

Fit testing of respirators with ear loop straps

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ABSTRACT

Background: Due to large demand for respirators during the COVID-19 pandemic, particularly filtering facepiece respirators (FFP) level 3 (FFP3) in Great Britain (GB), an increasing number of FFPs with ear loop straps were imported into GB from outside of Europe. Many of these FFPs were incorrectly and often dually marked, showing a European “CE” (“Conformité Européenne”) mark which indicates conformance with the European standard BS EN 149 for respiratory protective devices (RPD), and a KN95 marking, which shows conformity to the Chinese standard GB 2626-2006 for respiratory protective equipment (RPE). There is evidence suggesting FFPs with ear loop straps do not pass a fit test on a significant proportion of the intended population, with many studies throughout the world demonstrating a low fit testing pass rate of FFPs with ear loop straps.

Objective: The aim of this study was to evaluate the fit of KN95 style respirators with ear loop straps on volunteers representative of GB users, using a quantitative fit testing method.

Methods: Eight models of respirators with ear loop straps, with no certification documentation, were selected from different manufacturers. Quantitative fit testing using an ambient particle counting method was conducted on 29 volunteers. The order of the fit testing on each respirator was randomised. The study followed the fit testing protocol as described in Health and Safety Executive (HSE) guidance on RPE fit testing, INDG 479.

Results: From the 232 fit tests completed, only one achieved a fit factor above the pass/fail criteria of 100. The data showed a 95% confidence that the geometric mean of the overall fit factors lies between 3.0 and 4.7, and is significantly lower ($P < 0.05$) than the pass/fail criteria of 100.

Volunteer comments on the perceived fit of the respirators with ear loop straps included being loose on the face, and feeling leakage around the edges of the respirator. Discomfort of the straps around the wearers' ears was also described.

Conclusion: The testing confirmed that there is a very low fit testing pass rate for FFPs with ear loop straps. Comments from volunteers also indicated that the perceived fit was poor.

Keywords: COVID-19 pandemic, healthcare, filtering facepiece respirators, ear loop straps, quantitative fit test, KN95, discomfort, ears.

INTRODUCTION

Many industry sectors, particularly healthcare and health and social care, used Personal Protective Equipment (PPE) and Respiratory Protective Equipment (RPE) to protect workers during the COVID-19 pandemic. During the pandemic, European conformity “CE” (“Conformité Européenne”) marked RPE, classified as filtering facepiece (FFP) level 3 (FFP3) respirators according to BS EN 149 (BSI, 2009), were used in Great Britain (GB) to protect healthcare workers from airborne bioaerosols while caring for infected patients during aerosol generating procedures. CE marking indicates the RPE has been tested and approved to the relevant European standard by a “notified body”. A “notified body” is an organisation

designated by an EU country to assess the conformity of certain products before being placed on the market" (European Commission, 2024). FFP respirators are subjected to different regulatory standards in different countries, which specify performance requirements such as mechanical strength and filter penetration.

Although RPE is CE marked, this marking indicates that its physical properties have been tested and conform to the standard, it does not account for any wearer variability, including differences in facial sizes. A study into the differences in facial sizes of the United States workforce was carried out by Zhuang *et al.* (2010). This demonstrated statistically different facial sizes between gender, ethnic groups and age. The ethnic groups categorised in that study were African-American, Caucasian, Hispanic and other ethnic groups composed primarily of Asian subjects. Zhuang *et al.* state the importance of these findings in the design of RPE. Du *et al.* (2008) carried out facial measurements from a sample of Chinese civilian workers and found differences when compared to the American population.

Standards for tight-fitting RPE, for example BS EN 149, do not account for the wearer and their differing facial shapes or sizes, and so do not test how well it fits each individual. Even though one type of respirator may be CE marked, it may not be suitable for all individuals due to their facial shape or size, so a tight-fitting respirator must be fit tested to the wearer (HSE, 2013). INDG 479 (HSE, 2019) sets out how to undertake fit testing.

Although there is no direct comparison between the subject test panels in different countries, it is reasonable to assume that tight-fitting RPE manufactured and certified to the European standard, BS EN 149, is primarily suited to western European facial sizes, given they are typically certified by notified bodies using volunteers of a western European origin. Tight-fitting RPE purchased from outside of Europe and certified to standards other than BS EN 149 may not be designed for or tested on subjects with facial features representative of the western European population, but rather representative of the area where the RPE is certified.

Due to increased demand for respirators, particularly FFPs, and issues with manufacturing and supply chains, there was a worldwide shortage of respirators during the COVID-19 pandemic. As a result of the shortages, an increased number of respirators were imported into GB and other countries, from outside of Europe. Many of these imported FFPs had ear loop straps and, based on the authors' observations during their work in the COVID pandemic, were incorrectly and often dually marked, showing both the European CE mark for conformance with the European standard BS EN 149 for respiratory protective devices, and also to the Chinese standard GB 2626-2006 for RPE, marked with a KN95 classification (GB, 2006). If products were genuinely marked with a KN95 classification according to GB 2626-2006, they would only require testing by the manufacturer, and a self-declaration of compliance, with no independent certification or assurance of their quality from an independent test house being needed, unlike the CE mark.

Previous studies

Evidence provided by the Emergency Care Research Institute (ECRI), a not-for-profit organisation that provides advice to healthcare stakeholders on product safety, in an article published in September 2020, included their findings that up to 70% of imported KN95 respirators they tested did not meet the performance requirements given in GB 2626-2006 (ECRI, 2020).

The ability of FFPs, with ear loop straps, to provide an adequate seal to the wearers face and ultimately provide adequate protection, has increasingly come into question within many countries throughout the world. The National Institute for Research and Safety (INRS) published an article in May 2020, detailing a study into a selection of seven models of FFP2s with ear loop straps, and found less than 1% successfully passed a fit test (INRS, 2022).

Other research into the fit of KN95 respirators with ear loop straps has been carried out using qualitative fit testing methods. In a letter to the editor of the European Respiratory Journal (ERJ), Kleinjohann and Lange (2020) described a study on the fit testing of four models of KN95 respirators with ear loop straps. From a

total of 82 healthcare workers fit tested in a hospital environment, all 82 failed the qualitative fit test. The fit testing was carried out according to the Occupational Safety and Health Administration (OSHA) fit testing protocol (OSHA, 2004).

Similarly, in a letter to the editor of the International Journal of Infection Control, Caoili *et al.* (2020), described a study into fit testing of three models of KN95 respirator with ear loop straps on 26 healthcare workers. From a total of 42 qualitative fit tests, only three achieved a pass. The fit testing was carried out according to manufacturer's instructions. Caoili *et al.* described a common observation from the fit tests that failed, that the ear loop straps were loose, and the respirators slid down the wearer's face.

Mottay *et al.* (2021), carried out a study with varying combinations of 12 models of KN95 respirators with ear loop straps, and seven volunteers with previous experience of wearing FFPs. A total of 36 user seal checks were conducted with only one perceived to be a pass by the volunteers. Modifications to improve the tension of the ear loop straps, and tape to increase the seal with the wearers face, increased the 36 user seal checks being perceived as a pass, to 15. These 15 volunteers, with the modified KN95 respirators, all failed subsequent qualitative fit tests. The fit testing was carried out according to the OSHA fit testing protocol.

O'Kelly *et al.* (2021) also carried out quantitative fit testing, comparing the fit of FFPs, including a KN95 type with ear loop straps, with surgical style masks and fabric face coverings. Only one KN95 respirator with ear loop straps was included, and this was quantitatively fit tested on seven volunteers according to the OSHA fit testing protocol. A mean fit factor of 2.2 (OSHA pass/fail criteria of 100) was recorded, with comparable results recorded for the surgical masks and cloth face coverings.

Fakherpour *et al.* (2021) also studied the fit of respirators available to healthcare workers in Iran during the COVID-19 pandemic. Although this was not a specific study of KN95 respirators with ear loop straps, one of the respirators included was one of this type. Quantitative fit testing was carried out according to the OSHA fit testing protocol, on 37 volunteers. A mean fit factor of 11 was recorded with only two above a fit factor of 100 and passing.

Aim

The aim of this study was to evaluate the fit of KN95 style respirators with ear loop straps on a selection of subjects from GB using a quantitative fit testing method and according to the fit testing protocol used in GB, INDG 479 (HSE, 2019).

METHODS

Volunteers

The study was given ethical clearance to proceed by the University of Sheffield Medical School Research Ethics Committee (internal ethics document, reference number HSE32). A total of 29 volunteers were recruited from an internal medically screened volunteer pool, including both males and females. Medical screening was undertaken by an external medical provider and included questionnaires and face to face appointments with a physician to undertake physical exercises to ensure they were medically fit to participate in the testing required by the study. All male volunteers were clean shaven before each fit test.

Respirators

A selection of eight KN95 style respirators with ear loop straps was sourced from both the quarantined stock in the PPE storage and distribution centre for GB healthcare during the COVID-19 pandemic, and respirators readily available online to purchase at the time of the study in Autumn 2021. This selection represented a range of KN95 style respirators with ear loop straps available to the GB population. All respirators were of a vertical fold design with ear loop straps and nose clips. The respirators were from

different Chinese manufacturers, and had no certification documentation, but each had varying markings. Table I gives details for each respirator tested, with the manufacturer's details anonymised.

Table I. Details of the respirators tested.

Respirator	Markings on the respirator	Nose clip
A	GB 2626-2006 KN95 EN 149 2001+A1:2009 FFP2NRD CE 1282	Internal with internal foam strip
B	(Manufacturer's identifying marks) GB2626-2006 KN95	External
C	KN95	Internal
D	(Manufacturer's identifying marks) Markings presumed to be Chinese writing	Internal
E	(Manufacturer's identifying marks) KY2020 FFP2 NR CE EN149-2001+A1:2009 KN95 GB2626-2006	External
F	KN95	Internal
G	GB2626-2006	External
H	KN95 CE FFP2 EN149-2001+A1 :2009	Internal

Protocol

Quantitative fit testing was carried out on each volunteer with each of the eight respirators with ear loop straps. A new respirator was used for each fit test and all fit testing equipment cleaned using antibacterial wipes, according to the in-house risk assessment, between fit testing volunteers. The quantitative fit test method employed was the ambient particle counting method using a TSI Portacount model 8038 Pro+, with N95 technology enabled, and a pass/fail criteria of a fit factor of 100. The fit testing protocol given in HSE guidance document INDG 479 was followed and included the exercises in the following order: normal breathing, deep breathing, head side to side, head up and down, talking, bending over, and normal breathing. Exercises were undertaken whilst stepping (except the bending over exercise), and each was undertaken for one minute. The only variation from the INDG 479 protocol was if a respirator failed an exercise, the fit test was continued to generate fit factor results for subsequent exercises and also to provide an overall fit factor result. The fit testing was carried out by competent fit testers with current Fit2Fit (Fit2Fit, 2023) accreditation at the time of the testing.

A standard metal sampling probe from a TSI fit test probe kit was used to connect the in-mask sample tube from the Portacount to each respirator. These were suitably positioned on the respirator to enable sampling as close to the wearer's breathing zone as possible, close to the face approximately mid-way between the nose and mouth, as defined in INDG 479. The in-mask sample was taken from flush within the mask without any extending sample tubes. Seven of the respirators had the metal sampling probes located in approximately the same location on the left-hand side, as worn by the wearer. One of the respirators had an embossed marking at this location, and so the metal sampling port was located at the equivalent location on the right-hand side, as worn by the wearer.

The volunteers were given opportunity to read any instructions provided by the manufacturer and donned the respirators to achieve the best fit possible under guidance from the fit testers if required. The order in

which the volunteers were fit tested on each respirator was randomised, with the eight fit tests spread over three sessions. The volunteers had the opportunity to rest and drink water at their discretion between each fit test.

Additionally, the volunteers were asked to provide comments on the fit of each mask before and after each fit test, and also comment on their perceived tightness of the ear loop straps.

Statistical analysis

Fit factors tend to be log-normally distributed and so results are calculated using geometric means and geometric standard deviations. Arithmetic means also aid comparison with the relevant standard but are not recommended as a summary measure for log-normal data.

Linear regression with robust standard errors was used to test if, overall, there were differences between respirator types. The dependent variable was the logarithm of the overall fit factor, with the categorical variable of respirator type as the independent variable. The joint Wald test was used to test the overall statistical significance of respiratory type.

RESULTS AND DISCUSSION

Fit testing

A total of 29 volunteers (nineteen males and ten females) were fit tested on eight different respirators, achieving 29 overall fit factor results for each respirator. No statistical analysis was undertaken on the sex of the volunteers, and all volunteers were of a western European origin. No other people of other origin volunteered to take part. No further data analysis was therefore undertaken on ethnicity. The results are summarised in Table II.

Table II. Statistical analysis of overall fit factor results.

Respirator	Geometric mean	Geometric standard deviation	Minimum	Maximum	95% confidence interval for the geometric mean	Arithmetic mean
A	3.5	1.8	1	10	2.8-4.4	4.1
B	3.5	2.4	1	47	2.5-4.8	5.7
C	6.4	2.9	1	198	4.4-9.4	14.2
D	4.1	2.8	1	66	2.8-5.9	8.2
E	4.4	2.7	1	33	3.1-6.4	7.2
F	5.5	2.3	2	35	4.1-7.4	7.8
G	1.9	2.5	1	32	1.4-2.7	3.7
H	2.7	2.6	1	64	1.9-3.9	5.3
Total	3.8	2.6	1	198	3.0-4.7 ^a	7.0

^a used cluster robust standard errors to allow for within-participant correlation.

Of the 232 fit tests conducted, there was only one fit test that achieved an overall fit factor above the pass/fail criteria of 100, which was respirator C on one volunteer, with an overall fit factor of 198. The next highest overall fit factor was 66. Combining the overall fit factors for all the respirators, the geometric mean overall fit factor was 3.8 with a 95% confidence interval of 3.0-4.7. This indicates there is 95% confidence of the actual geometric mean overall fit factor lying between 3.0 and 4.7. This was statistically significantly lower than the pass/fail fit factor criteria of 100 (at $p < 0.05$ since the 95% confidence interval did not include 100).

The linear regression found statistically significant evidence that the overall fit factors differed by respirator type (joint Wald test $p < 0.001$). Respirator G had the lowest geometric mean overall fit factor of 1.9 and respirator C had the highest geometric mean overall fit factor of 6.4. The geometric means for each respirator were statistically significantly lower than the pass/fail criteria of a fit factor of 100.

Volunteer comments

Before and after each fit test, the volunteers were asked to comment on their perceived fit of the respirator. These were grouped into common themes and are summarised in Table III. The volunteers' perceived tightness of the ear loop straps for each respirator are detailed in Table IV. Not all volunteers provided comments.

Table III. Summary of comments from volunteers on perceived fit of the respirator.

Respirator	Comments
A	Movement of the respirator on the face, leakage can be felt by the volunteer around the nose clip, glasses steamed up, very large on the face, uncomfortable on the bridge of the nose
B	Movement of the respirator on the face, leakage can be felt by the volunteer around the nose clip, glasses steamed up
C	Movement of the respirator on the face, leakage can be felt by the volunteer around the nose clip
D	Movement of the respirator on the face, leakage can be felt by the volunteer around the nose clip, glasses steamed up
E	Movement of the respirator on the face, leakage can be felt by the volunteer around the nose clip, glasses steamed up, end of the nose visible to the volunteer when looking down
F	Movement of the respirator on the face, leakage can be felt by the volunteer around the nose clip, glasses steamed up
G	Movement of the respirator on the face, leakage can be felt by the volunteer around the nose clip, glasses steamed up, end of the nose visible to the volunteer when looking down, very loose fit
H	Movement of the respirator on the face, leakage can be felt by the volunteer around the nose clip, glasses steamed up, end of the nose visible to the volunteer when looking down

Comments were provided from 211 fit tests with a spread on the volunteers' "perceived tightness" of the ear loop straps given in Table IV. There is no statistical data to suggest that this "perceived tightness" has any impact on the adequacy of the respirators; however, it does impact on the suitability in terms of comfort, with 58% of volunteers that commented stating the ear loop straps were not OK.

The lack of comfort due to the ear loop straps being too tight was often visually evident to the fit tester without communication from the volunteer. Of the volunteers who found the ear loop straps to be too tight, distortion of the ear was clear to see, and the amount of distortion was dependent on the volunteer and on the respirator. An example of the distortion due to the ear loop straps, compared to no ear loop straps, is given in Figure 1. It is highly likely that prolonged use of ear loop straps that cause ear distortion to this degree would severely impact on the comfort to the wearer, even with regular breaks for the wearer to rest.

Table IV. Numbers of comments on the perceived tightness of ear loop straps for each respirator.

Respirator	Ear loop straps too tight	Ear loop straps too loose	Ear loop straps OK
A	2	7	16
B	20	0	7
C	3	3	20
D	19	1	3
E	6	6	14
F	24	2	3
G	1	17	10
H	4	8	15
Total	79 (37%)	44 (21%)	88 (42%)

**Figure 1. Example of ear distortion due to ear loop straps being too tight (left), compared to no ear loop straps (right).****Fit factor comparison against the BS EN 149 total inward leakage requirements**

Fit testing is not the same as total inward leakage testing. Fit testing measures the fit of the respirator on the individual, whereas total inward leakage requirements in the European standard for filtering facepieces, BS EN 149, consists of face seal leakage, exhalation valve leakage and filter penetration.

The overall fit factors generated during this research were considered against the total inward leakage requirements.

An inward leakage result can be converted to a fit factor by the following equation (Rengasamy *et al.*, 2014):

$$\text{fit factor} = \frac{100}{\% \text{ inward leakage}}$$

A KN95 respirator, according to Chinese standard GB 2626:2006, would be approximately equivalent to an FFP2 certified to BS EN 149. The KN95 style respirators with ear loop straps fit tested in this study were not certified to BS EN 149, but were being purchased by end users in GB to be used as FFP2 respirators.

According to BS EN 149, the total inward leakage requirements for an FFP2 are given below with the corresponding fit factor given in bold:

'For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than 11 % for FFP2' (fit factor 9)

'and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 8 % for FFP2' (fit factor 12.5)

Fit testing was undertaken in this study, total inward leakage testing was not. It should be noted that although the conversion given by Rengasamy *et al.* can be used to convert total inward leakage results to fit factors, the fit testing undertaken in this study is not directly comparable to the total inward leakage testing requirements detailed in BS EN 149, and so are indicative only. This is because there were some factors, for example, the exercise protocols, the volunteer numbers (29 in this study, 10 in BS EN 149), and differences in particle sizes between the methods, which were not exactly the same. In terms of exercises, for fit testing, as per INDG 479, the exercises were performed whilst undertaking a stepping exercise, each for one minute. Exercises in BS EN 149 are undertaken on a treadmill at 6 km/h, each for two minutes. INDG 479 also incorporates a bending over exercise (non-stepping), which BS EN 149 total inward leakage testing protocol does not.

Although only indicative, using the above comparison conversion factors, these suggest that for a FFP2 respirator to achieve the total inward leakage requirements of BS EN 149, it has to achieve a minimum fit factor of 9 and 12.5.

In this study, the arithmetic means of the fit factors for each respirator with ear loop straps were less than 12.5 and 9, except for respirator C which had an arithmetic mean of 14.2 (Table 2). Note that for respirator C, with the exclusion of the high fit factor result of 198, the arithmetic mean is 7.6. Some individuals across all the respirators with ear loop straps tested in this study, did achieve higher than 12.5 and 9 during the study. From the fit testing data generated in this study, 13% (29/232) of fit tests achieved a fit factor of at least 12.5 and 19% (43/232) of fit tests achieved a fit factor of at least 9.

Further detailed analysis of the fit testing data generated in this study could be undertaken in future using the exact criteria as set out in the BS EN 149 total inward leakage test method, including the same exercises.

Summary

The fit testing data for the tested respirators with ear loop straps shows there is a 95% confidence that the geometric mean of the overall fit factors lies between 3.0 and 4.7, and is significantly lower than the pass/fail fit factor criteria of 100. From the 232 fit tests completed, only one achieved a fit factor above the pass/fail criteria of 100.

Although not a direct comparison, the equivalent fit factors to the total inward leakage requirements given in BS EN 149 were considered. The arithmetic means of the fit factors for each respirator with ear loop straps were less than 12.5 and 9, except for respirator C which had an arithmetic mean of 14.2. Some individuals across all the respirators with ear loop straps, tested in this study, did achieve higher than this.

Comments from the volunteers indicate the overall perceived fit of the respirators tested was poor. The respirators felt loose with leakage around the nose area. In 58% of fit tests, the wearer thought the perceived comfort of the ear loop straps were too tight or too loose. When the ear loop straps were too tight, a distinct distortion of the ears was visible.

CONCLUSIONS

The testing confirmed that there is a very low fit testing pass rate for FFPs with ear loop straps. Comments from volunteers also indicated that the perceived fit was poor.

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