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. A randomized trial was conducted with children with OSA and craniofacial anomalies who had previously failed CPAP treatment. Two groups were compared: a) baseline CPAP; and b) 3D printed personalized CPAP mask. The results indicate that 3D printed masks offer improvements over the standard of care in CPAP therapy in children with craniofacial anomalies.

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).8 The facial model is then used to map a custom mask 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, Leuven, Belgium) (Fig. 1c-e). 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-1818 and PSQ sleep disordered breathing subscale18) were collected from the patients 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 AH1 of 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 (22.2 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 (AHl). All improvements were sustained after 3 months of use.

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 AH1 in an infant 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.

References


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