Development of Customized CPAP and BiPAP Therapy Masks for Enhanced Treatment Efficacy

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Abstract. Continuous Positive Air-way Pressure and Bi-level Positive Airway Pressure therapy have been used to treat mild chronic obstructive sleep apnea and chronic obstructive pulmonary disease. These medical conditions are associated with impaired breathing efficiency. Such therapy requires a face mask with typical leakage of air for optimal therapy. A solution to the problem of leakage of air is to design a face mask for therapy customized to individual face geometry. We used 3D scanning of individual faces using Scandy Pro. The 3D face scans were processed using Meshmixer for cleaning the meshes, closing of the objects in face and cropping the scan to get the area of interest developed in the geometry. The methodology implies creating reference planes, generating sketches with exact dimensions, patterning points, and applying boundary surface commands to achieve an optimal fit.

Keywords: BIPAP, 3D scanning, face geometry, additive manufacturing, customized Mask

1 Introduction

BiPAP is a non-invasive ventilation method that improves breathing, vital signs, and hemodynamic stability in patients with acute respiratory failure, congestive heart failure, and pulmonary edema, reducing hospital stays and mortality rates [1] [2], [3].

Patients suffering from sleep disturbances often reported with obstructive sleep apnea (OSA) syndrome. Numerous chronic medical problems linked to breathing difficulties have been treated with noninvasive ventilator devices, specifically CPAP and BiPAP machines [4]. CPAP therapy by Colin Sullivan, is the gold standard for treatingOSA by delivering air through a mask. [5] BiPAP a non-invasive ventilation support has improved breathing and sleep quality. [6] The maintenance of such pressure withinan FDA-specified pressure range ± 1.5 cm H_2O of the set pressure) is necessary as a quality-assurance measure that would ensure that the device maintains a certain prescription pressure for the patient [7]. A standard CPAP system consists of a pump, a

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flexible hose, a facial mask, and headgear. The mask establishes the connection between the user's facial shape and the pressured air hose. Nowadays, different needs andpossible breathing patterns are taken into consideration while designing traditional CPAP interfaces, such as full faced masks, nasal masks, nasal pillow masks, oral masks,and entire face masks. Table 1 lists the most common CPAP mask configurations that are sold commercially along with their airflow justifications. [8] These breathing devices work well; however, some patients stop using them because the masks don't fit properly.[9]

Table 1. Categorization of distinct types of CPAP mask therapy. [1]

Mask	Contact area	Air delivery path
Full face masks	Cover both nose and mouth	Through nose and mouth
Nasal masks	Cover nose only	Through nose and mouth
Nasal pillows	Cover inside rim of the mouth	Through nose only
Oral masks	Cover moth only	Through mouth only
Total face mask	Cover entire face	Through nose and mouth

2 MethodologySmart Fit Approach

Figure 2 depicts the schematic diagram summarizing the project's process. The process starts with a generalized face geometry as a base model. 3D scanning application namely Scandy Pro captures detailed facial features. An application called Meshmixer then integrates these captured features with the generalized geometry, modifying the base model to create a customized mask tailored to the individual's unique facial characteristics.

2.1 Scanning Application overview

The smartphone application Scandy Pro was found to produce the most accurate scans in terms of facial similarity, based on a visual evaluation. During the scanning process, it is crucial for the user to keep their head stationary and ensure that the phone remains immobile to achieve optimal results. The size of each scan file ranges between 55 to 90 MB. This application is available exclusively on the iOS platform [10]. The hardware used was Iphone 12, which uses an infrared camera and TrueDepth technology to acuiredepth information.

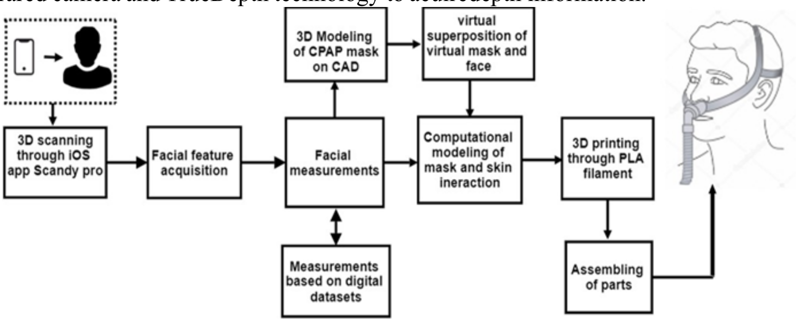


Fig. 1. Schematic diagram to show the overview of methodology

This resulted in a solid 3D digital facial model. Measurements of important facial traits in 2D and 3D formats can be easily obtained by utilizing 3D databases of volunteer faces. These metrics offer valuable insights for improving CPAP mask selection and creating customized masks.

2.2 3D Face Modeling with Scandy Pro: Mehran University Case Study

Six participants from Mehran University of Engineering and Technology Jamshoro created 3D face models using the Scandy Pro application on an iOS device in figure 1. The participants' facial features were captured with resolution of 1 mm and precision of 0.16 mm using the Scandy Pro application, serving as case studies to illustrate the methods used in the investigation as shown in figure 2.

Fig. 2. 3D generated face models of six volunteers with IOS application Scandy Pro

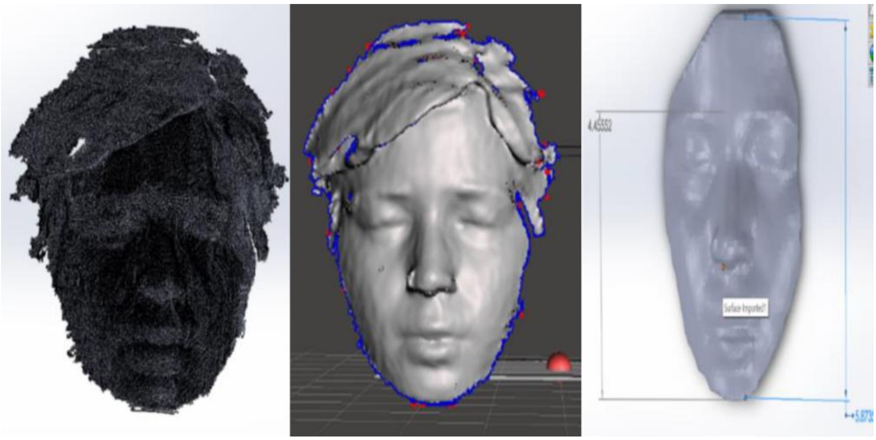


Fig. 3. Facial feature acquisition: (a) raw scan with noise (b) close whole mesh body (c) 3D adapted mesh model that has been intricately modified through computational methods.

Figure 3 demonstrates the comprehensive steps for acquiring and refining facial features. Initially, a raw scan is conducted, which inherently includes noise and imperfections. This raw data is then processed in Meshmixer, where the entire mesh is thoroughly cleaned to achieve accurate and detailed facial features. Once the mesh is refined, it is imported into SolidWorks. At this stage, it is essential to verify that the dimensions of the mesh remain consistent with those obtained from Meshmixer to ensure the integrity of the model. This verification is crucial for ensuring precision and reliability in the final 3D model.

2.3 Quantifications of facial characteristics

To create a detailed 3D facial model with 2mm accuracy, start with a 2D sketch on "new plane 1" by drawing a 31mm radius circle centered 25mm from a reference point. Use the linear pattern command to generate nine points spaced 2.5mm apart and mirror them. Apply the circular pattern command to position 25 points at 180-degree intervals around a center point and mirror these. Finally, draw 3D points based on the 2D sketches and patterns to complete the model, capturing detailed facial features like distances and angles between key landmarks.as seen in figure 4 and 5.

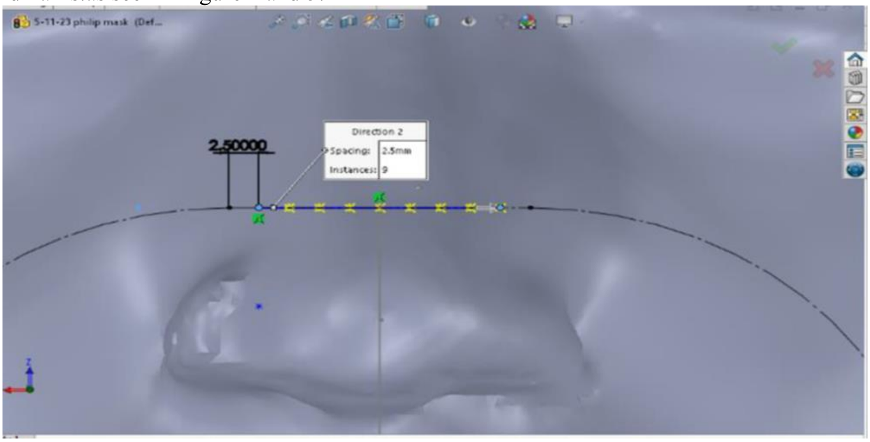


Fig. 4. Number of points 9 with distance of 2.5mm (about 0.1 in)

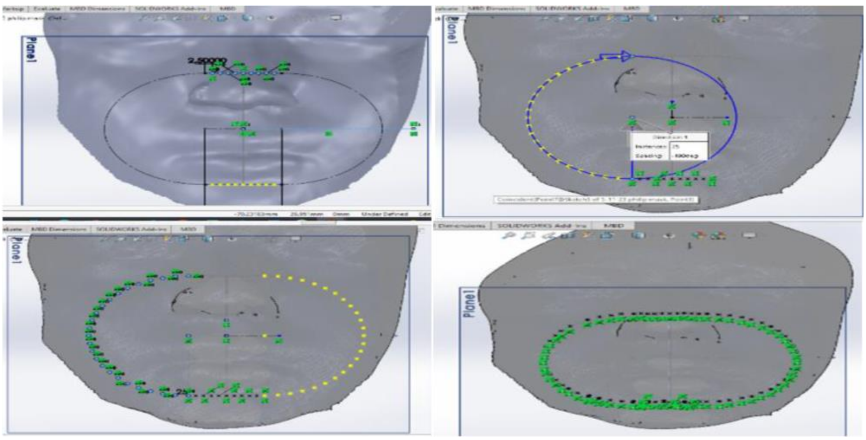


Fig. 5. Key facial markers for precise localization: (a) mirror all patterned points. (b) No of points 25 and angle 180 degree clockwise. (c) now mirror all circular points. (d) draw 3D points.

2.4 Digital dataset acquisition

A 3D sketch was created, with the outer edge of the mask selected. A 3D curve was created using the "convert entities" command. Linear and circular patterns were used, and a mirror command was applied on the sketch's outer boundary. The thicken command was then utilized as shown in figure 6.

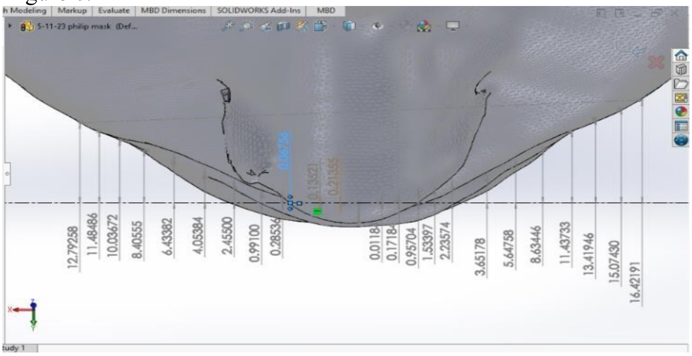


Fig. 6. Measuring the points from reference plane.

Table 2. Measurement of 2D Mesh Model features [8]

Item	Dimensions in (+-3mm)	Dimensions in inch
Width of mouth	63.5	2.5
Height of mouth	26.13	1.02875
Bottom of Nose to upper lip	14.68	0.578
Length of nose	33.32	1.312
Width of nose	Top: 25.04 Middle:26.79Bottom: 33.3	Top:0.986 Middle:1.05 Bottom:1.312

A 3D mask design was created using various commands, including convert entities andpatterns, to generate points, define editable lines, construct curves, and create surfaces. Thickening, extrusion cut, and sweep were used for finishing.

2.5 Enhancing Prototyping Efficiency through 3D Printing and Iterative Design

In this project, we utilized a lab-scale 3D printer from Ender 3D Pro. The Creality slicer 4.8.2 software was used to prepare 3D models by slicing them into layers, creating theprinting path, and tracking the printing time. The Ender 3D printer was configured with a nozzle temperature of 200°C and a bed temperature between 68 and 80°C. The fan speed was set to 255, and the flow rate was adjusted to 110%. PLA plastic was chosen for its advantageous properties, including a low softening point and high durability, which made it ideal for producing the CPAP mask.

3 Results

Figure 7 shows the effectiveness of customized CPAP and Bi-PAP therapy masks designed. We examined the design process by considering individual facial dimensions to achieve an optimal fit. The smart fit approach enabled us to precisely customize mask designs, thereby improving both the fit and effectiveness of the therapy.

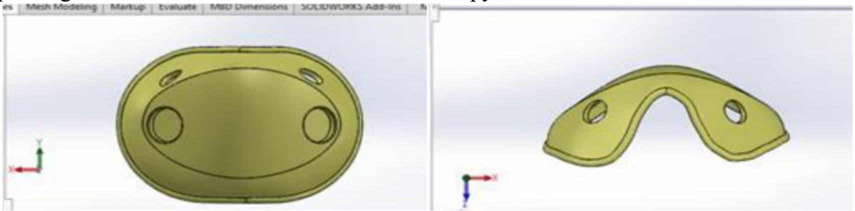
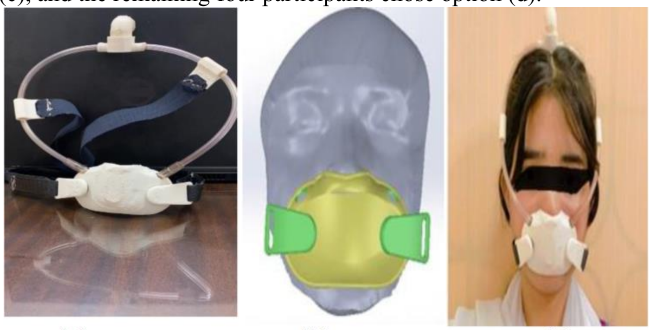


Fig. 7. Complete design of CPAP and Bi-PAP therapy mask

Figure 8 shows the final customized mask. Our investigation confirms the success of the proposed design, as evidenced by the mesh model and the mask worn by a volunteer. We sought qualitative feedback from the participants, each of whom put on the customary mask as well as the customized mask one by one for 5 minutes each. They were asked to compare the experience of wearing the customized mask as compared to the customary mask, with four options: a) Worse than the customary, b) same as the customary, c) better than the customary, and d) much better than the customary. One ofthe participants chose option (b), one participant chose option (c), and the remaining four participants chose option (d).



(a) **(b)** **(c)**

Fig. 8. (a) 3D printed customized CPAP and Bi-PAP therapy Mask (b) mask mesh model in 3D (c) 3D printed mask wearing by volunteer.

4 Discussion

This research investigated the use of 3D scanning and printing to create personalized CPAP/BiPAP masks for sleep apnea and COPD patients. Here, 3D facial scans were captured using Scandy Pro and processed with Meshmixer software for cleaning and refinement. The methodology involved creating reference planes, precise sketches, patterned points, and applying boundary surface commands to design a mask with optimal fit. While this approach offers promise for reduced leakage and improved comfort, challenges like cost-effectiveness, 3D printing limitations, and data privacy require further exploration. Future developments might include creating remote scanning capabilities, all things considered, this research provides a glimpse into the potential for improved patient outcomes and experiences with customized CPAP/BiPAP therapy in the future.

5 Conclusion

The research explores a method for creating customized mask frames based on individual physical characteristics 3D scanning, 3D CAD design. Traditional masks are uncomfortable and less effective due to their wide range of facial features and preferences. Factors like OSA severity, past CPAP experience, and unique sleep and breathing habits complicate mask effectiveness. Designing masks with human factors can improve CPAP therapy outcomes and patient comfort. Future developments in mask technology could enhance treatment success by emphasizing customization and flexibility.

Disclosure of Interests. The authors state that none of the work presented in this studymay have been influenced by any known conflicting financial interests or personal ties.

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