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Qualitative fitting characteristics of elastomeric half face-piece respirators using Isoamyl acetate agent

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Abstract: To examine the fit testing of elastomeric half face-piece respirators (EHRs), a total of 41 candidates were randomly assigned into seven EHRs equipped with organic vapor (OV) cartridges which were commonly used in the Iranian industrial workplaces. The qualitative fitting into the facial dimensions was assessed using the Allegro Isoamyl Acetate fit test kit. While the studied EHRs showed very low passing fit testing rates, the 3M, AoSafety (Medium), and AoSafety (Large) had the highest passing rates with 22.0%, 14.60%, and 9.76%, respectively. The AoSafety (All sizes) delivered a higher passing fit test rate than the 3M brand (29.30 vs. 22.0%). The one size fits all respirators including the DUO and Climax showed lower proportions of passing fit tests compared with AoSafety three-size system brands (2.40% and 4.90% vs. 29.30%). Low fit test passing rates were determined among different respirators. The respirators with various sizes and styles had more opportunities for different wearers to pass the fit test than single size models. The initial and annual fit testing requirements shall be developed by local government. Also, the manufacturers are required to pay attention to respirator features and subject characteristics during the production to obtain satisfactory protection for the end-users.

Key words: Qualitative fit testing, Isoamyl Acetate (IAA) challenge agent, Elastomeric half face-piece respirators, Organic vapor cartridges, Respirator brands

Introduction

Respirator fit testing is one of the most crucial components of the respiratory protection program (RPP). Considering the severity of the risk due to the exposure, the proper fit test shall be performed to assure the respirator wearers would be protected against the chemical and biological hazards in the work environment. The capability of fitting a respirator's face-piece into the anatomical dimensions of the wearers is one of the essential factors affecting the optimal respiratory protection against the airborne contaminants which is called "respirator fitting characteristics". To comply with the respiratory protection standards[1–3], it is required to perform fit testing for all included in the RPP before entering into the contaminated workplace.

Overall, fit testing techniques are categorized into the quantitative fit testing (QNFT) and qualitative fit testing (QLFT). The QNFT reduces the test subjectivity by quantifying the capability of the respirator face-piece fitting into the facial dimensions using an instrument to measure the challenge agent concentration inside the respirator (C_{in}) into its concentration outside the respirator (C_{out}) while carrying out a series of fit test exercises and provides the quantitative fit factor ($QNFF=C_{out}/C_{in}$)[2].

The QLFT is based on the subjective response (pass/fail) to the challenge agents with a specific taste or odor consisted of four common challenge agents including the Bitrex™ (denatonium benzoate), saccharin, isoamyl acetate (IAA), and irritant smoke (stannic chloride) to realize the face seal leakage between the face-piece and wearers' face while performing the same set of the fit test exercises. The Bitrex™ with a bitter taste and saccharin with a sweet taste utilized for fit testing of disposable particulate or filtering face-piece respirators (FFRs). The IAA agent with an odor like banana oil was utilized for fit testing of reusable elastomeric half face-piece respirators (EHRs) equipped with organic vapor (OV) cartridges. The irritant smoke was used as a qualitative challenge agent for fit testing of the EHRs equipped with high-efficiency particulate air (HEPA) or P100 filters[2].

There are two vital factors determining the quality of respirator fit: firstly, the fitting characteristics of a respirator with the specific make, model, style, and size to provide acceptable fitting into the large proportions of the general population with various face sizes; secondly, the accuracy of the fit testing techniques. On the other hand, each fit testing technique has its own inherent errors which in turn leads to exposing wearers to the hazardous contaminants[4].

Although, the QNFT methods present more accurate and precise results; however, in some cases, due to the inaccessibility and high expense of the QNFT instruments, the QLFT was used inevitably. It should be mentioned that several studies were conducted regarding the qualitative Bitrex™ and saccharin fit tests[5–9] and quantitative fit tests [10–12] on half face-piece EHRs equipped with particulate filters. Moreover, some studies concerning the QLFT procedure were performed on the particulate respirators in Iran[13–18]. However, few studies evaluated the qualitative fitting of the half face-piece EHRs until now. Considerably, all of the EHRs are imported and some of them have no size-system classification (two- or three-, or five-size system). The manufacturers design and make these respirators based on the facial dimensions of the proposed population; also, the mentioned respirators might not be fitted adequately to the Iranian faces. Therefore, according to the above reasons, this study was conducted to assess the qualitative fit testing of the EHRs equipped with dual OV cartridges using the IAA agent on a selected population group in Iran.

Subjects and Methods

Study Design

A cross-sectional study was conducted on the students of School of Public Health, Shiraz University of Medical Sciences, Iran in 2019.

Participants

A total of forty-one student candidates consisting of 22 females and 19 males with a mean age of 23.66 ± 3.48 years took part in the study. The experiments were conducted on the participants in the Industrial Safety Laboratory of the School of Health.

Ethical Features

This study was approved by the Research Ethics Committee of Shiraz University of Medical Sciences (approval code IR.SUMS.REC.1398.1166). The researcher explained the purposes and procedures of the study. Then, all participants signed the informed consent form before joining the study, according to the ethical guidelines.

Exclusion Criteria

The participants with cardiovascular or respiratory diseases; smell disorders (such as anosmia, etc.); facial hair, or deformity were excluded from the study. Also, participants who were not able to characterize the banana-like odor of the IAA agent during the preliminary screening step, were excluded from the study.

Study Procedure

This study was performed based on the OSHA 29 CFR 1910.134, IAA fit testing protocol[2]. To do so, IAA Qualitative Fit test Kit Part Number 0203 (Allegro Industries, Paramount, Calif.) contained >99.98% IAA and <0.10% water utilized to conduct fit testing[19, 20]. Before the study began, all participants refrained from eating, drinking, and chewing gum for at least 15 minutes. The simple randomization technique was utilized to randomly allocate all seven studied EHR respirators equipped with OV cartridges to each participant. Also, the respirators were randomly coded and labeled from A to G (Table 1). Since the studied respirators were reusable; they were disinfected and sanitized by an alcohol-based disinfectant (Ethanol: 70 (%v/v)) before beginning the tests on the participants.

Odor Threshold Screening (OTS)

In order to assure the participants would be able to smell reliably and accurately the IAA challenge agent's odor, the

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OTS test was conducted. To prevent olfactory fatigue, the preparation of the solutions, OTS procedure, seal checks, and fit tests were performed in separated rooms.

In the first stage, the four bottles containing the IAA stock solution, IAA sensitivity test solution, and two blank solutions were prepared. The IAA stock solution was made in the second bottle by adding 1 ml of pure IAA using a pipette (1 ml) to 800 ml distilled water in the 1 l bottle and shaking for 30 seconds. The IAA sensitivity test solution was prepared by adding the 0.4 ml (400 μl) of the IAA stock solution into 500 ml distilled water using a pipette (1 ml), shaking for 30 s, and allowing to stand for about 2–3 min to equilibrate the IAA concentration outside of the solution's bottle. The blank solutions were made in other bottles by adding 500 ml distilled water. Those solutions were made and labeled randomly to ensure that the participants could distinguish the odor of the IAA challenge agent (banana oil) from the odorless distilled water.

The participants were instructed to shake the bottles for a few seconds; then, they opened the bottles' lids, sniffed at the mouth of the bottles, and reported as they detected the odor of the IAA challenge agent. If the participants were able to correctly smell the odor of the IAA challenge agent, they proceeded into the fit testing procedure. Noticeably, in order to increase the validity of the procedure, the IAA stock and sensitivity test solutions were made weekly and daily, respectively[2].

User Seal Checks (USCs)

The seven EHRs equipped with OV cartridges which were commonly used by the wearers in the industrial workplaces and accessible in the Iranian marketplaces, were selected for the study. In this step, the participants were randomly allocated to each respirator. Notably, they wore the respirators in the area separate from the room used for fit testing in order to prevent olfactory fatigue. The administrator instructed the participants concerning the proper donning and doffing of the studied respirators and performing the user seal checks (USCs) including the negative pressure and positive pressure checks to ensure the proposed respirators were worn properly; on the other hand, if the participants observed any leakages across the sealing surface area between the skin and face-piece respirators; they adjusted the head straps, positioned the respirators on their faces and cheeks or fitted the respirators across their nose bridges. In the meantime, the participants wore the respirators for at least 5 min to assure the comfortability of the donned respirator[2].

IAA Fit Tests

Firstly, the administrator hung the paper towel folded in half which was wetted with 0.75 ml (750 μl) of pure IAA agent at the top of the 55-gallon (0.21 m^3) clear fit test chamber and diameter of 60.96 cm (0.61 m); so that the top of the chamber was about 15.50 cm (0.1550 m) above the heads of the participants[2]. Approximately, a 100 parts-per-million (ppm) concentration of the IAA vapor was produced by evaporating 17.30 ml of the liquid per 1,000 ft^3 (about 28 m^3) of the enclosed volume[21]. Meanwhile, a 2-min period was last to equilibrate the concentration of the IAA fit test agent before starting the fit test exercises.

Secondly, a copy of the "Rainbow Passage" was taped inside of the test chamber. Thirdly, the participants were asked to enter the test chamber while putting on the respirator. Fourthly, they were trained to carry out the seven fit test exercises, consisting of normal breathing (NB); deep breathing (DB); turning head side to side (HSS); moving head up and down (HUD); jogging in place (JO); talking (reading the "Rainbow Passage"); and normal breathing (NB). If the participants identified the banana-like odor of the IAA agent during the fit test exercises; the respirator failed the fit test and it was assumed to have a qualitative fit factor (QLFF)<100. Inversely, if they did not smell the odor of the IAA agent; the respirator passed the fit test and it was considered to have a QLFF≥100. The QLFF considered as the certified value for proper donning of the respirators and acceptable fitting into facial dimensions before entering into the contaminated workplace. On the other side, the QLFF represents how well a tight-fitting respirator fits a wearer during the QLFT procedure.

At the end of the fit test, the paper towel was removed and sealed in the zipper storage bags to prevent contamination of the fit testing room by the IAA vapors[2]. Furthermore, a 10 min break was spent between the fit testing procedures of the EHRs to prevent from olfactory fatigue by the tested participants (Fig. 1). The video of the IAA fit testing procedure utilized in this study[22]. All study findings including name, age, gender, respirator brand, passed/failure proportions of IAA fit tests (Eq.1) were recorded in the data collection form to conduct analysis.

$$Pass/fail = \frac{Proportions\ of\ failure/passed\ fit\ tests}{\text{Total proportions of conducted fit tests}} \times 100 \qquad \text{Eq.1}$$

Fig. 1. The participant was inside the test hood during the IAA fit testing procedure.

Table 1. Features of the elastomeric face-piece respirators (EHRs) equipped with dual organic vapor (OV) cartridges used in the present study

Code	Picture	Manufacturer	Model Number (s)	Face-piece size	Material (Rubber or Silicone)	Country	Certified by legal bodies
A		3M	6200	M	Silicone	USA	NIOSH
B		MSA Comfo Classic	HYCAR Classic	M	Rubber	USA	NIOSH
C		Spasciani DUO	-	OSFA	Silicone	Italy	EN14387:2004
D		Climax	755	OSFA	Silicone	Spain	EN14387:2004
E				S			
F		AoSafety	95090	M	Silicone	USA	NIOSH
G				L			

OSFA: One size fits all
S: Small
M: Medium
L: Large

Measurement of facial dimensions

The facial dimensions of the participants including face length (120.22 ± 7.97 mm) and face width (126.12 ± 10.43 mm) were measured by a calibrated Stainless Steel digital caliper (model HB-101–111, Guanglu instrumets Co., Ltd, China) according to the ISO/TS 16976-2:2010[23]. The participants' face sizes were classified into three groups: small (cells 1–3), medium (cells 4–7), or large face size (cells 8–10) according to the NIOSH bivariate fit test panel which developed for the first time by Zhuang *et al*[24].

Statistical Analysis

The descriptive statistics were applied to calculate the pass/fail rates during the IAA fit tests by the respirator brands. Furthermore, the Kappa statistics (k) were measured between the seal checks and fit tests by the respirator brands. Meanwhile, the k value was determined to examine the statistically significant agreement between the fit test passing rates of the best fitting respirator (3M) and remaining respirators.

The logistic regression model with confidence intervals (CIs) was applied to evaluate the effects of the respirator brand on the respirator fit testing. To find out the adjusted effects of the study variables, first, we entered the age and sex into the logistic regression model. Then, we utilized the Backward Likelihood Ratio (LR) variable selection method. Also, since the results obtained from the IAA fit tests were dichotomous (pass/fail), the Chi-squared test of independence ($\chi 2$) was proposed to check the statistical effects of the respirator brands on the IAA fit tests. A p-value of 0.05 was considered significant. The data analyses were conducted using SPSS version 22.0.

Results

All participants were able to detect the banana-like odor of the IAA agent during the sensitivity test. The proportions of passing fit tests by consideration of the studied respirator brands and participants' gender are summarized in Table 2. Overall, the 3M, AoSafety (Medium), and AoSafety (Large) brands had the highest fit testing passing rates of all studied respirators (22.0%, 14.60%, and 9.76%, respectively).

However, the AoSafety (All sizes) had a higher passing fit test rate than that of the 3M brand (29.30 vs. 22.0%). There were significant differences between the proportions of passing fit tests among the respirator brands with Medium sizes including the 3M, MSA, and AoSafety (p>0.05). The one size fits all (OSFA) respirators including the DUO and Climax brands had lower proportions of passing IAA fit tests compared to the AoSafety brands with a three-size system (2.40% and 4.90% vs. 29.30%).

As can be seen, of all participants who passed the USCs by the 3M brand, about 81.81% passed the IAA fit test. Also, of the participants who passed the USCs by the AoSafety brand (Medium), 85.71% passed the IAA fit test. The Kappa statistics between the proportions of the USCs and IAA fit tests by the AoSafety (Medium), 3M, and AoSafety (Large) brands were computed as the highest of all EHRs [AoSafety (Medium): 0.91, 95%CI (0.64–1.0), 3M: 0.87, 95%CI (0.66–1.0), and AoSafety (Large): 0.77, 95%CI (0.30–1.0), respectively]. The overall k value between the USCs and IAA fit tests was calculated as 0.71, 95%CI (0.56–0.82).

The failure rates of the studied respirator brands in different fit test exercises were illustrated in Fig. 2. As depicted, the most proportions of failing IAA fit tests occurred during the first exercise (NB) per studied respirator brand (3M: 78.12%; MSA: 90.0%, DUO: 87.50%; Climax: 87.18%; AoSafety (Small): 69.23%, AoSafety (Medium): 88.57%, and AoSafety (Large): 69.44%, respectively).

Table 3, the comparison of the fitting characteristics between the best fitting respirator (3M) and all studied EHRs were made based on the adjusted logistic regression model. As shown, no significant differences were found between the results from the IAA fit testing of the AoSafety (Medium) and AoSafety (Large) brands with the 3M one.

Obviously, the odds ratio (OR) for passing fit tests of all studied EHRs were lower than the OR for that of the 3M brand. Among all, the OR for passing fit test of the 3M brand was 1.64 times the OR for the AoSafety (medium) and 2.63 times the OR for the AoSafety (large), respectively. Overall, the OR for the AoSafety (All sizes) was 2.58 times the OR for that of the 3M brand.

Considerably, the highest significant agreements were reported between the results from the IAA fit tests of the Climax and DUO brands with the 3M results (k=0.31 and 0.16, respectively). In addition, there were no significant agreements between the IAA fit testing passing rates of the AoSafety respirators with various sizes. Moreover, the Chi-squared tests indicated that there were significant differences between the studied brands by fit test results (p-value<0.01).

Fig. 3. depicts that 25 (61%) of the participants' facial dimensions fell within cells 4–7 of the NIOSH bivariate panel which were representative of their medium face sizes. Also, most of the study participants had long/narrow shapes (48.80%). In addition, 9 (22%) of the study participants fell outside of the NIOSH bivariate fit test panel.

Table 2. Proportions of passing user seal checks (USCs) and Isoamyl acetate (IAA) fit tests by respirator brands

Variable		Seal check		IAA Fit test		Kappa	95% CI for k	
Brand/Size		Pass N(%)	Fail N(%)	Pass N(%)	Fail N(%)	(k)	Lower	Upper
3M (M)		11 (26.80)	30 (73.20)	9 (22.0)	32 (78.0)	0.87	0.66	1.0
MSA (M)		5 (12.20)	36 (87.80)	1 (2.40)	40 (97.60)	0.30	0.0	0.79
DUO (OSFA)		5 (12.20)	36 (87.80)	1 (2.40)	40 (97.60)	0.30	0.0	0.72
Climax (OSFA)		2 (4.90)	39 (95.10)	2 (4.90)	39 (95.10)	0.47	-0.04	1.0
AoSafety	**S**	4 (9.76)	37 (90.24)	2 (4.90)	39 (95.10)	0.64	0.0	1.0
	M	7 (17.10)	34 (82.90)	6 (14.60)	35 (85.40)	0.91	0.64	1.0
	L	6 (14.60)	35 (85.40)	4 (9.76)	37 (90.24)	0.77	0.30	1.0
	All sizes	17 (41.50)	24 (58.50)	12 (29.30)	29 (70.70)	0.74	0.54	0.91

OSFA: One size fits all
S: Small
M: Medium
L: Large

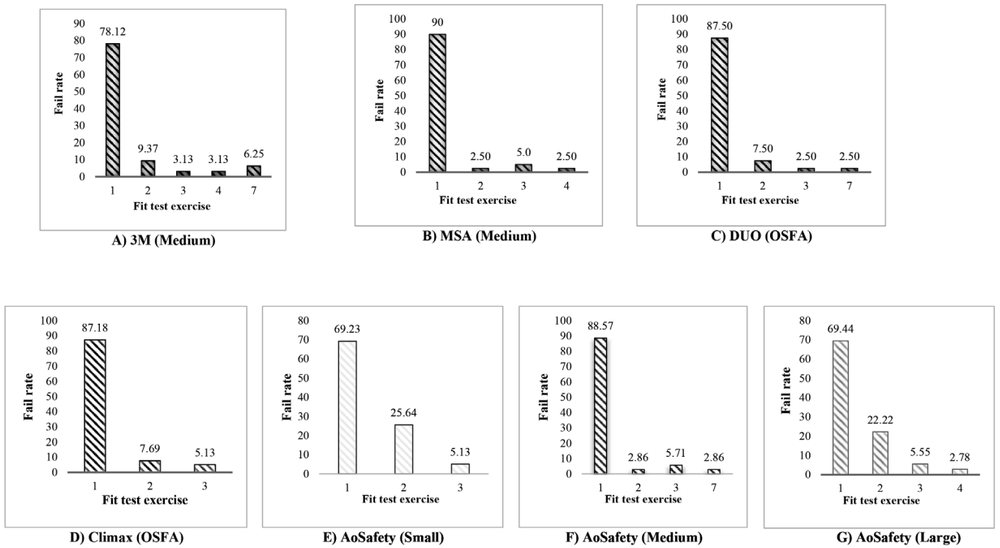

Fig. 2. Failure rates of the studied respirator brands in different fit test exercises (1. Normal breathing, 2. Deep breathing, 3. Turning head side to side, 4. moving head up and down, and 7. Normal breathing).

Table 3. The fitting characteristics of the studied EHRs compared to best fitting respirator (3M) by the adjusted logistic regression model

	Variable		Coefficient (β)	SE	$OR^{\dagger}$	95% CI for $OR^{\dagger}$		p-value	Kappa (k)	95% CI for k		Accuracy (%)
						Lower	Upper			Lower	Upper	
Respirator brand	MSA (M)		-2.42	1.08	0.09	0.01	0.72	0.024	-0.05	-0.13	0.0	86.90
	DUO (OSFA)		-2.42	1.08	0.09	0.01	0.72	0.024	0.16	0.0	0.54	
	Climax (OSFA)		-1.73	0.82	0.18	0.04	0.89	0.036	0.31	0.0	0.64	
	AoSafety	S	-1.73	0.82	0.18	0.04	0.89	0.036	0.11	-0.11	0.44	
		M	-0.49	0.58	0.60	0.19	1.91	0.389	-0.05	-0.27	0.23	
		L	-0.97	0.65	0.38	0.10	1.36	0.136	0.02	-0.19	0.32	
		All sizes	0.95	0.5	2.58	0.97	6.85	0.058	0.05	-0.25	0.35	
Age			0.09	0.05	1.10	1.01	1.24	0.046				

β: Coefficient
SE: Standard Error
† Odds Ratio
CI: Confidence Interval
K Kappa
OSFA: One size fits all
S: Small
M: Medium
L: Large

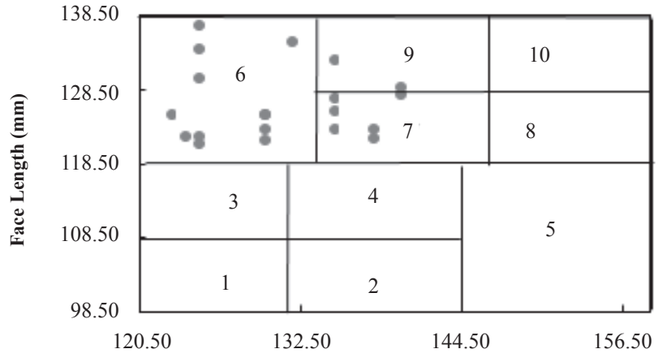

Fig. 3. Distribution of study participants in the NIOSH bivariate respirator fit test panel

Consequently, the NIOSH bivariate fit test panel was not representative of the Iranian facial dimensions.

Discussion

In this study, all participants were able to detect the banana-like odor of the IAA agent during the sensitivity test; however, most of the IAA fit tests were failed during the first exercise (NB). It seems that participants were able to find the gross leakage across the sealing surface between the face-piece and skin by detecting the odor of the IAA challenge agent. Other reasons are due to the constant concentration of the IAA agent (approximately 150 ppm in the fit test chamber within all fit test exercises) was generated entire the test chamber; moreover, two minutes was allowed for the IAA test concentration to be stabilized before starting the fit test exercises. Additionally, due to the detectable odor of the IAA agent, the study participants could identify the banana-like odor of the IAA agent during the first fit test exercise (NB). It draws the conclusion that the IAA fit test could be considered as an acceptable procedure for assessing the leakage into the respirators. According to the previous study, the IAA fit testing protocol was considered as a safe and valid procedure for qualitative assessment of the leakage into the respirator[25, 26]. Han *et al.* evaluated the IAA fit test compared to the condensation nuclei counter (CNC) QNFT procedure and showed that the IAA fit test passing rate was 72.70%. About 76.90% of this value passed the QNFT procedure (FF>100). Also, the probability of failing the IAA fit test when an adequate FF value occurred during the QNFT procedure and probability of passing the IAA fit test when an inadequate FF value occurred during the QNFT procedure were calculated as α error=0.08 and β error=0.07, respectively[27]. Another study by Kuhlman *et al.* highlighted some substitutions for the IAA fit test agent including t-Butyl mercaptan, Methyl salicylate, Nonanoic acid, and 3-Methyl indole; therefore, the t-butyl mercaptan was considered as a surrogate for the IAA fit test agent[28].

The overall passing fit rates of all studied respirators were computed very low. One possible explanation for this finding might be due to the availability of some models of the EHRs that were being assessed. It leads to the conclusion that one size does not fit all unlike the improper beliefs of some wearers and employers in the workplaces; it confirms that more than one size and model of the respirators are required to be prepared[29]. Another reason for this finding might be that the manufacturers design and make the studied EHRs based on the facial dimensions of the proposed workforces, not the Iranian people, and due to the variety in facial dimensions of different ethnic groups, it leads to low passing fit testing rate[30].

Similarly, the study by Yu *et al.*, addressed that only two of the 10 studied N95 FFRs had the highest passing rates (44.70% and 20.0%, respectively). The passing rates for remaining respirators were less than 10%. Considerably, 54% of the Chinese subjects passed none of the 10 studied N95 FFRs in which the reason could be attributed to the only size of the most of the FFRs was available in the market, despite the high quality of the material being used for the FFRs. To do so, this study concluded that the Chinese manufacturers are required to consider the facial dimensions during the design process to make benefits of optimal respirator fitting for the end-users via the various selection of the respirator brands and styles[31].

In contrast, the study by Hardis *et al.* and Nelson *et al.*[26, 32], showed that most of the American subjects passed the IAA fit tests. Meanwhile, Skretvedt *et al.* stated that 98% of the clean-shaven subjects passed the IAA fit tests; however, the bearded subjects were considerably more at risk than the clean-shaven ones[33]. The high passing rates of the previously studied respirators could be due to those respirators were made for the American people. The discrepancy in pass rates of the IAA fit tests between our study and previous studies could be due to various makes, models, styles, and sizes of the EHRs being tested. While the studied EHRs were designed and made based on the facial dimensions of the proposed population but not Iranian people. For instance, the 3M, MSA, and AoSafety brands were manufactured for the American, DUO brand for the Italian, and the Climax brand for the Spanish wearers; then, it led to low passing IAA fit test. Also, previous studies reported that the respirators' molds which were representative of the Korean, Chinese, or Japanese wearers with short and wide faces were not appropriate for the Iranian facial dimensions[34, 35].

Zhuang *et al.* developed the respirator fit capability (RFC) test for half face-piece air-purifying respirators and point out that when >75% (19/25 subjects) of panel subjects was the panel passing rate (PPR) criterion, the percentage of passing models for grouped-family respirators was higher than non-grouped family ones (29% vs. 48%) and suggested that the two respirator sizes are needed to test the respirators with two-size and three-size families using two numbers of donning[36]. Further work should be conducted to assess the validity of this finding.

In this study, while the AoSafety brand (All sizes) showed low passing rates, the measured rates were still highest compared with other respirators (29.30%); however, approximately 29 participants (70.70%) failed the IAA fit tests. The most likely reason for this finding might be due to the availability of AoSafety brand with three sizes (S, M, and L) for the wearers.

According to the study participants' experiences, the 3M brand had soft and comfortable silicone material, with adjustable headbands, light-weight dual OV cartridges compared to the remaining EHRs. The AoSafety had thick and hard straps to adjust them on their faces. The donning of the DUO brand was too heavy for a long time; although, the adjustment of the face-piece (flexible material) into the face was acceptable. This finding concentrated on the respirator style is a vital indicator affecting the respirator fitting. Also, the manufacturers are required to design and make respirators in a variety of sizes and styles in order to provide more opportunities for the wearers to select the well-fitting respirator and satisfactorily protect from respiratory hazards.

Gutierrez *et al.* developed a new prototype respirator for

the automotive painters' facial dimensions and considered a single cartridge for odor filtration (to make the respirator lighter), adjustable headband design for straps (to provide acceptable fitting), and silicone as material (to address the skin comfort)[37]. The automotive painters were satisfied with all features of the prototype. Only one negative point regarding the high-weight of the developed prototype with a single cartridge was reported by the wearers.

In this study, the OSFA respirators, including the DUO and Climax brands had lower proportions of passing IAA fit tests compared to the AoSafety brands with a three-size system (2.40% and 4.90% vs. 29.30%). One explanation for this finding was that each brand of studied respirators resulted in significantly different results[38–41]. Meanwhile, the respirator brands with system-size classifications (two-, three-, five-sizes) and various styles provide more options to select the well-fitting respirators by the wearers, as specified by the respiratory protection standards[1–3]. Another important aspect of this finding is related to the fact that the workforces, even employers, in many workplaces believe that the OSFA respirators could fit all; whereas, there are no universal or OSFA respirators which are capable of fitting all wearers with various face sizes and shapes[42]. This study corroborates the findings of Zhuang *et al*. who determined that the proportions of passing grouped-family respirators compared to non-grouped family ones considerably increased[36].

In the current research, about 22% of the participants fitted into the 3M brand with only Medium size. This finding proved that not only the respirator features (sizes and styles) are important factors, but also the subject characteristics (face sizes and shapes) are necessary to pay attention during the production process. Thus, the manufacturers are required to develop the optimal respirator fit test panel (RFTP) by providing the comprehensive anthropometric databases of the proposed population and make the respirators based on the respirator features and subject characteristics simultaneously. This is to provide satisfactory respiratory protection for the wearers via the selection of the appropriate size and style of the respirator which is capable of optimal fitting into facial dimensions.

In the current study, the odds for passing fit test of the 3M brand was 1.64 (or 1/0.61) times the odds for that of the fit testing of the AoSafety (Medium) and 2.63 (or 1/0.38) times the odds for that of the fit testing of the AoSafety (Large), respectively. This finding confirms that the facial dimensions were fitted into the 3M brand more than all studied EHRs. Noticeably, the OR for passing the IAA fit test of the AoSafety (All sizes) was 2.58 times greater than the OR for that of the 3M brand. On the other hand, there were opportunities for the study participants to pass the IAA fit test by the AoSafety (All sizes) compared to the 3M brand with only Medium size (OR=2.58)

Most of the participants had medium face sizes (61%) and long/narrow shapes (48.80%). Noticeably, 22% of the study participants fell outside of the NIOSH bivariate fit test panel. The finding of the current study was consistent with those of Jahangiri *et al.*[13, 16] conducted on the Iranian people (19.40% and 22.50%, out of the panel, respectively). This finding was in agreement with earlier studies which showed that 12–35%, and 26.20% of the Chinese subjects were out of the NIOSH fit test panel boundaries, respectively[5, 43]. In contrast, another research showed that only 5.0% of the Chinese subjects' facial dimensions were out of the NIOSH fit test panel[34]. Because 22% of the study participants were outside of the NIOSH bivariate fit test panel boundaries which was higher than the 10% (acceptable value)[24], it is required to develop an optimal fit test panel representative of the Iranian facial dimensions.

The most limitation of this study was that only some brands of the EHRs were evaluated. To do so, various results would be obtained from different subjects with different brands, models, styles, and sizes. It seems that another research regarding both quantitative fit test and qualitative fit test procedures are needed to perform simultaneously on the subjects to assess the validity of this finding.

Conclusion

In summary, low fit test passing rates were obtained from the present study. The respirators with various sizes and styles had more opportunities for the different wearers to pass the IAA fit test than the ones with only one size. Besides the initial and annual fit testing requirements which shall be developed by local government, the manufacturers are required to pay attention to respirator features and subject characteristics during the production process to obtain satisfactory protection for the end-users. They also need to develop the optimal respirator fit test panel based on the Iranian facial dimensions. Meanwhile, the manufacturers are required to provide various brands, models, sizes, styles, and structures (rubber, or silicone) of the EHRs based on the proposed population in order to choose the well-fitting respirator before carrying out the job to obtain satisfactory protection.

Conflicts of Interest

None declared.

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