Commentary

Fit for purpose? The role of fit testing in respiratory protection

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INTRODUCTION

Fit testing of tight-fitting respiratory protective facepieces has been in use for some years, but there are still widespread misconceptions and misunderstandings about what a fit test pass actually signifies. Various aspects frequently generate research papers, and there are three relevant ones in this issue (Han and Lee, 2005; Kuo et al., 2005; Vaughan and Rajan-Sithamparanadarajah, 2005). In this commentary we will try to place fit testing in context with respect to UK and international practice, and describe its relevance to achieving effective control of exposure by using respiratory protective devices (RPDs).

FIT AND PROTECTION—WHAT IS THE DIFFERENCE?

To be sold within Europe, RPDs must be CE marked. This is usually achieved by complying with a harmonized European (CEN) standard. One of the tests that is applied to nearly all RPDs (except mouthpiece devices) is the measurement of total inward leakage (TIL), which comprises face seal leakage, filter penetration and exhalation valve leakage. For devices with high efficiency filters or a clean air supply, the greatest contributing factor is face seal leakage, which is defined as the inward leakage of the ambient atmosphere between the face and the facepiece. TIL is routinely measured either by the use of sodium chloride aerosol or sulphur hexafluoride gas; both methods are acceptable.

TIL methods determine, with a good degree of accuracy, the protection provided by the RPD under ideal laboratory conditions. But when the RPD is actually used in the workplace, another important variable is introduced—the wearer. In the past this was often overlooked, and this is where RPD fit testing has an important role to play.

In USA it is the responsibility of the National Institute for Occupational Safety and Health (NIOSH) to test and certify RPD. TIL testing has not been part of their certification process and evaluation of fit has relied on individual fit testing and fit checking procedures as mandated by the Occupational Safety and Health Administration (OSHA). NIOSH is currently implementing TIL testing in the certification process to evaluate RPD performance under laboratory conditions, but this is not intended to replace individual fit testing.

Many studies (e.g. Cohen, 1984; Galvin et al., 1990; Howie et al., 1995; Myers et al., 1984; Wallis et al., 1993) have shown that the protection afforded by the RPD during laboratory tests is not achieved when they are used in the workplace. The assigned protection factor (APF; see (BSI, 1997)) has been defined to provide a more realistic measure of the protection likely to be achieved in the workplace and this value should be used when selecting adequate RPD. The APF is the level of respiratory protection that can realistically be expected to be achieved in the workplace by 95% of adequately trained and supervised wearers using a properly functioning and correctly fitted RPD. Therefore by definition, APFs for mask-based RPDs can only be used after adequate fit has been demonstrated.

WHY FIT TEST?

What do we understand by fit testing? American National Standard ANSI Z88.10 (ANSI, 2001) states that the purpose of respirator fit testing is to verify
that the selected make, model and size of a facepiece adequately accommodate an individual’s facial characteristics, and that this provides assurance that the wearer can don the facepiece properly and can achieve the anticipated protection during use. The respirator committee responsible for the production of BS4275 (BSI, 1997) was more cautious, stating that fit testing only identifies gross misfits and does not guarantee adequacy of fit.

This requires further explanation. Passing a fit test does not guarantee that every time a wearer dons a facepiece an adequate fit will be achieved. It identifies that a certain facepiece has the potential to provide an adequate fit, but to go on achieving this the wearer must always fit the mask correctly and check the fit by performing the user fit checks as described in the manufacturer’s user instructions.

A simple analogy can be used—when you buy a pair of shoes, you try them on for fit before handing over the cash. But then, once you have the correct size of shoes you still have to fit them properly—tie the laces, fasten the buckles, etc. Even then if you’ve purchased a pair of sandals of the correct size they would not be suitable for use on a building site!

**FIT TEST METHODS**

The fit of a facepiece can be determined by qualitative or quantitative methods. Qualitative methods (QLFT) rely on the wearer’s subjective response to a test agent, usually a sprayed solution of a sweet or bitter tasting substance. Quantitative methods (QNFT) provide an objective measure of the fit, generating a number referred to as a fit factor. A fit factor is the ratio of the concentration of a substance outside the facepiece to the concentration inside the facepiece.

A number of QNFT methods exist. Test chamber methods that are employed in CE certification testing are generally considered to be the reference standard for fit testing, but are neither practical nor cost effective for routine fit testing applications. The most common QNFT method in use employs an ambient particle counting device (PortaCount™). An alternative method employs controlled negative pressure (CNP) (FitTester 3000™).

Since these methods utilize different techniques they give rise to different fit factors and many studies have been conducted to compare these methods, such as the studies by Oestenstad and Graffeo (1993) and Crutchfield et al. (1995). All these methods have strengths and weaknesses. It is a case of striking the right balance between a fit test method that is scientifically sound but often not very practical and a method that is easy to use whilst providing an acceptable assessment of fit. What is important, however, is that the fit tester is aware of the limitations of a particular method, and takes these into account. Two important limitations are discussed here.

One disadvantage of the ambient particle counting method is that it cannot differentiate between particles that have leaked around the face seal of the facepiece and those that have been generated by the wearer. Fairchild et al. (1987), da Roza et al. (1991) and Clayton (2001) found that wearers generate particles during the fit test exercises. This has the effect of falsely reducing the measured fit factors, especially during the talking exercise. The impact of this effect can be reduced by ensuring that the ambient particle count is sufficiently high.

One disadvantage of the CNP method is that it cannot distinguish between face seal leakage—which is the measure of fit—and any exhalation valve leakage. The problem here is due to the fact that exhalation valves are permitted to leak slightly under a static negative pressure (BSI, 1969; AS/NZS, 1994; CFR 2002). This negative pressure is of the same order as the test pressures employed in the CNP procedure. This has the effect of falsely reducing the fit factor (HSE, 2003), and may explain why comparative studies into QNFT methods invariably conclude that CNP provides a more conservative fit factor.

**STANDARDS, REGULATIONS AND GUIDANCE**

Fit testing has been a requirement in the USA for over 30 years—introduced in the American Standard ANSI Z88.2 in 1969 (ANSI, 1969). The Occupational Safety & Health Administration (OSHA) Standard 1910.134 sets out accepted fit test protocols. The American National Standard Institution (ANSI) Z88.10-2001 provides guidance on how to conduct fit testing and appropriate methods to be used (ANSI, 2001).

Fit testing is comparatively new in the UK. It was introduced into the Control of Asbestos at Work (CAW) Approved Code of Practice back in 1999 and then expanded across all of industry in 2002, when the fit testing requirement was incorporated into the Approved Code of Practices supporting the COSHH (Control of Substance Hazardous to Health) and CLAW (Control of Lead at Work) regulations. The UK Health and Safety Executive (HSE) issued an information document HSE 282/28 to provide guidance on fit test methods and procedures (HSE, 2003).

There are some fundamental differences between the USA, Canada, Australia and UK fit test protocols and requirements. USA, Canadian and Australian standards require that fit testing is undertaken either annually or biannually. In the UK a repeat fit test is only considered necessary when changing to a different facepiece model or if there has been significant change to the facial characteristics of the wearer.
e.g., as a result of weight gain/loss or dentistry. However, HSE recently held a meeting with fit testing stakeholders to discuss this and other issues. Many stakeholders were in favour of the introduction of repeat fit testing, even though no evidence is currently available to justify this change. What is known is that RPD users forget how to correctly don and use their respirators. Training can be poor at times and repeat fit testing can play a role as a tool in refresher training.

In the UK, minimum fit factors of 2000 for a full face mask and 100 for a half mask and filtering facepiece have been set. Elsewhere the general principle of 10 times the nationally accepted APF of the RPD is used as the criterion, with half masks and filtering facepieces requiring a minimum fit factor of 100 and either 500 or 1000 for a full face mask. The important difference, however, is that in the UK, HSE requires that a pass be achieved in each of the fit test exercises and not just the overall figure. The reasoning behind this difference was that an overall pass could be achieved even if a device did not achieve a very low fit factor. For example, the failed exercise was the up and down head movement and a particular wearer’s task involved this movement, then the wearer may not achieve the required level of protection.

Regardless of these differences, in all cases the authorities agree that passing a fit test at the required level is a prerequisite for being able to apply the accepted APF for mask-based RPD. The fit factor does not, as some people would like to think, indicate the level of protection that the device will provide to the wearer.

**COMPETENCE**

In the US, where fit testing is a legal requirement, methods and protocols that must be followed are specified in ANSI and OSHA standards. However, in the UK no particular fit testing methods and protocols are mandated. Whilst the HSE guidance document plays a vital role in educating both fit testers and RPD users, in promoting good practice and in setting a benchmark, following this guidance is not compulsory. Pressure to reduce workers’ downtime has on occasions placed pressure on the fit tester to cut corners. Conducting a correct fit test requires competence, diligence and time. A badly conducted fit test can result in poorly fitting facepieces being used, leading to wearer exposure. HSE, in collaboration with stakeholders, is considering how best to establish a competence framework for fit testers.

**WHAT NEXT?**

As with many things in life, there is a desire to complete tasks quicker and quicker, and fit testing is no exception. There is a drive to reduce the length of time a fit test takes. A well-conducted fit test can take between 15 and 20 min. A shortened variant of the CNP fit test method (Crutchfield, 1999) was accepted by OSHA in 2004; the ‘REDON’ method includes three test exercises and two facepiece redonnings and can be completed within 5 min.

A recent paper by Nelson et al. (2003) explored the possibility of reducing the duration of a qualitative fit test employing a bitter aerosol (Bitrex™). The authors reported that by reducing individual exercise durations from 60 s down to 15 s, adequacy of fit could still be determined. Another recent study by Zhuang et al. (2004) concluded that the fit test exercise regime for the ambient aerosol method (Portacount™) could be reduced from the usual seven exercises down to three exercises, providing scope for either shortening the length of time required for a fit test, or permitting the development of a multi-donning protocol.

Although the inclusion of redonning the facepiece can have value, the role that the exercises play, in our opinion, has not been fully considered. There must be a careful balance between the time taken for a fit test and minimization of down time for the RPD wearer, and care should be taken to ensure that the value of a fit test is not reduced. Perhaps consideration could be given to a two-tier system, where the initial fit test requires the full exercise duration and subsequent repeat tests, whether annually or at some other frequency, could be abbreviated.

The International Standardization Organization (ISO) is developing new global standards for RPD. ISO/TC94/SC15 have adopted the principle of writing the standards around the RPD user rather than around RPD design. This focus on the user should result in improved RPD in the future. It has been recognized that global standards must encompass the global range of face sizes, shapes, gender and ethnic diversity—a point made by Han and Lee (2005) in this issue. However, the ISO standard on RPD selection will recommend the importance of individual fit tests.

**CONCLUSION**

No method of measuring facial fit is without its disadvantages. However, each method when applied correctly can provide an acceptable assessment of mask fit. Fit testing also plays an important role in reinforcing training. The future ISO standard on RPD selection, use and maintenance will incorporate fit testing within its scope and will take full advantage of the wealth of experience and information that exists on RPD fit testing.

Whilst fit testing has a key role to play, it must not be forgotten that this is only one small part of an RPD programme. For adequate respiratory protection to be
achieved in the workplace a comprehensive and effective RPD programme must be in place. HSE guidance HSG53 (HSE, 2005), British standard BS4275 and American standard ANSI Z88.2 (ANSI, 1992) provide very useful guidance for establishing such a programme.

REFERENCES


