A Customized Mask Retainer and Its Effects on Improving the Fit Performance of Surgical Masks

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Research

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Abstract

Background: With the outbreak of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), the effectiveness of providing mask protection is important for people. This article introduces a customized mask retainer to improve the fit performance of face masks.

Methods: The participant's 3D face scans with and without a surgical mask were taken by using a 3D face scanner. The fitter was designed on the 3D face scan data according to the facial anthropometric landmarks, and examined and adjusted on the face scan data with a mask. The fitter was 3D printed using a metal printer for Titanium. The effectiveness of the fitter on augmentation of fit of surgical mask was test according to the Chinese Standard. Tests were repeated three times per participant, and compare differences between groups by Wilcoxon Matched-Pairs Signed-Ranks Test using software (a=.05).

Results: The effectiveness test of the retainer on augmentation of fit performance showed a result more than 25-fold increase of overall Fit Factor, which have met the fit requirement for KN95 respirators in China.

Conclusions: Fit Factor results indicated that by using the retainer, the Fit Factors of overall and each exercise have significantly increased as compared to that of face mask alone group. It may provide a solution to the shortage of N95 respirators the world is now encountering as fighting against the COVID-19 epidemic.

Background

Healthcare workers face a higher risk of infection than ordinary people.[1] Infectious aerosols generated by patient cough, sneeze, or interventions such as endotracheal intubation and dental treatments using high-speed handpieces and ultrasonic instruments may contain various pathogenic microorganisms,[2–5] including the newly outbreak epidemic of severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2.[6,7] Disposable face masks, together with N95 respirators, gloves, gowns and face shields are recommended personal protective equipment (PPE) against nosocomial infection in clinic.[8] Face masks are reported to have lower acute respiratory infection protection capacity than N95 respirators both in laboratory and clinical settings, mainly because the former have lower leak-tight fit to the user's face,[9] leading to the leakage of contaminated air from and into the breathing zone.[10–12]

To improve fit performance of facepieces, several studies have employed auxiliary devices to achieve better border seal and adaptation.[13–17] 3D facial scanning technique was recently used to collect facial anthropometric data for the design and 3D printing of customized respirator accessories with better adaptation to the individual's face contour.[15–17] However, methods to improve the leak-tight fit of commercialized face masks have been seldomly reported. The aim of this article was to introduce a digital workflow of a customized face mask retainer. Common digital equipment such as smartphone and 3D printer have been successfully applied to improve personal protection significantly.

Methods

3D facial soft tissue profile for both with and without a face mask were captured by using a 3D facial scanning APP (Dental Pro; Bellus3D) installed on a mobile phone (iPhone 11 Pro; Apple Inc.), according to the APP's instructions (Fig. 1). The scan data was saved as standard tessellation language (STL) file format and imported into a CAD software (Magics v24.0; Materialise). The main contour line of the retainer was extracted on the basis of constant anatomical facial landmarks: the superior border retainer was placed at the rhinion (the anterior tip at the end of the suture of the nasal bones) and the margo infraorbitalis plane to the processus temporalis ossis zygomatici, and the flanks were extended to the angulus oris plane (Fig. 2A). Triangle patches of the main contour were extracted and solidified to a thickness of 1.2 mm, with supports for elastic straps provided at the upper and lower border of the flanks (Fig. 2B). The design of the retainer was checked on the facial scan with a face mask for contour scope and adaptation, so that the retainer does not exceed the border of the mask (Fig. 2C).

The CAD of the retainer was exported into STL file format, and printed using a metal printer for Titanium (Ti150; Profeta Intelligent Technology Co., Ltd.) in Ti6-Al4-V alloy, and finished by removing the support and polishing manually (Fig. 3).

Fit Factor tests were performed to validate the actual effect of the retainer on seal of face mask. Ten participants (dentists, 5 males and 5 females, average age: 41.6 years old) were enrolled. This research was approved and supervised by the Ethics Committee. A retainer was fabricated with the method stated above for each participant. A commercialized elastic strap was attached to the retainer with a length adjusting clip. The retainer was put on the outside of a face mask, and adjusted to achieve ideal adaptation and comfort. Fit Factors (FF) of face mask (Surgical Mask; Winner Medical Group Inc., China) without retainer (M group, n = 10) and with retainer (MR group, n = 10) were tested with a respirator fit tester (Portacount Pro+; TSI) according to the Chinese Standard "Technical requirements for protective face mask for medical use" (GB 19083 – 2010). FF was calculated as a ratio of concentration of air particles in the environment and in the inhaled air under the mask during a cycle of 6 exercises (each for 1 min): initial normal breathing (iNB), deep breathing (DB), head movement from side to side (Head L/R), head movement up and down (Head U/D), talking (Talk) and final normal breathing (fNB) (Fig. 4). Fit Factor tests were repeated three times per participant, and medians of individual and overall FF were used to compare differences between groups by Wilcoxon Matched-Pairs Signed-Ranks Test using software (IBM SPSS Statistics v22.0; IBM Corp) (a = .05).

Results

The results shown in Table 1 indicated significant increases of FF for the MR group in each exercise, and a more than 25-fold increase of overall FF (M:6; MR:154) which have reached the requirement for KN95 respirator as in the Chinese Standard.

Table 1
Scores of Fit Factor of face mask with and without retainer.

Group	Exercises						Overall Score
	iNB	DB	Head L/R	Head U/D	Talk	fNB	
M	10	7	4	7	6	8	6
MR	188	136	123	144	84	165	154
Z Value	-2.805	-2.805	-2.807	-2.807	-2.807	-2.805	-2.805
P	.005	.005	.005	.005	.005	.005	.005

M, group of face mask without retainer. MR, group of face mask with retainer. iNB, initial normal breathing. DB, deep breathing. Head L/R, head movement from side to side. Head U/D, head movement up and down. fNB, final normal breathing.

Discussion

The global outbreak of COVID-19 pandemic has posed great challenge to PPE supply to healthcare workers and patients.[18,19] Although some reports have considered N95 respirators better than face masks in protection against transmissible acute respiratory infections, recent meta-analysis and clinical trials have indicated insufficient data to determine definitively whether N95 respirators are superior to face masks in clinical settings,[20–22] and other main issues include their sources of supply, cost, comfort and breathing resistance.[23,24] Face masks are more accessible, low-cost and more comfortable with reduced respiratory resistance. However, their sealing ability is often poor, attributing insufficient adaptation to the individual's face contour, especially during talking and head and mandible movements.

To improve seal of face masks, a digitalized workflow for a mask retainer incorporating 3D face scan and 3D printing techniques was presented. The intaglio surface of the retainer could be precisely designed to acquire maximum adaptation to the user's face contour on the digital face scan data without a mask, and the scope of the retainer could be adjusted according to the face mask borders while not contacting the skin on the scan data with a face mask. The choice of Ti-alloy with 1.2 mm thickness allowed for adequate strength while providing flexibility to achieve better adaptation when pulled towards the mask, and could go through several sterilization methods including pressure steam sterilization. Other advantages of the presented technique include cost-effectiveness and lightweight (approx. 15 g).

Primary results of Fit Factor tests of face mask supplemented with a retainer indicated a significant improvement as compared to face mask alone group. Fit test is not mandatorily requested for face masks by Chinese Standard, and our results revealed comparatively a rather low FF value for the face mask alone group. By using the retainer, FF has been increased to > 100, which has already reached the Chinese Standard "Technical requirements for protective face mask for medical use" (GB 19083 – 2010) for respirators like N95. As smartphone is getting popularized among the public, people may get their 3D facial scans through commercially available face scanning APPs without much price. And data could be easily delivered to local CAD/CAM center for design and printing of their customized retainer.

Conclusion

This article presents a customized retainer to improve fit of face masks. The workflow incorporated smartphone face scanning and 3D printing techniques. Fit Factor results indicated that by using the retainer, the Fit Factors of overall and each exercise have significantly increased as compared to that of face mask alone group, and have met the Fit requirement for KN95 respirators in Chinese Standard. It may provide a solution to the shortage of N95 respirators the world is now encountering as fighting against the COVID-19 epidemic. Further experiments are needed to systematically evaluate the effectiveness of the presented technique.

Declarations

Ethical Approval and Consent to participate

The experimental protocol was established, according to the ethical guidelines of the Helsinki Declaration and was approved by the Human Ethics Committee of Nanjing Stomatological Hospital, Medical School of Nanjing University.

Consent for publication

Not applicable

Availability of data and materials

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Competing interests

The authors declare that they have no competing interests

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Authors' contributions

X.C.: The conception and design of the study, acquisition of data, analysis and interpretation of data, drafting the article and revising it critically for important intellectual content.

Q.X.: The conception and design of the study, acquisition of data, analysis and interpretation of data, drafting the article.

W.L.: The conception and design of the study, acquisition of data.

F.S.: Analysis and interpretation of data, acquisition of data.

L.W.: Acquisition of data, analysis and interpretation of data.

L.Z.: Acquisition of data, analysis and interpretation of data.

G.W.: The conception and design of the study, analysis and interpretation of data, final approval of the version to be submitted.

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Figures

Figure 1

3D face scan by using scanning APP. Participant taking 3D face scan with scanning APP installed on smartphone. Whole process cost less than 1 minute.

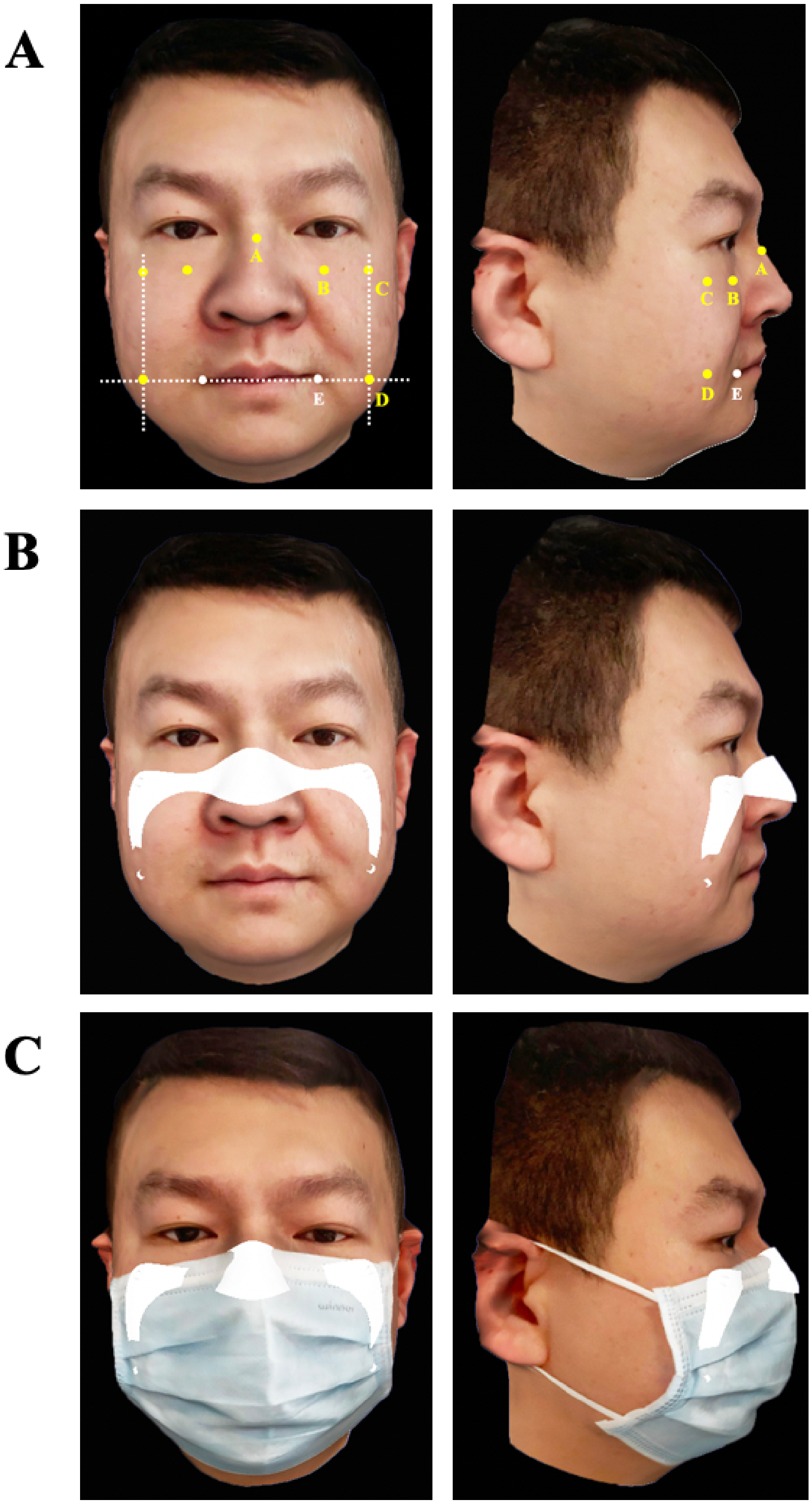

Figure 2

3D face scans acquired with face scanning APP and CAD of retainer. Panel A shows anatomical facial landmarks used to determine border of retainer: A, rhinion; B, margo infraorbitalis; C, processus temporalis ossis zygomatici; D, vertical line at angulus oris plane; E, angulus oris. Panel B shows CAD of retainer merged on 3D face scan. Panel C shows CAD of retainer merged on 3D face scan with mask. CAD, computer aided design.

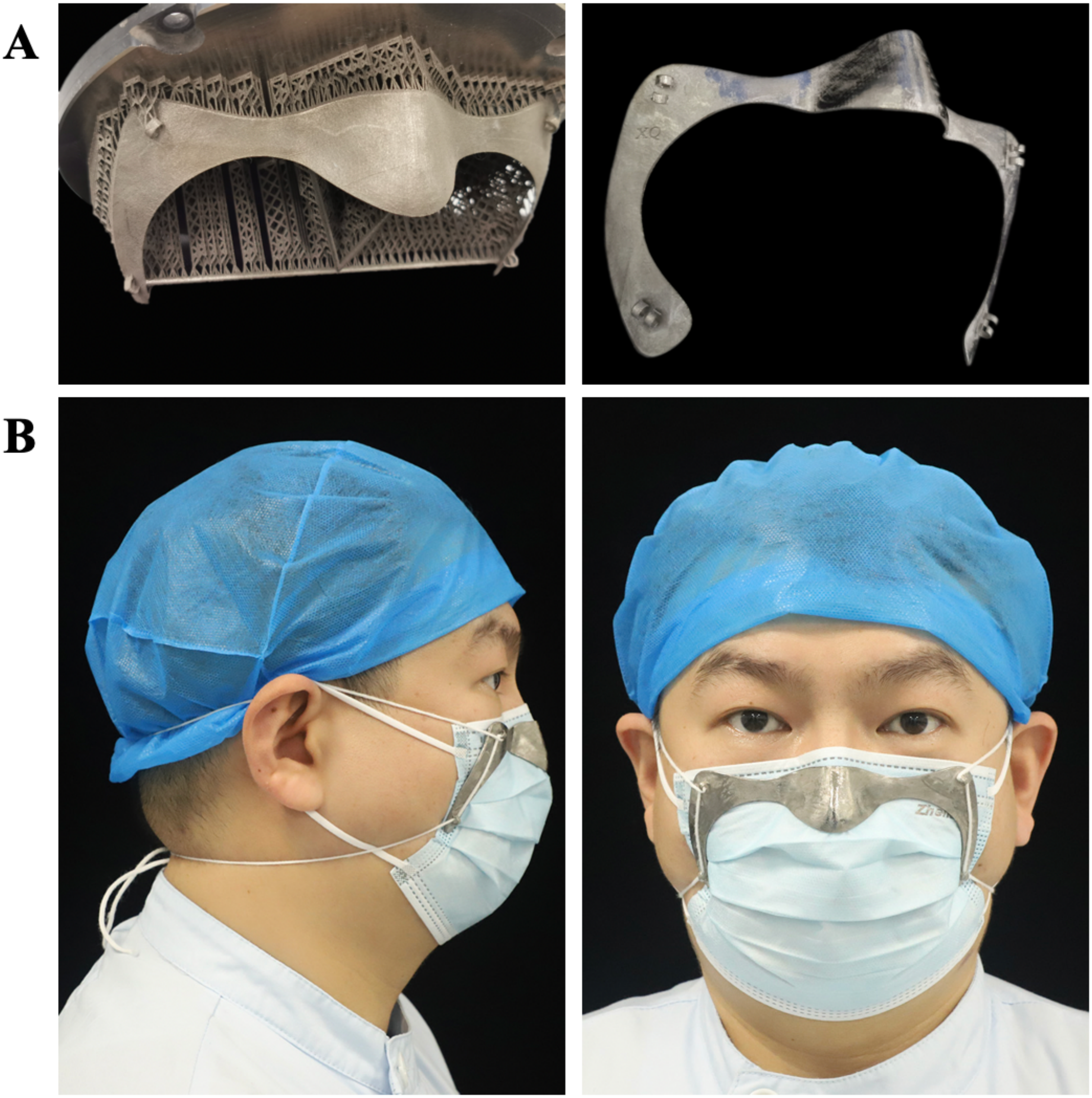

Figure 3

Face mask retainer. Panel A shows fabrication of the retainer by using 3D printing technology before and after support was removed. Panel B shows participant wearing face mask supplemented by the retainer.

Figure 4

Participant taking Fit Factor test. Shown is fit testing situation for participant wearing face mask supplemented by retainer.