Personalized 3D-Printed CPAP Masks Improve CPAP Effectiveness in Children with OSA and Craniofacial Anomalies

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Abstract

The high prevalence of obstructive sleep apnea (OSA) in children with craniofacial anomalies has been well-described. Failure of continuous positive airway pressure (CPAP) therapy may require potentially morbid surgery. Yet, achieving a functional mask-face interface using conventional masks is difficult due to leak and discomfort resulting from atypical facies. The objective was to develop a personalized CPAP mask using patient-specific computer-aided design (CAD) and three-dimensional (3D) printing for children with OSA and craniofacial anomalies which prevent effective CPAP therapy. University of Michigan Institutional Review Board approval was granted prior to initiating the study. A 3D model of a personalized CPAP mask based on the patient's anatomy was designed using 3D photography (3dMD, Atlanta, GA) and CAD software (Materialise, Leuven, Belgium). The model is converted into a mold which is 3D printed (Stratasys, Rehovot, Israel) then filled with medical grade silicone to create the final mask. Validated OSA questionnaires (the OSA-18 and PSQ sleep disordered breathing subscale) and CPAP machine downloads were collected from the subject's family at enrollment, after 1 month of consistent use of the mask, and at termination of use. Three patients have been enrolled to date. Results obtained to date are promising. Median leak improved by 74%, nightly compliance improved by 5.5%, and residual apnea-hypopnea index improved by 24%. Personalized CPAP masks can be successfully created utilizing 3D photography, patient-specific CAD, and 3D printing for children with craniofacial syndromes and OSA suffering from ineffective CPAP therapy. Results indicate this design and manufacturing process may improve CPAP therapy effectiveness in this patient population.

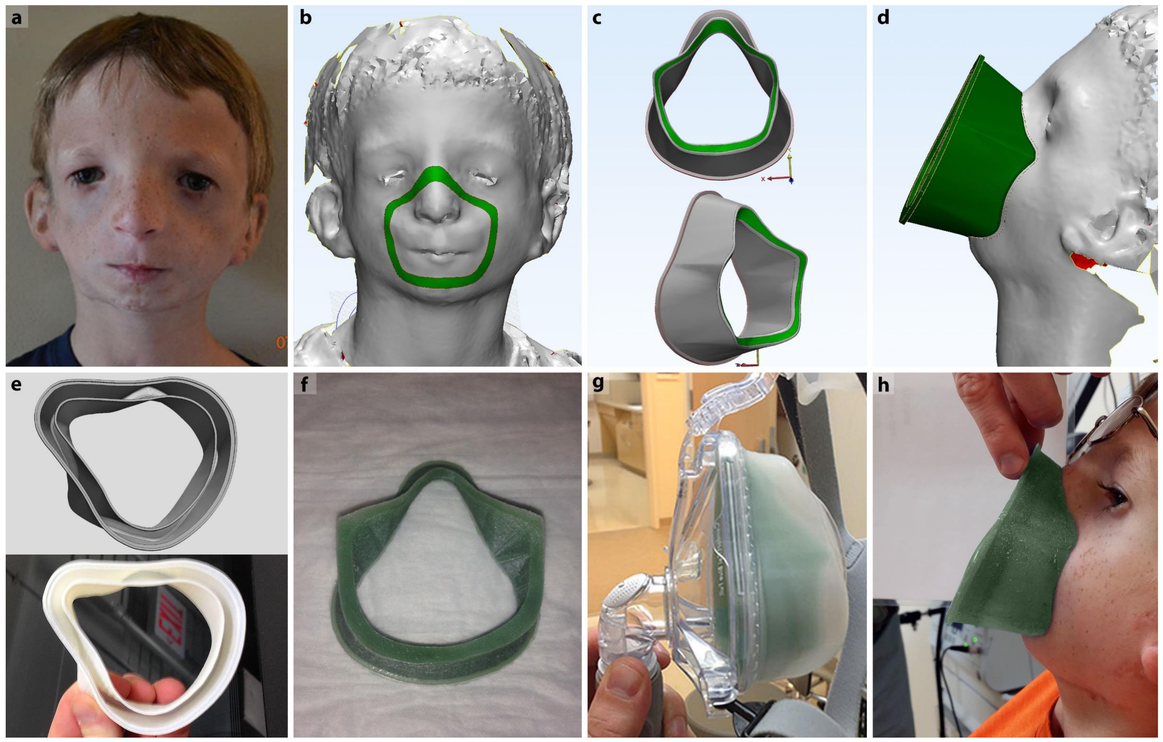
Introduction

Obstructive Sleep Apnea (OSA) is highly prevalent among children with craniofacial anomalies and syndromes involving the mid-face and mandible[1-7]. Traditional surgical interventions to treat OSA are often unsuccessful in these children, who then often require continuous positive airway pressure (CPAP)[8-10]. However, mask fit issues and high leaks are common in children with dysmorphic features and can create significant barriers to effective CPAP therapy[11-13]. Creation of a customized mask using 3D printing technology could potentially alleviate this obstacle.

Methods

A three-dimensional (3D) model of the patient's face is generated using 3D photography (3dMDface, 3dMD) (Fig. 1b)[14]. The facial model is then used to map a custom mask:face interface along the desired facial contours. This interface is then extruded into a CPAP mask insert, and converted to a digital mold using patient-specific computer-aided design (CAD) (Mimics Innovation Suite, Materialise, Leuvian, Belgium) (Fig. 1c-d). The mold is then manufactured on a 3D printer (Objet Connex, Stratasys Inc.) and silicone is cured into the mold creating a unique mask insert (Fig. 1e-f).

Validated OSA questionnaires (the OSA-18[15] and PSQ sleep disordered breathing subscale[16]) were collected from the parents at enrollment and after 1 month of use of the custom mask. CPAP machine downloads were collected at enrollment, after 1 month of use of the mask, and at termination of participation.

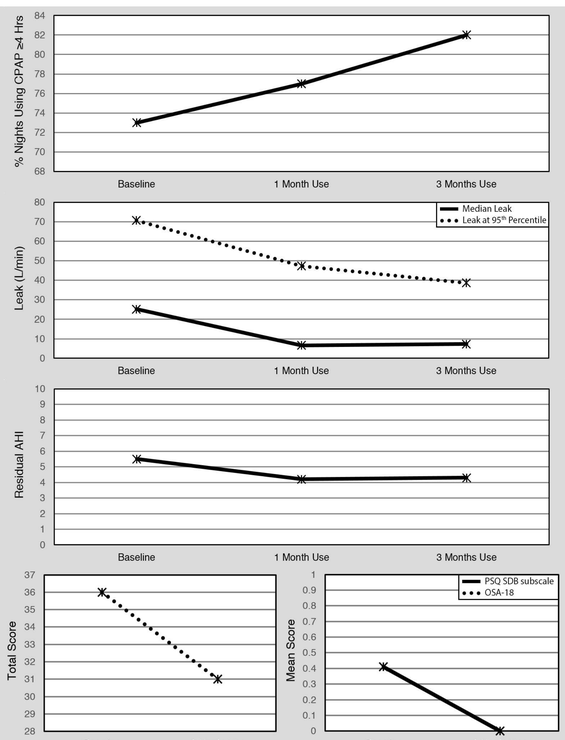


Results

One patient with Treacher Collins Syndrome and severe OSA (baseline AHI=16.4) has completed trial participation. Three additional patients have completed trial enrollment and are undergoing on-going data collection.

CPAP machine downloads were compared between the patient's prior best-fitting commercial mask and the customized interface. There was a significant improvement in measured median leak (25.2 L/min vs. 6.6 L/min) and leak at the 95th percentile (70.6 L/min vs. 47.3 L/min). There was a 9% increase in compliance and 24% decrease in residual apnea-hypopnea index (AHI). All improvements were sustained after 3 months of use.

Pre- and post- comparison of the OSA-18 questionnaire demonstrated an improvement of 14% (total score 36 vs. 31) and comparison of the PSQ demonstrated an improvement of 100% (total score 0.41 vs. 0, >0.33 is positive).



Discussion

Personalized CPAP masks can be successfully created utilizing 3D photography, patient-specific CAD, and 3D printing for children with craniofacial syndromes and OSA suffering from ineffective CPAP therapy. These custom masks have demonstrated the ability to reduce interface leak, increase compliance, and reduce residual AHI on an initial patient with Treacher Collins Syndrome. There were corresponding improvements in validated pediatric OSA metrics.

This technology could potentially increase CPAP adherence among patients with craniofacial anomalies who have issues with the mask interface. Further trial recruitment is necessary to ascertain whether the benefit is seen with other facial dysmorphisms. Ultimately, this process may potentially be utilized for the many CPAP users who experience poor mask fit when using commercially available interfaces.

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