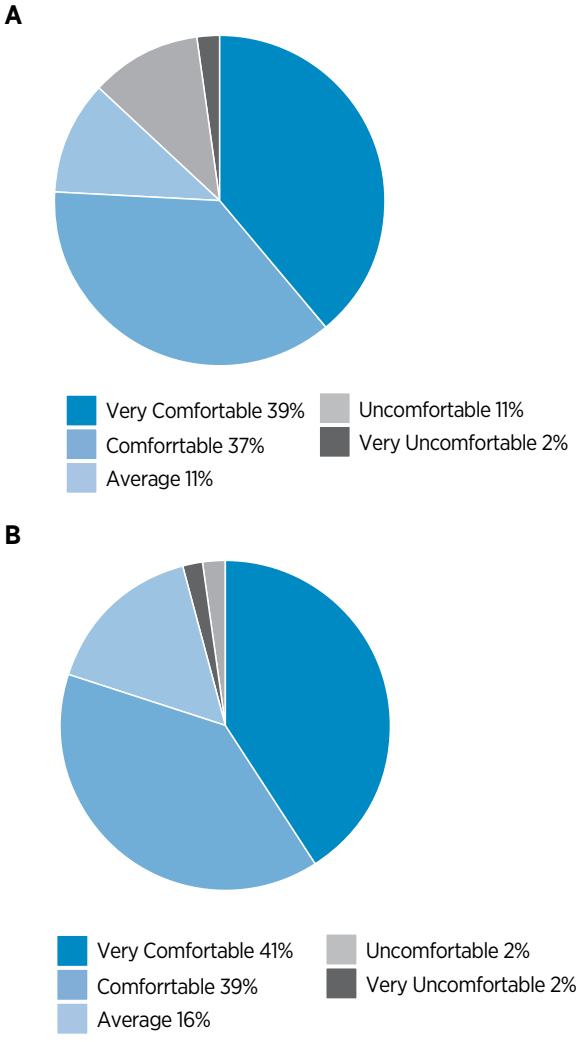

***Figure 4**. Comfort outcomes of F&P Evora Nasal mask: (**A**) Mask cushion comfort. (**B**) Headgear comfort.*

The Evora Nasal is a compact nasal mask that fits into an emerging category of nasal masks that seal under the nose (sub-nasal). In our study, 73%[26] of participants were not existing sub-nasal mask users and studies show that acclimatizing to a new mask type takes some time.[15] To see how the Evora Nasal performs in participants acclimatized to this mask type we performed a further analysis on sub-nasal mask users. Of the 11 participants who were existing sub-nasal mask users, 81.8% did not report issues with stability (rated as "very stable" "stable", or "neither stable or unstable").[27]

4.0 Discussion

PAP therapy adherence is the main barrier to effective treatment of the OSA population at present.[28] A recent study showed that adherence rates have not improved significantly over the past 20 years, with an average nonadherence rate of 34.1%.[29] There is a strong need to increase adherence in the OSA population. Effective PAP therapy can treat OSA and improve both clinical outcomes and quality of life for patients, and at a healthcare system level, increased adherence reduces total healthcare cost and utilization.[30] A recent study showed that increased PAP adherence was associated with reduced hospital visits and less likelihood of having positive costs from hospital visits.[30] Barriers to adherence include lack of initial mask fitting and support, mask discomfort, leak, and claustrophobia.[31,32] To increase adherence, mask manufacturers need to design masks with these issues in mind.

The Evora Nasal is a compact nasal mask featuring CapFit headgear, designed to be put on like a cap. The floating seal and stability wings form the next generation of Dynamic Support, allowing freedom of movement while keeping the mask comfortably in place throughout the night.[33] This comfort-guided design was well received in participant feedback, with both the seal and headgear rating highly in terms of comfort.[23,25] Claustrophobia can be a significant concern for many PAP users and is a common cause of nonadherence.[12,34] The design of the Evora Nasal helps to overcome this issue with its compact nasal profile and minimal contact with the face. Indeed, the majority of users found their vision was completely unobstructed when wearing the Evora Nasal.[24]

Headgear plays a significant role in the patient's impression and adherence to a new mask[12,35] and a patient's early experience with PAP therapy is a strong predictor of long-term compliance.[36] By designing the Evora Nasal mask fitting process to be similar to putting on a cap, patients are instantly more familiar with their new mask. Feedback from patients showed that 93% compared its fitting and removal to that of a baseball cap.[1] In addition, 95% of the mask-fitting SMEs rated fitting of the Evora Nasal as simple.[3]

A number of mask features influence the time required for the initial consultation and ongoing support. Patients need to be taken through processes including fitting, cleaning, education, and resolving mask problems. F&P aimed to simplify this process as much as possible when designing the Evora Nasal. Feedback from SMEs confirmed the simplicity of the Evora Nasal across several key processes: fitting[37] and removal,[38] assembly[39] and disassembly,[40] and mask cleaning.[41] By simplifying these steps, we aim to provide patients with a well-fitted mask the first time around, thereby reducing the time needed for the initial consultation. Healthcare systems are already struggling with staffing and resources; streamlining this process can therefore be seen as valuable for business efficiency.

Restless sleep is a common symptom of OSA;[42] a recent study showed its incidence in OSA populations ranges from 20.8% to 79.7%.[43] This can be problematic for patients undergoing PAP therapy, as the mask may become dislodged, contributing to issues like mask discomfort and leak. This is particularly evident in certain types of mask, market feedback indicates that stability is a concern in sub-nasal masks. The Evora Nasal, with its floating seal and stability wings, is designed to maintain a stable seal throughout the night despite the user tossing and turning. Our analysis on stability among sub-nasal mask users showed that 82%[27] felt that the Evora Nasal provides sufficient stability.

There were several limitations in this investigation. This was a non-blinded study; as a result, we cannot eliminate potential bias from the study participants and investigators. Another limitation is the lack of a cross-over with a control or alternative mask type; this means that at this stage we cannot generate comparative data against other mask types.

In conclusion, the feedback from a two-week in-home trial suggests that the Evora Nasal may improve patients' experience of PAP therapy and thus adherence to treatment. For patients new to PAP therapy or those who are established on therapy but having issues with usability or comfort, the Evora Nasal should be considered. Given the increasing prevalence of OSA, each of these steps taken to improve patient adherence contributes to improving the treatment of this condition.

References

1. *41 of 44 participants likened the action of putting on the mask as similar to putting on a baseball hat or cap. Internal validation study conducted by Fisher & Paykel Healthcare on 45 participants in United States of America (2019)*.
2. *43 of 44 participants were able to don and doff the F&P Evora Nasal mask once fitted/adjusted, in the dark. Internal validation study conducted by Fisher & Paykel Healthcare on 45 participants in United States of America (2019)*.
3. *20 out of 21 mask fitting subject matter experts rated the simplicity of the Evora Nasal mask as very simple or simple to fit. Internal validation study conducted by Fisher & Paykel Healthcare on 21 mask fitting SMEs in the United States of America (2019)*.
4. Strollo, P. J. & Rogers, R. M. Obstructive Sleep Apnea. *N. Engl. J. Med*. 334, 99–104 (1996).
5. Fletcher, E. C. The relationship between systemic hypertension and obstructive sleep apnea: Facts and theory. *Am. J. Med*. (1995). doi:10.1016/S0002-9343(99)80395-7
6. Bonsignore, M. R., Marrone, O., Insalaco, G. & Bonsignore, G. The cardiovascular effects of obstructive sleep apnoeas: Analysis of pathogenic mechanisms. *European Respiratory Journal* (1994). doi:10.1183/09031936.94.07040786
7. Benjafield, A. *et al*. Global Prevalence of Obstructive Sleep Apnea in Adults : Estimation Using Currently Available Data. *Am J Respir Crit Care Med* (2018). doi:doi:10.1164/ajrccm-conference.2018.197.1_MeetingAbstracts.A3962
8. Friedman, M. *et al*. Clinical predictors of obstructive sleep apnea. *Laryngoscope* (1999). doi:10.1097/00005537-199912000-00002
9. Deng, X. *et al*. Age-group-specific associations between the severity of obstructive sleep apnea and relevant risk factors in male and female patients. *PLoS One* (2014). doi:10.1371/journal.pone.0107380
10. Vicini, C. *et al*. The aging effect on upper airways collapse of patients with obstructive sleep apnea syndrome. *Eur. Arch. Oto-Rhino-Laryngology* (2018). doi:10.1007/s00405-018-5163-5
11. Sullivan, C. E., Berthon-Jones, M., Issa, F. G. & Eves, L. Reversal of Obstructive Sleep Apnoea by Continuous Positive Airway Pressure applied through the nares. *Lancet* (1981). doi:10.1016/S0140-6736(81)92140-1
12. Weaver, T. E. & Grunstein, R. R. Adherence to continuous positive airway pressure therapy: The challenge to effective treatment. *Proceedings of the American Thoracic Society* (2008). doi:10.1513/pats.200708-119MG
13. Weaver, T. E. & Sawyer, A. M. Adherence to continuous positive airway pressure treatment for obstructive sleep apnoea: Implications for future interventions. *Indian Journal of Medical Research* (2010).
14. Wolkove, N., Baltzan, M., Kamel, H., Dabrusin, R. & Palayew, M. Long-term compliance with continuous positive airway pressure in patients with obstructive sleep apnea. *Can Respir J* 15, 365–369 (2008).
15. Bachour, A., Vitikainen, P. & Maasilta, P. Rates of initial acceptance of PAP masks and outcomes of mask switching. *Sleep Breath*. (2016). doi:10.1007/s11325-015-1292-x
16. Scharf, M. T., Keenan, B. T., Pack, A. I. & Kuna, S. T. Mask refills as a measure of PAP adherence. *J. Clin. Sleep Med*. (2017). doi:10.5664/jcsm.6810
17. *41 of 44 participants rated the CapFit headgear as very simple or simple for putting on the mask. Internal validation study conducted by Fisher & Paykel Healthcare in United States of America (2019)*.
18. *42 of 44 participants rated the CapFit headgear as very simple or simple for taking off the mask. Internal validation study conducted by Fisher & Paykel Healthcare on 45 participants in United States of America (2019)*.
19. *40 of 44 participants rated the simplicity of use of the F&P Evora Nasal mask as very simple or simple to use. Internal validation study conducted by Fisher & Paykel Healthcare in United States of America (2019)*.
20. *39 of 45 participants rated cleaning of the mask as easy or very easy. Internal validation study conducted by Fisher & Paykel Healthcare in United States of America (2019)*.
21. *When assessing disconnecting individual components of the mask, 42 of 45 participants (or higher) rated this task as easy or very easy. Internal validation study conducted by Fisher & Paykel Healthcare in United States of America (2019)*.
22. *For 42 of 43 patients, the average AHI did not increase by more than 5 when using the Evora Nasal relative to that of their usual mask. Internal validation study conducted by Fisher & Paykel Healthcare in United States of America (2019)*.
23. *38 of 44 participants rated the comfort of the F&P Evora Nasal seal under the nose as very comfortable, comfortable or average. Internal validation study conducted by Fisher & Paykel Healthcare on 44 participants in United States of America (2019)*.
24. *38 of 44 participants rated their field of vision as completely unobstructed or unobstructed by F&P Evora Nasal. Internal validation stduy conducted by Fisher & Paykel Healthcare on 44 participants in United States of America (2019)*.

25. *42 of 44 participants rated the F&P Evora Nasal headgear as very comfortable, comfortable or average. Internal validation study conducted by Fisher & Paykel Healthcare on 44 participants in United States of America (2019)*.

26. *Validation trial of the Evora Nasal mask included users of nasal (53%), sub-nasal (27%), and nasal pillows (20%) masks. Internal validation study conducted by Fisher & Paykel Healthcare in United States of America (2019)*.

27. *9 of the 11 previously sub-nasal mask users rated the stability of F&P Evora Nasal as stable, very stable, or neither stable or unstable. Internal validation study conducted by Fisher & Paykel Healthcare on 44 participants in United States of America (2019)*.

28. Sawyer, A. M. *et al*. A systematic review of CPAP adherence across age groups: Clinical and empiric insights for developing CPAP adherence interventions. *Sleep Medicine Reviews* (2011). doi:10.1016/j.smrv.2011.01.003

29. Rotenberg, B. W., Murariu, D. & Pang, K. P. Trends in CPAP adherence over twenty years of data collection: A flattened curve. *J. Otolaryngol. - Head Neck Surg*. (2016). doi:10.1186/s40463-016-0156-0

30. Kirsch, D., Yang, H., Maslow, A., Stolzenbach, M. & McCall, A. Association of Positive Airway Pressure Use With Acute Care Utilization and Costs. *J Clin Sleep Med* **15**, (2019).

31. Baratta, F. *et al*. Long-term prediction of adherence to continuous positive air pressure therapy for the treatment of moderate/severe obstructive sleep apnea syndrome. *Sleep Med*. (2018). doi:10.1016/j.sleep.2017.09.032

32. Bollig, S. M. Encouraging CPAP adherence: It is everyone's job. *Respir. Care* (2010).

33. 30 of 43 patients found the F&P Evora Nasal mask stable enough so that they could sleep in their preferred position throughout the night always or most of the time. Internal validation study conducted by Fisher & Paykel Healthcare in United States of Amer.

34. Aljasmi, M. *et al*. The Use of a Validated Claustrophobia Questionnaire in Predicting Future Compliance to Continuous Positive Airway Pressure (CPAP) in Obstructive Sleep Apnea (OSA). in *D57. DON'T BE A DO-BADDER: NEW INTERVENTIONS FOR OSA* A7460–A7460 (American Thoracic Society, 2016). doi:doi:10.1164/ajrccm-conference.2016.193.1_MeetingAbstracts.A7460

35. Brown, D. L., Concannon, M., Kaye, A. B., Zupancic, M. & Lisabeth, L. D. Comparison of two headgear systems for sleep apnea treatment of stroke patients. *Cerebrovasc. Dis*. (2009). doi:10.1159/000185610

36. Budhiraja, R. *et al*. Early CPAP use identifies subsequent adherence to CPAP therapy. *Sleep* **30**, 320–324 (2007).

37. *20 of 21 mask-fitting SMEs shall rate fitting the F&P Evora Nasal mask as easy or very easy. Internal validation study conducted by Fisher & Paykel Healthcare in United States of America (2019)*.

38. *21 of 21 mask-fitting SMEs shall rate removing the F&P Evora Nasal mask as easy or very easy. Internal validation study conducted by Fisher & Paykel Healthcare in United States of America (2019)*.

39. *19 of 21 mask-fitting SMEs shall rate the reassembly of the F&P Evora Nasal headgear back strap as easy or very easy. Internal validation study conducted by Fisher & Paykel Healthcare in United States of America (2019)*.

40. *20 of 21 mask-fitting SMEs shall rate the disassembly of the F&P Evora Nasal headgear as easy or very easy. Internal validation study conducted by Fisher & Paykel Healthcare in United States of America (2019)*.

41. *18 of 21 mask-fitting SMEs shall rate cleaning the F&P Evora Nasal mask as easy or very easy. Internal validation study conducted by Fisher & Paykel Healthcare in United States of America* (2019).

42. Rowley, J., Lareau, S., Fahy, B. & Garvey, C. What Is Obstructive Sleep Apnea In Adults; Patient Information Series. Am. *J. Respir. Crit. Care Med*. 179, 5–6 (2009).

43. Keenan, B. T. *et al*. Recognizable clinical subtypes of obstructive sleep apnea across international sleep centers: A cluster analysis. *Sleep* (2018). doi:10.1093/sleep/zsx214

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