

## Home-Use Sleep Mask (Noctura 400) Wear Before and During The COVID-19 Pandemic with its Associated Lockdowns in England

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### Abstract

**Objective:** The Researchers looked to determine over a 2-year period whether patients with early diabetic macular oedema (DMO) would wear a mask (Noctura 400) during sleep and maintain a good level of use throughout the study period, with regular follow ups to monitor and discuss use. As the COVID-19 pandemic began during this study, the researchers also had the opportunity to evaluate mask use during lockdown periods in England and while there was massive disruption to hospital ophthalmic services.

**Methods:** A total of 26 patients were recruited for the study and, for each one, regular phone and text support was put in place to help with Noctura 400 wear. In the first year, regular 3 monthly hospital visits were provided whereas in the second year the visits mostly did not take place due to COVID-19 restrictions, though phone calls and texts continued for the entire duration.

**Results:** In a questionnaire at the end of year 1, the vast majority of the patients found the sleep mask comfortable and easy to use. A total of 21 out of 26 completed the whole 2 years of home treatment and none of those who dropped out did so for light mask related reasons. The researchers found with the appropriate level of support and encouragement that a high level of mask wear compliance was achieved (76.1% for the 2 years). The initial compliance was 80.1% that dropped slightly to 76.6% at year-end but was maintained throughout the second year with a final median compliance of 75.1%. Compliance dropped slightly (but not significantly) during the ongoing pandemic that included 3 lockdowns in England and disruption of hospital services such that in the second year 18 of the 21 (85.7%) completing patients had no hospital visits.

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**Conclusion:** The Noctura 400 sleep mask was worn effectively for a protracted period of time by the group of patients when appropriately supported even when there was severe hospital service disruption. The need for effective home treatments during these unpredictable times is highlighted.

**Keywords:** Diabetic retinopathy, Home use, Light mask, Compliance, COVID-19, Lockdown.

## Introduction

The World Health Organization declared COVID-19 pandemic status on 11th March 2020. Subsequent social curbs and lockdowns initiated by national governments in order to curb the spread of the disease and relieve pressure on health services have had a substantial impact on healthcare systems globally.

In England there has been (since March 2020) around 25 weeks of full lockdown although it is important to say that some level of restriction has been in place in England from 23rd March 2020 to the end of the present investigation (May 2021). In addition, hospital services, clinics and theatre time have been disrupted and compromised over much of this period [1].

Advice given by the Royal College of Ophthalmologists at the end of March 2020 to Eye Departments [2,3] was to cancel all elective surgery and to postpone non-urgent outpatient activity. From that date to current times services have been severely curtailed. For example, one eye hospital reported a 63% and 67% reduction in the outpatient and surgical workload in June 2020 compared to that month the year previously [4]. The prolonged hospital ophthalmology crisis is further exacerbated by the periodic redistribution of ophthalmic clinical staff to COVID-19 duties at key time points. [5] In addition clinical work required adaptation of usual services so as to provide reasonable protection for both patients and staff. Further early PPE issues and appropriate selection of masks etc. was

worrisome [6] especially as preliminary reports from China indicated that Eye staff were at particular risk. Indeed, it has been confirmed in the USA that ophthalmology alongside emergency medicine and anaesthesiology are at highest risk of contracting COVID-19 [7].

The pandemic has highlighted a need for more flexible clinical provision whether that is diagnosis, monitoring or treatment. Clearly telemedicine and more specifically teleophthalmology are now regarded more favourably with some successful hospital adoption being reported [8]. However, going beyond consultation and ophthalmic advice, home assistance in various forms is more than desirable. On the home front patient involvement in the own monitoring of possible disease progression is expanding with [9] and without teleophthalmic or telephone backup. One example is the wider use of the Amsler grid in a home setting. This and more sophisticated tools for the determination of central vision deterioration in age related macular degeneration (AMD) are expected to become even more commonplace in the near future [9]. On the other hand, home-based ocular therapies are as yet less in evidence but of great potential benefit in these difficult times. One such treatment for diabetic retinopathy (DR) patients with early diabetic macular oedema (DMO) is a light mask called Noctura 400 (PolyPhotonix, Sedgefield, UK).

Hypoxia, along with oxidative stress, is one of the key drivers of abnormal retinal vessel development in diabetic retinal disease [10-

12]. The retinal rod photoreceptors have an enormous oxygen consumption that increases dramatically when people are fully dark adapted [11,13]; a time of maximum risk of hypoxia and oxidative stress for those with DR and DMO who have retinal vessel dysfunction. For most of the people in the Western World, complete dark adaptation occurs only when people are asleep so prevention of dark adaptation by wearing a light-emitting device is a potential therapeutic option by avoiding retinal hypoxia through the reduction of retinal night-time oxygen consumption [10,11].

Noctura 400 is as yet the only CE marked light mask designed to treat DR and DMO patients by nightly wear. There are several publications reporting the safety, compliance and efficacy of this device [14-17]. All agree that Noctura 400 is safe but in one investigation mask wear was poor with subsequent lack of efficacy [16]. On the other hand, the other three, all be the patients smaller studies, showed good compliance and exhibited levels of anatomic [14,15,17] and visual [15,17] improvement. Given that an effective home therapy for such an important eye disease as DR and DMO would be a huge boost to the diabetic patient, it is crucial to determine how optimal mask wear can be achieved with respect to Noctura 400. Indeed, as mentioned earlier, the presence of the COVID-19 pandemic only further accentuates the need for home therapeutic devices but only if it works and the patient adheres to treatment.

The Noctura 400 device glows while the patient is sleeping but also has a capacitive sensor that detects whether or not the mask is being worn. A study conducted at an eye centre in the UK reported good mask wear and decent efficacy up to one year [17].

However, the centre continued to monitor Noctura 400 nightly wear up to two years after initiation of this investigation. It is clear that good compliance is crucial if the light mask is to have reasonable therapeutic potential. Therefore, the researchers undertook furthermore-detailed analysis of the initial study year in combination with the follow-on year. As the investigation was conducted between June 2019 and May 2021, it allowed us to compare mask wear before and throughout an extended period of hospital disruption caused by the COVID-19 pandemic. The timeline also includes three periods of full lockdown. At the completion of the first year each patient was requested to complete a written satisfaction survey and the overall findings are also reported here.

## Materials and methods

### Noctura 400

The Noctura 400 Sleep Mask is a light emitting pod that is worn overnight and contained within a fabric mask (Figure 1). The mask is held in place over the eyes by adjustable Velcro straps. The light for both eyes is provided by organic light emitting diodes (OLEDs) that in this device emit light with a peak spectrum of  $502 \pm 5$  nm. The intensity was a constant  $74 \pm 10$  cd/m<sup>2</sup>, which is considered to deliver sufficient energy to the retina through closed eyelids to effectively suppress dark adaptation [18].

The patient activates the Noctura 400 light sources in the pod and then inserts the activated pod into the fabric mask before settling down to sleep. Mask users initially are aware of a gently glowing green light through the closed eyelids; however, patients adapt to this constant light exposure and no longer are aware of the

green lighting after a few minutes (related to Troxler's fading). As OLED emission is homogenous, the usual eye movement

during sleep does not alter significantly the degree of retinal illumination.



**Figure 1:** Noctura 400 consists of a black fabric mask and a white pod (containing light source, battery and mask wear capacitive sensors) that fits inside the mask.

The maximum period of illumination is programmable and was set at 8 hours for this study as was the case for other investigations of this device [14-17]. Capacitive sensors (housed in the pod) detect if the mask is being worn. Every two seconds, the mask detects if it is in operational use or not and stores this data in an on-board memory chip as a record of mask wear, for later download. At the reading centre (in this study, PolyPhotonix, Sedgefield, UK), the data was downloaded, using RFID technology. Anonymity is established through a unique identifier so that subsequently the pod can be matched accurately to the appropriate patient. This data is then available at the end of each 3-month period of use to provide an accurate picture of the mask wearing habits of each patient.

### The patients

The study throughout was conducted in accordance with the Declaration of Helsinki. The patient group consisted of 26 diabetic patients recruited because group had DR and DMO but at the time of recruitment did not qualify for established anti-VEGF or implant therapy because patients had a central macular thickness of less than 400  $\mu\text{m}$  [a central macular thickness greater than 400  $\mu\text{m}$  is required to initiate anti-vascular endothelial growth factor (VEGF) treatment in the UK]. Recruited patients needed to be over the age of 18 and any female was excluded if pregnant.

Of the 26 patients, 6 had previous laser or anti-VEGF intervention but not less than 6 months prior to recruitment. A total of 5

females and 21 males joined the study and the median age of the group was 62.5 years. Of these, 3 had type I diabetes and 23 had type II. Only 1 was on diet control while the rest were on insulin injection or tablets.

### **The investigation**

The present study was undertaken to investigate Noctura 400 mask wear over an extended period of time (in this case 2 years) and whether or not it is a suitable home wear device. Following a baseline visit the patients were issued with the first mask. Over the first year the patients were due to visit the clinic every 3 months in order to complete a clinical assessment to determine the progress of the condition (anatomic and functional improvements in the first year have been reported elsewhere [17]) and suitability to be issued with the next mask was determined.

The previous mask was collected, and the data downloaded to provide a record of patient nightly mask wear and for comparison against the self-reported sleep duration. Subsequent to the patients' visits to the clinic over the first year, the patients were contacted regularly by phone and text to discuss any issues with the mask and solve the issues where possible in order to maintain strong patient involvement in the therapy. Therapist/patient interactions of this type have been found to help with adherence to treatment [19]. Difficulties relating to adherence to treatment protocols is a recognized issue associated with diabetic patients [20].

### **Patient sleep and satisfaction analysis**

At baseline assessment, the recruits were asked to complete the Pittsburgh Sleep Quality Index (PSQI) as it is a widely accepted subjective measure of sleep quality

and daytime sleepiness [21]. Researchers were particularly interested to note any changes that took place in association with protracted mask wear. At the end of the first year the last efficacy visit was staggered into the second year (13 months plus) because of COVID-related hospital clinic availability issues. At this visit, in addition to clinical assessment, mask wear interview and PSQI the 24 patients remaining in the study were asked to fill in a bespoke patient satisfaction survey to highlight Noctura 400 treatment issues good and bad. Prior to designing this bespoke Noctura 400 Patient Satisfaction Survey (NPSS), publicly available NHS satisfaction surveys (such as the Care Quality Commission's NHS Inpatient Survey) were reviewed and considered; however, none of the surveys met the very specific requirements of this evaluation. The questions needed to be focused on the patient's experience of the service, ease of access to information, the comfort with wearing the mask and the perception of the impact. Patients were asked if patients had a positive or negative experience using the treatment and patients were also asked the standard NHS friends and family test—would the patients recommend the treatment to a friend or member of the family? Prior to first use, an amendment to the survey was made, to allow one additional question to be included on patient phone support during COVID-19 lockdown.

### **COVID-19**

The investigation was initiated in June 2019 allowing us approximately 3 cycles of mask wear (9 months) prior to the first COVID-19 lockdown in England (23rd March 2020) thereafter the study period encompassed 2 further lockdowns (starting on the 3rd October 2020 and then again on the 6th

January 2021) with the third lockdown still partly in place at study completion (end of May 2021). It is the case however that for the whole of the 15 months this study ran during the pandemic, some level of social restriction was in place and hospital clinic service disruption was the norm. In the second study year, COVID-related interruption of ophthalmic clinical services at the study NHS Trust hospital was such that appointments were cancelled to the extent that 18 of 21 (85.7%) of the patient group had no hospital visits up to May 2021 the study end date. On the other hand, home telephone and text support encouraging mask wear continued unabated. The rise of COVID-19 in the UK interrupted the planned visits and the established mask delivery schedule. For the study recruits, this meant that patients could not visit the clinic as the diabetes placed within the clinically vulnerable groups who were advised to shield even outside lockdowns. Adjustments to the study were made to ensure that patients could continue treatment. Masks were posted and contact with patients continued, with previous scheduling of telephone calls rolled over to remain in line with the original pattern. Final mask returns took place during May 2021 with masks returned by post at that date. For the purposes of continuation of treatment, patients were given masks to follow on beyond the end of the study if the patients wished.

## Results

### Patients

From a total of 26 recruits, 24 completed mask wear through the first year (92.3%) while that number fell to 21 at the end of the second year (87.5% completion for that year) resulting in an overall 80.8%

completion for the whole 2-year study. Of the 5 lost to investigation, one patient dropped out after failing to attend the first clinical visit at 3 months returning a mask that had been worn minimally if at all. A second person developed severe systemic pathologies during the first year and was required to withdraw. At the completion of the first year of investigation, 2 patients preferred not to continue as part of the second follow on year. An explicit reason for withdrawal was not provided at feedback. The last patient left the study due to development of severe feet ulcers that caused profound disruption of sleep pattern so making mask wear impractical. No patient stopped the nightly use of Noctura 400 because of issues relating to the light source.

For 3 eyes of 2 patients over the 2 years the maculae deteriorated such that one was given laser treatment while the other patient had 3 anti-VEGF injections in the right eye over a 3-month period and 1 in the left eye. For these patients no other clinical interventions took place but the option of wearing Noctura 400 continued given that it is a double eye therapy. Thus 3 eyes within the study time period needed more aggressive intervention while the remaining 39 eyes of patients who completed the mask wear did not require anything beyond continued nightly mask wear.

### Patient sleep and satisfaction analysis

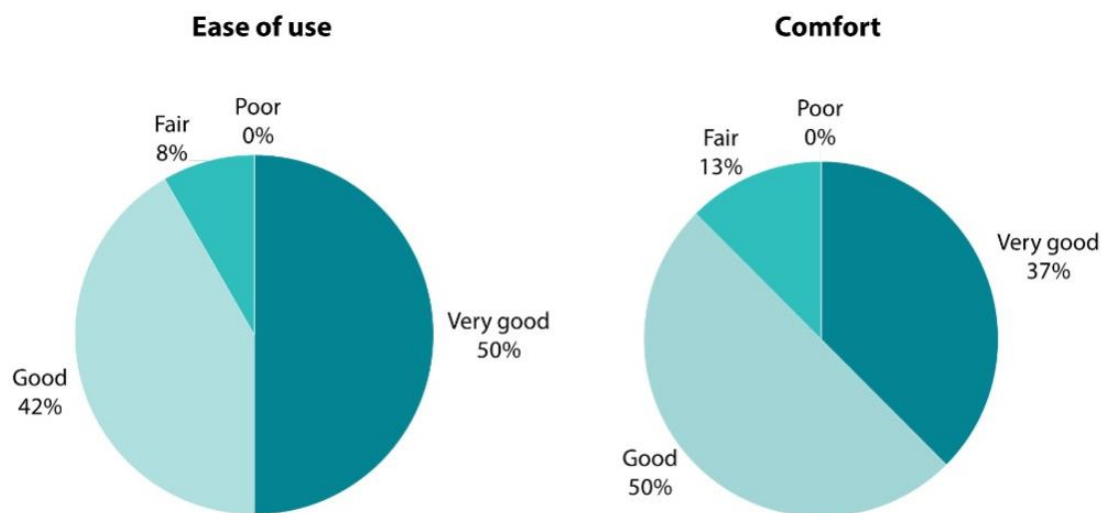
The PSQI questionnaire at baseline gave an overall score in terms of mean and standard error of the mean (SEM) that was  $4.88 \pm 1.01$  and at exit visit after a period of 1 year (or slightly over) retained a similar score of  $4.82 \pm 0.76$ . As such the questionnaire showed us that the subjects retained a stable sleep quality for the first year with a mean change

from base line to exit visit from the efficacy study<sup>17</sup> of  $-0.06 \pm 0.79$ . However, during the second-year post study period of mask wear no PSQI questionnaires were completed by the patients because of the absence of hospital clinic visit assessments.

The bespoke NPSS was either completed in clinic or, if not, at the patients' homes such that all 24 of the completing patients at one year plus returned the questionnaire. Some patients did not answer all the questions but to avoid introducing bias, no attempt subsequently was made to get the outstanding questions answered. No follow up on the survey was conducted at the final

2-year exit point due to COVID-19 restrictions.

Scoring the question of how the patients rated Noctura 400 and the whole Noctura 400 experience, 16 patients (67%) gave a score of 9 or 10 while 23 of 24 scored 7 or above. Questions on the mask itself, as can be seen in the pie charts (Figure 2). 87% of the patients rated "comfort" as being either good or very good, with the majority being good. If anything, "ease of use" scored slightly better with 92% giving a rating of good or very good and 50% being in the very good category (Figure 2).



**Figure 2:** Pie charts showing patient responses for mask "Ease of use" and "Comfort" with 92% and 87% respectively rating the device either good or very good.

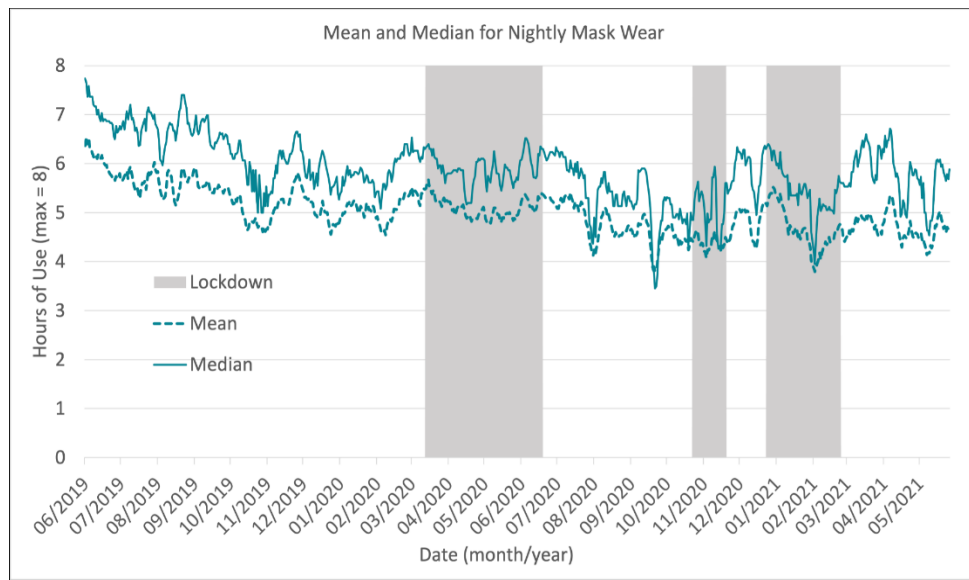
With reference to the levels of support received, 96% felt the patients received enough support from the telephone team, 88% found the phone support gave the patients greater confidence to wear the mask and 96% felt patients had learnt quite a lot more about the eye condition. 92% were positive about considering mask wear long term if recommended by the ophthalmologist. In addition, 83% would recommend the use of Noctura 400 to an appropriate friend or family member.

### Noctura 400 mask wear

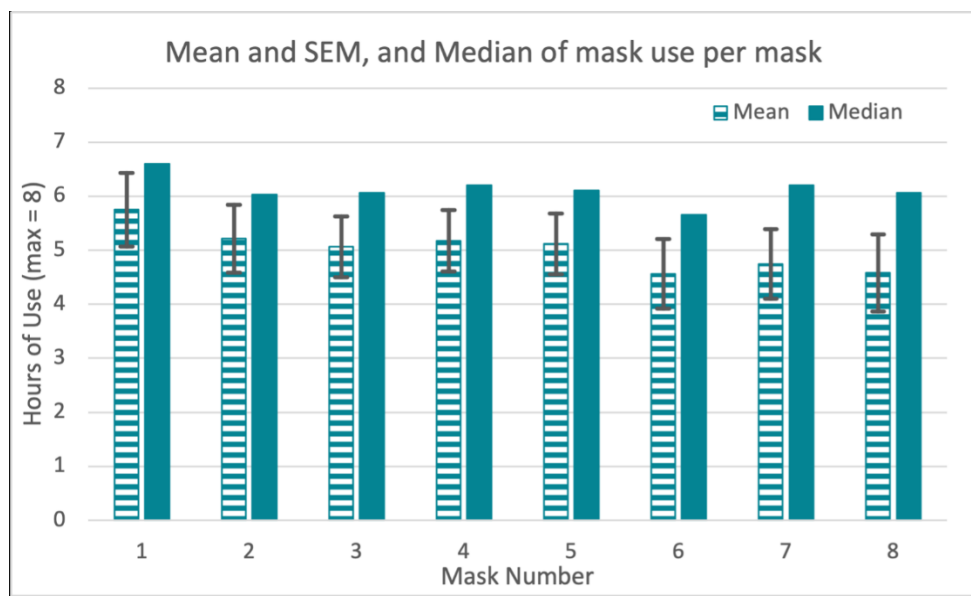
On receipt of the used Noctura 400 pods, mask wear could be downloaded from the pods' memory chips (see Materials and Methods) for collation and thereafter usage over any desired time period, such as per mask, or per year, calculated from the appropriate software as a mean or a median. To determine compliance, the researchers used the same calculation adopted in the previous publication [17] based on the recorded mask wear and patient reported

sleep. The median values for mask wear were higher than the mean values on all occasions (Figure 3). At the first 3 monthly mask return (p<sub>1</sub>), the median wear was 7.1 hours per night while the mean  $\pm$  SEM for the same initial time slot was  $5.4 \pm 0.4$  hours per night resulting in a calculated median compliance of 80.1%. Whereas thereafter

the mean dropped slightly but not significantly (Student t test) up to the end of year 1 on completion of the 4th mask change (p<sub>4</sub>). At p<sub>4</sub> the mean  $\pm$  SEM for nightly mask wear was  $5.1 \pm 0.5$  hours (Figure 4) equating to a median compliance of 76.6%.



**Figure 3:** Graph showing length of mask use (hours) on the y axis and date (months) on the x axis. Rolling weekly values for mean (dashed) and median (solid) nightly mask wear over the whole period of 2 years are displayed. The three lockdown periods are shown as grey columns.



**Figure 4:** Histograms showing mean  $\pm$  SEM (patterned) and median (solid) of nightly mask wear for each period of 3 monthly mask return extending from pod 1 up to pod 8, two years later.



At the end of the second year, when the patients reached the final mask change (pod 8), the median mask wear was 6.5 hours per night (Figure 3) while the mean  $\pm$  SEM was  $5.0 \pm 0.5$  hours and so not significantly (Student t test) different from the 4th mask change approximately a year earlier (Figure 4). As a result, compliance remained consistent at a level of 75.1%. Effectively there was only a 5% drop in compliance over the 2 years of study of which a mere 1.5% occurred in year 2 of study.

During the whole 2-year period, the mean  $\pm$  SEM for mask wear per night was  $5.1 \pm 0.4$  hours with a value of  $5.2 \pm 0.4$  hours in the first year and  $5.0 \pm 0.4$  hours in the second year. These values were not significantly different from each other (Student t test). The overall compliance estimated for the 2 years of study averaged out at a median compliance of 76.5%. Examination of the week-by-week night-time mask wear graph (Figure 3) showed a gradual but slight drop in mean and median wear over the first 6 months but thereafter mask wear recovered a little and mostly stabilized for the rest of year 1 and all of year 2. Absent from year 1 but apparent in year 2 were small but sharp drops in mask wear that recovered almost immediately forming a sharp spike. Spikes can be seen at August 20 and May 21 but the biggest is around October 20 (Figure 3).

COVID-19 Pandemic and Lockdowns. Throughout the study none of the group of patients were diagnosed with COVID-19. During the pre-COVID-19 pandemic part of the study, the mean  $\pm$  SEM for mask wear per night for the group of patients was  $5.2 \pm 0.4$  hours while during the pandemic it dropped a little going down to  $4.6 \pm 0.4$  hours but not significantly (Student t test).

Of the 3 lockdowns during the investigation, 2 were in the first year and 1 in the second. During the first lockdown of 7 weeks, starting March 2020, the patients wore the mask for  $5.2 \pm 0.5$  hours per night whereas through the second lockdown, starting in November 2020 for 4 weeks, mask wear per night was  $4.4 \pm 0.5$  hours. The longest lockdown was initiated during the second year of study stretching to around 14 weeks and starting January 2021. The mean and SEM for mask wear during this 3rd lockdown was  $4.4 \pm 0.5$  hours. Total lockdown during the study added up to around 25 weeks producing a lockdown mask wear figure of  $4.7 \pm 0.5$  hours that is like mask wear throughout the pandemic regardless of lockdown.

## Discussion

The idea of reducing oxygen consumption by light exposure to the diabetic retina during sleep to combat DMO and DR is neither new [10-12,22] nor is it without scientific and clinical support [14-15,17,23]. However, the main issue boils down to whether at present there is a home use sleep mask sufficiently effective that it can be used by patients appropriately for an extended period of time [16,24]. The researchers conducted a real-world study of 26 patients from a single hospital setting who wore Noctura 400 for a year. Mask wear was more than satisfactory and both anatomic and functional efficacy was reported [17]. In addition (see above) patient sleep quality, based on PSQI scores, was similar at study beginning and at end of first year for the mask wearers.

Also reported above were the findings of the bespoke NPSS questionnaire that focused on mask wear and patient satisfaction. Negativity to treatment is known to have

severe adverse effects on continued adherence to agreed therapy [25] so it was good to know that patient enthusiasm for Noctura 400 was high. It turned out that 23 of the 24 completing patients scored the Noctura 400 mask experience 7 out of 10 or better. Indeed, the vast majority considered the mask to be comfortable to wear in bed while even more thought it easy to use. Nearly everyone (96%) found the support provided over the year to be appropriate and felt patients had a better understanding of the condition. Both are well-established strategies for improving patient compliance [26]. A key patient question was whether the patients would recommend the device to others and well over 80% said yes while all but two said the patients would continue using Noctura 400 if the ophthalmic specialist recommended the home treatment.

Because of the high clinic and surgical throughput, the COVID-19 disruption to ophthalmic services was particularly severe [27]. Unfortunately, that disruption has remained, as is also the case for other medical and surgical specialties. A devastating quality of treatment issue has been created for patients and health workers alike that exists to the present time and will extend beyond the present. In addition, much discussion has focused on the likelihood that medical services in the future may not mirror exactly the pre pandemic set up [27] with there being more emphasis on home-based consultations and treatment.

Instigated by initial study findings and the questionnaire data the patients were invited to continue with the mask wear into a second year. Clearly the first-year study was a planned and appropriately funded

investigation (albeit date and time disrupted by the pandemic) whereas the second year was opportunistic. As a result, appropriate hospital-based efficacy appraisals and other trial features such as questionnaires were not in place but an uninterrupted supply of Noctura 400 devices and the necessary telephone support and encouragement was available and stayed in place throughout. Clearly the lack of hospital assessments is a weakness in the second year of study but having 2-year data on mask wear and compliance provides invaluable information.

Previous clinical studies that determined nightly usage of Noctura 400 have maintained a better than 5 hours per night average, but these were only 3 month [14] and 6 month [15] investigations. However, the 2-year phase III CLEOPATRA trial [16] failed to achieve reasonable compliance from the outset and average mask wear per patient deteriorated progressively such that 76% of subjects failed to reach 4 hours per night at trial end. Indeed, although an entirely accurate calculation cannot be made from the data available, the average mask wear throughout the study was likely to be lower than 2 hours per patient per night! (See also the discussion in Meyer-Bothling et al [17].)

On the other hand, the present study showed that high levels of mask wear of not less than a mean of 4.5 hours and a median of 5.5 hours per night per patient can be maintained for at least 2 years with the correct patient support. Examination of the weekly (Figure 3) and 3 monthly (Figure 4) mask wear data shows a small (although not significant) drop in wear in the 6 months of study but thereafter, for the remaining 18 months, the mask wear is pretty stable. The

study therefore eliminates the possibility arising from CLEOPATRA [16] that patients are incapable of wearing Noctura 400 nightly for a protracted period of time. Thus, the high levels of nightly mask wear achieved in short term studies [14, 15] can be sustained if relatively simple and inexpensive compliance supporting strategies are in place [25,26] as adopted here where compliance over the 2 years was a respectable 76.5% overall. For instance, it compares favourably with diabetic patients' compliance to the diet (25% to 65%) [28] and is in line with patient adherence to oral diabetes medication (65% to 85%) [29].

Unexpectedly at the outset of the study, the pandemic had its part to play. Before COVID-19 came to the UK, mask wear was over 5 hours per patient per night but during the pandemic it dropped below 5 hours but not by much (11.5% decrease in wear). Of particular interest was mask wear during lockdown and not surprisingly it was down only a little on pre COVID times but remained virtually identical to overall pandemic values. The slight drop in mask wear during the pandemic and lockdown might at least be partly explained by widespread reduced sleep time. Fewer sleep hours were recorded by patients in the sleep reports during the problematic parts of the first year however sleep issues might be assumed to continue throughout all of the pandemic so far [30] and the three lockdowns [30,31].

It was started with 26 volunteers and ended up after 2 years with 21 in total who completed the mask wear programme. Of the dropouts, 2 did not wish to continue past the first year while the other 3 exited the study for health reasons unrelated to the mask. Terminations from protracted studies

are expected but the reasons for dropping out can be of concern. In an earlier Noctura 400 study by Sahni et al [14] light intolerance was one reason for withdrawal from that investigation, fortunately light from the mask was not an issue in the present investigation. Indeed, it turns out all of the light-related discontinuers in the Sahni [14] publication is from her non-diabetic groups.

It was shown that, like any home use medical device needing repeated use, Noctura 400 is not without compliance/adherence challenges. If these are addressed by appropriate patient support and encouragement however, sustained high levels of mask wear is shown here to be a practical proposition. In present times when the usual gold standard hospital-based therapies are disrupted [1-4], home-based alternatives are an essential development [27] not just for now but also in the foreseeable future. It is believed that effective use of Noctura 400, or any such device, does require a level of patient empowerment in the individual home treatment. A concept frequently heralded for chronic illness [32] like diabetes with its ocular side effects including DR and DMO.

Many years ago Szasz and Hollender [33] defined the doctor-patient relationship (today it would be "health provider-patient relationship") into three models as the researchers saw it. The first is where the health provider is completely dominant and the patient's passive both in terms of treatment and understanding of the medical condition. The second model is intermediate while in the third of the models the patient and health provider share responsibility as equally as possible. Others [34] have inferred that model one is

only appropriate in acute illness where the patient is incapacitated whereas in chronic conditions such as diabetes, model three needs to be adopted wherever possible. It is clear to us that the patients for the most part were empowered in terms of the personal nightly treatment and remained so throughout the 2 years. The Szasz and Hollender third model [33,34] was working for the patients otherwise patients would not have used the light mask efficiently for such a long time and the mask wear may well have collapsed during the pandemic and the lockdowns.

Obviously, the researchers did not recruit on the basis of patient enthusiasm for home therapies but only on the DMO and DR status. As a result, the researchers feel that the programme for diabetic eye disease education and emphasizing patient support contributed to the development of a positive treatment attitude in the subjects.

Whether or not this is the case it is hugely encouraging that the Noctura 400 treatment device was worn to study end by the vast majority of the patient group for 2 years (21 of 26) and through the unforeseen adverse conditions of the COVID-19 pandemic when routine hospital

ophthalmic services were in complete disarray [1-5].

## Conclusions

When accompanied by regular telephone follow-ups and support, the Noctura 400 sleep mask was worn consistently for two years by a group of patients, who responded positively to the experience with the mask. Dropouts were largely unrelated to the mask itself and were the result of other health issues. When taking into account patient stated sleep hours, usage was high. Despite the COVID-19 pandemic and associated lockdowns, impact on sleep and reduced clinic visits, patients still maintained good compliance with the treatment.

## Conflicts of interest

Alison L. Farrar and Duncan Hill are employees of PolyPhotonix.

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