

FEATURE



N95S, ELASTOMERICS, FIT-TESTING AND COVID-19: RESPIRATORY PROTECTION FOR FRONTLINE HEALTHCARE WORKERS IN AUSTRALIA

There were a lot of things we didn't know prior to COVID-19: how to tackle remote schooling, how to use Zoom and how to self isolate with a sustainable toilet paper supply without joining the ranks of hoarders. Other things many Australian anaesthetists have become better acquainted with in 2020 are terms like N95 respirators, elastomeric respirators, fit-testing and fit-checking. This has been a highly topical area for anaesthetists during the course of the pandemic, as we navigate the dynamic guidance issued by our hospitals and government bodies who have worked at breakneck speed to respond to this crisis.

Frontline healthcare workers are at particular risk whilst delivering care

to infected patients be they of known or unknown status. This necessitates consideration of appropriate personal protective equipment (PPE) for staff who have a high risk of exposure to virally-loaded aerosol and droplets from COVID-19 patients. Of particular risk are the aerosol generating procedures (AGPs) encountered by anaesthetists on a daily basis through procedural airway management.¹ These particles are small enough to remain suspended in air for a prolonged period of time and retain their infective capacity.² Surgical masks do not confer sufficient protection from aerosols.³

A key element of PPE is respiratory protection by way of a filtering respirator. These can be classed as disposable and

reusable. Unlike surgical masks, these are designed to filter all the inspired air to remove significant particulate matter, including those carrying infectious agents. Respiratory protection is a major part of PPE and many of the recommendations from overseas call for a fit-tested N95 respirator.⁴

WHAT IS FIT-TESTING?

To work effectively, an N95 respirator must form a tight seal against the user's face such that all inhaled air traverses the filter material rather than through the gaps between the face and respirator. When an N95 respirator is worn poorly, it is only as effective as a surgical facemask.⁵ Since we all have different facial characteristics, fit-testing is required to ensure that the

chosen N95 respirator is able to create a seal on the user.

In the largest study to date, over 6,000 healthcare workers in South Australia were tested as part of pandemic influenza response in 2006-2007.⁶ In this study, out of 5,024 healthcare workers who had completed the questionnaire, 4,472 (89%) could be successfully fitted while 552 could not be fitted with three or more N95 respirators. Of those who were successfully fitted, 3,707 (82.9%) were able to be fitted with the first N95 respirator that was tried, a further 551 (12.3%) required testing with a second model and 214 (4.8%) required three or more models to be tested. Healthcare workers who identified as Asian were the cohort that was most likely to fail fit-testing (16.3% vs white 9.8%) [p=0.011].

In Canada, McMahon et al conducted qualitative fit-testing on 1,271 health care workers. Only six were unable to be fitted and 95% were able to be fitted with the first N95 respirator that was tried. A total of seven types of N95 respirator were available for testing.⁷ A further study on qualitative fit-testing was conducted in a Darwin ICU. In this study, 50 volunteers underwent fit-testing with three types of N95 respirators. Fourteen participants found that none of the N95 respirators fit, 18 passed with one type, eight with two types and 10 with all three types.⁸ This highlights the importance of fit-testing and for hospitals to stock more than one brand of N95 respirators.

A fit-test is not the same as a user seal check, or fit-check. A user seal check is a self-determined test which is done every time a respirator is worn. It can involve a negative and positive pressure check as well as checking that the respirator and straps are seated correctly. The positive pressure fit check confirms that a positive pressure is generated in the respirator during exhalation while the negative pressure check confirms that a vacuum is created causing the respirator to be drawn in slightly during inspiration. Many studies have shown that fit-checking is a

poor surrogate for fit-testing. A study on Canadian healthcare workers by Danyluk et al found that out of 643 participants that identified as having an adequate seal after the fit check, 25% failed the subsequent quantitative fit-test and 14% failed the qualitative fit-test.⁹ This result has been replicated in many other studies. Lam et al tested 638 Chinese nursing students and found that fit checking was not helpful in identifying gross leakage.¹⁰ Similarly in Huh et al the sensitivity for a user fit check for determining passing a qualitative test was low at 17.5%-53.8%.¹¹

According to Australian Standards (AS/NZS 1715:2009) fit-testing of a tight-fitting respirator such as a P2 or N95 respirator is mandatory.¹² However this is not legislated. Fit-testing is also recommended by the NHMRC¹³ and more recently both the ASA and ANZCA have joined the call for fit-testing.^{14,15}

There are two methods for conducting fit-testing; qualitative or quantitative. Qualitative testing is performed by aerosolising a sweet or bitter substance (saccharin or Britex®) into a clear hood that is worn by the user while wearing

a N95 respirator.¹⁶ A series of dynamic movements such as bending over and talking are performed according to the test protocol. If the user cannot taste the substance throughout the test, then the fit-test is successful. If the user can taste the substance at any time, then an adequate fit has not been obtained. This test can only generate a pass or fail outcome and is dependent on the user being able to subjectively taste the substance.

On the other hand, quantitative testing uses a machine such as the TSI PortaCount to sample the number of microscopic particles in ambient air and compares it to the microscopic particles within the N95 respirator. Again a series of dynamic movements are performed. To pass fit-testing, the overall fit factor calculated by the machine has to be greater than 100. This means the microscopic particles in the N95 respirator have to be 100 times less than ambient air. Unlike qualitative testing, quantitative testing is objective and generates a 'fit factor' which reflects how well the N95 respirator fits the user.¹⁷ In Australia, testing can be done by any



FEATURE

Table 1: Number of respirators which passed fit-testing

Respirator	Pass	Total	Percentage
3M 1860/3M 1860S	51	63	81
BSN Medical Proshield (S) or (M)	8	32	25
Halyard	5	13	38
3M 8210	3	7	43
3M 1870+	5	5	100
Other disposable N95 respirator*	1	9	11
Sundstrom Elastomeric Half and Full Face (SR100/SR 200)	26	26	100
3M Elastomeric Half and Full Face	22	23	96
Total	121	178	68
Total disposable N95 respirators that passed	73	129	57
Total elastomeric respirators that passed	48	49	98

* Only respirators with five or more counts were analysed individually. Respirators with less than five counts were grouped together in 'other'.

competent person although processes for credentialing fit-testers are currently in development. Another benefit of quantitative testing is the 'real time mode' which is available on the PortaCount machine. This mode can be used to educate users on how to correctly don the N95 respirator as adjustments to the respirator are reflected in a real time fit factor.¹⁸

ASA AND FIT-TESTING

Due to interest by members, the ASA organised fit-testing in Epworth Richmond and in Albury-Wodonga Health. Katie Blair and Alycia Campbell from Onsite Safety Australia (NSW) were enlisted to help us with testing. Katie is the respiratory specialist from Onsite Safety, with over 15 years of experience in respiratory safety including fit-testing.

Over two days, we tested 60 participants and 178 N95 respirators and elastomeric respirators. There were 33 male and 29 female anaesthetists. The results for respirators which resulted in a pass are shown in Table 1.

The most commonly tested disposable N95 respirator were the 3M 1860 and

3M 1860S as these were provided by the ASA from OnSite Safety Australia. Other disposable respirators that were tested were provided by the participants. The BSN Medical Proshield N95 was the second most commonly tested disposable N95 respirator, as these respirators are commonly available in public hospitals in Melbourne and can be purchased from pharmacies. Other N95 respirators that were tested include the Halyard N95 respirator, 3M 8210 and 3M 1870+. A total of 12 different types of disposable N95s were tested.

Overall the pass rate of the disposable N95 respirators was 73/129 (57%). It is interesting to note that the combined 3M 1860 and 3M 1860S pass rate is 51/63 (81%) compared to the BSN Medical Proshield N95 (in either S or M) which is 8/32 (25%). Amongst other disposable N95 respirators, the Halyard had a pass rate of 5/13 (38%), 3M 1870+ had a pass rate of 5/5 (100%) and 3M 8210 had a pass rate of 3/7 (43%). Note however, that it would be inaccurate to compare the respirators which have a small denominator with those with a larger denominator. Furthermore, this is not a formal study where comparisons between

the different N95 respirators were sought, thus statistical tests cannot be applied. Nonetheless it is interesting to note that the BSN Medical Proshield, which is so prevalent in Melbourne, had a very low pass rate during our testing session. The overall results are consistent with the industry experience of our professional fit-testers.

In our dataset, there was no difference in the overall pass rate for both disposable and elastomeric respirators between men (67/99 respirators tested) vs women (54/79 respirators tested). There were also no obvious differences in pass rate between people of different age groups, height, BMI or ethnicity.

During the ASA testing session, there was also the opportunity to purchase and test elastomeric respirators. According to the Australian Standards, any tight fitting respirator including elastomeric respirators should also be fit-tested.¹² The elastomeric respirators available included the 3M half face and full face series; and the Sundstrom half face (SR100) and full face (SR200) respirator. Compared to disposable N95 respirators, the pass rate for these respirators were significantly higher. Out of 49 elastomeric respirators that were tested, 48 passed fit-testing. The single failed fit-test was of a member who tried two different sizes of the 3M full face elastomeric and found that the small size fit but not the medium size.

ELASTOMERICS

Elastomeric respirators are a class of respirators designed to be reusable. These include the Sundstrom and 3M half and full face models used in the ASA Fit-test Session. Elastomerics are so named due to the rubber material comprising the facepiece and can be used as an alternative to N95 respirators when mounted with a user-replaceable filter. These filters perform to specifications rated by the manufacturer for their suited purpose. They are at least as protective as N95 respirators. The Sundstrom SR510



and 3M 6035 filters perform to a P3 rating, although overall protection on a half-face respirator is capped due to a rating limit in assigned protection factor (APF) placed on the design.¹⁹

Elastomeric respirators are not widely used in Australian healthcare. They see more common use in industrial settings where exposure to fine particulate matter such as asbestos, silica or concrete dust can result in chronic lung disease.²⁰ They can be useful under the crisis conditions of a pandemic when national stockpiles and manufacturer supply chains can be stretched, or when frontline healthcare workers fail fit-testing of hospital supplied N95 respirators.²¹ Elastomerics are seeing successful deployment overseas where major PPE shortages and price rises have driven a need for alternative solutions.^{22,23}

Impediments to wide use include lack of familiarity within the health sector, reduced clarity of speech, increased involvement with donning and doffing, perceived complexities with disinfection as well as upfront costs.²¹ When compared, 3M 1860 N95 masks showed superior speech intelligibility to 3M 6000 series elastomeric half masks, though both exceeded the minimum communication criteria as set



by the National Institute for Occupational Safety and Health (NIOSH).²⁴

Institutional elastomeric respirator programs require additional consideration for cleaning, disinfection, storage, consumables and maintenance. They can allow a more forgiving seal due to deformability of the rubber compound and presence of adjustable straps, as reflected in their high pass rate in our results. Personnel can be rapidly fit-tested and trained in the use of these devices.²⁵ They offer advantages including higher APF,¹⁹ reduced waste and reduced cost in the long term.^{21,22}

Concerns about cleaning and disinfection can be overcome by instituting a set of standard operating procedures for healthcare workers which are concise, efficacious and simple to follow. Where a hospital network has multiple sites, a protocol that is broadly applicable to the conditions at each site allows them to be rapidly implemented with minimal training, as is required for pandemic conditions.²⁶

Some manufacturers recommend discarding the filter after each use during conventional demand settings. The Centers for Disease Control and Prevention (CDC) recognises that

shortages during contingency or crisis situations may warrant cleaning of the filters. Care must be taken to only clean and disinfect the filter housing, unless the filter media itself has been shown to withstand exposure to the cleaning solutions without degrading performance. Occupational Safety and Health Administration (OSHA) only deems it necessary to replace filters when soiled, contaminated or clogged.²¹

SUMMARY

As case numbers rise and parts of Australia re-enter heightened restrictions,²⁷ it is prudent to evaluate our approach to staff protection and ensure use of respiratory protection is consistent with global standards on fit-testing. Hospitals should stock multiple types of N95 masks as it is unlikely for a single type and size to provide adequate protection for the entirety of their frontline staff. The level of protection can only be ascertained through formal fit-testing as embodied by our own Australian Standards, as well as the standards of our craft group representatives ANZCA and ASA.^{12,14,15}

Elastomeric respirators provide a solution for those who fail fit-testing and beyond

FEATURE



that, can be an alternative to disposable respirators with at least equivalent protection and viable long term cost-effectiveness.^{21,22} With no clear end in sight to the COVID-19 pandemic, healthcare providers need to explore sustainable PPE options. Elastomeric respirators are able to augment existing supplies of respirators for hospitals and in cases where a dedicated program exists, have the potential to successfully replace N95s as the sole respiratory protection.

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Note: The fit-testing was conducted on 2-3 June at Epworth Hospital, Richmond and 4 June at Albury Wodonga Hospital. Victoria has since seen several further escalations with Stage 4 restrictions underway at time of publication.

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