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RESEARCH ARTICLE



## 3DPiPPIN: 3D printing of positive airway pressure (PAP) therapy interfaces: a single site feasibility study

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### ABSTRACT

Sleep-disordered breathing (SDB) affects 14% of the population. Positive airway pressure (PAP) therapy is standard, but commercially available interfaces may be ineffective due to poor fit. Three-dimensional (3D) printing can customise PAP therapy interfaces. Is it feasible to manufacture and use 3D-printed customised oronasal PAP interfaces in clinical practice? Do customised interfaces improve patient comfort and reduce side effects compared to off-the-shelf interfaces? A single-site feasibility study involving 10 healthy and 10 patient participants was undertaken. A 3D facial scan was used to 3D print a mould, injected with medical-grade silicone to create a oronasal customised interface. Participants underwent a 10-minute trial with both off-the-shelf and customised interfaces. Comfort (Visual Analogue Scale), skin reactions, and interface leak (L/min) were measured. Patient participants used the customised interface for five nights at home, with data collected on Apnoea Hypopnoea Index (AHI), interface leak, and PAP therapy concordance. The study recruited 20 participants. Customised oronasal interfaces showed a failure rate in manufacturing (23.75% 3D printing, 50%: silicone injection). Adverse reactions were 10% in the patient study. Comfort scores were similar between interfaces. Interface leak was lower with customised interfaces after five nights. AHI was reduced with customised interfaces, but with a trend towards decreased PAP therapy concordance. The study demonstrated 3D-printed customised oronasal PAP interfaces can be manufactured, with potential benefits of reduced interface leak and AHI. Improvements in manufacturing processes are needed to reduce failure rates. Further research via a randomised controlled trial with a longer duration is warranted.

**Clinical Trial Registration** [Clinicaltrials.gov](https://clinicaltrials.gov): NCT04179123, 25/11/2019

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## Introduction

Sleep-disordered breathing (SDB) describes several conditions, including obstructive sleep apnoea (OSA), complex sleep apnoea and chronic ventilatory failure. SDB is common, affecting approximately 14% of the population, with this estimate likely to increase [1]. SDB can be treated using positive airway pressure (PAP), either with continuous positive airway pressure (CPAP) or non-invasive ventilation (NIV). PAP is delivered *via* a tight-fitting interface attached to the patient's face. Treatment effectiveness is influenced by interface fit. Patients often find the interface uncomfortable, thus limiting concordance with treatment [2]. Pressure ulcers related to the interface are a documented side effect of PAP therapy [3]. Patients are known to develop skin reactions such as dermatitis

and have reported side effects of oronasal dryness, nasal congestion, sinus/ear pain, gastric bloating and eye irritation [4,5]. Interface leak has been found to cause: ineffective ventilation [6,7], high residual Apnoea Hypopnoea Index (AHI) [8], persistent nocturnal desaturations [6] and ultimately, failure of PAP therapy [9]. Concordance with PAP therapy is essential for treatment success, with four hours of nightly PAP use required for a reduction in excessive daytime sleepiness [10] and five hours of nightly use required for a reduction in hypertension [11,12]. Interfaces are currently limited to conventional (off-the-shelf) solutions supplied by PAP device manufacturers, which come in standard sizes (generally small, medium, large) and are designed to conform to a wide range of facial morphologies, but are not optimised for any one individual morphology.

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Three-dimensional (3D) printing is a revolutionary technology that has been applied in various medical contexts. Researchers have explored its potential for creating customised interfaces. In paediatric cases, studies have shown that customised interfaces significantly reduce interface leak, leading to better compliance, more effective PAP therapy (evidenced by lower residual AHI), and improved health-related quality of life (HRQoL) [13–17]. A feasibility study with five adult, healthy subjects compared off-the-shelf interfaces and 3D printed customised interfaces for one night and reported an increase in comfort with customised interfaces, although interface leak was not reduced [18]. A small crossover study [19] ( $n=6$ ) assessed the feasibility of 3D-printed customised nasal interfaces, finding that interface leak rates were similar between customised and conventional interfaces, and confirmed that the customised interfaces could deliver the required PAP therapy pressures. A cohort study [20] compared off-the-shelf and customised nasal PAP therapy interfaces in 30 participants with known OSA. PAP therapy interfaces were worn for 10 min. Increased comfort, but also increased interface leak were reported with the customised interface. Cheng et al. [21] also evaluated a customised nasal interface manufactured using rapid tool techniques (with computer numerical control) against a conventional cushion, reporting a lower residual AHI with the customised interface. However, these studies are limited by their focus on a single ethnic group or specific patient group (such as paediatric patients with facial deformities), which limits the generalisability of the results. Additionally, existing research has primarily focused on short-term outcomes.

In this article, we report on the feasibility of our manufacturing pipeline developed and tested to produce customised oronasal interfaces to be used with PAP therapy.

## Aims and objectives

The primary objective was to determine the feasibility of 3D printed customised oronasal PAP interfaces in clinical practice. Secondary objectives were to assess the comfort of customised oronasal interfaces compared to off-the-shelf interfaces; whether there were side effects to the customised oronasal interfaces, including dermatitis, pressure ulcers and eye symptoms; and to assess changes in mask leak in the customised interface compared to off-the-shelf. A further secondary objective was to consider the feasibility of a randomised controlled trial.

## Materials and methods

**Clinical Trial Registration** Clinicaltrials.gov: NCT04179123, 25/11/2019.

## Study design

A feasibility study was undertaken to test the reliability of the facial scanning process, to determine if customised oronasal PAP interfaces could be manufactured successfully and to ensure no side effects. The study aimed to recruit 10 healthy participants and 10 patient participants. Healthy participants were enrolled first to assess for potential adverse reactions, particularly skin reactions as the customised interfaces were a new untested medical device. A sample size of 20 was designed to provide sufficient data [22] to make initial assessments and inform the design of a larger, more definitive study whilst being deliverable within the confines of the funding and ensuring participant safety.

## Manufacturing pipeline

A 3D scan of the participant's face was obtained using a handheld scanner (Structure Pro scanner, Structure, USA). Acquired facial surface scans were post-processed to engineer a face-specific computer-aided design mould. This was designed in parts to allow for silicone injection and easy extraction of the manufactured interface. The mould was 3D printed using a Stereolithography (SLA) printer (Form 3, Formlabs, USA), using biocompatible resin (Surgical Guide, Formlabs, USA) and injected with medical-grade silicone (Biopor AB, Dreve, Germany) to produce an oronasal interface cushion that could be attached to a standard PAP interface frame. [Figure 1](#) shows an example customised interface.

## Recruitment

Healthy participants were recruited from the Thoracic Medicine and Therapy Services departments at the Royal Free London NHS Foundation Trust (RFL). Healthy participants were screened for SDB using the STOP-BANG [23] and Epworth Sleepiness Score (ESS) [24]. A combined STOP-BANG score of  $>3$  and ESS of  $\geq 10$  were indicative of SDB. Patient participants were recruited from those under the care of the sleep and ventilation service at RFL. Patients with a confirmed diagnosis of SDB, being treated with PAP therapy with known interface issues (interface leak, poor mask fit, pressure ulcers, reduced PAP therapy effectiveness), were approached to take part.

## Inclusion

Healthy participants:

- Members of staff working at RFL
- Patient participants:

- Patients under the care of RFL, with a SDB diagnosis with known interface concerns (interface leak, poor mask fit, pressure ulcers, reduced PAP therapy effectiveness).

### Exclusion

Healthy participants:

- Known SDB.
- Suggestion of SDB on screening with the STOP-BANG questionnaire and ESS.
- History of eczema.
- History of allergies.
- Known reaction to medical materials.

Patient participants:

- History of eczema.
- History of allergies.
- Known reaction to medical materials.
- Clinically unstable as assessed by a clinician.
- Signs of active infection.
- PAP therapy use >16h in a 24-h period.

### Consent to participate declaration

The study was conducted in accordance with the amended Declaration of Helsinki. An independent ethics committee approved the protocol (REC reference 18/0052), and written informed consent was obtained from all patients.

### Measurements

Healthy participants underwent a 10min trial of PAP therapy using an off-the-shelf mask, whilst patients used their already prescribed off-the-shelf mask. For healthy subjects, an auto CPAP device was used with the prescription set at 4 to 20cmH<sub>2</sub>O, the 10min trial in healthy awake subjects meant the pressure did not increase from 4cmH<sub>2</sub>O. Patients used their own device with their usual prescription. An experienced clinician fitted the masks, the clinician applied a consistent, pragmatic approach across all participants to achieve a good seal and comfort, in line with standard practice. Comfort scores (Visual Analogue Scale [VAS 0 to 10]), skin reactions and interface leak (L/min) were recorded. Interface leak was recorded from the PAP therapy device using secure data (SD) card downloads into either EncoreAnywhere (Philips Respironics, USA) or Prisma TS (Lowenstein, Germany). EncoreAnywhere reports total leak (intentional plus unintentional leak),

whereas PrismaTS reports unintentional leak only. Both healthy and patient participants underwent a 10min trial of PAP therapy using the customised oronasal interface manufactured according to the pipeline described above, with the same measurements repeated. The PAP device used in the healthy subject feasibility study was a Philips Dreamstation (Philips Respironics, USA), and for the patient participants, Lowenstein (either Prisma Smart or Vent 40, Lowenstein, Germany) PAP therapy devices were used. If there were no adverse reactions, patient participants took the customised oronasal PAP therapy interface home to use for five nights. PAP therapy data were collected for AHI (events/h), interface leak (L/min) and concordance with treatment measured as hours used/night and percentage of nights used >4h. Patient participants completed a purpose-developed interface questionnaire for both the off-the-shelf interface and the customised oronasal interface, and repeated the comfort score after five nights of PAP therapy with the customised oronasal interface. Adverse reactions were recorded, including skin reactions. Patients returned their customised oronasal interface after the five-night trial.

### Data analysis

Descriptive statistics were used to report on the differences between the measurements. The small number of participants ( $n=10$  in each component) meant that further statistical analysis was inappropriate as the statistical power would be too low to detect true differences.

### Results

Ten healthy participants and ten patient participants were recruited. Table 1 states the demographics of the participants. 100% of the patient participants were compliant with their PAP therapy at the time of entering the study (defined as  $\geq 4$ h/night on  $\geq 70\%$  of nights in the previous 30 days).

One healthy participant required a repeat facial scan due to an error when exporting the file. The four component parts of the mould were printed individually, with a printing failure rate of 32.5%. The silicone injection failure rate was 50% ( $n=10$ ).

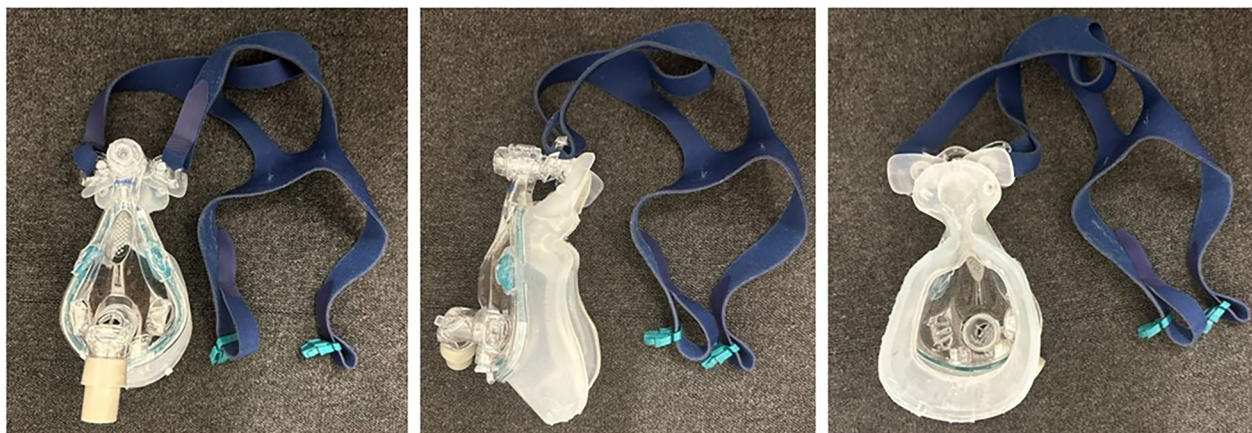
Table 2 and Figure 2 display the comfort score results. Comfort scores varied widely between participants. The median scores indicated that the comfort scores between the two interfaces were marginal.

Table 2, Figure 3 (10min, healthy and patient phases combined), and Figure 4 (after five nights, patients only) show the results of the interface leak. Three participants had a much higher leak with the customised

**Table 1.** Demographics of participants.

	Healthy participants	Patient participants
Age (years)	36 [32.5 to 43]	67.5 [58.5 to 79.75]
Sex (M:F)	6:4	6:4
Ethnicity <i>n</i> (%)		
Caucasian	6 (60%)	5 (50%)
Asian	3 (30%)	3 (30%)
Black	1 (10%)	2 (20%)
BMI (kg/m <sup>2</sup> )	22.7 [20.8 to 24.7]	32.2 [31.4 to 37.9]
Smoking status <i>n</i> (%)		
Smokers		2 (20%)
Ex-smokers		6 (60%)
Never smokers		2 (20%)
ETOH consumption (units/week)		0.5 [0 to 6.25]
Waterlow score		8.5 [5.25 to 11.25]
Duration of PAP therapy (years)		2.87 [1.67 to 6.65]
Number of PAP interfaces used		3 [2 to 3.75]
Current PAP therapy device		
CPAP <i>n</i> =		6
NIV <i>n</i> =		4
Current PAP therapy prescription		
CPAP		Auto CPAP Median pressure: 4.2 to 20cmH <sub>2</sub> O
NIV		Auto ST
		Median min EPAP: 8.3H <sub>2</sub> O
		Median max EPAP 17.7H <sub>2</sub> O
		Median min IPAP 15.3H <sub>2</sub> O
		Median max IPAP 39cmH <sub>2</sub> O
Current PAP therapy interface style <i>n</i> =		
Nasal pillows		0
Nasal		0
Minimal contact full face mask		6
Oronasal		4
Mobility status <i>n</i> (%)		
Independent		8 (80%)

Interquartile ranges are presented in square brackets.



**Figure 1.** Image of an example customised oronasal interface.

oronasal interface compared to the off-the-shelf interface. The design of the customised oronasal interface contact points were amended because of these participants. While some healthy participants had a higher leak with the customised oronasal interface, the leak remained below 60L/min, the maximum leak threshold for the Philips Dreamstation. Median values (Table 2) suggested an overall reduction in interface leak with the customised oronasal PAP therapy interface following five nights of use at home in the patient participants. Lowenstein devices were used in the

patient feasibility trial. As they do not publish a threshold on the acceptable leak as a set figure, it is not possible to report if the leak was at a level that would affect the algorithm of the PAP device.

Table 2 shows the adverse events; in all cases, the redness faded quickly within 5 min. This small sample size showed that skin reactions to the customised oronasal PAP therapy interface were low. One participant died of a cause unrelated to the trial before they were issued with their customised oronasal PAP therapy interface; their data are excluded.

Table 2 shows the difference in PAP therapy data after five nights of use between the off-the-shelf interface and the customised oronasal interface. The median values and Figure 5 indicate a reduction in AHI with the customised oronasal interface. As measured by both hours and percentage, concordance was reduced with the customised oronasal interface; however, the median figures were still within

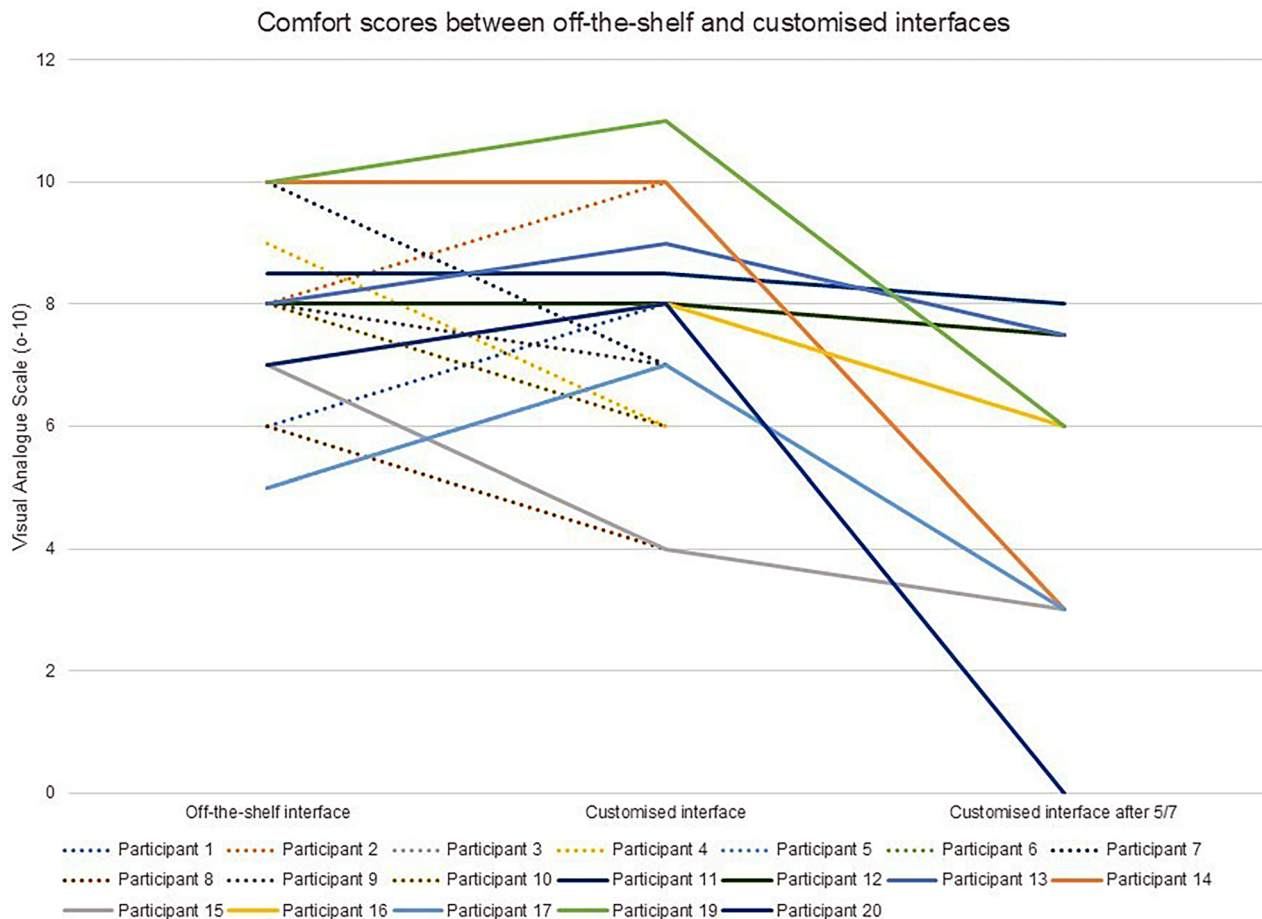
thresholds to be considered concordant with treatment. Relationships between comfort and PAP therapy concordance were explored with a scatter plot (Figure 6). The results from the interface questionnaire comparing off-the-shelf and customised oronasal interfaces are displayed in Figure 7. From the open questions in the questionnaire, patient participants commonly reported the most discomfort on the

**Table 2.** Comfort scores, interface leak and PAP therapy data for patients in the feasibility trial.

	Healthy subjects (n=10)		Patients (n=9)	
<b>Comfort score following 10 min trial, Visual Analogue Scale 0 to 10</b>				
Off-the-shelf interface	7.5 [6.3 to 8.0]		8.0 [7.0 to 8.9]	
Customised interface	7.0 [6.0 to 8.0]		8.0 [8.0 to 9.0]	
Interface leak during 10min trial (L/min)*	Philips Respironics Dreamstation*		Lowenstein Prisma Smart or Vent40*	
Off-the-shelf interface	25.5 [22.3 to 26.0]		0 [0 to 4.4]	
Customised interface	37.7 [30.0 to 47.0]		2.5 [0 to 5.0]	
<b>Adverse events</b>	Off-the-shelf interface	Customised interface	Off-the-shelf interface	Customised interface
Skin redness (%)	6 (60%)	3 (30%)	1 (10%)	0 (0%)
<b>PAP therapy data – over 5 nights</b>				
AHI (events/hr)			Off-the-shelf interface	Customised interface
Leak (L/min)			6.5 [3.0 to 7.8]	4.0 [1.0 to 5.0]
Compliance h/night (hh:mm)			40.0 [11.3 to 45.0]	30.0 [12.5 to 45.0]
Compliance >4h/night (%)			06:50 [05:29 to 07:40]	06:08 [04:47 to 07:13]
Comfort score following 5-night trial, Visual Analogue Scale 0 to 10			100 [77.0 to 100]	80 [80.0 to 100]
				6.0 [3.0 to 7.5]

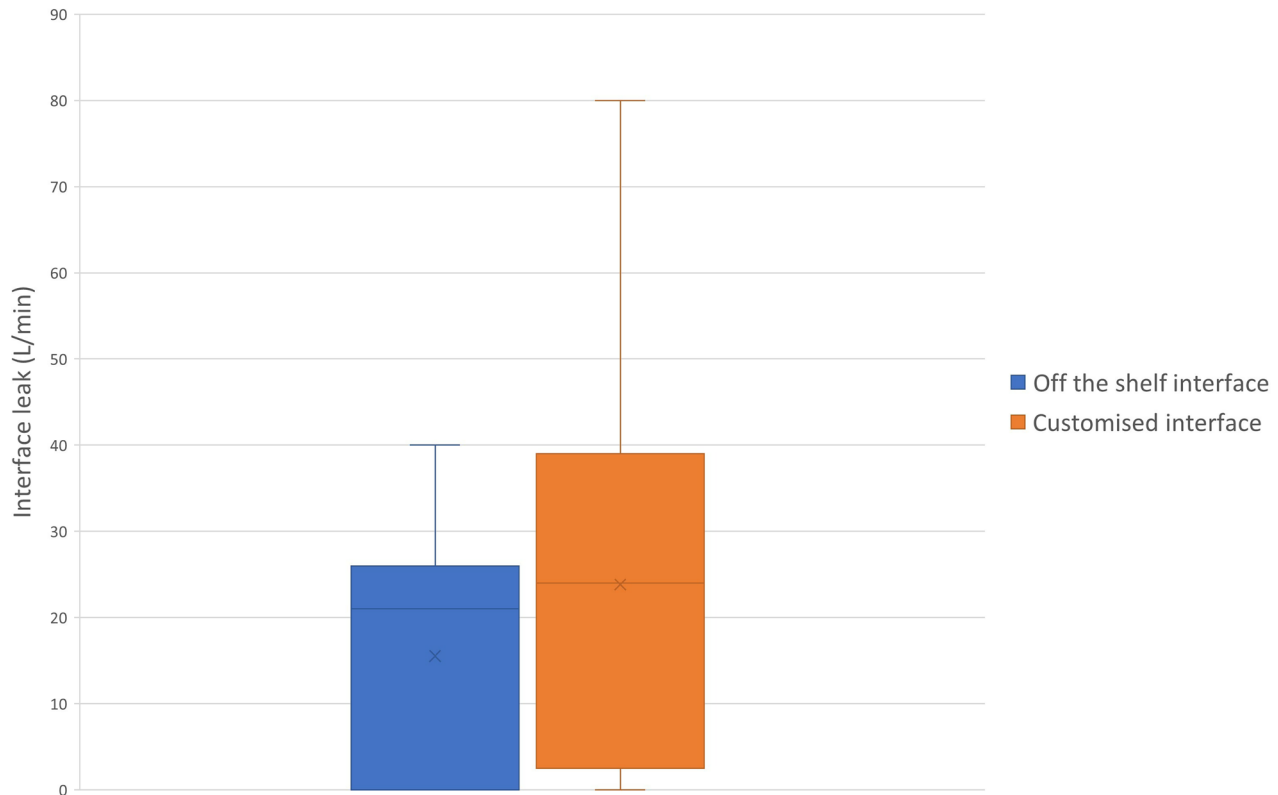
Interquartile ranges are presented in square brackets.

\*Different devices were used between phases because of a global product recall on Philips devices.



**Figure 2.** Comfort scores between off-the-shelf and customised interfaces.

### Differences in leak between off-the-shelf and customised interfaces after 10minute PAP therapy trial



**Figure 3.** Differences in leak between off-the-shelf and customised masks after 10min PAP therapy trial for healthy and patient phases combined.

bridge of their nose and cheek bones. They provided feedback that they wanted the customised mask to be smaller and lighter in weight.

### Discussion

Despite the small sample size, the cohort was heterogeneous in terms of participant demographics in both the healthy and patient feasibility trials for age, ethnicity and sex, which are representative of a real-world clinical population. As might be expected, the patient participants were older and had a higher BMI than the healthy participants. Other authors have focused on paediatric populations [13–17] or healthy subjects [18,19]. Nam et al. [20] and Cheng et al. [21] both investigated patient populations: their participants had OSA, were predominantly males (76 and 77%, respectively), with an average age of 49 and 52 years, respectively, whilst neither author reported ethnicity. The willingness of a variety of participants in this feasibility study indicates that recruitment to a large-scale RCT could be representative of a patient population, making the results of an RCT more generalisable.

There was a low rate (5%) of failures in the scanning process, indicating that the scanner and scanning process were reliable and could be used within clinical practice and a larger-scale RCT. However, there was an overall high failure rate in both the 3D printing of the moulds (23.75%) and the silicon injection process (50%). Duong et al. [19] report a 33% failure rate in their injection process. Other authors have not reported the failure rates within their manufacturing process, making it difficult to compare the results of this feasibility study with those of previous work. Regardless, changes to the mould design and manufacturing pipeline would be required to reduce the failure rates and increase the feasibility of manufacturing higher volumes of customised PAP therapy interfaces, which would be needed in clinical practice and for an RCT.

In both the healthy subject and patient participant feasibility trials, the median comfort scores during the 10min trials showed negligible differences between the off-the-shelf interface and the customised oronasal interface. There was a trend towards reduced comfort during the five nights of use with the customised oronasal interface in the patient feasibility trial.

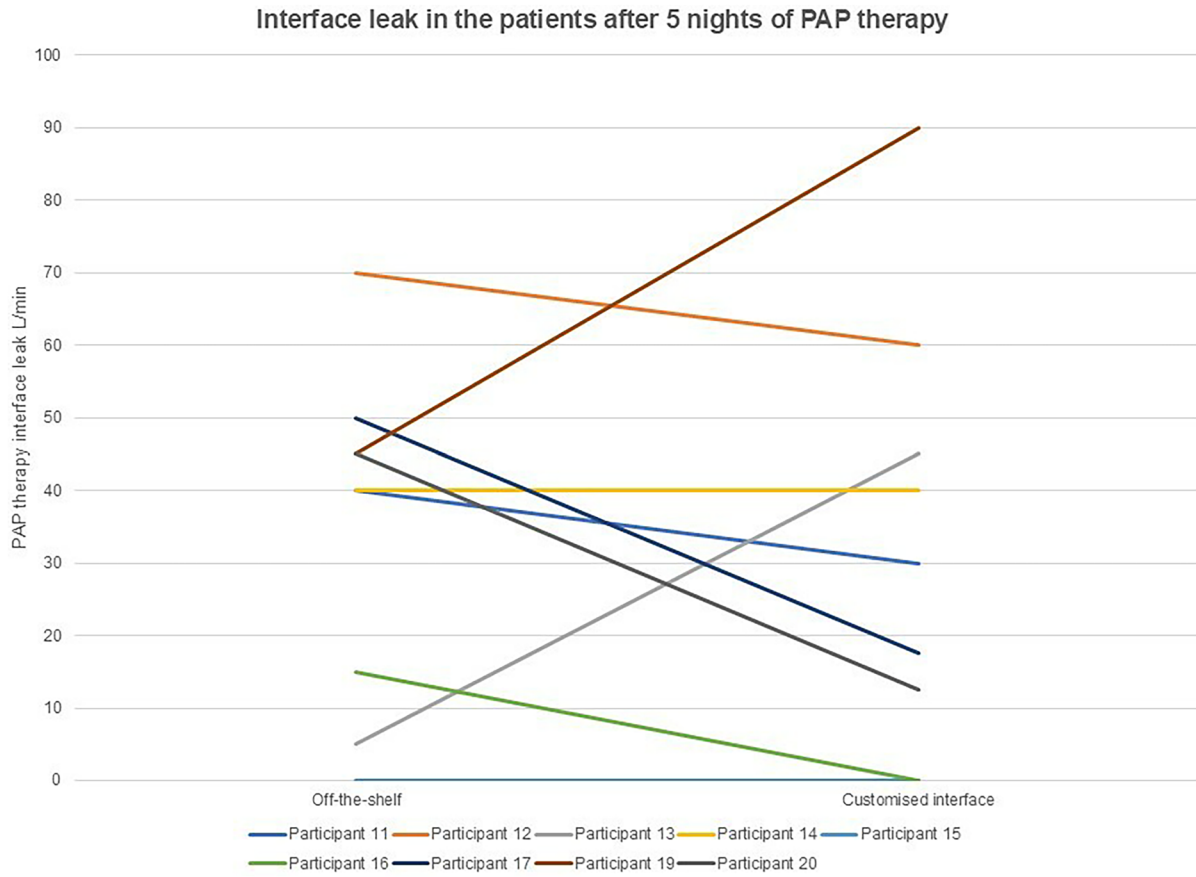


Figure 4. Interface leak in the patients after 5 nights of PAP therapy.

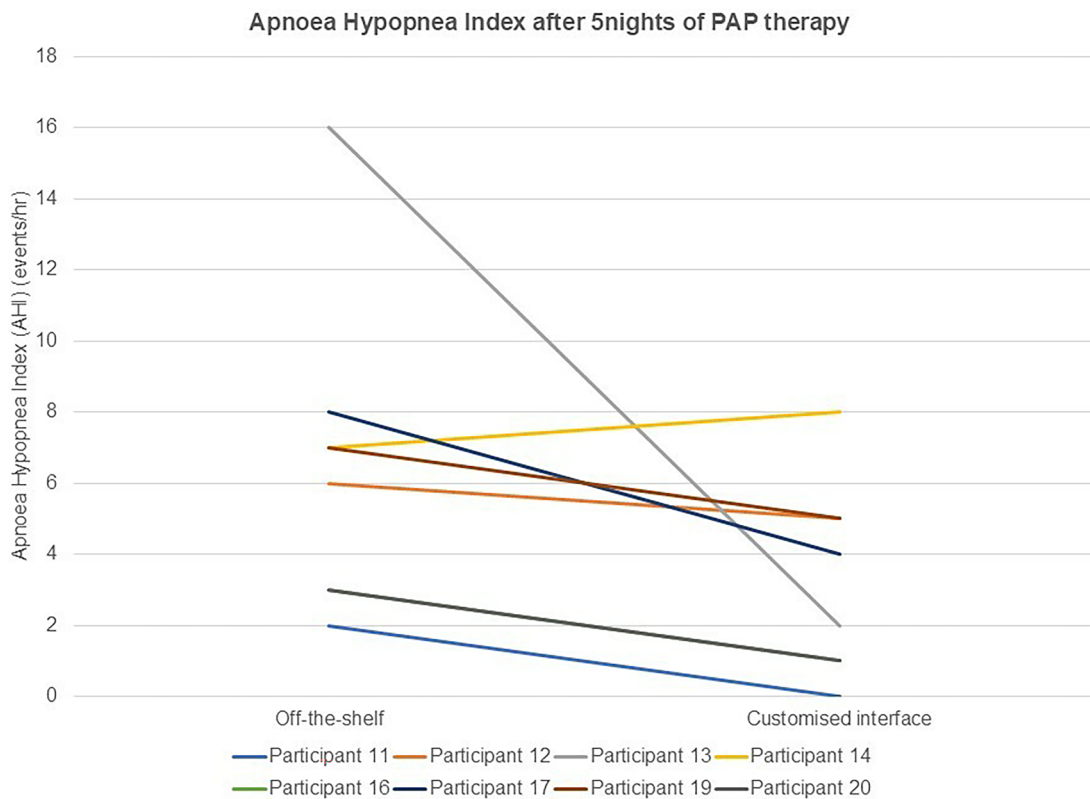
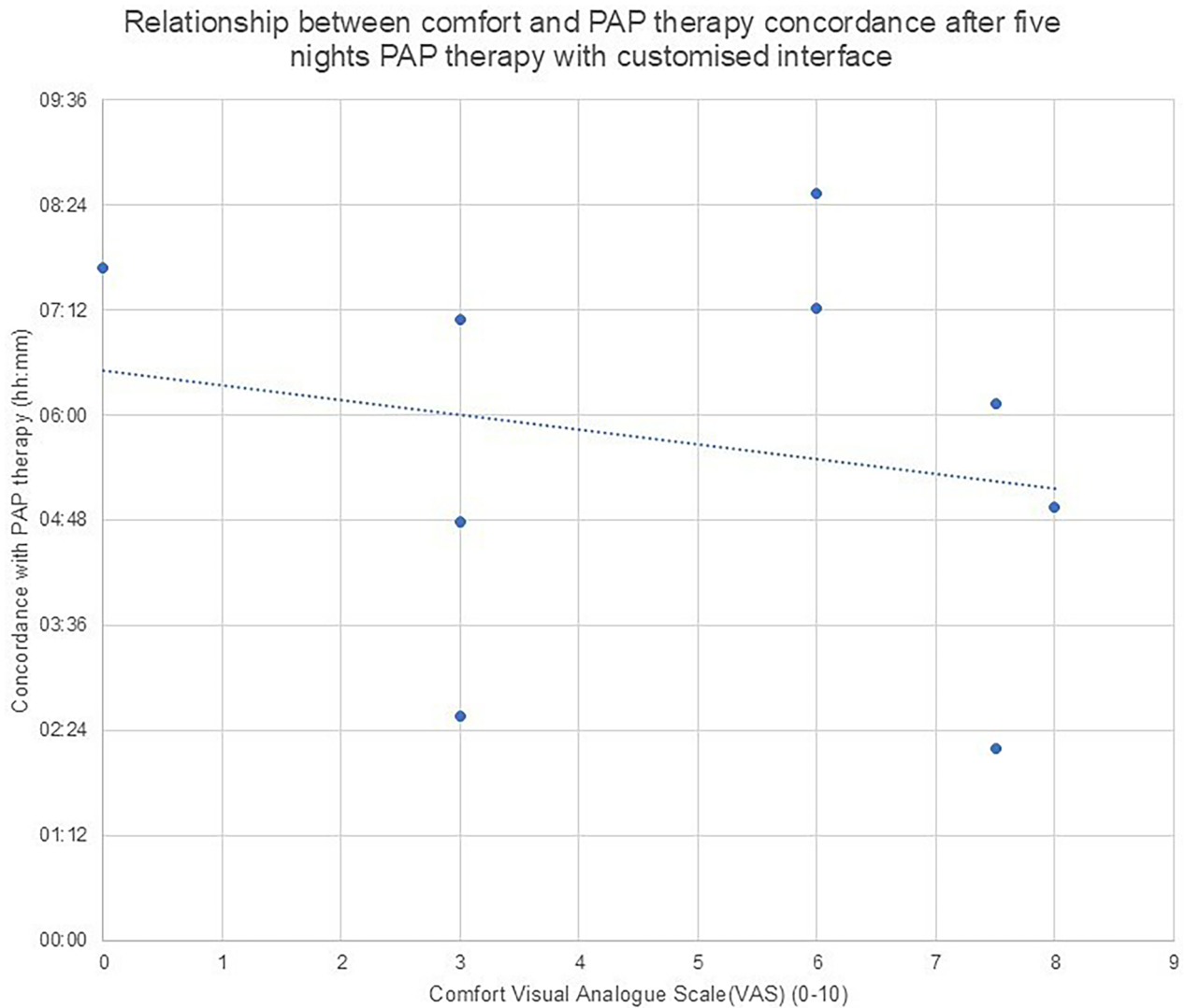


Figure 5. Apnoea hypopnea index after five nights of PAP therapy in the patient participants.

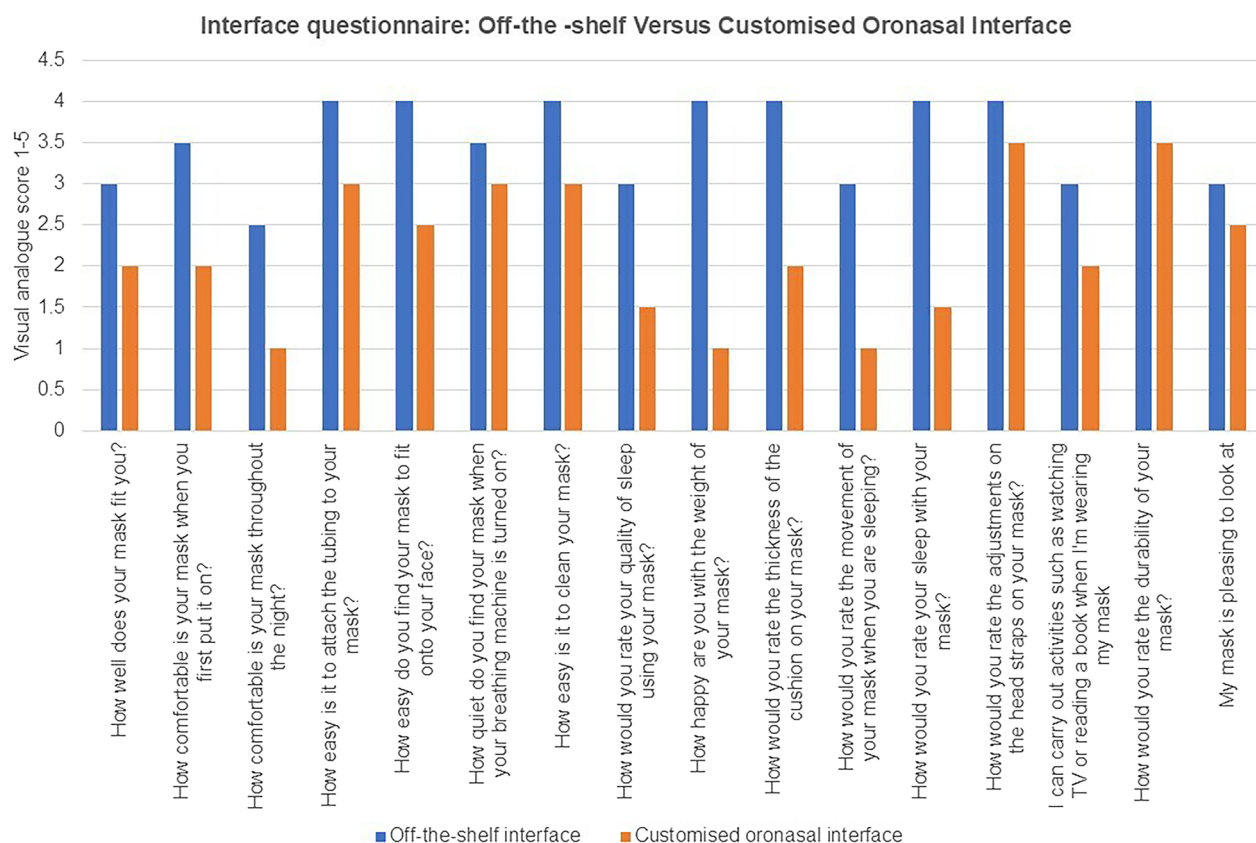


**Figure 6.** Relationship between comfort and PAP therapy concordance after five nights of PAP therapy with customised interface.

The customised oronasal interfaces were heavier than the off-the-shelf interface, which could be a contributing factor. These data suggest that refinement of the customised PAP therapy oronasal interface would be required to optimise comfort before use in clinical practice, or a larger-scale RCT could be considered feasible. The comfort scores were measured with a VAS (0 to 10), which may not be sensitive enough to change. In the healthy subject feasibility trial, there was a median (IQR) time of 77 (61 to 101) days between the PAP therapy trials and in the patient feasibility trial, 65 (38 to 70) days between the PAP therapy trials, which could add recall bias to the results as direct comparisons might not be recalled. A more detailed mask comfort questionnaire needs to be developed to better capture differences in interface comfort scores for a RCT. The comfort score results after 10min are in keeping with previous authors [18,20], who report

increased comfort scores with customised interfaces. Nam et al. [20] used a nasal interface worn for 10min, whereas the interface used in this feasibility study was an oronasal interface. Martelly et al. [18] recruited healthy participants who wore an oronasal interface for one night. The differences in interface type, participants and duration of PAP therapy use might explain the differences in reported comfort scores between this feasibility study and previous work.

The adverse events (skin redness rates) were lower after using the customised oronasal interface in the small sample of healthy participants. Smoking status, age, BMI and co-morbidities all contribute to an increased risk of skin reactions and pressure ulcers. It was, therefore, reassuring to see a lower rate of skin reactions in the patient participants compared to the healthy subjects despite these increased risk factors. This indicates that the customised oronasal PAP



**Figure 7.** Interface questionnaire: off-the-shelf versus customised oronasal interface.

therapy interface could be used in a larger scale and longer duration RCT. The reporting of adverse events by previous authors is lacking, with only two previous studies reporting adverse events. Martelly et al. [18] report skin redness in 20% of their healthy participants, whereas Martin-Gonzalez et al. [16] reported skin redness with the customised interface in their single case study.

There is currently no known minimal clinically important difference (MCID) for interface leak; different manufacturers have different recommendations, and the amount and type of PAP pressure impact on interface leak. Within the healthy subject feasibility trial, except for one participant, the leak remained below the maximum leak threshold for the Philips Dreamstation. Although the threshold on acceptable leak for Lowenstein devices is not available, median values in the patient cohort suggested an overall reduction in interface leak with the customised oronasal PAP therapy interface following five nights of use at home. The seemingly larger reductions in interface leak between the healthy and patient groups are due to the different ways the manufacturers measure leak as described above. This reflects observations in clinical practice that interface fit in an outpatient clinic cannot replicate interface fit in the patient's own

environment whilst sleeping. These results are in keeping with previous authors who have also reported reduced interface leak with customised PAP therapy interfaces in single case studies [16,17]. In contrast, other authors reported no significant difference in interface leak between customised and off-the-shelf interfaces [14,18–21]. The differences in interface type, participants and duration of PAP therapy use might explain the differences in reported interface leak between this feasibility study and previous studies.

Customised oronasal PAP therapy data downloads showed a median reduction in AHI; this could be related to the reduced interface leak. Arguably, AHI is the most clinically important parameter provided by the PAP therapy downloads. The adequate control of SDB with the customised oronasal PAP therapy interface suggested it would be safe to use the customised oronasal PAP therapy interfaces in a large-scale, longer-duration RCT. There is a paucity of reporting of the impact of customised interface on AHI. In keeping with our results, Morrison et al. [17] reported a reduction in AHI in their single case study, as did Cheng et al. [21] in their RCT.

There was a trend towards a reduction in PAP therapy concordance with 3D printed oronasal interfaces in the patient feasibility trial, although this did not seem

to be related to comfort. Given the short duration of only five nights of use, it is not appropriate to draw conclusions about the impact of customised oronasal interfaces on concordance with treatment. Furthermore, the patients were highly concordant with PAP therapy at baseline and may not represent a real-world population where concordance is problematic. Any change in PAP therapy setup can take time to adjust to; an exchange of interfaces can often take more than five nights for the patient to adapt to. This observed reduction in concordance is difficult to explain with the small sample size, but could be further explored in larger clinical trials. There is a paucity of reporting on the impact of customised interfaces on PAP therapy concordance. In small paediatric populations, previous authors have reported a small increase in concordance with customised PAP therapy interface treatment [14,17].

### Limitations

The sample size is small, which, whilst appropriate for a feasibility trial, means results are not generalisable. Additionally, as this was a feasibility cohort study, there was no control arm with which to make comparisons. Despite selecting a patient population with known interface issues, the baseline interface leak observed was low. The necessary design of feasibility trials meant that the duration of customised oronasal PAP therapy interface use in the patient component was of short duration, with use for only five nights. This was to ensure patient safety within the trial as the customised oronasal PAP therapy interface was untested and without a UK:CA or CE mark. Future trials should be for a longer duration, and this feasibility trial has demonstrated that this would be safe. Future studies should consider assessing the customised oronasal interface against ISO 18562: Biocompatibility Evaluation of Breathing Gas Pathway Devices to ensure there are no contaminants in the manufacturing process. Two different manufacturers of PAP therapy devices were used between the healthy and patient feasibility trial, making comparisons between the healthy subjects and the patients difficult, especially for the interface leak data. It was not possible to blind the participants, and resources meant that assessors could not be blinded; this could introduce potential reporting bias to the results.

### Conclusion

The preliminary data from the feasibility study reassured the investigating team that the customised oronasal interfaces could be manufactured for clinical practice,

albeit with some improvements to the mould design, and are safe for use in a patient population within a clinical trial. These data were essential in refining the manufacturing process for a future RCT [25]. Further product development of the customised oronasal PAP therapy interface will be required to increase not only large-scale manufacturability but also comfort and concordance with treatment.

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### Author contributions

CRedit: **Stephanie K. Mansell**: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Validation, Visualization, Writing – original draft; **Oliver Olsen**: Resources, Writing – review & editing; **Francesca Gowing**: Funding acquisition, Project administration, Resources, Writing – review & editing; **Zaid Muwaffak**: Conceptualization, Data curation, Funding acquisition, Methodology, Project administration, Resources, Writing – review & editing; **Cherry Kilbride**: Conceptualization, Funding acquisition, Project administration, Supervision, Writing – review & editing; **Stephen Hilton**: Conceptualization, Data curation, Funding acquisition, Investigation, Methodology, Resources, Supervision, Writing – review & editing; **Eleanor Main**: Data curation, Project administration, Supervision, Writing – review & editing; **Silvia Schievano**: Investigation, Project administration, Resources, Software, Supervision, Writing – review & editing; **Swapna Mandal**: Conceptualization, Data curation, Funding acquisition, Methodology, Project administration, Supervision, Writing – review & editing.

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### Institutional review board information

London Dulwich Research Ethics Committee REC reference 18/0052.

## Data Availability statement

The data generated and/or analysed during the current study are not publicly available due to data protection and intellectual property protection.

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