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Mask Selector 3D

Philips Mask Selector: A 3D scanning system for data-driven PAP mask fittings

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Introduction

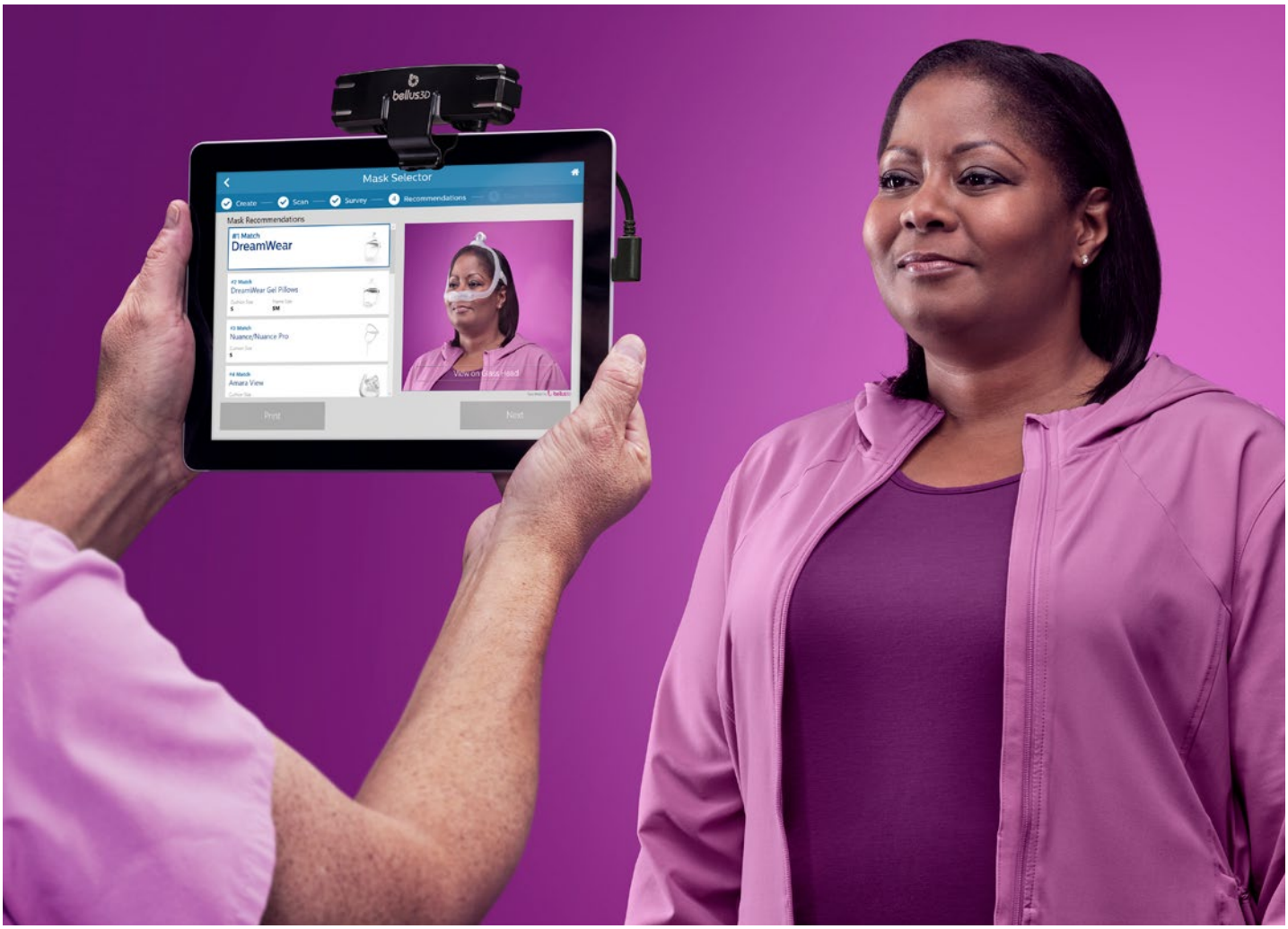
Positive airway pressure (PAP) therapy for sleep-disordered breathing (SDB) comprises a blower device, tubing, and a mask that acts as the interface between the device and the patient. A variety of mask styles and sizes are available on the market; however, there is no standardized process for selecting an appropriate mask for a given patient.[1] Poor mask fit can negatively affect a patient's treatment experience and adherence, and can be burdensome to providers due to the requirement for phone calls and visits for troubleshooting and additional fittings.[2-4] Further, masks that are trialed during an appointment but not selected for home-use often go to waste or require extensive cleaning prior to re-use, which is associated with additional expense.

Philips has developed a novel solution utilizing a three-dimensional (3D) facial scanner and associated software to assess facial anatomy characteristics, which aims to make the mask fitting process more efficient. The Mask Selector system (Philips; Pittsburgh, PA) consists of a computer or tablet, an after-market 3D camera, and proprietary software that combines facial images and responses to a six-item questionnaire to generate an ordered list of up to four Philips masks for an individual patient, along with the recommended size, which is then displayed to the clinician. The primary aim of this randomized controlled trial was to assess the impact of the system on mask selection for SDB patients who initiate first-time PAP treatment, hypothesizing that the Mask Selector arm would have a greater proportion of patients assigned only one mask over a 90-day period, compared to usual care consisting of traditional mask fittings.

Methods

This study was a multi-center, open-label, parallel-arm, randomized controlled trial with follow-up duration of 90 days, conducted in five sites (Bogan Sleep Consultants, SC; the Center of Sleep & Wake Disorders, MD; Pulmonary Rehabilitation Associates, OH; Pulmonary Disease Specialists, FL; Berks Schuylkill Respiratory Specialists, PA). The study was approved by the Western Institutional Review Board (20190624) and registered at ClinicalTrials.gov (NCT03948152). All participants provided written informed consent.

Participants were recruited from sleep clinics. Inclusion criteria were age 21-85 years; diagnosed with SDB at any severity level; prescribed first-time PAP therapy; fluent in English. Exclusion criteria were a prescription for adaptive servo-ventilation, facial feature/s that would preclude a mask fitting; silicone allergy; recent or planned eye or ear/nose/throat surgery; and any acute or chronic medical condition that would preclude a mask fitting and/or data collection.



Eligible participants were randomized 1:1 to the Mask Selector or usual care arms. Participants in the Mask Selector arm began by undergoing a scan, during which the clinician used the system to take a series of 3D pictures of each participant's face while they sat upright and stationary. Upon scan completion, participants answered six questions in the app regarding sleep habits/routines, allowing the system to generate an ordered list of recommended masks. Mask fittings proceeded in the sequence recommended by the Mask Selector platform, compatible only with Philips masks, during which the clinician applied therapeutic pressure for 2-5 minutes. If both the clinician and the participant were satisfied with the fit of the first mask, the fitting was considered complete. Otherwise, the process was repeated with the remaining recommended masks in sequence. If all masks were deemed to be unsatisfactory, the participant was discontinued from the study and a Mask Selector failure was recorded. Participants in the usual care arm underwent the fitting process according to their clinician's usual procedure, including the application of therapeutic pressure for 2-5 minutes. There were no limits on the mask manufacturer or mask type in the usual care arm. Following mask fitting, PAP therapy was initiated following usual clinical procedures. The requirement for mask re-fits over the 90-day follow-up period was guided by usual clinical care. Re-fits in the Mask Selector arm were undertaken following the original sequence of masks generated by the software. Participants were asked to return to the sleep clinic after 90 days to complete a satisfaction survey. Adherence and leak data were accessed through EncoreAnywhere (Philips; Pittsburgh PA). The percentage of participants meeting adherence criteria was evaluated, defined as ≥ 4 hours use on ≥ 70% of nights during a consecutive 30 days over the initial 90 days of treatment. Data were statistically compared between arms using SAS 9.4 (Cary, North Carolina).

Results

A total of 310 participants were consented and randomized (Mask Selector arm, n=155; Usual Care arm, n=155). Analyses were based on the per-protocol samples of n=153 for Mask Selector and n=157 for usual care. Demographic and clinical characteristics are presented in Table 1.

	Mask Selector; n=153	Usual Care; n=157
Age (years)	50.2 ± 13.4	51.2 ± 11.7
Male sex	58.2% (89)	61.1% (96)
Ethnicity		
Hispanic/Latino	15.0% (23)	11.5% (18)
Non-Hispanic/Latino	85.0% (130)	88.5% (139)
Race		
White	86.3% (132)	78.3% (123)
Black / African American	11.8% (18)	19.1% (30)
Other race or not specified	2.0% (3)	2.5% (4)
Body mass index (kg/m2)	36.8 ± 22.7	36.1 ± 15.8
Diagnostic Apnea-Hypopnea Index (events/hour)	25.7 ± 20.4	25.4 ± 21.3

Data are provided as mean ± standard deviation or % (n).

Table 1: Demographic and clinical characteristics

During the initial visit, 90.8% of the Mask Selector arm and 58.0% of the usual care arm were fitted with only one mask (p<0.001). Over the entire 90-day follow-up period (including the initial visit), 61.4% of the Mask Selector arm and 40.1% of the usual care arm used only one mask (p<0.001), making the Mask Selector group 53% more likely to use their first recommended mask through the first 90-days of PAP use, compared to usual care (see Figure 1). Through 90 days, a participant in the Mask Selector arm was fit with an average of 1.5 masks, versus 2.1 masks in the usual care arm, which equates to a 27% reduction in mask fittings, and a 52% reduction in refits (p<0.001). The distribution of the first take-home mask was significantly different between arms, with 18%, 82%, and 0% of the Mask Selector arm using oronasal, nasal cushion, and nasal pillows masks, respectively, and 41%, 46%, and 13% of the usual care arm using oronasal, nasal cushion, and nasal pillows, respectively (p<0.001).

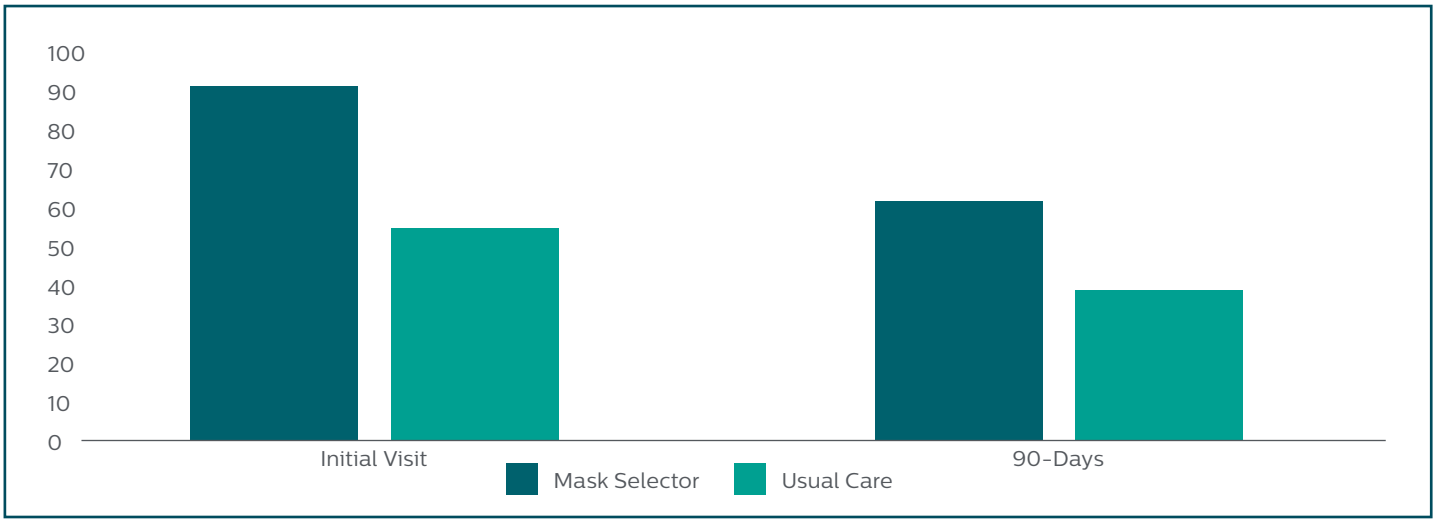


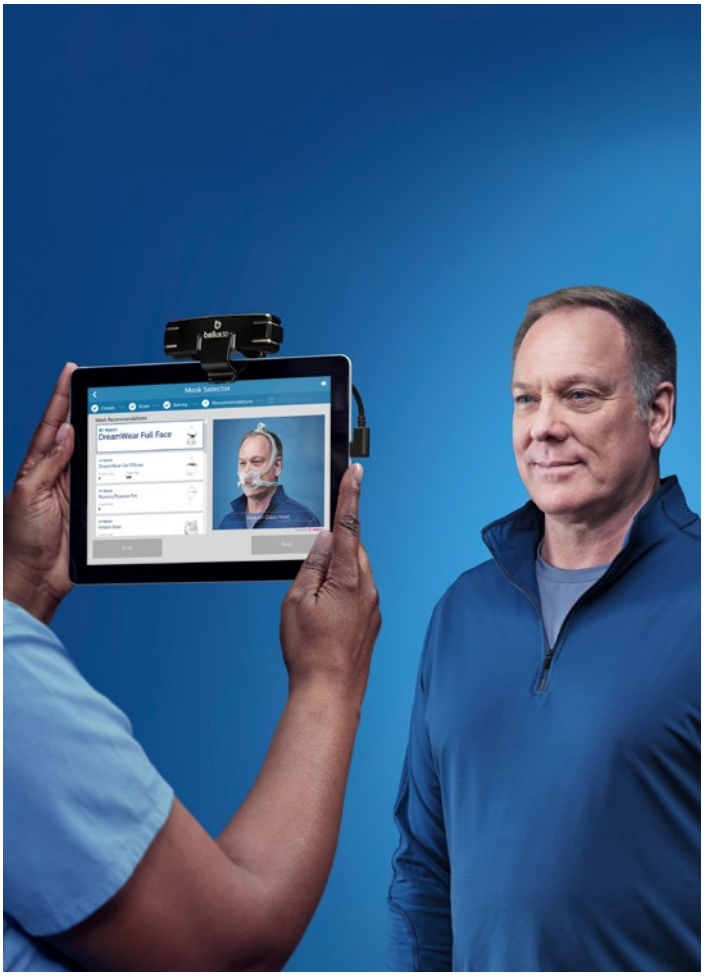
Figure 1: The percentage of participants in each arm who used only one mask during the initial visit and over 90 days (between-arm difference p<0.001 at both time points).

There was no significant difference in adherence rates between arms (60.7% and 59.2% in the Mask Selector and usual care arms, respectively). Mask Selector participants had 14% lower average mask leak than those who underwent traditional mask fittings (median 25.5 vs. 29.6 liters/minute; p=0.049). At the conclusion of the study, participants in the Mask Selector arm expressed greater confidence that they will continue to wear their assigned mask compared to those in the usual care arm (on a scale of 0-10, confidence score of 8.5±2.2 vs. 7.9±2.7; p=0.04).

Discussion

In this randomized controlled trial, the use of a novel, automated mask fitting system resulted in fewer masks being used during the initial fitting process and over 90-days, compared to usual care, as well as significantly lower average mask leak. Participants who underwent the automated mask fitting process were 53% more likely to keep their first allocated mask, and they experienced 52% fewer mask refits than those who underwent a traditional mask fitting. Over 90 days, the masks selected by the automated system exhibited a 14% reduction in average leak compared to the masks selected by traditional fitting methods. Although adherence was similar between arms, participants in the Mask Selector arm expressed a significantly higher level of confidence in, and satisfaction with, the mask selection process compared with usual care.

Our data suggest that use of the Mask Selector system may result in improved durable medical equipment (DME) company and sleep clinic efficiency and reduced costs associated with the use of multiple masks per patient. The exact means in which masks are cleaned, disinfected and re-used after fittings is not known, although in a survey of sleep clinics conducted by Philips (unpublished), 60% reported disposing of masks after a single use, citing safety concerns and the labor-intensity of cleaning and record-keeping as the most common reasons for adopting a single-use model. We envision that this trend will continue to grow with the global COVID-19 pandemic, and that most clinics will adopt the practice of avoiding reusing masks for multiple patients. In addition, the Mask Selector system has the advantage of being a contact-less mask fitting method. The Philips Mask Selector 3D scanning system delivers an efficient, consistent mask fitting process that is personalized based on facial characteristics and sleeping preferences aligned with mask design.



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Caution: U.S. federal law restricts these devices to sale by or on the order of a physician.

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