A Randomized Crossover Efficacy Trial of Oral CPAP (Oracle) Compared with Nasal CPAP in the Management of Obstructive Sleep Apnea

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Study Objectives: To determine the therapeutic efficacy and viability of a novel oral interface for continuous positive airway pressure (CPAP) compared with conventional nasal interfaces.
Design: A randomized single-blind crossover study.
Setting: Hospital-based sleep laboratory.
Patients or Participants: 21 CPAP-naïve patients with obstructive sleep apnea (baseline apnea-hypopnea index, 85 ± 36)
Interventions: Nasal CPAP and oral CPAP
Measurements and Results: Patients were each treated for two 4-week periods using nasal CPAP and oral CPAP. The CPAP titrations were undertaken at the start of each treatment arm. Outcome measures were recorded at baseline and at the end of each treatment arm. These included polysomnography variables, CPAP compliance, subjective sleepiness, obstructive sleep apnea symptom ratings, and adverse effects. There were no significant differences between oral and nasal interfaces for the on-CPAP frequency of apneas and hypopneas (mean difference, nasal-oral [95%CI] = -4.6[-10.1-1.0]/h; P=0.06) or arousals (-3.0 [-7.8-1.8]/h; P=0.23). There were also no statistically significant differences between interfaces for scores on the Epworth Sleepiness Scale (-0.7 [-3.1-1.7]; P=0.20), obstructive sleep apnea symptoms (-7.7 [-17.7-2.4]; P=0.052), CPAP compliance (0.3 [-0.5-1.1] h/night; P=0.50), CPAP pressure (0.05 [-0.66-0.76] cmH20; P=0.73), CPAP side effects scores (-2.0 [-5.3-1.4]; P=0.23), or mask preference (P=0.407). In addition, both nasal and oral interfaces significantly improved polysomnographic variables, Epworth Sleepiness Scale scores, obstructive sleep apnea symptoms, and CPAP compliance from baseline (all P<0.05).
Conclusions: This preliminary study indicates that oral CPAP has similar efficacy to traditionally applied nasal CPAP in treating obstructive sleep apnea. Additional large studies are required to determine the range of clinical situations where oral CPAP is indicated.
Key Words: Oral CPAP, obstructive sleep apnea, crossover, compliance, treatment, randomized trial
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INTRODUCTION

NASALLY APPLIED CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) THERAPY HAS REMAINED THE TREATMENT OF CHOICE FOR OBSTRUCTIVE SLEEP APNEA (OSA) SINCE IT WAS FIRST INTRODUCED BY SULLIVAN AND COLLEAGUES IN 1981.[1] Despite being first-line therapy, CPAP compliance is relatively low. It has been estimated that less than 50% of patients are considered regular CPAP users, defined as using CPAP for more than 4 hours a night for 70% of nights.[2] A crucial element of compliance, and hence effectiveness of treatment, is acceptance of the interface.[3] Up to 50% of patients who use CPAP complain of at least 1 side effect due to the nasal mask.[3] A common adverse effect of nasal CPAP is mouth leak.[4] Mouth leak causes considerable drying of the nasal mucosa and, consequently, complaints of nasal congestion or dry nose and throat.[2,3]

Full-face masks are sometimes used to prevent mouth leak but at the expense of inducing further complaints such as claustrophobia, other air leaks,[5] and lowered compliance.[4] In addition, some of the commonly reported complaints are unresolved with the full-face mask, including skin abrasions, conjunctivitis, limited sleeping positions, and cumbersome headgear.[4,5] These problems have prompted continuing efforts to improve CPAP interfaces with the aim of enhancing compliance.

The Oracle (Figure 1) is an innovative modular device that enables positive pressure to be delivered via the mouth. The Oracle is constructed of a rigid plastic framework that is encased by 2 separate silicone components. The first silicone component, the *SoftSeal*, rests inside the mouth and incorporates a silicone protrusion (*tongue guide*) that is designed to prevent the tongue from blocking the flow of air from the CPAP. The *SoftSeal* also provides an adequate pressure seal against the inner cheek. The second silicone component, the *SnapFlap*, rests on the outer cheek region and provides a secondary pressure seal. This also retains the device in the patient's mouth without the aid of headgear. The rigid part of the mask provides a framework for these components and ensures a patent route for CPAP delivery.

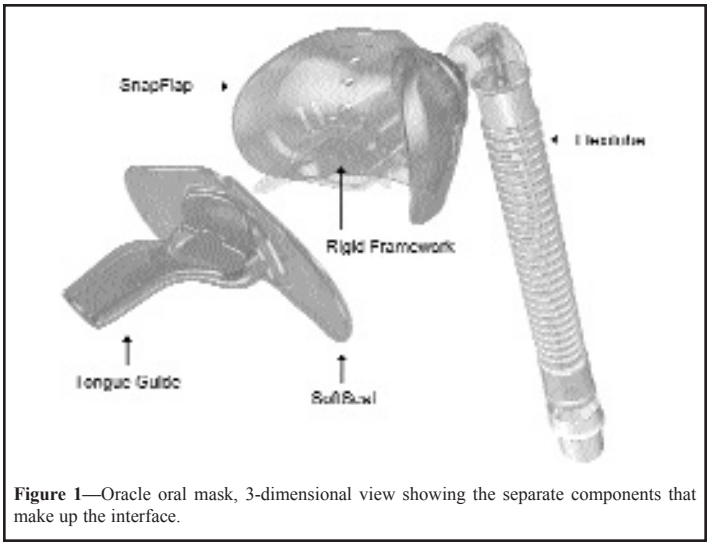

Figure 1—Oracle oral mask, 3-dimensional view showing the separate components that make up the interface.

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The aim of this randomized crossover study was to assess whether CPAP applied solely through the mouth via an oral interface (Oracle) is effective and, therefore, a viable alternative to CPAP applied through current nasal masks.

METHODS

Participants were recruited prospectively from consecutive patients medically referred to the Greenlane Hospital Sleep Disordered Breathing Unit. Inclusion criteria were an apnea-hypopnea index (AHI) greater than 20, an Epworth Sleepiness Scale (ESS) score greater than 12, and at least 2 symptoms of OSA.[6] Exclusion criteria were previous CPAP therapy for OSA, coexisting chronic obstructive pulmonary disease, coexisting sleep disorders, claustrophobia, gum or mouth disease, inability to communicate in English, and no home telephone for communication with investigators. Forty-two CPAP-naïve patients were recruited for the study prior to polysomnography (PSG) diagnosis. Twenty-five of these patients fulfilled study criteria, and all 25 agreed to participate. This study was approved by the Auckland Ethics Committee, and each study participant provided written informed consent.

Procedures

This study design was a crossover trial. Patients were randomly assigned to receive CPAP treatment via a nasal interface (Aclaim, Fisher & Paykel Healthcare; Sullivan Modular, Mirage or Ultra Mirage, ResMed) or via an oral interface (Oracle, Fisher & Paykel Healthcare). Randomization involved allocating equal numbers of oral and nasal spaces. Consecutive patients were then allocated their first treatment at random using sealed envelopes.

The protocol required patients to spend 4 weeks using the first interface before crossing over to the alternate interface for 4 weeks. There was no washout period between treatment arms because it was deemed unethical to withhold CPAP therapy from this OSA population.

The diagnosis of OSA and CPAP requirements were ascertained using a standard split-night PSG protocol.[7] Prior to this overnight PSG, all patients attended a CPAP-education and mask-fitting session. The monitored physiologic variables included electroencephalogram (C3-A2, C4-A1), electrooculogram, submental electromyogram, nasal pressure (during diagnosis only), thoracoabdominal movements, pulse oximetry, heart rate, body position, and leg movements.[8,9] If a diagnosis of OSA was confirmed (AHI > 20/h sleep) after a 2-hour minimum diagnostic period, CPAP therapy was initiated with the first treatment interface. The CPAP was then manually titrated to the minimum pressure required to eliminate all evidence of upper airway obstruction for the remainder of the night. Patients were issued this first interface and a CPAP machine with integrated heated humidification (Fisher & Paykel HC201; Auckland, New Zealand) set at the titrated pressure. After 4 weeks, the patients returned to the sleep laboratory to undergo a second manual PSG full-night titration study with the alternate interface. Patients were issued the second interface and CPAP machine with integrated heated humidification at the new titrated pressure.

Measurements

Self-assessed daytime sleepiness was measured using the ESS.[10] Symptoms of OSA were self-reported using a 12-item questionnaire with a 4-point Likert scale (0 = never to 3 = always). The symptom questionnaire was modified from one that has been used previously.[11] Patients were asked to rate the severity of the following symptoms: snoring, choking, breathing pauses, nocturnal awakenings, poor sleep quality, feeling unrefreshed on awakening, headaches, daytime sleepiness, concentration difficulties, decreased well-being, and daytime and evening napping. The symptom scores were calculated by totaling the scores for each symptom and then expressed as a percentage of the maximum possible score. Any symptoms scored as *don't know* were excluded from the maximum possible score.

Measurements of CPAP compliance and CPAP side effects were recorded at the end of each treatment arm. The CPAP compliance was recorded from the hour meter of the CPAP machine (run-time). Patients were unaware that compliance was being monitored. The CPAP side effects were evaluated using a posttreatment questionnaire. This questionnaire contained a list of 19 possible side effects, based on previous reports of side effects from nasal CPAP[12] and clinical research and development studies using oral CPAP.[13,14] Patients were asked to indicate the severity of each problem on a 4-point scale. The aggregate side-effect score for each patient was calculated for each interface (0 = no problems, to 57 = a major problem for each side effect). At the completion of the 8-week trial, patients indicated their mask preference and remained on this interface for ongoing treatment, unless recommended otherwise by the sleep physician.

Follow-up telephone calls were conducted 3 times during the first week following each titration and once a week thereafter. The purpose of these calls was to address issues of discomfort experienced with either interface and to ensure ongoing support throughout the trial.

Sample Size and Data Analysis

Given the cross-over study design, it was calculated that 25 subjects would be required to have an 80% power to exclude differences of more than 0.6 SD between the treatments, with $\alpha = 0.05$.

A qualified PSG technologist who was blinded to mask sequence analyzed the diagnostic portion of the first study and each of the on-treatment studies, at the final titrated pressures. Sleep was staged in 30-second epochs according to Rechtschaffen and Kales criteria.[15] Sleep-stage values were expressed as a percentage of total sleep time (TST). Arousals were scored according to American Sleep Disorders Association criteria.[16] Both spontaneous and respiratory-related arousals were included in the arousal frequency. An apnea was defined as complete cessation of airflow for a minimum of 10 seconds. A hypopnea was defined as a 50% reduction in the amplitude of a valid measure of breathing lasting for a minimum of 10 seconds or a clear amplitude reduction in a valid measure of breathing that did not reach the previous criteria but was associated with either an oxygen desaturation of at least 3% or an arousal.[8] The total number of respiratory events was divided by TST to give the AHI per hour slept.

All patients who completed both arms of the trial were included in the analysis regardless of CPAP use. Polysomnographic variables and questionnaires at baseline, on oral CPAP and on nasal CPAP were compared. Compliance was also compared between oral CPAP and nasal CPAP use. Analysis of paired data was carried out using repeated measures 2-way analysis of variance for normally distributed data with treatment as a within-subject factor and order of treatments as a between-subject factor. Paired Wilcoxon tests were carried out for nonnormally distributed

Table 1—Polysomnography variables at baseline, on nasal CPAP and on oral CPAP (mean [95%CI])

Outcome measure	Baseline	Nasal CPAP	Oral CPAP	Difference between treatments	*P* - value (nasal vs oral)
Arousal index (#/h)	69 [55-83]	12 [8-16]	15 [11-19]	-3.0 [-7.8-1.8]	0.23
AHI (#/h)	85 [69-100]	11 [5-18]	16 [10-22]	-4.6 [-10.1-1.0]	0.06
Sleep efficiency (%)	82 [78-86]	92 [87-96]	93 [91-96]	11.7 [-5.9-2.6]	0.85
Minimum SaO2 (%)	70 [65-75]	87 [84-90]	86 [82-89]	1.3 [- 3.0-5.6]	0.64
Awake (%)	12 [8-15]	6 [3-9]	5 [3-7]	1.1 [-1.8-4.0]	0.90
Stage 1 (%)	16 [10-23]	4 [2-5]	4 [3-5]	-0.1 [-1.7-1.6]	0.97
Stage 2 (%)	53 [47-59]	46 [41-51]	46 [40-52]	0.3 [-6.2-6.8]	0.88
Slow wave (%)	9 [4-14]	22 [17-27]	19 [13-25]	2.8 [-3.0-8.6]	0.50
REM (%)	10 [6-14]	22 [17-27]	26 [21-31]	4.1 [-1.5-9.8]	0.16

CPAP = continuous positive airway pressure; AHI = apnea-hypopnea index; $Sa0_2$ = arterial oxygen saturation; REM = rapid eye movement (sleep)

data. Mask preference was analyzed by the χ^2 test. The CPAP pressure and treatment success, as determined by changes in AHI from baseline (Baseline AHI – on-treatment AHI), were examined using Spearman rank correlation coefficients. Demographic data of subjects who completed the study and dropouts were compared using the Mann-Whitney U test, with the exception of sex, which was compared using the binomial test. All data were analyzed using SPSS (V.10 Windows, SPSS INC., Chicago, Illinois, USA).[17] All data are expressed as mean differences and 95% confidence intervals (CI).

RESULTS

Patient Characteristics

Twenty-five eligible patients were enrolled in the study and were randomly assigned to commence CPAP via a nasal (N = 13) or oral (N = 12) interface. Patients used the nasal mask that provided them with maximal individual comfort. Three patients dropped out after randomization for the following reasons: 1 refused to use the CPAP machine (nasal); 1 was unable to tolerate the nasal mask and switched to the oral mask for continued therapy (nasal); 1 was unable to tolerate the oral mask and refused any further treatment (oral). An additional patient was excluded from analysis due to unobtainable compliance data (oral). The AHI and ESS scores were significantly higher at baseline in the subjects who completed the study compared to the dropouts ($P<0.05$). However there were no significant differences in sex, age, body mass index, or OSA symptoms (all $P>0.10$). The remaining 21 participants (10 oral, 11 nasal; 17 men) had a mean (± SD) age of 46 ± 12 years and body mass index of 43 ± 8 kg/m^2.

Polysomnography Findings

Comparisons of the PSG variables from titration 1 (split-study) and titration 2 (full-titration night) demonstrated no significant differences in TST (mean TST titration 1 = 167.7 [135.7-199.8] minutes; titration 2 = 185.3 [137.3-233.3] minutes) or sleep-stage proportions at the final titrated pressure (all $P>0.10$). There were no significant differences in PSG variables between oral and nasal CPAP (Table 1; Figures 2A, 2B & 2C). In addition, there was no evidence of a carryover effect between the 2 treatment arms for any of the PSG variables (all $P>0.05$). Analysis of the diagnostic, first titration, and second titration PSGs demonstrated that both interfaces significantly reduced the AHI and arousal frequency from baseline (all $P<0.001$ vs baseline; Table 1). However, 2 patients had on-CPAP AHIs greater than 20 per hour with both treatment interfaces. Both of these cases with residual on-CPAP OSA had very severe baseline AHIs (71/h and 103/h). Sleep quality was significantly improved with both treatment interfaces (all $P<0.05$ vs baseline; Table 1). Mean CPAP pressure was also similar (mean difference [95% CI] = 0.05 [-0.66-0.76] cm H_20; $P=0.73$; Figure 2C).

Table 2—Ten most commonly reported side effects of nasal and oral CPAP and their severity (N = 21)

Side effect	Nasal CPAP				Oral CPAP			
	0	1	2	3	0	1	2	3
Dry mouth/throat	13	7	1	0	2	8	8	3
Excess salivation	19	2	0	0	11	5	4	1
Sore gums/lips	19	2	0	0	10	6	3	2
Skin irritation	15	6	0	0	15	4	2	0
Air leaks from mask	6	13	0	2	12	7	2	0
Congested nose	14	4	3	0	13	6	2	0
Mask dislodgment	11	6	3	1	11	7	2	1
Pressure from straps/mask	9	8	4	0	15	5	0	0
Difficulty fitting mask	11	10	0	0	18	2	1	0
Claustrophobia	20	0	0	1	17	4	0	0

CPAP=continuous positive airway pressure. Key: 0 = no problem at all, 1 = a slight problem (did not interfere with CPAP), 2 = moderate problem (sometimes I could not use CPAP), 3 = a major problem (I often could not use CPAP)

Table 3—Epworth Sleepiness Scale score and obstructive sleep apnea symptoms (mean [95%CI]) at baseline, on nasal CPAP and on oral CPAP (n = 21)

	Baseline	Nasal CPAP	Oral CPAP	Difference between treatments	*P*-value (nasal vs oral)
ESS	17 [16-18]	6 [4-8]	7 [5-9]	0.7 (-1.7 - 3.1)	0.20
Symptoms	70 [64-76]	17 [10-25]	25 [17-33]	7.7 (-2.4 – 17.7)	0.052

CI = confidence interval; CPAP = continuous positive airway pressure; ESS = Epworth Sleepiness Scale.

Compliance with CPAP

There was no significant difference in CPAP compliance between the 3 interfaces with means of 3.8 and 3.5 hours per night recorded for nasal and oral CPAP use, respectively (0.3 [-0.5-1.1] h/night; $P=0.50$; Figure 2D). When the oral interface was in use, 12 of 21 (57%) patients used CPAP for at least 3 hours per night compared with 13 of 21 (62%) patients with the nasal interface.

Side Effects of CPAP and Mask Preference

The 10 most commonly reported side effects and their severity are shown in Table 2. Total side-effect scores revealed no significant difference between the 2 interfaces (oral 8.3 [5.4-10.6], nasal 6.3 [4.2-8.4]; mean difference = 2.0 [1.4-5.3]; $P=0.23$). During oral CPAP use, the side effects rated severe enough to limit the use of treatment were dry mouth or throat, excess salivation, and sore gums or lips. During nasal CPAP use, the side effects severe enough to limit the use of the treatment were pressure from the mask or straps, air leaks from the mask, and mask dislodgment.

At study completion, 6 of 21 patients (29%) chose to remain on the oral interface, while the remaining 15 patients (71%) chose to remain on a nasal interface for ongoing treatment. Despite the greater proportion of patients preferring nasal CPAP, a $\chi 2$ test on these data revealed no statistically significant difference between mask preference across the 2 treatments (P=0.407). The main reasons for choosing the oral interface were 1) it was perceived as easier to fit and use and 2) it was perceived to improve sleep quality more, through freedom to move causing no mask leakage. The main reasons for choosing the nasal interface were 1) it was perceived to be more comfortable and 2) it was perceived to provide better humidity levels. Three of the patients who chose to continue treatment with a nasal mask added that they would have preferred the oral interface if more humidity could be provided to reduce dryness of the mouth/throat.

Scores on the ESS and OSA Symptom Ratings

There was no significant difference between oral CPAP and nasal CPAP use for ESS scores (0.7 [-1.7-3.1]; $P=0.20$; Table 3; Figure 2E). There was also no significant difference in OSA symptoms (7.7 [-2.4-17.7]; $P=0.052$; Table 3; Figure 2F), but there was a trend for oral CPAP to lead to higher OSA symptom scores. In addition, both the ESS and symptom scores significantly improved with CPAP from baseline ($P<0.001$).

Treatment Pressure Versus Treatment Success

In order to establish whether a relationship existed between the success of a device and the titrated treatment pressure of that device, Spearman rank correlations were undertaken. This test revealed no significant relationship between oral CPAP pressure and treatment success, as defined by residual AHI (r = 0.025; $P=0.914$), nor any significant relationship between nasal CPAP pressure and treatment success (r = 0.059; $P=0.799$).

DISCUSSION

This preliminary study demonstrates that, overall, oral CPAP

offers comparable efficacy to nasal CPAP in the management of OSA. This was confirmed through PSG measures of AHI and arousal frequency; objective CPAP compliance monitoring; and self-reported measures of OSA symptoms, daytime sleepiness, and side effects. The equivalence of outcomes using both CPAP interfaces suggests that the Oracle oral interface may have a role in the treatment of OSA.

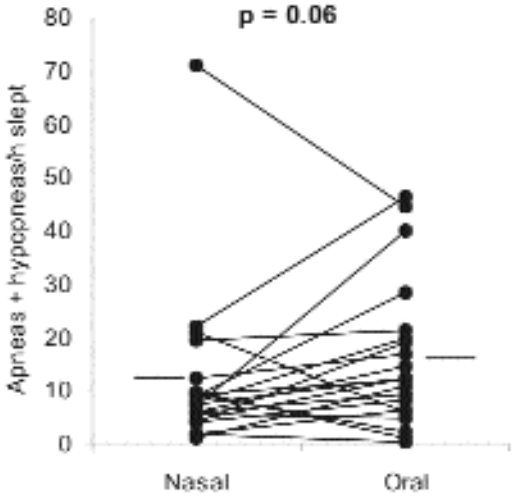

Figure 2A

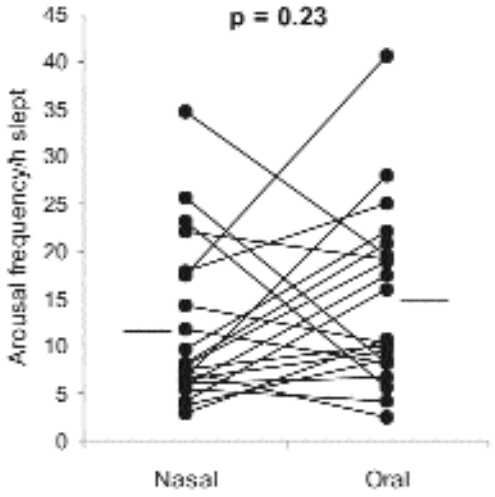

Figure 2B

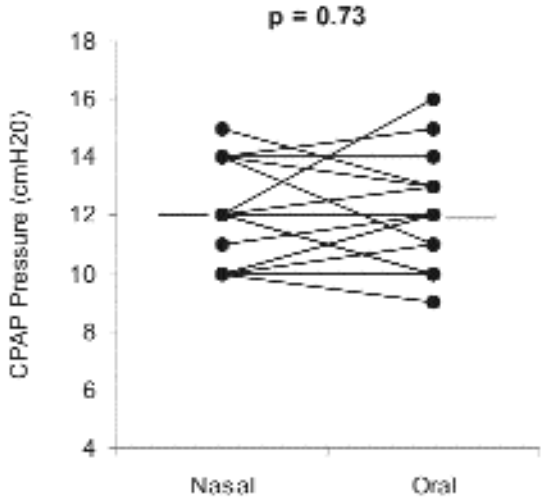

Figure 2C

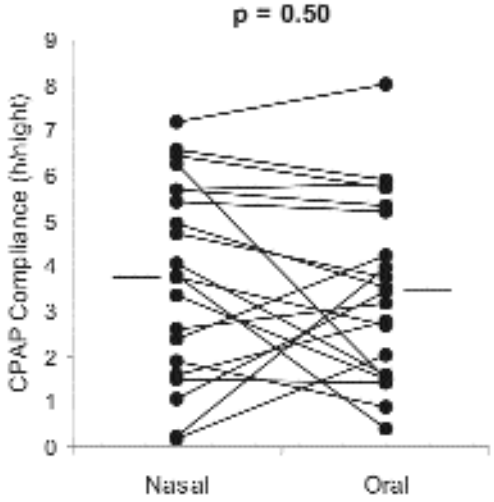

Figure 2D

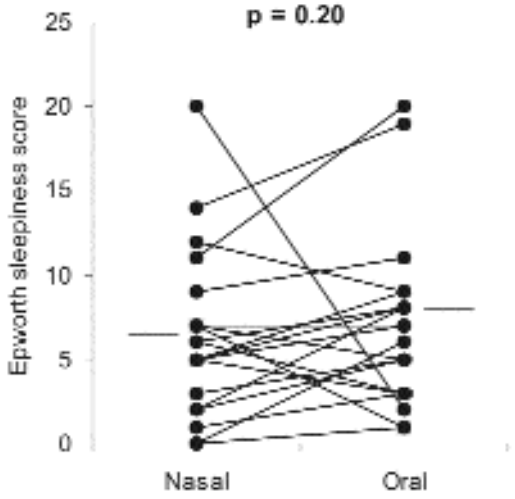

Figure 2E

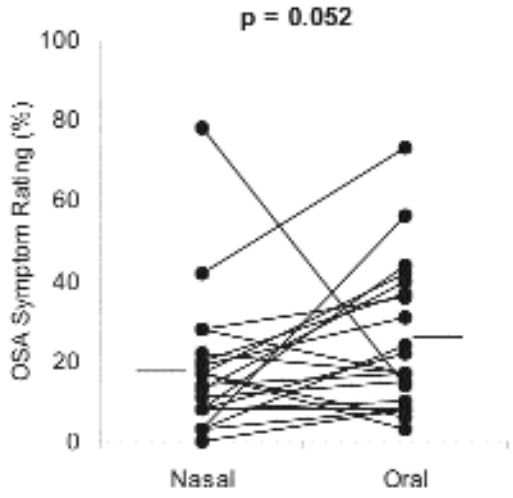

Figure 2F

Figure 2—Individual patient values on nasal continuous positive airway pressure and oral continuous positive airway pressure for: (A) Apnea-hypopnea index; (B) Arousal frequency; (C) Continuous positive airway pressure (CPAP); (D) Continuous positive airway pressure (CPAP) compliance; (E) Epworth Sleepiness Score; (F) Obstructive sleep apnea (OSA) symptom rating

No significant differences were found between the 2 CPAP interfaces for any of the on-CPAP PSG measures of OSA. Our findings agree with previous pilot studies using earlier iterations of the oral interface.[13,14] Both oral and nasal interfaces significantly improved OSA severity and sleep quality compared to baseline, as measured by PSG variables. These results are also in keeping with the improvements obtained using nasal CPAP in previous studies.[18,19]

Although there was no statistically significant difference found between the interfaces for the on-CPAP AHI, the results revealed a trend toward a lower AHI with nasal CPAP compared to oral CPAP. Whether a larger study would have revealed clinically important differences is unknown, but it appears unlikely given the small differences observed. It was also found that the on-CPAP AHI remained high in a subgroup of the study population. These high on-CPAP AHIs occurred independently of interface type, suggesting that the inability to abolish the remaining respiratory events was not due to a limitation of 1 particular interface. When performing CPAP titrations in patients with such severe OSA, it is important to balance the most effective CPAP pressure against the highest pressure a patient can tolerate without disturbing sleep.[20] Thus, although it is a concern that OSA was incompletely treated in some patients, both on nasal CPAP and oral CPAP, a major clinical improvement was nevertheless achieved.

Optimum CPAP pressures were similar with both interfaces. There were also no carryover effects between the 2 treatment arms, suggesting that the lack of a washout period did not alter the required CPAP pressure for the second limb of the trial. These findings suggest that both interfaces were working in a similar manner to alleviate upper airway collapse. In addition, given that CPAP pressures were individually titrated for both interfaces, we explored whether treatment outcomes were dependent upon titration pressure. No significant relationship was found. Patients' assessments of sleepiness and OSA symptoms improved significantly from baseline with the use of both oral and nasal CPAP. These improvements in sleepiness and symptoms from baseline are in agreement with previous crossover studies.[21,22] Improvements in these self-assessments of daytime function often predict future CPAP use.[18] These findings suggest, therefore, that long-term benefits with the use of oral CPAP are likely to be comparable to those of nasal CPAP. It should be noted that there was a nonsignificant trend for lower OSA symptom scores with nasal CPAP than with oral CPAP. This is reflected in the greater preference for nasal CPAP at the end of the trial.

There were no significant differences in CPAP run-time (compliance) while using the 2 CPAP interfaces. The mean values for compliance in this study were low. Previous CPAP crossover trials have reported a range of CPAP run-times from 3.2 hours per night[21] to 5.4 hours per night.[22] It has previously been demonstrated that AHI and ESS scores are independent predictors of long-term CPAP use.[23] Therefore, in the current study, we anticipated higher levels of compliance in patients with such high disease severity and subjective sleepiness. In addition, these patients had frequent contact and encouragement from a sleep professional throughout the first 2 months of treatment and were issued a heated humidifier at CPAP initiation, both of which have been shown to increase compliance.[24,25] The reasons for relatively poor compliance with treatment are unclear. However, the fact that compliance rates were comparable with both interfaces provides reassurance that the novel interface per se did not result in poorer patient acceptance.

Delivering CPAP via the oral interface eliminated many of the common complaints and adverse effects experienced with the use of nasal CPAP. These included air leaks from the mask, mouth leak, cumbersome headgear, and the complications of fitting the mask each night. However the oral interface was not without its own adverse effects. The most common complaint from patients after using oral CPAP was dryness of the mouth or throat. In an effort to minimize airway dryness, all patients were titrated on heated humidification and issued a CPAP machine with an integrated humidifier. Despite this, some patients still reported drying when using the oral interface, and it is possible that compared with nasal CPAP, oral CPAP may require greater levels of humidity. The dry mouth or throat that occurred from oral CPAP use in some patients could be attributed to a number of factors. Firstly, administering CPAP via the oral route bypassed the nasal passages, which normally warm and moisten the inspired air. Secondly the Oracle is designed to hold the tongue in place with the tongue guide. In doing so, the patients' natural method of saliva distribution around the mouth might have been impaired. Further work to fully understand and reduce this side effect with the oral interface is required to improve the acceptance of this device. Given the extent of drying experienced by some patients, it is currently not recommended to initiate oral CPAP therapy without heated humidification. Because heated humidification was supplied to each patient during this trial, the findings cannot be generalized to nonhumidified CPAP.

At the end of the trial, a greater proportion of patients preferred CPAP treatment with the nasal interface. Despite this finding, statistical comparison of mask preference revealed no significant difference between the oral or nasal interfaces. This suggests that the availability of an oral interface may be helpful and important in optimizing CPAP treatment among a broad population of patients, including those who are intolerant of nasal masks, who currently have no alternative positive-pressure interface options.

There are a number of limitations to our study. Firstly, this study had power limitations. A sample-size calculation estimated that 25 patients would be required for 80% power to show a 0.6 SD difference. Unfortunately, the data from 4 of the 25 recruited patients were excluded from analysis. Therefore, although no statistical differences were found, the trends showing more favorable AHI and OSA symptoms with nasal versus oral CPAP require that our data be interpreted cautiously. Secondly, we used a split-night study prior to the first treatment arm. This was necessary in the context of a resource-limited and publicly funded sleep service. For this reason, the results for titration studies were analyzed only once the optimum titration pressure had been established. The results demonstrated no significant differences in PSG variables between the 2 studies. It has previously been demonstrated that a split-night study results in similar CPAP use and posttreatment ESS scores to those obtained following a standard full-night CPAP titration.[7] Thirdly, there was no washout period between the 2 arms of the study. A washout period prior to the CPAP retitration at the start of the second arm would have allowed a more accurate CPAP titration due to the reduction of possible carryover effects from the previous treatment period. However, it is unlikely that any carryover effect would last 4 weeks, and due to the disease severity of our population, it was deemed unethical to withhold CPAP therapy for any length of time. Fourthly, the study lasted for only 8 weeks, and, as a consequence, the long-term effects of oral CPAP use are not known. We intend to follow patients who remain on the oral interface at regular intervals. Our study patients had severe OSA, with a high mean AHI and body mass index. It would be of interest to explore the role of this oral interface in a population with milder OSA, a group of patients who often fail to accept nasal CPAP therapy. Lastly, the CPAP titrations in our study were conducted manually in a hospital setting. For this reason the results cannot be generalized to automatic titration with intelligent CPAP. Further investigations using these automatic devices in conjunction with the oral interface are required in order to determine its efficacy in this setting.

In conclusion, sleep variables, CPAP compliance, and subjective questionnaires have provided evidence that oral CPAP is largely comparable to nasal CPAP at treating moderate to severe OSA and associated symptoms. Titrated pressures for the 2 interfaces were also comparable. For some patients who might prefer CPAP delivery via the oral route or encounter difficulties using a nasal interface, the Oracle is a viable alternative to conventional nasal masks. Further studies and clinical experience are required to determine the range of situations in which the use of this oral interface is indicated.

ACKNOWLEDGEMENTS

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ABBREVIATIONS

AHI – Apnea-hypopnea index
CPAP - Continuous positive airway pressure
ESS – Epworth Sleepiness Scale
OSA – Obstructive sleep apnea
PSG - Polysomnography
REM – Rapid eye movement (sleep)
TST – Total sleep time
SPSS – Statistical Package for the Social Sciences

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