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Reviewed Paper

DEVELOPMENT OF A CUSTOMIZED CPAP MASK USING REVERSE ENGINEERING AND ADDITIVE MANUFACTURING

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Abstract

Continuous positive airway pressure (CPAP) therapy has been widely used to treat moderate and/or severe Obstructive Sleep Apnoea (OSA) syndrome since its invention. However, CPAP mask interface induced side effects, such as air leak, noise, discomfort and facial skin problem, considerably affect the overall effectiveness of CPAP treatment. Conventional CPAP masks designed with averaged individual facial characteristics have standard configuration and limited material selection. Mask size ranges are limited, only coming with small, medium, and large. The material used for the mask interface fabrication is mainly silicone-based material. Besides the limitations on mask configuration and material, there are no comprehensive mask selection templates and guidance offered by CPAP mask suppliers. Individuals have completely different physical characteristics, such as face topology, skin sensitivity, the severity of OSA syndrome, sleep habit and breathing pattern. Therefore, conventional masks cannot properly fit individual's physical characteristics. Customization of CPAP mask using Reverse Engineering and Additive Manufacturing techniques offers the great potential to minimize the CPAP mask interface induced side effects.

1. Introduction

Obstructive Sleep Apnoea (OSA) syndrome is a typical type of sleep-disordered breathing syndrome. Continuous Positive Airway Pressure (CPAP) therapy has been widely used to treat OSA syndrome for several decades. However, compliance and dissatisfaction with the use of CPAP masks have been frequently reported. CPAP mask interface induced side effects, such as air leak, noise, discomfort, and facial skin problem, considerably affect the overall effectiveness of CPAP treatment [1-6]. Conventional CPAP masks found in marketplace include Full-face mask (Oronasal mask), Nasal mask, Nasal pillow, Oral mask and Total face mask. Table 1 shows the comparison amongst different types of CPAP masks in terms of contact area and air delivery pattern.

Table 1. Classification of different types of CPAP mask

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 only
Nasal pillows	Contact inside rim of the nostrils	Through nose only
Oral masks	Cover mouth only	Through mouth only
Total face masks	Cover entire face	Through nose and mouth

Mask interface related side effects can be developed, despite of the type of masks used. Basically, CPAP mask selection is decided by clinical effectiveness, patient's individual characteristics, previous experience of medical devices and economic aspects [1]. Although CPAP masks greatly vary from configurations and materials, mask concept design and size range are mainly based on the averaged individual characteristics. CPAP mask size ranges are very limited only coming with small, medium. Mask manufacturers often provide sizing templates to guide patients in mask selection. However, these sizing templates are very simple only considering individual's 2D facial features.

In fact, individual's 3D facial features, which completely vary between individuals, have significant influence on the mask fitting. Unfortunately, conventional CPAP masks do not consider much on the variation of 3D facial features in mask design. In addition, there is no comprehensive mask selection system suggesting OSA patients to select the suitable mask before CPAP treatment. It is not rare that some OSA patients have more than two CPAP masks with them due to mask unfitting.

2. Method

The combination of Reverse Engineering and Additive Manufacturing offers the possibility to design and fabricate a bespoke CPAP mask which has the ability to fit individual's physical characteristics.

2.1 Digital facial feature acquisition

In this study, a total number of 20 volunteers were recruited from School of Engineering, Newcastle University after obtaining the ethical approval. Reverse Engineering technique was used in this study to acquire individual's facial features. A handheld Creaform Go-Scan 3D scanner with an accuracy of 0.1mm was used to acquire the volunteer's 3D facial datasets, which is a structure-light projection scanner (white light source). During the 3D scanning process, the 3D scanner was revolved around the volunteer's whole head to obtain the qualified 3D datasets. To well explain the methodology adopted in this work, several volunteer's facial databases were selected as examples.

2.2 Modification of 3D scanned image

3D scanning software, Creamform VXelements, was used to edit the 3D scanned facial datasets. The original 3D scanned images may contain several missing datasets and not smooth. Modification of 3D scanned facial datasets was done with Creamform VXelements, remaining the front view of the facial model. A solid 3D digital facial model was then generated after the facial mesh modification.

2.3 Measurement of facial feature based on 3D datasets

With the 3D datasets of volunteer's facial feature, measurement about dimensions of the key facial features, both of 2D and 3D, can be easily obtained. These key dimensions measured will provide guidance on further CPAP mask selection and customized mask design.

3. Results

3.1 Digital facial acquisition and facial mesh modification

In this study, 20 volunteers were involved, including 15 males, and 5 females. The whole scanning process for each volunteer was approximately about 1 minute. Original 3D scanned image should be edited properly by filling the missing datasets and smoothing the image. Figure 1 shows an example of one volunteer's 3D facial datasets before and after image editing.

People have totally different facial characteristics; some volunteer's 3D facial datasets may be more difficult to edit compared to others. For example, as shown in Figure 2, this volunteer has lots of facial hair, which increases the difficult when editing the 3D image. These missing datasets must be fully filled before exporting for further use.

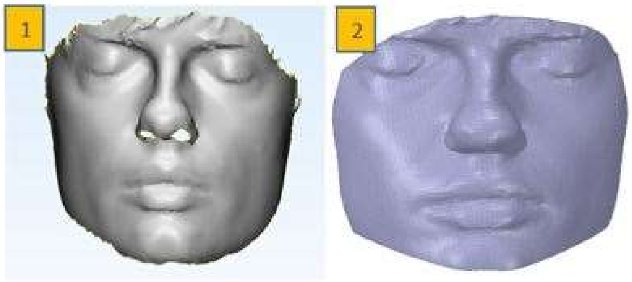

Fig 1. An example of 3D facial datasets before (1) and after (2) editing

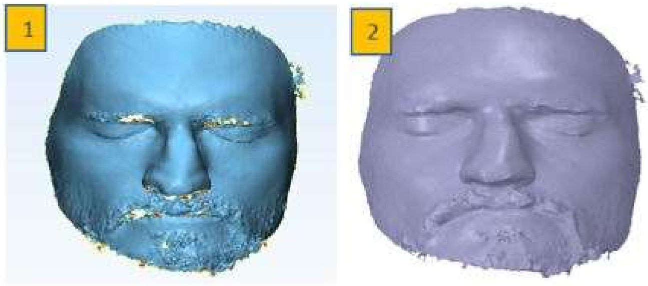

Fig 2. An example of 3D facial datasets before (1) and after (2) editing

3D facial mesh modification of all volunteers was shown in Figure 3.

Fig 3. Facial mesh modification of all volunteers

After facial mesh modification, a solid digital facial model was generated. Figure 4 shows the front and lateral views of the edited 3D digital images of the volunteer's facial feature.

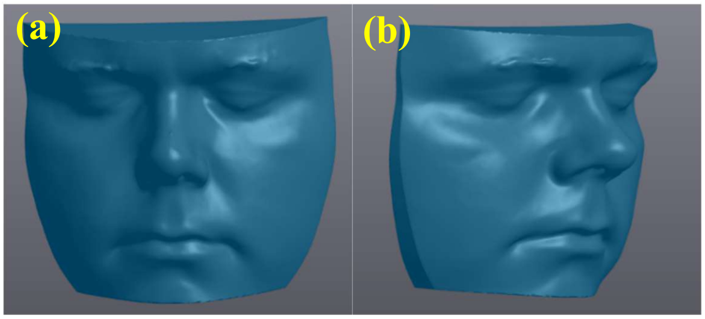

Fig 4. Front (a) and Lateral (b) view of a solid facial model

3.2 Measurement of facial features

Measurement of facial features can be done easily and precisely with the help of 3D digital facial datasets. In this study, 3D software (3-Matic), was used to measure the dimensions of facial features. Take one of the volunteer's 3D facial model as an example. The first step is to mark all key facial features on the digital facial model. As shown in Figure 5, a total number of 22 targeting locations were marked covering all key facial features related to mask design and selection. With these marked targeting points, dimensions of facial features, both of 2D and 3D, can be measured.

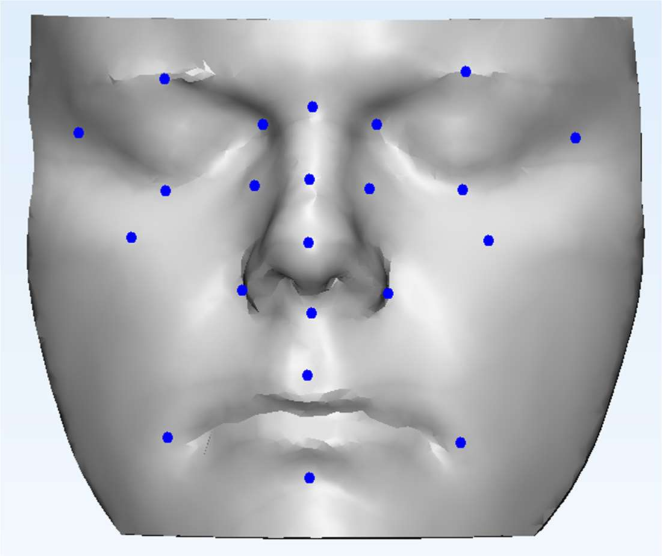

Fig 5. Key facial feature targeting locations

Because these targeting points were marked manually, therefore, multiple measurements of facial features were done repeatedly considering the deviation contained. For this facial model, measuring processes were conducted 4 times. Dimensions of 2D facial feature indicated in Table 2 were calculated on average.

Except for the difference on the 2D facial features, variation of the 3D facial features of individuals presents a higher challenge on CPAP mask design and selection. Individual's 3D facial features are difficult to be measured manually on people's face. Conventional CPAP mask designed with less consideration of individual's 3D facial features cannot guarantee a perfect fit for all individuals, despite several sizes of masks can be offered. However, measurement of 3D facial features for individuals can be easily done from the analysis of 3D digital facial datasets. Individual's 3D facial features, for example, all details of nose structure, can be precisely obtained using 3D measuring software (3-Matics). Figure 6 depicts the 3D digital nose structure of a volunteer.

Table 2. Measurement of 2D facial features

Item	Dimension (mm)
The distance between eyes (eyelid)	26.26
The distance between eyes (Centre of eyes)	72.94
Width of eye	45.26
The distance between double cheeks	84.14
Eyebrow to Eye	27.48
Width of mouth	67.94
Height of mouth	23.36
Bottom of the nose to Upper Lip	16.25

This volunteer's nose was transversely separated with 9 points into three sections to easily collect the detailed characteristics of nose structure, as shown in Figure 6. These three sections are named as top section, middle section, and bottom section. By analysing these three sections, the width of nose and angle of the nose can be collected. The deviation of all dimensions is about ±3mm.

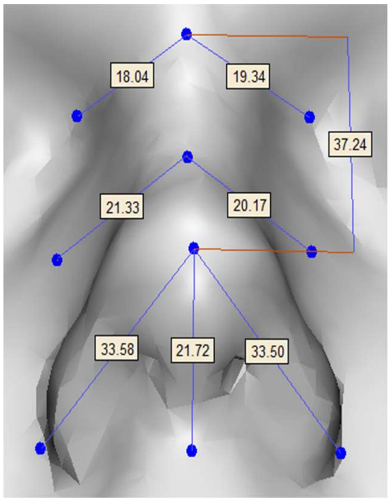

Fig 6. The 3D digital dataset of the nose structure

Table 3 Measurement of 3D facial features

Item	Dimension (mm)
Length of nose	37.24
Width of nose	Top: 26.26 Middle:26.55 Bottom:33.80
Angle of nose	Top:89.33 Middle: 87.17 Bottom:60.51
Slope of nose (left view)	Top:18.04 Middle: 21.33 Bottom: 33.58
Slope of nose (right view)	Top:19.34 Middle: 20.17 Bottom: 33.50

Figure 7 shows the details of the slope of nose measured based on the 3D digital datasets. Figure 8 depicts the angles of nose measured from different sections based on the 3D digital datasets.

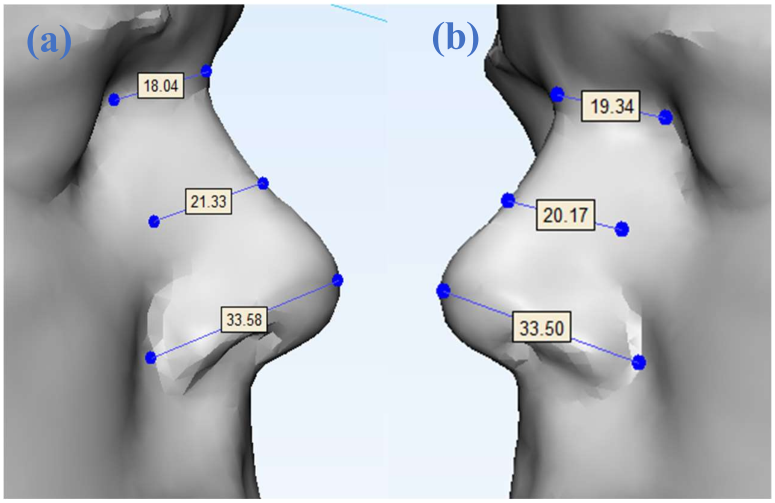

Fig 7. The slope of nose measured from right view (a) and left view (b)

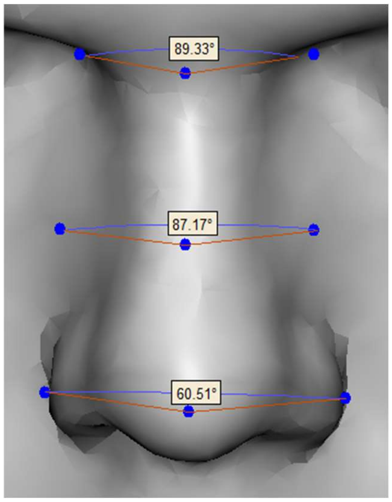

Fig 8. The angle of nose measured

4. Customization mask design and fabrication

Full-face masks have been mostly selected compared to other types of CPAP masks, such as Nasal masks and Nasal pillows. Full-face masks are designed to cover both the nose and mouth area, which is ideal for OSA patients who are mouth breather. However, Full-face mask induced side effects, such as air leak, noise, discomfort, and facial skin problems have been reported frequently. If a patient wears an ill-fitted Full-face mask, a gap between facial skin and mask interface can be developed. Unintentional air leak can occur due to the occurrence of this gap, which can affect the effectiveness of CPAP therapy and cause noise. To minimize the air leak and noise, one of the solutions may be tightening the mask strap to minimize the gap. Based on the facial anatomy analysis, nasal bridge has the thinnest facial skin. Consequently, facial skin damage can be easily developed around the mask, particularly at the nasal bridge area, when suffering prolonged excessive contact pressure caused by overly tightening the mask strap. Therefore, conventional Full-face mask design cannot properly fit individuals due to its standard configurations.

4.1 Customized Full-face mask concept design

The possibility of generating a customized Full-face mask which is expected to minimize the side effects caused by wearing an ill-fitted conventional Full-face mask was explored in this study.

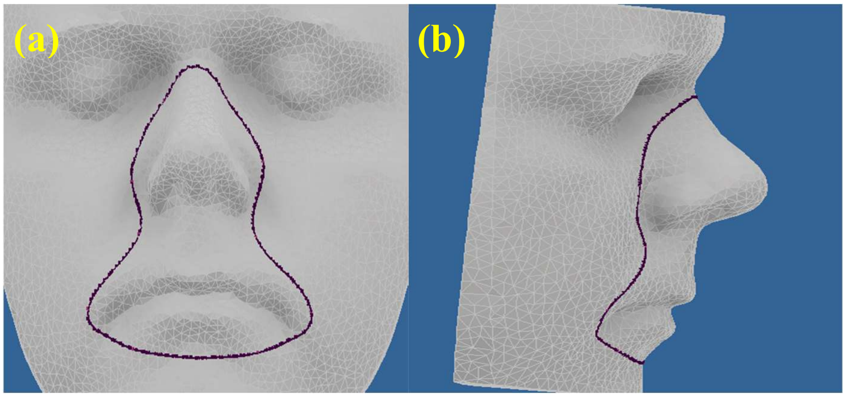

Fig 9. The profile of designed curve front view (a) and lateral view (b)

With the help of 3D digital facial model obtained using reverse engineering technique, customized Full-face mask design was started by sketching a curve onto the digital facial model. The defined curve can be various meeting different requirements. In this study, this specific curve was designed avoiding the facial bony (cheeks) areas, which can minimize the development of facial skin damages when mask strap was being tightened during treatment. By adopting the methodology introduced in this study, there will be no gap between facial skin and mask interface, therefore effectively minimizing the occurrence of air leak and noise. The comfort level with the mask configuration is estimated to be increased. To achieve this curve, 3D CAD software (Inventor) was used. Figure 9 shows the designed curve profile.

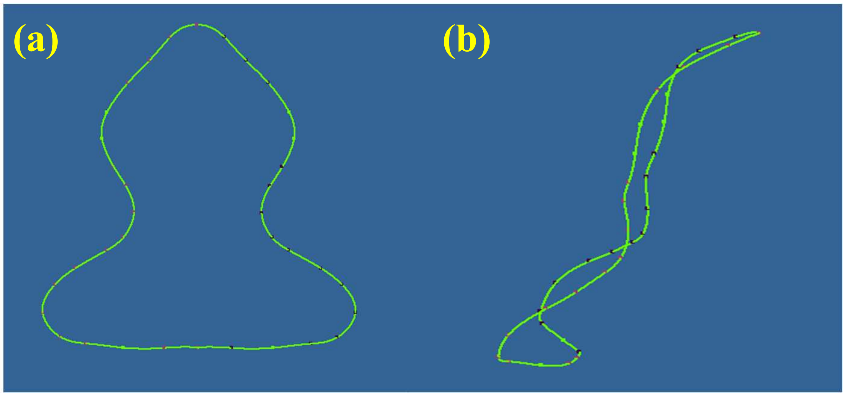

Fig 10. The profile of redesigned curve front view (a) and lateral view (b)

The designed curve needs to be redesigned as a symmetry part before creating the entire mask configuration. Figure 10 shows the profile of the redesigned curve.

Based on the curve designed, a series of curve sets can be further generated. The aim of sketching these curve sets is to generate the surface of the customized mask configuration. Figure 11 shows the surface generation. The final step is to convert this surface geometry into a solid part using thicken function. For this case, 4mm was assigned to form this solid part. Figure 12 shows the solid Full-full mask.

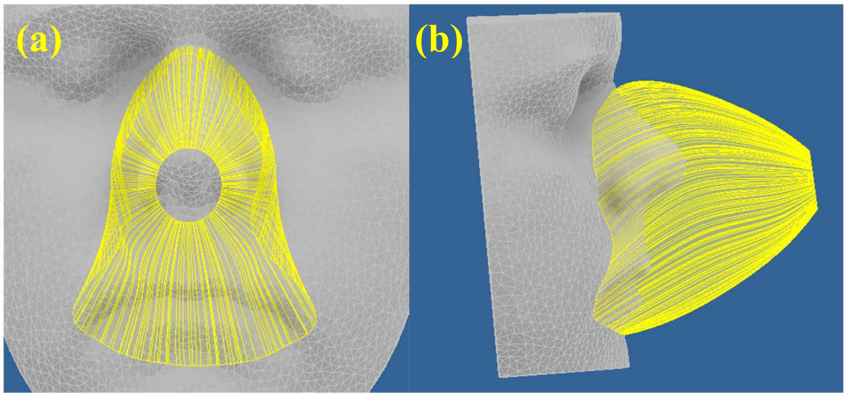

Fig 11. Surface generation of Full-face mask front view (a) and lateral view (b)

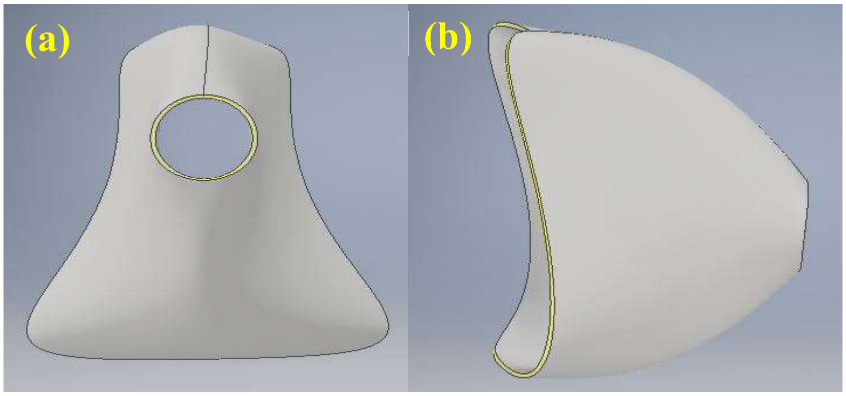

Fig 12. Development of solid Full-face mask, front view (a), and lateral view (b)

4.2 Customized mask concept prototyping

Conventional CPAP masks are mainly fabricated using injection modelling technique. Using traditional injection modelling technique, mass production can be easily achieved. Conventional masks with standard configuration can be quickly formed. However, these standard products have significant limitations on design configuration, and sizes. In the case of CPAP masks, probably only few sizes can be selected, such as small, medium and large sizes. It is obvious that these standard masks cannot perfectly fit individual's physical characteristics.

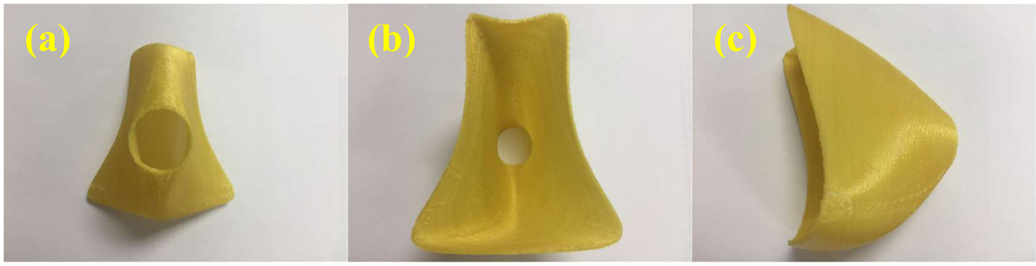

Fig13. 3D printed customized Full-face mask frame front view (a), back view (b), and lateral view (c)

Different from conventional CPAP mask manufacturing technique, additive manufacturing technique builds parts by adding layer upon layer of materials, which provides a great deal of flexibility on product design and fabrication. Using additive manufacturing technique can easily fabricate a complex object which is hard to be generated using traditional manufacturing technique. The higher efficiency presented by using additive manufacturing technique can be seen as another aspect makes it more optimal to fabricate the customized mask frame.

Additive manufacturing was used to fabricate these customized mask designs. In this work, Fused deposition Modelling (FDM) printer was used to fabricate this customized CPAP mask frame. The material used to form this part is PLA. The total fabrication time was about 2 hours. Figure 13 shows the 3D printed customized Full-face mask frame.

5. Conclusion

This paper has explored a possible way in which a customized mask frame can be designed and fabricated fitting individual's physical characteristics. The combination of Reverse engineering (3D scanning), 3D CAD design and Additive manufacturing offers the opportunity to achieve a customized mask frame. Human factors have been playing the important aspects challenging the mask fitting in CPAP treatment. Conventional CPAP masks cannot properly fit all individuals, because individuals have totally different facial characteristics, both of 2D and 3D facial features. Besides the influence of facial characteristics, in CPAP treatment, symptom related aspects, such as severity of OSA syndrome and previous experience with the use of CPAP mask, should also be considered carefully. In addition, individual preference, for example, sleep and breathing pattern, also challenge the effectiveness of CPAP treatment. Therefore, to improve the performance of CPAP masks, human factors must be considered carefully into the mask design.

Acknowledgements

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