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Feasibility and acceptability of switching from a previous-generation to a new-generation mask for positive airway pressure therapy of sleep apnea using remote care

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ABSTRACT

Purpose: Mask selection could affect an individual's experience with positive airway pressure (PAP) treatment for obstructive sleep apnea, but there is very limited data on the impact of switching to a different mask once established on PAP therapy. This study investigated the patient's experience when switching from a previous-generation PAP mask to a new-generation mask via remote care.

Methods: A new-generation mask (AirFit F30i or AirFit N30i) was successfully fitted to 215 participants during video conferencing sessions. Participants completed online questionnaires on day 1, day 3, day 7, day 30 and day 90 after mask switch to collect subjective feedback and quality of life data; objective PAP device data were also downloaded.

Results: Residual apnea-hypopnea index showed statistically significant difference from baseline at day 30 (+0.2 ± 0.9/h [p = 0.026]) and day 90 (+0.2 ± 0.8/h [p = 0.006]), however unlikely to be clinically relevant. Average daily usage was significantly increased from baseline at day 30 (+0.2 ± 1.2 h/day [p = 0.010]) but not day 90 (+0.1 ± 1.0 h/day [p = 0.126]). Functional Outcomes of Sleep Questionnaire (FOSQ-10) score was significantly higher at day 90 (change from baseline to day 90: +0.48 ± 2.29 [p = 0.015]). Subjective ratings for comfort, seal, and usability of the new-generation mask were significantly better than the predefined acceptability level. Rates of PAP-related side effects were generally acceptable.

Conclusion: Remote management of mask change was associated with good outcomes in terms of objective device data and patient acceptability. This approach could be used to improve the overall therapy experience for individuals requiring a PAP therapy mask change for any reason.

Clinical trial registration: http://clinicaltrials.gov (NCT05262439).

1. Introduction

Obstructive sleep apnea (OSA) is a common sleep-related breathing disorder [1] associated with increased risk for adverse outcomes ranging from decreased daytime alertness and impaired quality of life, to hospitalization and cardiovascular morbidity and mortality [2]. Continuous positive airway pressure (CPAP) therapy is considered to be the first-line treatment for moderate-to-severe OSA [3]. The benefits of CPAP include reductions in elevated blood pressure, improved cardiovascular disease outcomes, and a decrease in the risk of fatal and non-fatal cardiovascular events [4–6]. Recent real-world data showed good adherence in the first 90 days [7], but active use of PAP therapy has been shown to decrease over time [8].

The PAP mask could influence an individual's acceptance of PAP and adherence to therapy [9]. Among the many factors influencing adherence, a good mask fit is critically important to optimize user comfort and minimize air leak [10]. Although previous studies have compared different mask types [9,11], few have investigated the effect of mask renewal/refill or replacement. A retrospective study reported an association between mask refills in the first month of therapy and lower 90-day PAP usage, whereas a higher number of mask refills after 30 days was associated with better long-term PAP adherence [12]. Mask refill rate has been identified as a surrogate for predicting long-term adherence to PAP therapy [13], and replacement of mask or mask components was associated with better longer-term PAP adherence versus no resupply in a big data analysis [14]. However, previous studies have not specified whether refill/resupply was the same mask or a different type.

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Abbreviations

AASM	American Academy of Sleep Medicine
AHI	apnea-hypopnea index
CPAP	continuous positive airway pressure
FFM	full-face mask
FOSQ-10	Functional Outcomes of Sleep Questionnaire (short version)
OSA	obstructive sleep apnea
PAP	positive airway pressure

In addition, there is a lack of data on the patient's experience after switching to a different mask for any reason, including information about mask-related side effects [15].

The COVID-19 pandemic accelerated the adoption of telemedicine [16] and the American Academy of Sleep Medicine (AASM) has suggested that high-quality, comprehensive sleep care can be provided via telehealth modalities despite potential barriers [17]. This study investigated the patients' experience who underwent remote management of a switch from an older-generation PAP mask to a new-generation mask.

2. Methods

2.1. Study design

This prospective study was conducted from the ResMed Sleep Research Center with recruitment throughout Australia between May 2022 and June 2023. The study protocol was approved by the University of New South Wales Human Research Ethics Committee (Approval number HC220072). Each participant gave written informed consent via the e-Consent module of the Electronic Data Capture (EDC) system used for the study (Medrio, Inc, San Francisco USA).

2.2. Participants

Participants were recruited from the ResMed Trials Registry, a voluntary registry open to all individuals with OSA who are being treated with PAP. Eligible individuals were aged >18 years, diagnosed with OSA and had been established on PAP therapy for ≥6 months, currently using a previous generation mask as the PAP interface, willing to provide informed consent, and able to access remote meeting and online questionnaires. Those who were pregnant, using bilevel therapy, or had implants (self or bed partner) that prevented the use of the magnetic clips on the new-generation mask were excluded (only applicable to AirFit F30i).

2.3. Procedures

Eligibility for the study was assessed based on an online baseline questionnaire completed by participants and confirmed during subsequent calls. After enrolment, participants were contacted by telephone to determine mask size based on their estimation of head and nose size. Participants were asked for their usual hat size (small, medium, large) and self-estimation of nose width (narrow, medium, wide). Gender, race and current mask size were also taken into consideration to determine mask and headgear sizes. The new-generation mask (AirFit F30i for full face mask users or AirFit N30i for nasal mask users; ResMed Pty Ltd, Sydney, Australia) and related material were sent to the participant's home by courier and then mask fitting was performed during video conferencing. Compared to participants' own older-generation mask, key differences of the new-generation AirFit F30i and N30i are they ultra-compact in size and tube-up connection of the mask and PAP tubing. If the fit and size of the mask were deemed inappropriate at the initial fitting, different sizes of the mask cushion or conduit were couriered to the participant for a repeat fitting session. Participants used their own S9 or AirSense 10 series PAP device (ResMed Pty Ltd, Sydney, Australia) and their prescribed therapy settings (AutoSet or fixed CPAP).

After trialing the new-generation mask for one and three nights, the participant's initial experience was recorded using online questionnaires that participants were asked whether they would like to receive a call from the researchers to discuss concerns or issues, and whether they would continue with the remaining phases of the study. Participants went back to using their own mask if discontinued using the new-generation mask at any point of the study.

Participants continuing with the study received online questionnaires after day 7, day 30 and day 90. These questionnaires asked participants to rate the comfort, seal, ease of use, noise, intentional leak vent, and overall performance of the new-generation mask using an 11-point Likert scale (from 0 = major issue to 10 = highly positive) and collected data on PAP-related side effects. Severity of red marks was assessed using a different scale where 0 = marks lasted for >8 h and/or broken skin, 1 = marks lasted from >2 h to 8 h, 2 = marks lasted from >30 min to 2 h, 3 = marks lasted from 1 min to 30 min, and 4 = no marks). Similar questionnaire to assess mask usability and participant experience has been utilized for previous studies [18,19]. At each check-in, participants were also asked whether they would continue with the remaining follow-ups, given the opportunity to request a call to discuss any issues, and could report adverse events or device deficiencies.

Participants were also asked to complete the short version of the Functional Outcomes of Sleep Questionnaire (FOSQ-10) online at baseline before using the study mask and after day 90. PAP device data were collected for 30 days prior to starting the new-generation mask (baseline) for each participant and again at the end of the study. PAP device data were collected by downloading from SD cards and viewed via ResScan or via AirView (ResMed Pty Ltd, Sydney, Australia).

2.4. Outcomes

The primary outcomes were the effectiveness of PAP therapy (based on the residual AHI) and device usage. Secondary outcomes included subjective ratings and the FOSQ-10 score.

2.5. Sample size

Based on data from a previous study, the standard deviation for a between-group difference in AHI was 1.60/h and in usage was 1.18 h [19]. To detect an AHI difference of 1/h with 80 % power and alpha of 0.05 required a sample size of 23, while detecting a usage difference of 0.5 h with the same power and alpha required a sample size of 46. The minimum sample size defined for this study was 50 for each mask trialed.

2.6. Statistical analysis

Device data (residual AHI, usage, 95th percentile mask leak, 95th percentile pressure) were summarized descriptively at baseline (a 30-day period prior to starting the new-generation mask), and at 30 and 90 days after starting the new-generation mask using mean and standard deviation. The change from baseline was analyzed using a 2-sided paired *t*-test. Subjective ratings on the Likert scale were presented as median values at day 7, day 30 and day 90. For each subjective rating, the median rating was calculated across all 3 time point medians and compared against a reference score of 6 using a 2-sided Wilcoxon signed-rank test, as used previously [19,20], where a score ≥6 is considered 'acceptable' (with 5 being the midpoint of the scale). FOSQ-10 scores were summarized descriptively at baseline and 90 days using mean and standard deviation and change from baseline was analyzed using a 2-sided paired *t*-test. The percentage of participants with CPAP-related

side effects (self-reported via questionnaires) was summarized at baseline, day 7, day 30, and day 90. Logistic regression analyses were performed to investigate potential demographic and baseline predictors of study mask discontinuation and withdrawal from the study. The predictors examined were age, sex, race, facial hair, duration on PAP therapy, current mask model, current PAP device model, time since last mask update, humidifier use, heated tube use, chin strap use, and baseline ratings of seal, comfort, and performance of the current mask. The predictor analysis excluded participants withdrawn from the study for reasons unrelated to the study mask or process. Statistical analyses were performed with MiniTab (version 18, PA, USA) and SAS (version 9.4). P-values $\leq$0.05 were considered statistically significant.

3. Results

3.1. Study sample

A total of 314 individuals who met the pre-screening criteria were invited to participate (Fig. 1). Of the 215 participants successfully fitted with a new-generation mask via remote video conferencing sessions (78 % male, mean age 58.5 $\pm$ 11.9 years) (Table 1), one was lost to follow-up. The previous and new-generation masks used by study participants are listed in Fig. 2. One hundred and thirty-six (136) participants completed the study, and there were 78 early discontinuations over the 90-day study period. Approximately 75 % of the participants who stopped mask use and discontinued the study did so prior to day 30, with over half of the discontinuations occurring in the first two weeks (Fig. 3). Data from four participants who were withdrawn prior to the follow-up point (n = 2 at 26 and 29 days; n = 2 at 80 and 84 days) but had completed questionnaires and a data card provided during the follow-up window were included. Follow-up window for day 30 was ($\pm$7 days) and for day 90 was $-$14 days/+7 days.

3.2. Request for support/call from researchers

Participants were given the opportunity to indicate in the questionnaires (checkpoint day 1, 3, 7, 30 and 90) to request a call from the research team to discuss any issues or ask questions. The proportion of participants requesting a call from the research team ranged from 8 % to 13 % at the various checkpoints of the study.

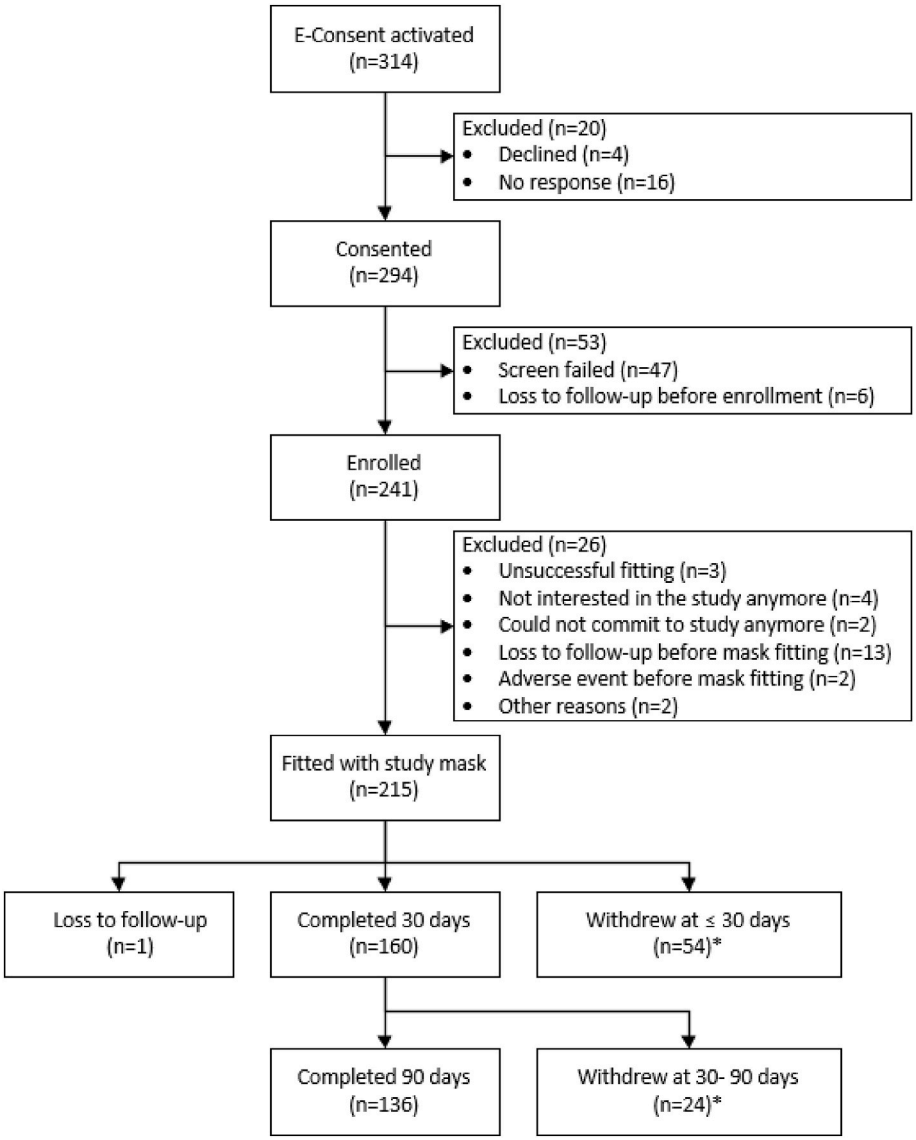


Fig. 1. Flow of participants through the study phases (consenting, screening, fitting and completion).
*Data from four participants who were withdrawn prior to the follow-up point but had completed questionnaires and a data card provided during the follow-up window were included; follow-up window for day 30 was ($\pm$7 days) and for day 90 was $-$14 days/+7 days.

Table 1
Baseline characteristics of study population.

	Participants (n = 215)
Male sex, n (%)	168 (78.1)
Age (years)	58.5 ± 11.9
Race Caucasian or White, n (%)	175 (81.4)
Older-generation full-face mask type, n (%)	
AirFit F20	78 (72.9)
Mirage Quattro	14 (13.1)
AirFit F10	6 (5.6)
Quattro Air	5 (4.7)
Quattro FX	4 (3.7)
Older-generation nasal mask type, n (%)	
Airfit N20	77 (71.3)
Airfit N10	5 (4.6)
Mirage FX	22 (20.4)
Mirage Activa	2 (1.9)
Mirage Softgel	1 (0.9)
Ultra Mirage Nasal	1 (0.9)
PAP device, n (%)	
AirSense 10 series	186 (86.5)
S9 series	29 (13.5)
Use heated tube (ClimateLine or ClimateLineAir), n (%)	177 (82.3)
Mean duration of CPAP usage (years)	10.6 ± 7.7

Values are mean ± standard deviation, or number of participants (%).

3.3. Device data

There were statistically significant changes from baseline in the residual AHI at day 30 (+0.2 ± 0.9/h; p = 0.026]) and day 90 (+0.2 ± 0.8/h; p = 0.006). Device usage significantly increased from baseline to day 30 after switching (mean change +0.2 ± 1.2 h/day; p = 0.010) but the change in usage from baseline to day 90 was not statistically significant (+0.1 ± 1.0 h/day; p = 0.126). At day 30 and 90, there was a statistically significant increase from baseline in mean 95th percentile leak (+3.2 ± 12.3 L/min; p = 0.001 and + 2.2±12.6 L/min; p = 0.044, respectively), and a statistically significant decrease from baseline in mean 95th percentile pressure (−0.2 ± 1.1 cmH_2O; p = 0.005 and −0.2 ± 1.1 cmH_2O, p = 0.016, respectively) (Table 2). In the sub-analysis of mean 95th percentile leak based on initial mask type, there was a statistically significant increase from baseline at 30 days (+3.8 ± 12.0 L/min; p = 0.001) and 90 days (+3.5 ± 12.2 L/min; p = 0.005) in participants who previously used the AirFit 20 series masks. In participants who previously used non-AirFit 20 masks, 95th percentile leak increased from baseline at day 30 (+1.4 ± 13.1 L/min; p = 0.491) and decreased from baseline at day 90 (−1.8 ± 13.1 L/min; p = 0.441) (Table 3).

3.4. Subjective ratings

Response rates to the online questionnaires ranged from 91.2 % to 99.4 % across all follow-up time points. Median Likert scale scores across all visits for all subjective performance ratings for the new-generation masks were significantly better than the reference score of 6 (Table 4). The median score for severity of red marks was 3 (marks lasted from 1 min to 30 min) at day 7, day 30 and day 90 (Table 4).

3.5. FOSQ-10

The mean change from baseline to day 90 in the FOSQ-10 score was statistically significant (0.48 ± 2.29; p = 0.015). In the subset of 51 participants who had a baseline FOSQ-10 score <17.9 (indicating impaired disease-specific quality of life [21]), there was a significant improvement in the mean FOSQ-10 score from baseline to day 90 (2.10 ± 2.12; p < 0.001), and 12/26 (41.1 %) had a FOSQ-10 score ≥17.9 at day 90.

3.6. Side effects

The most common self-reported PAP-related side effect was drying of the nose, mouth, or throat followed by skin rash/marking. Rates of all side effects during new-generation mask usage were similar to or lower than baseline rates during previous mask usage (Table 5).

3.7. Predictors of study mask discontinuation and withdrawal from the study

Among participants using a full-face mask (FFM), there was a weak but statistically significant association between duration on PAP therapy prior to the study and study mask discontinuation/withdrawal from the study; participants who had been on therapy longer were slightly more likely to discontinue (Odds Ratio (OR) = 1.108, p = 0.002). In addition, males with facial hair were significantly more likely to discontinue study participation than males with no facial hair (OR = 3.724, p = 0.021); females were more likely to discontinue than males with no facial hair, although this result was not statistically significant (OR = 3.011, p = 0.066) (Table 6). Similar trends were not observed in participants using a nasal mask. Instead the nasal users with a higher overall comfort rating for their own masks at baseline had significantly lower odds of withdrawal from the study (OR = 0.703, p = 0.006) (Table 6). No statistically significant trend was observed with combined analysis of FFM and nasal masks.

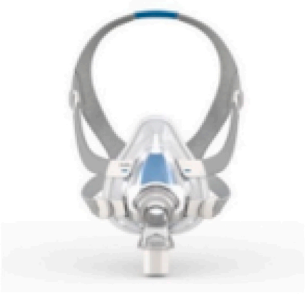
4. Discussion

The study results show that using remote set-up to change to a different mask was feasible for experienced PAP users. PAP therapy remained effective based on device usage hours and the residual AHI. Residual AHI and usage hours were significantly increased after the mask switch however the differences were small and deemed not clinically significant. Rates of PAP-related side effects were clinically acceptable, and disease-specific quality of life was maintained. Subjective ratings for the comfort, seal and usability of the new mask were significantly better than the predefined 'acceptable' score.

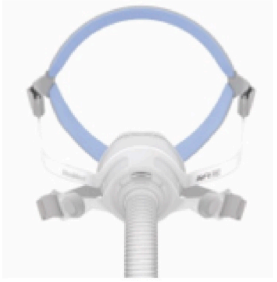
This study recruited established PAP users who had been using PAP for a mean duration of 10.6 years. Approximately 24 % of participants had a baseline FOSQ-10 score below the normative cut-off of 17.9, indicating impaired disease-specific quality of life. In this subgroup, the FOSQ-10 score at day 90 after switching to the new mask was significantly improved from baseline with mean improvement score of 2.1, which is greater than the minimally important difference of 1.8 [21]. These changes could indicate that individuals using PAP therapy could still be experiencing mask issues even after years of adherence with therapy and a change of mask had a beneficial impact. It should be noted that more than two-thirds of study participants reported CPAP-related side effects on their previous mask even though device usage was greater than 7 h/night. This suggests that, as well as the initial focus on CPAP acclimatization, monitoring of established CPAP users is important and a mask switch could further improve the therapy experience.

Leak was significantly increased from baseline at 30 days and 90 days after the mask switch but mean 95th percentile leak remained below 24 L/min, which is the commonly agreed clinically acceptable cut-off point for this parameter. In a subgroup analysis, the significant increase from baseline in 95th percentile leak after mask switch was only statistically significant in participants who had previously been using an AirFit 20 series. The AirFit F20 seals around the nose and mouth and the Airfit N20 seals around the nose, whereas the new mask (AirFit F30i & N30i) seals under the nose. Mask sealing under the nose could be more sensitive to tube drag or an individual's movements throughout the night, and the presence of facial hair. Indeed, the latter was found to be a significant predictor of discontinuing use of the new-generation mask among FFM users. This is an important finding for clinical practice suggesting that individuals with facial hair should be

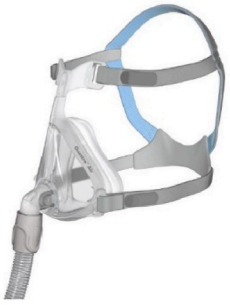
New-generation mask: AirFit F30i & Airfit N30i



Previous generation mask: AirFit F20 & Airfit N20



Previous generation mask: AirFit F10 & Airfit N10



Previous generation mask: Quattro Air

Fig. 2. Participants' own mask (previous-generations) and study mask (new-generation)

Previous generation mask: Quattro FX & Mirage FX

Previous generation mask: Mirage Quattro

Previous generation mask: Mirage Activa, Mirage Softgel & Ultra Mirage Nasal

Fig. 2. (*continued*).

monitored when they choose the compact mask (AirFit F30i) that has a smaller sealing surface.

Duration on PAP therapy was identified as a weak but statistically significant predictor of study mask discontinuation among FFM users. This is an interesting finding in a population that comprised well-established PAP users. It is possible that individuals who continued to use a much earlier generation mask and had not already switched to an updated mask may be more difficult to convert to a new-generation mask than those who had incrementally updated their mask over the years. This group of established and adherent patients may require additional clinical attention when switching to a different mask so that they do not become non-adherent when their previous-generation mask becomes obsolete. The trend of discontinuing the new-generation mask use within the first 2 weeks to 30 days was consistent with the literature that 25 % of individuals do not take up PAP or discontinue therapy in the first 2 weeks [22], and that longer-term adherence is predicted by adherence at 30 days [23]. Therefore, after a mask switch, it may be appropriate to provide clinical support or monitoring that is similar to that after initial set-up.

Use of remote care to implement a mask switch and perform post-switch follow-up is a unique feature of this study. The COVID-19 pandemic triggered the introduction of radical changes in sleep clinics, and the use of virtual visits and telemedicine in this setting is expected to continue [24]. Telemedicine has been found to be effective for the diagnosis and management of OSA [25,26] and this study added to the growing evidence that telemedicine can be used in addition to the traditional care model. The proportion of participants requesting support from the research team was stable until day 30. Remote care to implement a mask switch possibly mimics the fairly established trend that long-term use of PAP is related to use in the first weeks of treatment, so support needs to be concentrated during this time [27]. Innovative systems, such as machine learning (ML) and artificial intelligence (AI), have the potential to support clinicians in remote care models for the treatment of OSA. Recent studies have demonstrated the role of ML/AI in predicting treatment outcomes and personalizing therapeutic approaches [28,29].A limitation of this study is that only established PAP users were included, and therefore it cannot be determined whether the remote model would be appropriate for use during the acclimatization phase in new users of PAP therapy. Furthermore, these participants are well-acclimated to their CPAP therapy demonstrated by high baseline adherence. Consequently, the potential for improvement in mask-related outcomes is limited and likely to be marginal. The study

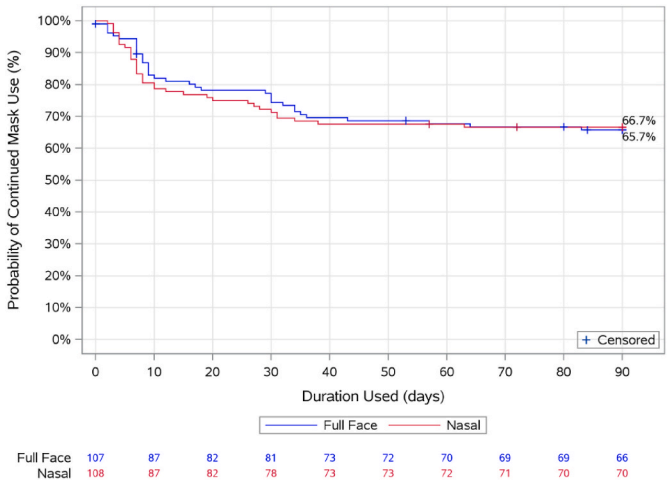


Fig. 3. Kaplan-Meier curve showing continuation of new-generation full-face mask usage over 90 days.
Seven participants were censored because they withdrew from the study for reasons unrelated to the study mask or process (one each due to study administrative issue, issues with continuous positive airway pressure therapy that were present before the study, an adverse event not related to the study, travel, loss to follow-up, and other).

identified only minimal improvements in objective data such as increased usage hours, which is not clinically significant. This study did not explore mask change from different categories, such as switching from nasal to FFM, that may involve increased monitoring and troubleshooting. Future studies could explore this aspect to better understand its impact on treatment outcomes, possibly in those less established on CPAP or satisfied with their current setup. It is important to note that the study sample was recruited from a volunteer database of individuals interested in research participation. As such, these participants may be more motivated and adherent, and caution should be exercised when generalizing the findings to broader populations. Another limitation is that only one new mask per mask category (FFM or nasal) was used for mask switch and participants did not have the option to try different new-generation masks in the same category, and therefore participants' experiences might have been affected by the study mask not being the best fit for them. The masks evaluated in this study were from a single manufacturer (ResMed Pty Ltd). The findings in this study may not be fully generalizable to users of masks from different manufacturers. Lastly, the majority of the participants who dropped out of the study discontinued due to the mask being unsuitable for them, so the subjective questionnaires may be biased by these dropouts not completing the questionnaires at the scheduled follow-up points. However, we believe this reflected the real-world experience because there is not a single mask that fits everyone, and the subjective questionnaires reflected patient experience for those in whom the mask is suitable.

5. Conclusion

As patient mask technology evolves, there is a likelihood that previous generations of masks will become obsolete. There was a lack of data on what might happen if the mask used by individuals established on PAP was no longer available, and there is a potential risk that mask switching could reduce adherence and therapy effectiveness. The results of this study showed that mask switch can be achieved using remote care and monitoring, with maintenance of device usage and therapy effectiveness. In addition, subjective ratings of the new mask and patient quality of life after the switch were clinically acceptable. Therefore, a

Table 4
Subjective ratings of new-generation PAP mask performance on a scale from 0 (major issue) to 10 (highly positive).

	Median score			p-value[a]
	Day 7 (n = 193)	Day 30 (n = 162)	Day 90 (n = 138)	
Comfort	8.0	9.0	9.0	<0.001
Seal	8.0	8.0	8.0	<0.001
Noise	8.0	8.0	8.0	<0.001
Venting	7.0	9.0	9.0	<0.001
Ease of use	8.0	9.0	9.0	<0.001
Overall performance	8.0	8.0	8.0	<0.001
Red marks	3.0	3.0	3.0	N/A[b]

[a] One-sample Wilcoxon test compared median rating across 3 follow-up timepoints with a reference score of 6.
[b] Scale of 0–4 for red marks, no statistical test pre-specified.

Table 2
Data downloaded from positive airway pressure devices.

Endpoint	Baseline (n = 196)	Day 30		Day 90	
		New-generation mask (n = 161)	Change from baseline (n = 161)[a,b]	New-generation mask (n = 136)	Change from baseline (n = 136)[a,b]
AHI (/h)	1.6 ± 1.5	1.7 ± 1.7	+0.2 ± 0.9 p = 0.026	1.7 ± 1.7	+0.2 ± 0.8 p = 0.006
Daily usage (hours)	7.1 ± 1.7	7.3 ± 1.4	+0.2±1.2[c] p = 0.010	7.2 ± 1.5	+0.1 ± 1.0 p = 0.126
95th percentile leak (L/min)	16.9 ± 18.2	20.1 ± 16.1	+3.2±12.3[c] p = 0.001	19.4 ± 16.3	+2.2 ± 12.6 p = 0.044
95th percentile pressure (cmH_2O)	12.0 ± 2.5	11.7 ± 2.3	−0.2±1.1[c] p = 0.005	11.7 ± 2.4	−0.2 ± 1.1 p = 0.016

AHI, apnea-hypopnea index.
[a] Change from baseline as mean ± standard deviation for all available paired data; p-value from a paired *t*-test.
[b] Day 30 and Day 90 results were not available for 2 participants who completed the study but did not return their device data cards.
[c] Data in 160 participants.

Table 3
Device data for 95th percentile leak: sub-analysis by initial mask type.

	Baseline	Day 30		Day 90	
		New-generation mask	Change from baseline[a]	New-generation mask	Change from baseline[a]
Initial mask					
AirFit 20 series	15.4 ± 15.1 (n = 140)	19.4 ± 14.4 (n = 119)	+3.8 ± 12.0 (n = 118) p = 0.001	19.6 ± 15.7 (n = 103)	+3.5 ± 12.2 (n = 103) p = 0.005
Non-AirFit 20 series	20.6 ± 24.2 (n = 55)	22.1 ± 20.3 (n = 42)	+1.4 ± 13.1 (n = 42) p = 0.491	18.8 ± 18.4 (n = 33)	−1.8 ± 13.1 (n = 33) p = 0.441

[a] Change from baseline as mean ± standard deviation for all available paired data; p-value from a paired *t*-test.

Table 5
Proportion of participants with continuous positive airway pressure-related side effects (each participant could report more than one side effect).

Side effect, n (%)	Baseline (n = 215)	Day 7 (n = 193)	Day 30 (n = 162)	Day 90 (n = 138)
Drying of the nose, mouth or throat	106 (49.3)	79 (40.9)	64 (39.5)	46 (33.3)
Skin rashes/marking	58 (27.0)	20 (10.4)	18 (11.1)	17 (12.3)
Eye irritation	23 (10.7)	10 (5.2)	10 (6.2)	3 (2.2)
Bloating	19 (8.8)	6 (3.1)	6 (3.7)	5 (3.6)
Ear or sinus discomfort	10 (4.7)	9 (4.7)	6 (3.7)	5 (3.6)
Nosebleed	7 (3.3)	5 (2.6)	7 (4.3)	4 (2.9)
Other	21 (9.8)	17 (8.8)	16 (9.9)	14 (10.1)
None	73 (34.0)	93 (48.2)	72 (44.4)	68 (49.3)

Two participants discontinued prior to day 30 but completed questionnaires within the visit window, and two additional participants discontinued prior to day 90 but completed questionnaires within the visit window. These responses are included.

Table 6
Baseline factors as predictors of withdrawal from study.

Parameter	P-value	Odds Ratio	95 % CI
Full Face Mask			
Duration of CPAP therapy (years)	0.002	1.108	1.037, 1.183
Facial hair by sex, overall			
Males, facial hair vs Males, no facial hair	0.021	3.724	1.222, 11.348
Females vs Males, no facial hair	0.066	3.011	0.931, 9.743
Nasal Mask			
Overall Comfort Score	0.006	0.703	0.547, 0.904

remote care model could be an economical option to facilitate a mask switch in individuals undergoing long-term PAP therapy.

CRediT authorship contribution statement

Xueling Zhu: Writing – review & editing, Writing – original draft, Supervision, Project administration, Methodology, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Adam Benjafield:** Writing – review & editing, Supervision, Methodology, Funding acquisition, Conceptualization. **Ross Deas:** Writing – review & editing, Supervision, Methodology, Funding acquisition, Conceptualization, and. **Leslee Willes:** Formal analysis, Data curation. **Jeff Armitstead:** Writing – review & editing, Supervision, Methodology, Funding acquisition, Conceptualization.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee (University of New South Wales Human Research Ethics Committee) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Xueling Zhu, Ross Deas, Adam Benjafield and Jeff Armitstead are employees of ResMed Pty Ltd. Leslee Willes received renumeration for statistical analysis services provided as part of this study.

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