

The effect of wearer stubble on the protection given by Filtering Facepieces Class 3 (FFP3) and Half Masks

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The effect of wearer stubble on the protection given by Filtering Facepieces Class 3 (FFP3) and Half Masks

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HSE Inspectors routinely come across workers with various degrees of stubble growth using respiratory protective masks, despite guidance to the contrary. This research studied the effect of 0-7 days stubble growth on the protection given by FFP3 filtering facepieces and half masks.

Fifteen male volunteers took part, each testing four masks. For most, three different design FFP3 and one half mask were tested, selected from seven models of FFP3 and 2 half masks. Fit tests were carried out immediately after shaving and repeated six times during the following week, without further shaving.

Results showed that the effect on protection was quite specific to the mask/wearer combination. Protection could be significantly reduced where stubble was present, beginning within 24 hours from shaving, and generally worsening as facial hair grew. Statistical analysis predicted this could reach an unacceptable level for all of the masks tested.

While some individual wearers did grow some stubble without significantly reducing protection with some masks, this was unpredictable and it would not be practical to conduct the necessary testing to confirm this for every individual wearer.

The current guidance advising being clean-shaven in the area of the mask seal is justified.

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EXECUTIVE SUMMARY

Wearers of tightfitting RPE facepieces are advised to be clean-shaven in the area of the faceseal as explained in the guidance supporting Health and Safety legislation. However, HSE Inspectors routinely come across workers wearing tightfitting facepieces who are not clean shaven and have various degrees of stubble growth of a few days after shaving. Whilst tests have previously been carried out which demonstrate that facial hair is detrimental to the protection given by reusable facepieces, there is little or no information on the impact of facial hair growth on the level of fit, and hence the degree of protection, given by disposable filtering facepieces. The purpose of this research was to investigate the effect of early (0-7days) stubble growth on the protection given by filtering facepieces and half masks.

Main findings

Tests were carried out using a range of facepieces including seven models of FFP3 with different overall designs and types of faceseal and two different half masks. Repeat fit tests were conducted over the course of one week from clean-shaven on 15 different male volunteer test subjects each using four of the facepiece models, aiming to include each type of faceseal design. Results are presented as percentage inward leakage in graph format to identify trends, and were statistically analysed for changes as stubble grew. Photographs recorded the appearance and development of stubble growth.

The results of these tests indicate that with the selected filtering facepieces and half masks the protection given to the wearer may be reduced where stubble is present. This stubble effect may begin within 24 hours from shaving, and increases as facial hair grows up to at least seven days. Percentage inward leakage varied for test subjects and facepieces. For some facepieces for several test subjects, percentage inward leakage increased significantly (to 3-6% or higher) by the end of day 4. With other facepieces, inward leakage increased for about 50% of wearers as stubble grew, but for other wearers no significant change in inward leakage occurred. The statistical analysis showed that by the seventh day, the predicted inward leakage may reach an unacceptable level (greater than 1%) in all of the facepieces tested. For some of the facepieces tested increased inward leakage occurred early in the trial period, with the percentage inward leakage increasing from the first day after shaving.

The research provides evidence that the effect of stubble is quite variable in the degree of increased face seal leakage which occurs with the various masks. The evidence suggests that the extent of face seal leakage is quite specific to the facepiece and test subject combination and is unpredictable. The study showed that individuals experienced high levels of inward leakage with some facepieces while, for other facepieces, stubble had only a moderate or even little effect on inward leakage.

Work activities may have a further influence on protection. Specifically where there is a frequent need to move and hold the head position, for example in some types of construction work, this may compromise the protection to a greater extent than more sedentary work.

Although, in theory, the research suggests that it may be possible for individual wearers to grow some stubble without loss of protection with some masks, the outcome cannot be predicted in advance and it would not be practical to conduct the necessary testing on each individual wearer in order to confirm this.

The results of this work support the statement given in the European Standard EN 529 (annex D.4.2) which advises that tightfitting facepieces should not be selected where there is unshaven

hair in the area of the faceseal. The definition of unshaven given is “In this context unshaven means hair which has not been shaved within the previous 8 hour period prior to the work shift” and this would seem appropriate. The research also reinforces the guidance which supports UK Health and Safety legislation that workers should be clean shaven in the area of the faceseal when wearing tight fitting respirators.

CONTENTS PAGE

1.	INTRODUCTION	%
1.1	Background Information	1
1.2	Project Aim	1
1.3	Project Objectives	7
2.	METHODOLOGY	'
2.1	Choice of Test Method	3
2.2	Test Subjects	3
2.3	Facepieces	4
2.4	Test Protocol	5
3.	RESULTS	'
3.1	Percentage Inward leakage	8
3.2	Summary Discussion of Results	28
4.	CONCLUSIONS	3&
5.	REFERENCES	3'
6.	APPENDICES.....	3(
6.1	Appendix A: Detailed graphs	34
6.2	Appendix B: Photographs 2 days	67
6.3	Appendix C: Photographs 7 days	75
6.4	Appendix D: Stubble Measurements	83
6.5	Appendix E: Statisticians Report	84

1. INTRODUCTION

1.1 BACKGROUND INFORMATION

Tightfitting facepieces are an important part of many types of respiratory protective equipment (RPE). For such RPE to work effectively it is important that the facepiece seals well to the wearer's face. Tightfitting facepieces include filtering facepieces, half masks and full facemasks, including facemasks for breathing apparatus.

The presence of a good seal between the respirator facepiece and the wearer's face, ensures that ambient air will be directed through the filter(s) as the wearer breathes in and/or, with powered devices, as a fan pushes air through. The filter (if correctly selected) removes hazardous substances allowing the wearer to breathe cleaner air. However, the filter material exhibits some resistance to air flowing through it such that even a very small gap between the respirator facepiece and the wearer's face, is an easier route for ambient air to get inside the facepiece, and hence is the route taken. Ambient air passing through a faceséal gap will take with it any hazardous substance present, to be breathed in by the RPE wearer, hence reducing the effectiveness of the RPE and the protection given. This fact is often not understood or appreciated by typical RPE users.

Similarly for breathing apparatus a good faceséal is necessary to enable good function of the RPE, allowing the wearer to inhale only the breathable quality air which is supplied to the RPE. As breathing apparatus is used in high hazard environments where there may be an immediate danger to life and health (e.g. where oxygen may be deficient or contaminants are present in high concentration or are of a highly toxic nature), and the wearer may be working at a heavy work rate and therefore breathing deeply, it is important that the wearer cannot breathe in ambient air through a poor faceséal. It is also important that breathable air is not wasted (reducing the working duration of the breathing apparatus) by continuous outflow through a poor faceséal.

HSE guidance (including COSHH ACoP para. 149) advises that the performance of tightfitting RPE facepieces requires a good contact between the wearer's skin and the faceséal and that this "can only be achieved if the wearer is clean shaven in the region of the faceséal"¹. This view is also supported in the European Standard EN 529 (annex D.4.2) where "In this context unshaven means hair which has not been shaved within the previous 8 hour period prior to the work shift"².

HSE Inspectors frequently challenge the wearing of tight fitting facepieces by workers who have a day or a few days of facial hair growth (stubble). Whilst studies have been carried out which show that the effectiveness of full facemasks is significantly reduced if the wearer has facial hair^{3,4,5,6}, little work appears to have been carried out to investigate the effect on filtering facepieces and half masks.

Filtering facepieces are comprised predominantly from fibrous filtering materials. The mask surface that forms the seal to the face (the faceséal) may be the fibrous filter material itself, or it may be an additional material attached to the edge of the filter material having either a knitted textile finish or a smooth elastomeric type finish. Half masks invariably have smooth elastomeric sealing surfaces, similar to those of full facemasks. This study focusses on the effect of stubble on filtering facepieces class3 (FFP3) and a half masks, the implications for FFP1 and FFP2 are also discussed.

1.2 PROJECT AIM

To assess the impact of wearer stubble, from a clean-shaven state to seven days growth, on the respiratory protection given by filtering facepieces and half masks with quantified statistical confidence in the results.

1.3 PROJECT OBJECTIVES

- To quantitatively measure the fit of selected facepieces on a number of different male volunteer test subjects when clean-shaven and as their facial hair grows for a few days.
- Include sufficient test subjects, with a target of achieving a high statistical confidence in the results.
- Measure the fit, under these stubble growth conditions, of a cross-section of filtering facepieces and a half mask which are in common use in industry.
- Assess the impact of stubble on the protection/performance (as shown by the change in percentage inward leakage of ambient air) of these types of respirator and draw appropriate conclusions.

2. METHODOLOGY

2.1 CHOICE OF TEST METHOD

There are two methods of fit testing which are in common use in the UK for determining the acceptability of fit of filtering facepieces and half masks in clean-shaven wearers. The qualitative method is a subjective test giving a pass/fail result only and therefore is not suitable for this work. The other method is a quantitative method, which uses the TSI Portacount machine to count ambient particles. The Portacount returns a numerical measure of the fit (the 'fit factor') which is based on the measured leakage of ambient air particles into the facepiece; therefore the extent and quality of the fit can be quantified and presented as the percentage of inward leakage into the facepiece:

$$\text{Percentage Inward Leakage} = \frac{100}{\text{fit factor}}$$

A further option for quantitative fit testing is to use the Laboratory Chamber fit test method. This method requires specialised equipment, the generation of salt aerosol and is relatively time consuming; hence this test is much more expensive to conduct than the Portacount fit test method. The advantage of this method over the Portacount is that it does not count particles which may be generated by the wearer, which can lead to false low readings especially with the talking exercise. Wearer-generated particles should not be a problem for these tests though as they are comparing results for each wearer against their own results; the amount of wearer generated particles depends on the wearer⁷ and should therefore be fairly constant, provided that the wearer is in good health (no cough or cold symptoms).

A further problem which affects both of the above methods is that some inward leakage can also occur through the filtering material⁸. For FFP3 this is proportionally less than typical inward leakage through the face seal, but as this work considers the performance of each facepiece model independent of tests on other models this should be fairly constant, although some variation may occur in the quality of the filtering material between examples of the same model⁹. It is also possible for a small amount of inward leakage to occur from exhale valve leakage; in practice, unless the valve is faulty, this is negligible.

The Portacount fit test method was selected for this study. The equipment used was a Portacount model 8030. As testing was carried out inside an air conditioned laboratory it was necessary to increase the concentration of natural ambient particles by use of a small salt aerosol generator (Collision atomiser) operated at 1bar from the breathable quality laboratory air supply.

2.2 TEST SUBJECTS

To establish the number of test subjects required, sample size calculations were carried out using data from a similar study investigating the effect of facial hair on fit. These calculations were undertaken using Stata V12.1 and PASS 2008 software. The calculations predicted that up to fifteen different test subjects would be required to enable statistical confidence in the results.

The fifteen different volunteer test subjects (identified as V1 to V16, with V10 having to withdraw before undertaking any tests) were selected from males in the HSL PPE test pool of volunteers who volunteered for this study. These volunteers had been medically assessed as suitable to take part in PPE studies and, in line with ethics requirements, test subjects had their heart rate monitored whilst carrying out the fit test exercises as a precaution against over-exertion. Some of these test subjects have taken part in previous studies or had other experience of wearing facepieces; others were new to RPE facepieces. The age of the test subjects ranged between 29 and 57.

2.3 FACEPIECES

The part of the facepiece which is designed to make contact with the face (referred to hereafter as the faceseal) is likely to be an important factor in determining the effectiveness of the seal. Filtering facepieces faceseals can broadly be categorised into 3 types:

1. An additional smooth surfaced material, about 20-30mm wide, that has been applied to the edge of the filtering material
2. An additional material comprising of a knitted fabric covering a smooth material, again about 20-30mm wide, and applied to the edge of the filtering material
3. Primarily the edge of the filtering material forms the faceseal but there may also be a strip of smooth surfaced material inside the facepiece in the area of the bridge of the nose

Table 1 Identification of faceseal type with facepieces tested

Facepiece	Class	Faceseal Type	Faceseal Type description
F1	FFP3	1	An additional smooth surfaced material about 20-30mm wide that has been applied to the edge of the filtering material
F2	FFP3	1	An additional smooth surfaced material about 20-30mm wide that has been applied to the edge of the filtering material
F3	FFP3	1	An additional smooth surfaced material about 20-30mm wide that has been applied to the edge of the filtering material
F4	FFP3	2	An additional material comprising of a knitted fabric covering a smooth material, again about 20-30mm wide and applied to the edge of the filtering material
F5	FFP3	2	An additional material comprising of a knitted fabric covering a smooth material, again about 20-30mm wide and applied to the edge of the filtering material
F6	FFP3	3	Primarily the edge of the filtering material forms the faceseal but there may also be a strip of smooth surfaced material in the area of the bridge of the nose
F7	FFP3	3	Primarily the edge of the filtering material forms the faceseal but there may also be a strip of smooth surfaced material in the area of the bridge of the nose
F8	half mask	half mask	Continuation of smooth elastomeric material the edge of which folds inwards forming a (20mm) wide faceseal.
F9	half mask	half mask	Continuation of smooth elastomeric material the edge of which folds inwards forming a (20mm) wide faceseal.

FFP3 tend to have examples of each of the faceseal types discussed above, FFP2 and FFP1 (lower classes hence lower protection expected) tend to be more limited in faceseal type (predominantly type 3 above). Two models of FFP3, in common use in industry in the UK, were selected to represent each of the above three faceseal types (that is six models in total). Apart from the faceseal the selected facepieces represented a diverse range of design features:

- Cup shapes; horizontal fold flat; vertical fold flat
- Fixed length straps; adjustable straps

- Adjustable nose clip; fixed nose shaping

From these it was expected that at least one of each face seal type would fit each of our test subjects, when clean-shaven, so that all three face seal types could be assessed by testing on all test subjects. A few additional models were also available in case the two selected were both unsuitable for a test subject (in practice an extra facepiece of Type 1 face seal was needed for one test subject).

Additionally two types of commonly used elastomeric halfmask (reusable) were available for testing, and one of these was selected for each test subject. Typically half masks are constructed of smooth elastomeric material the edge of which folds inwards forming a (20-30mm) wide face seal.

Table 1 shows the various face seal categories of each of the facepieces used in this study. All of the FFP3 (and the half masks) have exhalation valves.

2.4 TEST PROTOCOL

2.4.1 Preliminary testing: individual test subject facepiece selection

Individual test subjects each attended a preliminary testing session. Following this session the facepieces to be worn by each test subject were selected, aiming for three different FFP3 (one of each face seal type) and one half mask for each test subject, a total of four facepieces. This session took place about 2 weeks before their testing week was planned to start and was designed to select the best facepieces for them by taking measurements using the Portacount in real-time mode. It was necessary for the facepiece models selected for each test subject to adequately fit when clean-shaven as the expectation was for the quality of the fit to deteriorate (the inward leakage to increase) as facial hair grew; therefore scope was needed to measure such a potential change. Choosing facepieces at random is likely to give a low probability of an acceptable fit¹⁰. For this session the test subjects were required to be clean-shaven. This session also gave opportunity for test subjects to:

- Understand the purpose of the testing
- Discuss the alternative options for the test programme
- Receive instruction on donning and practice donning the range of facepieces
- Practice the exercise protocol

2.4.2 Testing programme

Test subjects followed one of two testing programmes, shown below in Table 2 and Table 3. Test subjects shaved initially (time zero) on a Monday and fit tests began as soon as possible thereafter. One test was conducted using each model of the four selected for that test subject. Testing was not continuous but test subjects rested between tests. The same set of four fit tests was repeated after either eight hours (programme 1) or sixteen hours (programme 2). Tests were then repeated at 24 hours from shaving and approximately every 24 hours thereafter up to the Friday. A further set of fit tests were carried out the following Monday (7 days after last shaving). The exact time of each fit test was recorded, relative to time zero.

To try to reduce variability due to factors other than facial hair the following requirements were put in place:

- At each fit testing session the same four facepieces were fit tested in the same order
- Individual fit tests were carried out allowing rests in between of about 20 minutes

- Test subjects were instructed to be as consistent as possible in donning the same model facepiece, with positioning on face, nosepiece shaping, strap tension etc.
- Test subjects were instructed to be consistent in the way in which they carried out the test exercises

Experienced fit testers are aware that there is always some ‘natural variability’ in fit test results, which is not due to facial hair. Statisticians advise that as we are looking for changes in the quality of fit over time there is more value in conducting more test runs with different test subjects than in measuring this ‘natural variability’. Examples of causes of ‘natural variability’ may include: variation in the quality of the filtering material from one FFP to another⁹, the way in which the facepiece is donned, and the way the exercises are conducted.

Each fit test was carried out using a new FFP3. This was for reasons of hygiene as well as some of the FFP3 being certified as not reusable with the potential of wear on components affecting the results. (If the same facepiece was to be reused in the study, it would require repeatedly reusing the same facepiece for seven days.) Before use each facepiece was inspected for quality, as advised by manufacturers. Several significant faults were found with the FFP3 and these faulty facepieces were not used in this study. During one test run it was not possible to conduct a test on test subject V7 on day 4 due to a faulty batch of F7 facepieces, these being the only ones of that model available at the time.

Delays in completion of the overall test programme were due to the ill health of some test subjects postponing start dates but fortunately no test subject became ill once their testing had begun. One day of testing was cancelled due to heavy snowfall closing the laboratory which affected day 4 for test subject V9.

Table 2 Test Programme 1

Day	Time				
Programme 1	08:00-09:00	08:00-12:00	13.00-16.00	16.00-17.00	16.00-20.00
Monday	shave	4 fit tests			4 fit tests
Tuesday		4 fit tests			
Wednesday		4 fit tests			
Thursday		4 fit tests			
Friday		4 fit tests			
Saturday	No tests				
Sunday	No tests				
Monday		4 fit tests	shave		

Table 3 Test Programme 2

Day	Time				
Programme 2	08:00-09:00	08:00-12:00	13.00-16.00	16.00-17.00	16.00-20.00
Monday				shave	4 fit tests
Tuesday		4 fit tests			4 fit tests
Wednesday			4 fit tests		
Thursday			4 fit tests		
Friday			4 fit tests		
Saturday	No tests				
Sunday	No tests				
Monday			4 fit tests	shave	

2.4.3 Fit test protocol

Fit tests were conducted according to the protocol for the Portacount fit test method specified in the current HSE OC 282/28 guidance document on fit testing¹¹. The type of exercise used to elevate the breathing rate and heart rate was stepping using an aerobics step, also facepieces were prepared for testing as described in paragraph 55 of the guidance document, with a ball or disc probe applied.

This fit testing protocol is within the scope of the generic ethics committee approval for PPE studies, ETHCOM/REG/11.01, and these procedures were adhered to; under the terms of this approval, HSE ethics committee were advised of this study.

2.4.4 Assessment of stubble growth

Photographs of the test subject were taken each day before testing began as a visual record of stubble growth as well as photographs with and without RPE for each individual fit test at each test session.

At the end of the final test at seven days of stubble growth test subjects were asked to shave an area of their face using a single blade razor in order to collect the stubble on the blade. Photographs of the area of the face shaved were taken. The stubble was collected, washed and filtered and when dry measurements of stubble mass, length and width were taken using an Olympus Microscope and the 'analySIS FIVE' software by Olympus Soft Imaging Solutions.

3. RESULTS

3.1 PERCENTAGE INWARD LEAKAGE

The results of this study are presented as percentage inward leakage in Figures 1 to 24. These are graphs of the percentage inward leakage of ambient air particles inside the facepiece from time zero (shave time) to 7 days of stubble growth. Figures 1 to 9 show the results grouped together by facepiece and Figures 10 to 24 show the *same* results presented grouped together by test subject. In this way trends by either test subject or facepiece are easier to observe and cross-reference. Note that test subject V10 had to withdraw from the study before any tests were carried out, therefore the results show 15 test subjects but they are labelled up to V16. In all Figures the Y-axis is scaled 0-7% inward leakage so that a direct visual comparison can be made between them. The X-axis is 0-8 days although most test runs were completed by approximately 7 days.

These results are overall percentage inward leakage (averaged over all fit test exercises). The full results are given in Appendix A with the result for each individual exercise given in the Figures 37 to 96. Table 4 summarises the number of test runs conducted with each facepiece type.

Table 4 Number of test runs per facepiece

Facepiece	F1	F2	F3	F4	F5	F6	F7	F8	F9
Class	FFP3	FFP3	FFP3	FFP3	FFP3	FFP3	FFP3	half mask	half mask
Number of test runs	8	7	1	4	9	5	10	7	9

3.1.1 Figures 1 to 9 Inward leakage results presented by individual facepiece

Figure 1 Inward leakage results for Facepiece F1

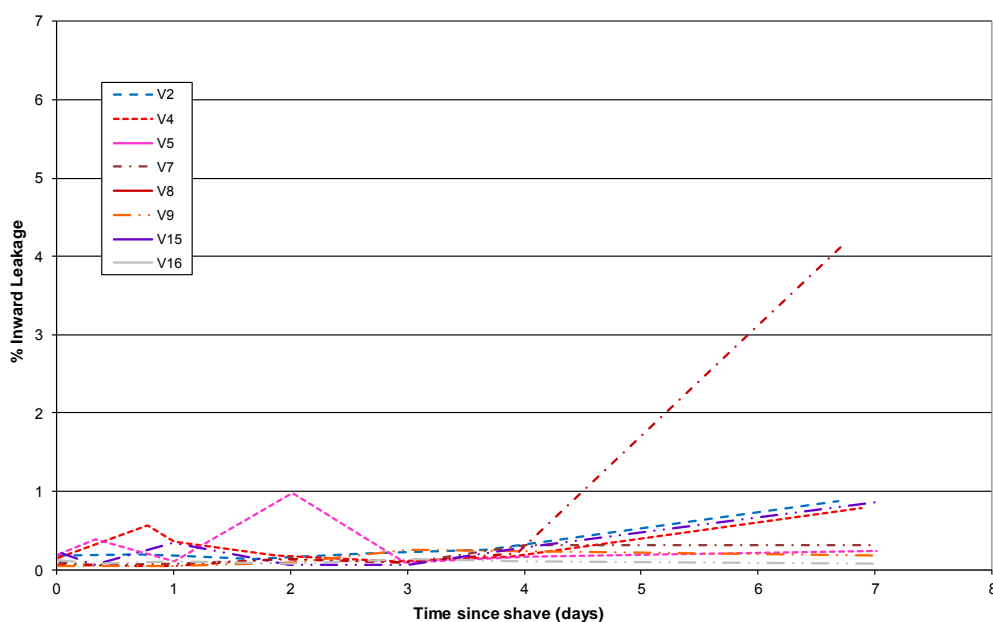


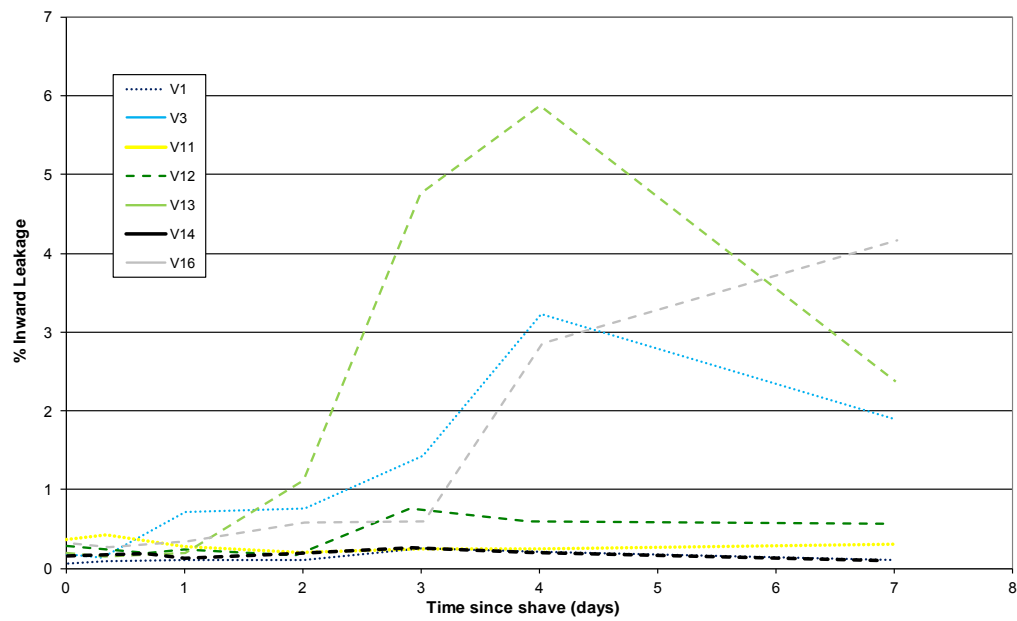
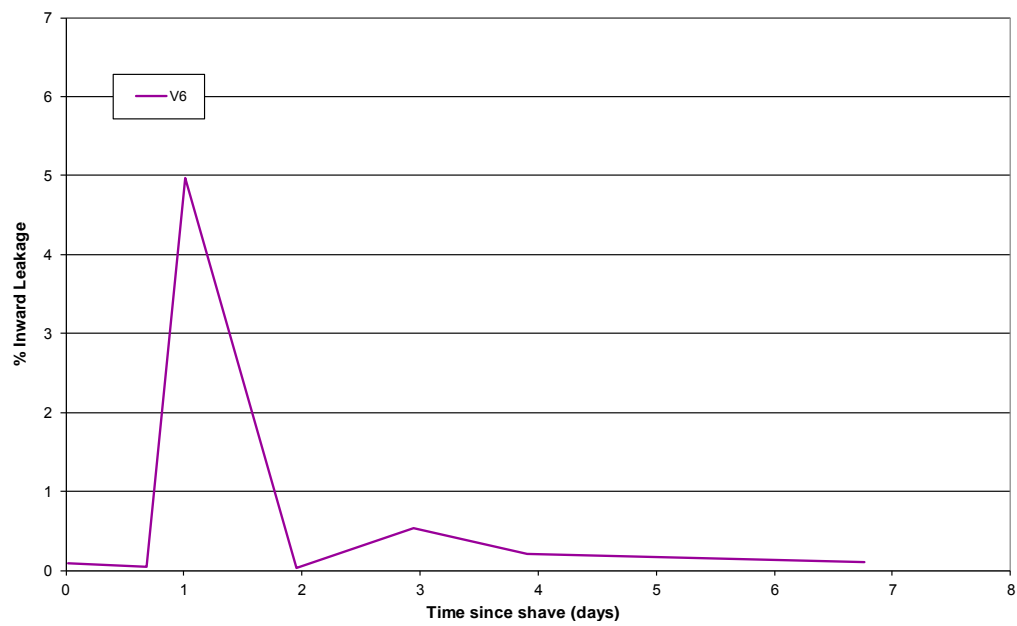
Figure 2 Inward leakage results for Facepiece F2**Figure 3 Inward leakage results for Facepiece F3**

Figure 4 Inward leakage results for Facepiece F4

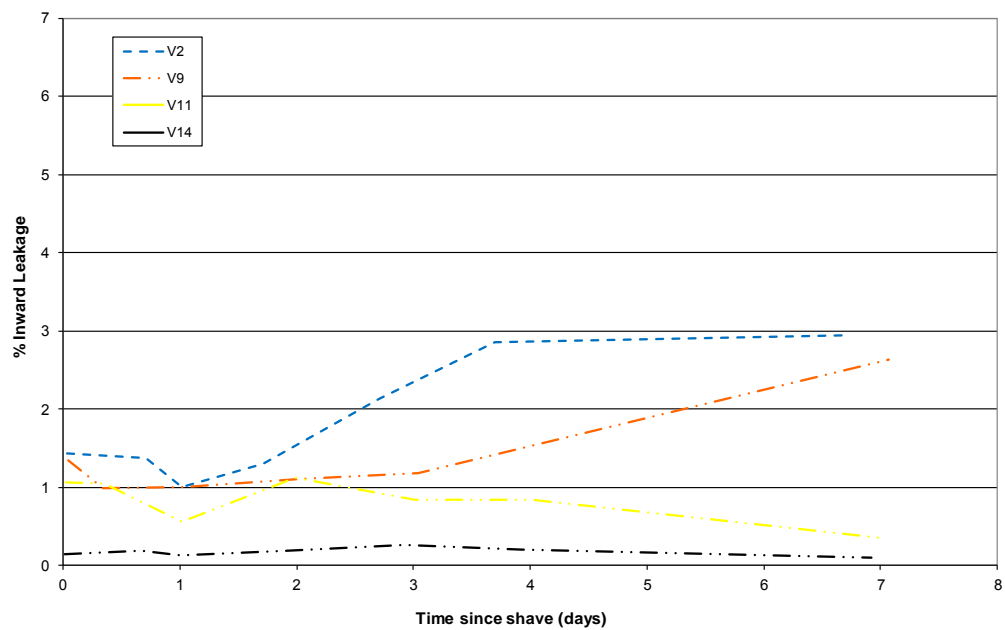


Figure 5 Inward leakage results for Facepiece F5

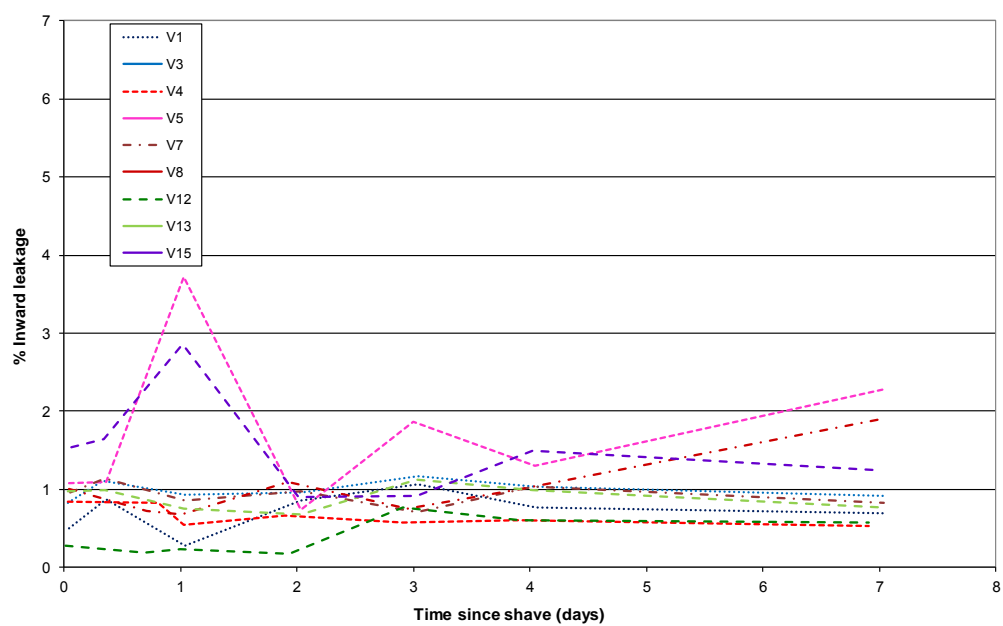


Figure 6 Inward leakage results for Facepiece F6

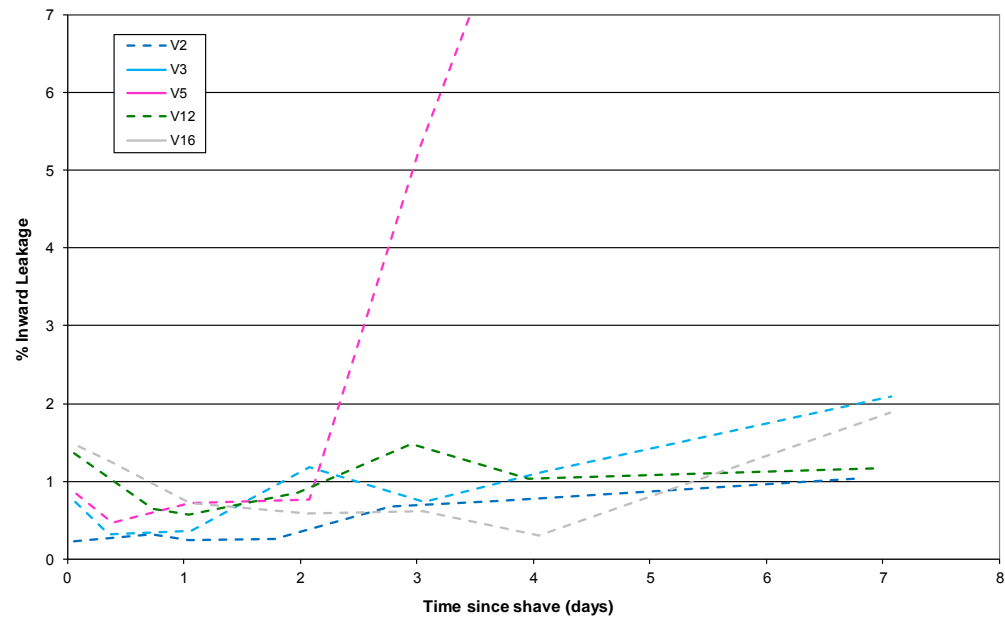


Figure 7 Inward leakage results for Facepiece F7

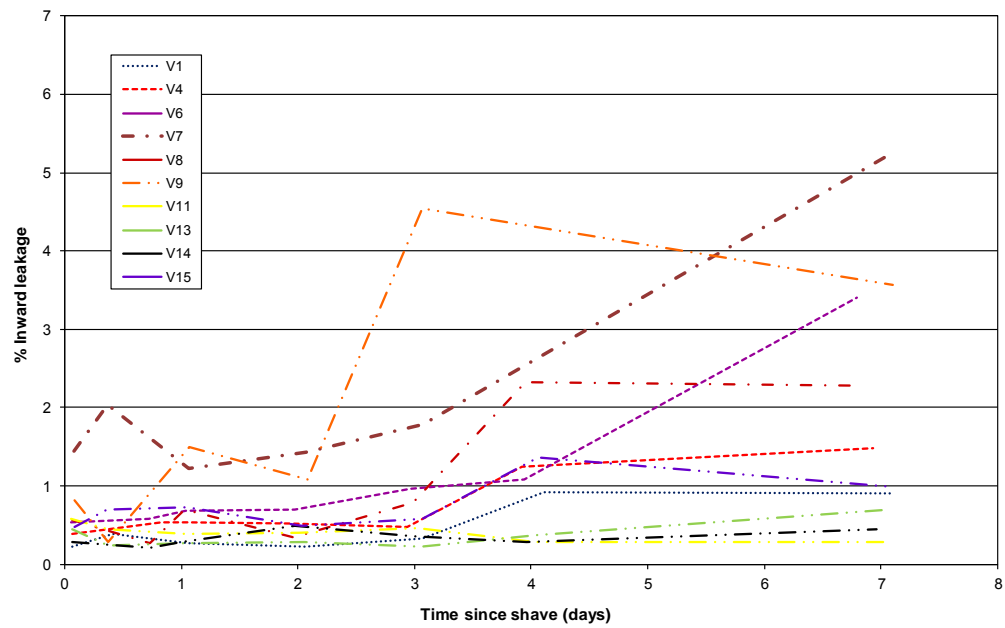
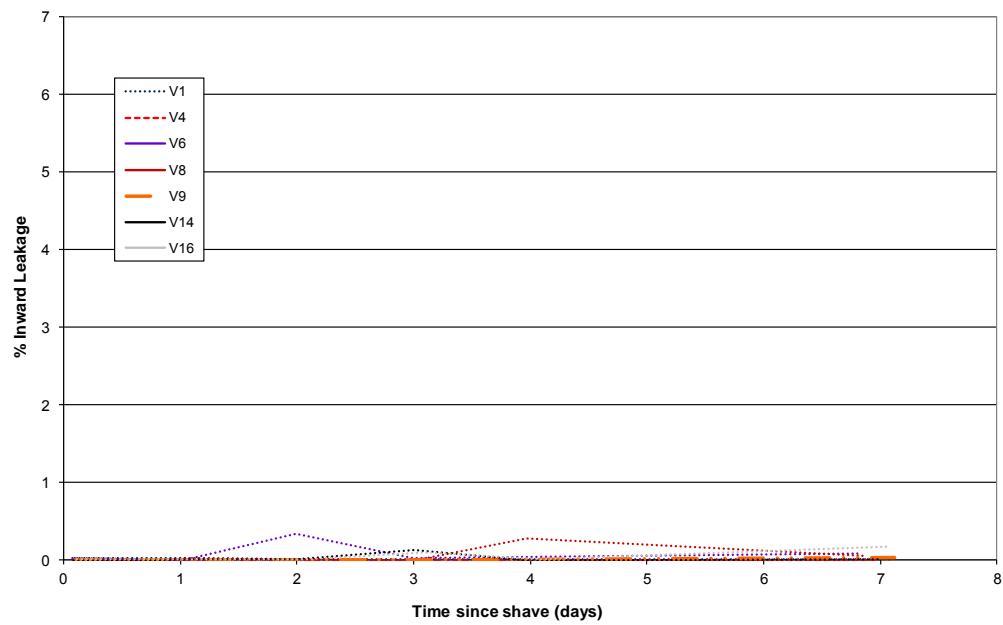
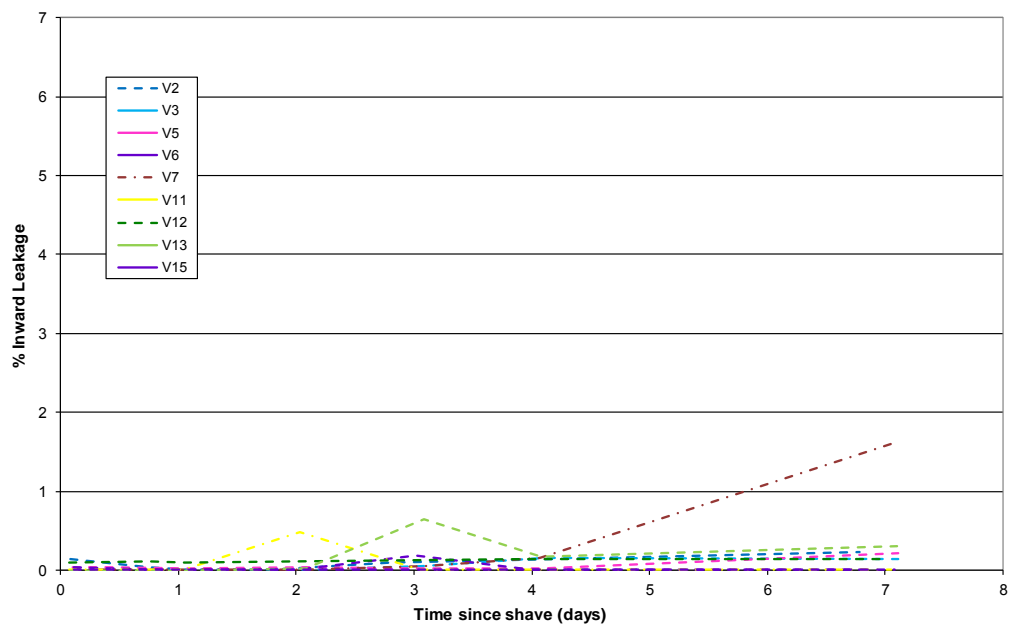


Figure 8 Inward leakage results for Facepiece F8**Figure 9 Inward leakage results for Facepiece F9**

3.1.2 Figures 10 to 24 Inward leakage results presented by individual test subject volunteer

Figure 10 Inward leakage results for test subject V1

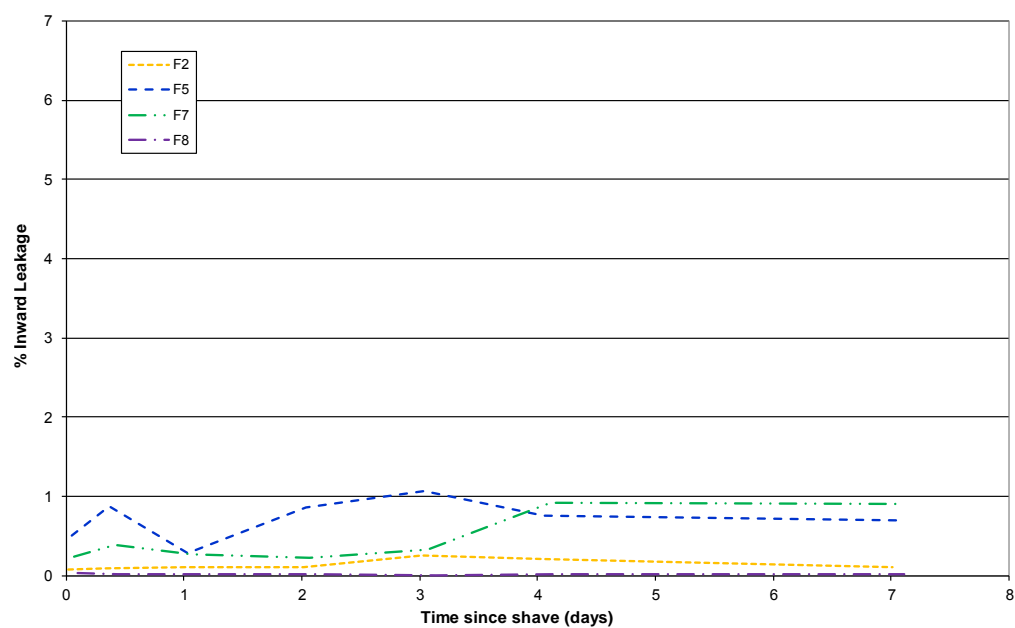


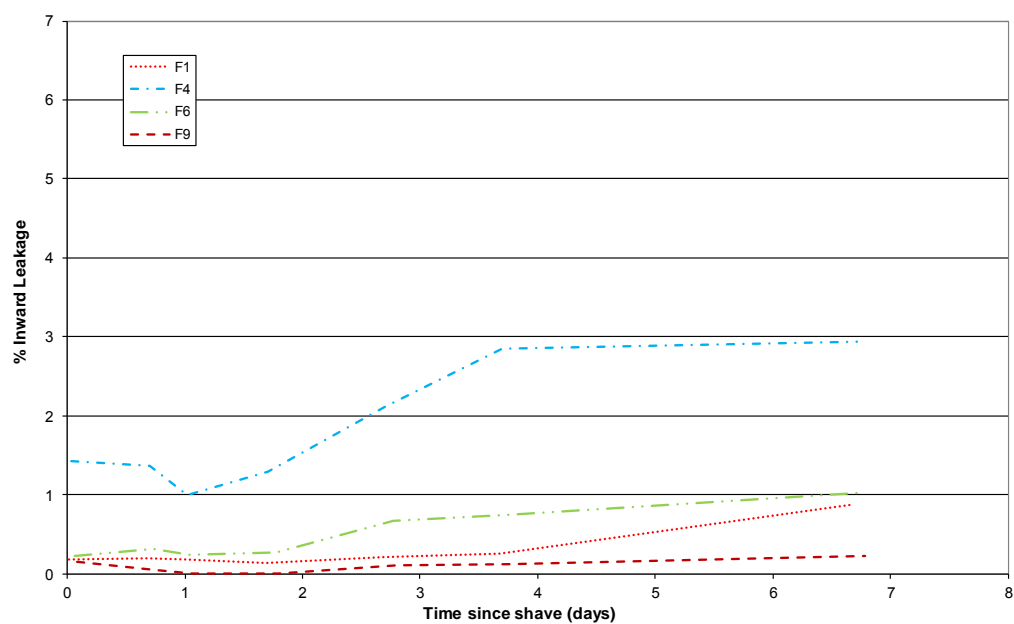
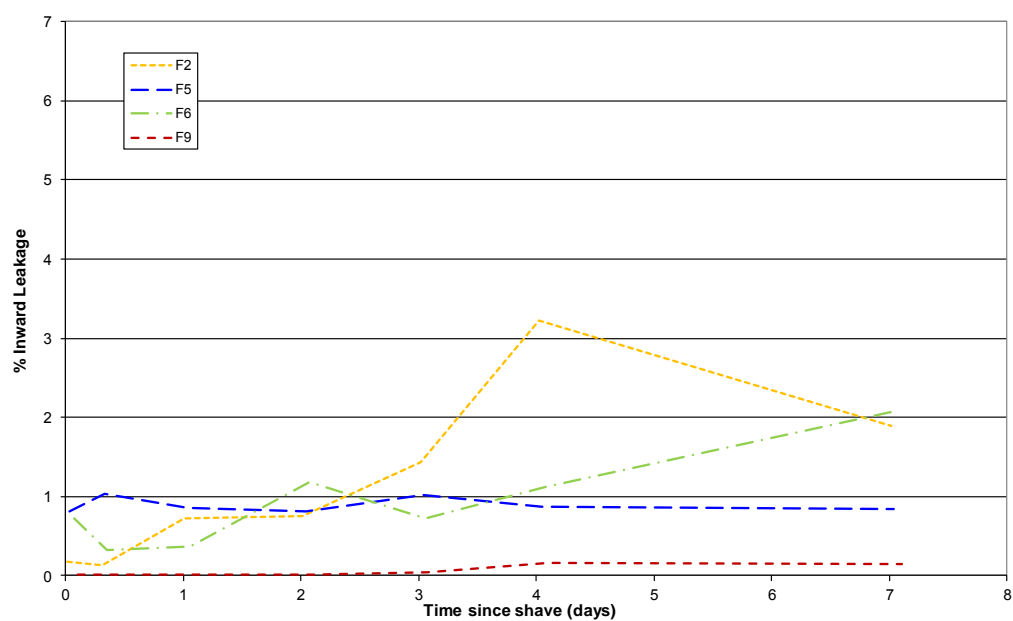
Figure 11 Inward leakage results for test subject V2**Figure 12 Inward leakage results for test subject V3**

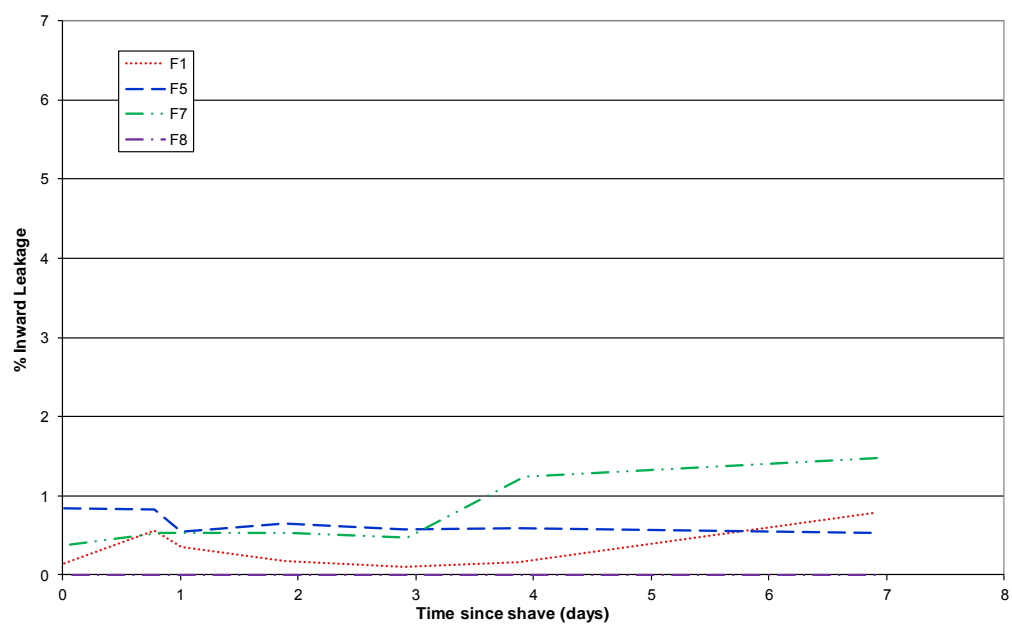
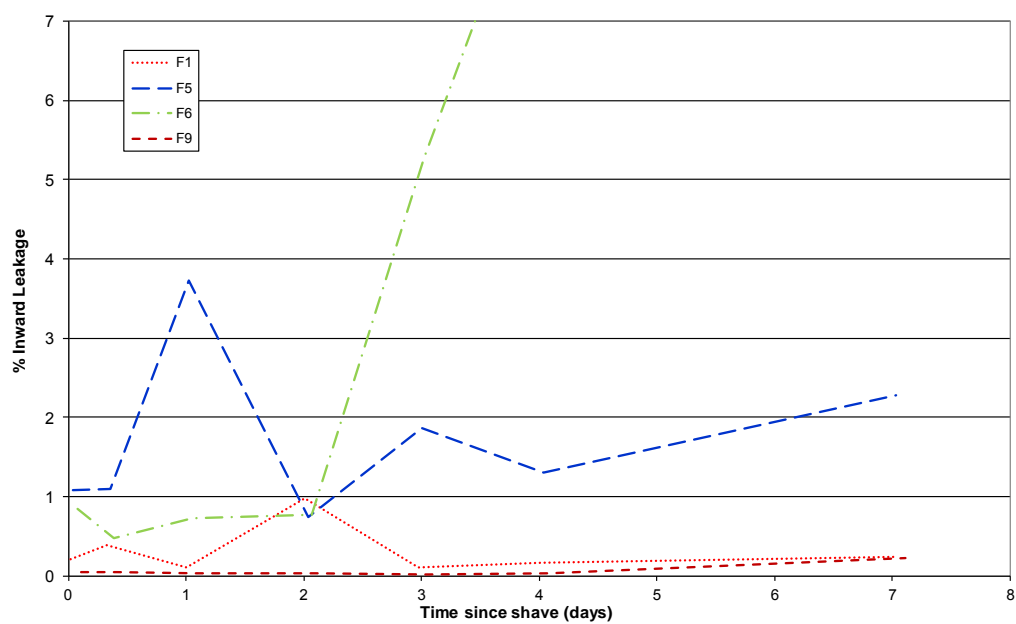
Figure 13 Inward leakage results for test subject V4**Figure 14 Inward leakage results for test subject V5**

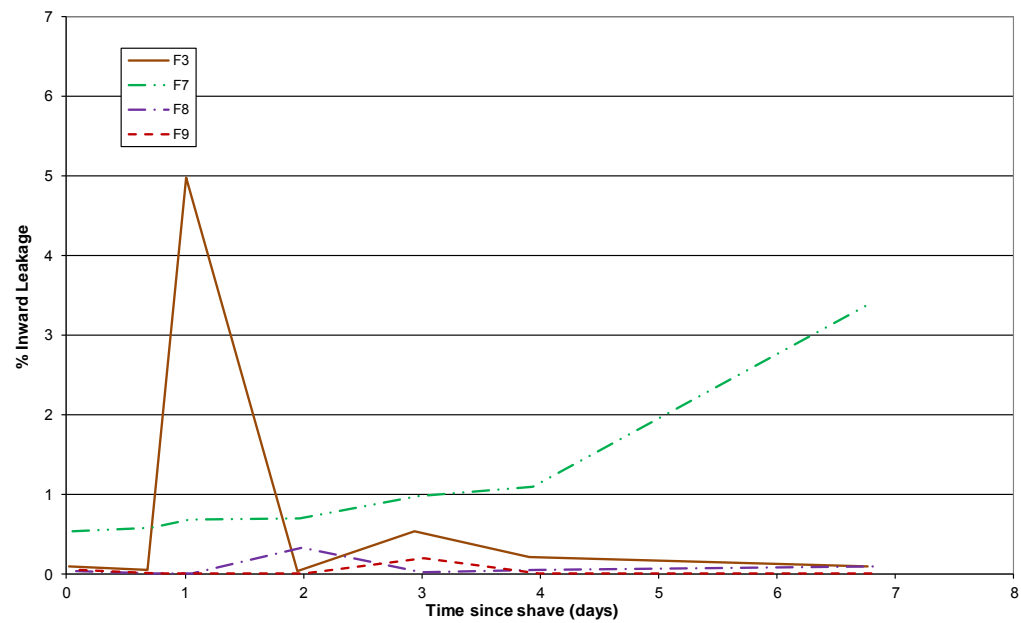
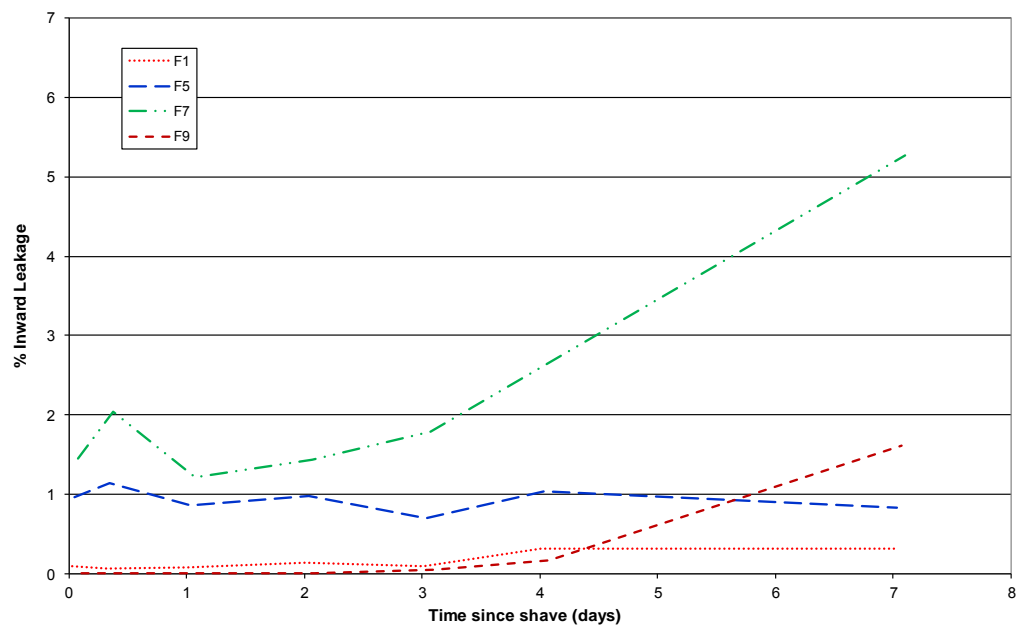
Figure 15 Inward leakage results for test subject V6**Figure 16 Inward leakage results for test subject V7**

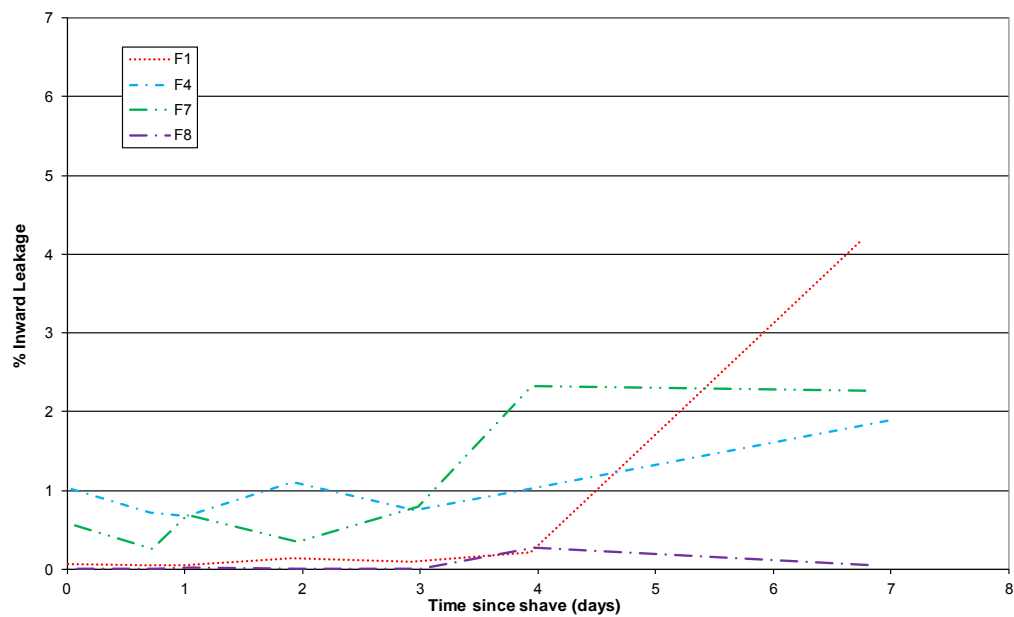
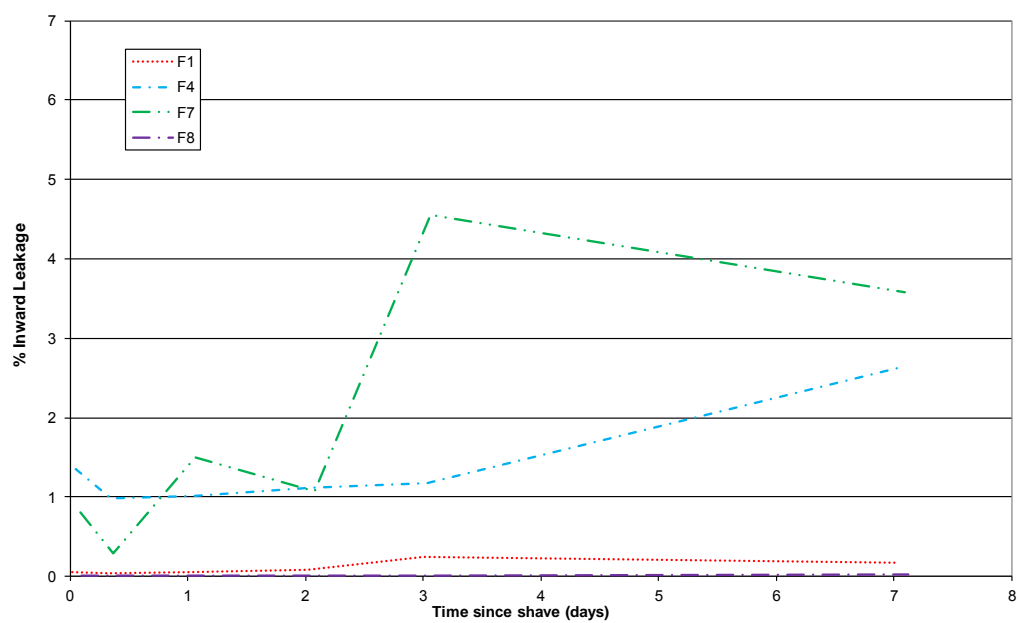
Figure 17 Inward leakage results for test subject V8**Figure 18 Inward leakage results for test subject V9**

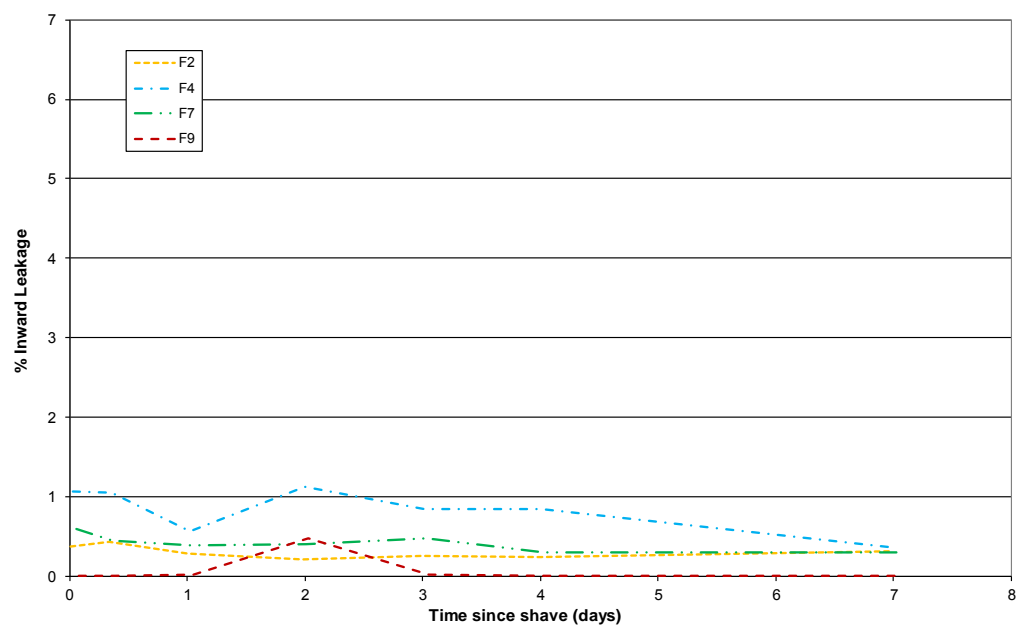
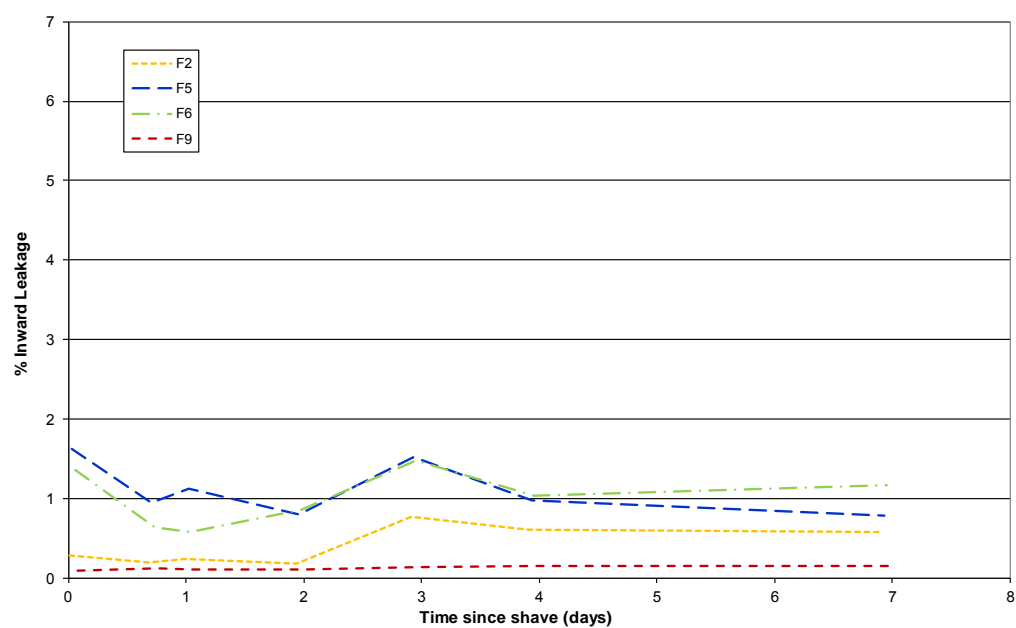
Figure 19 Inward leakage results for test subject V11**Figure 20 Inward leakage results for test subject V12**

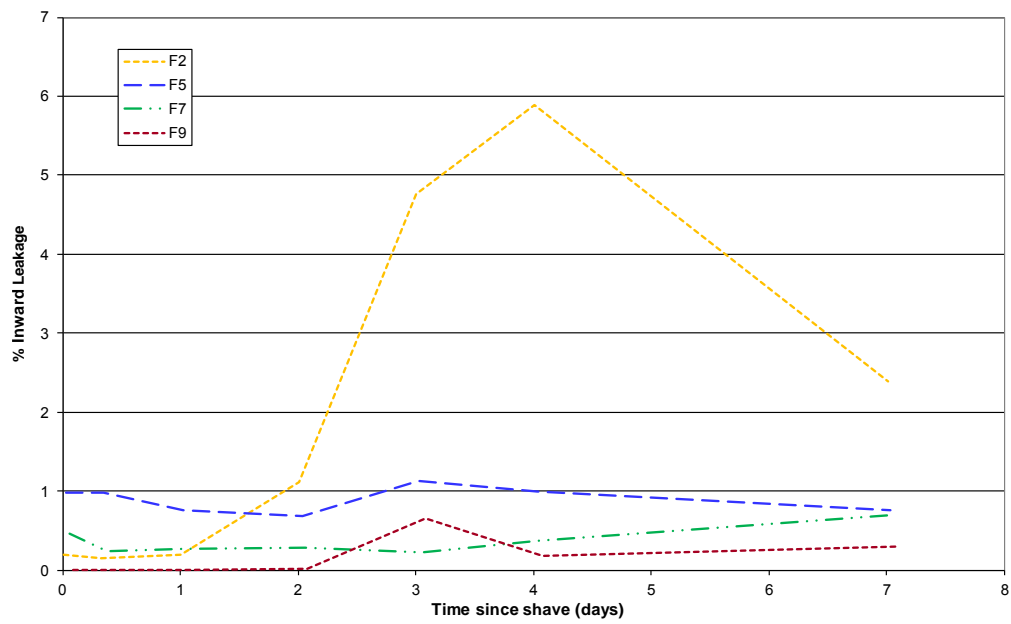
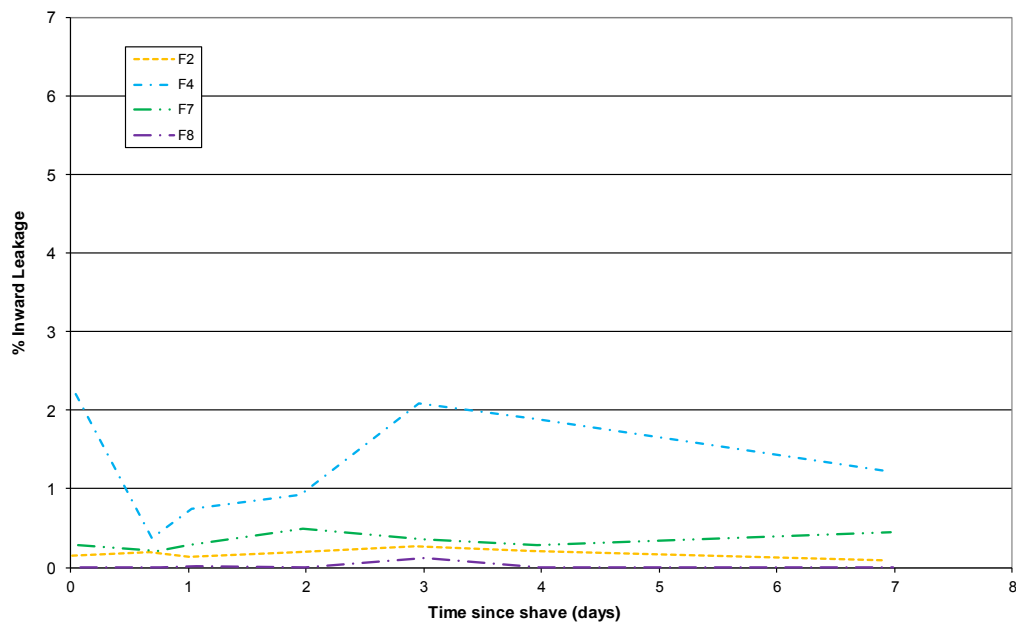
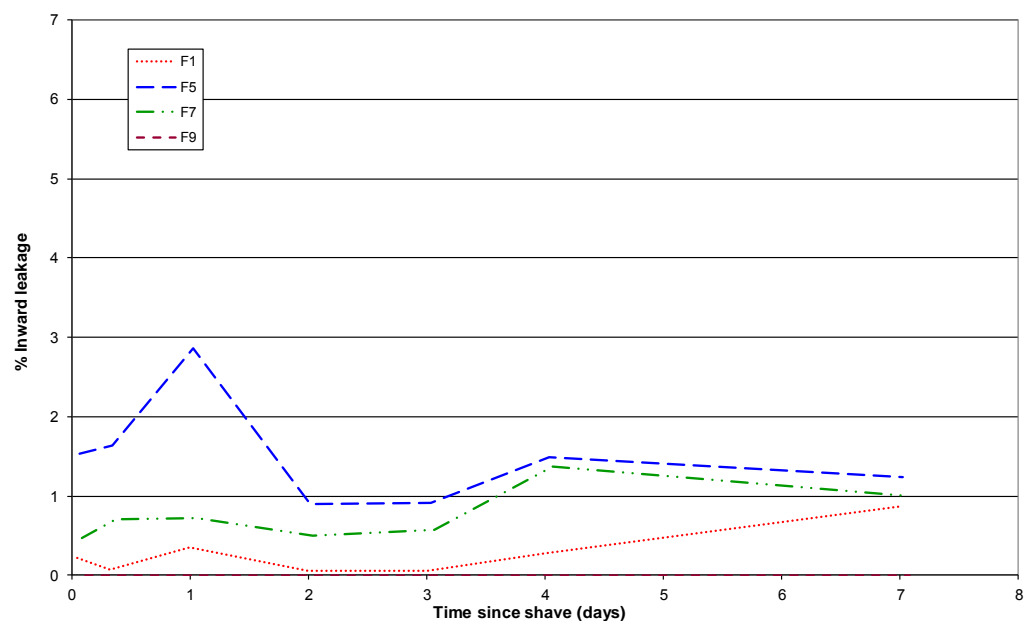
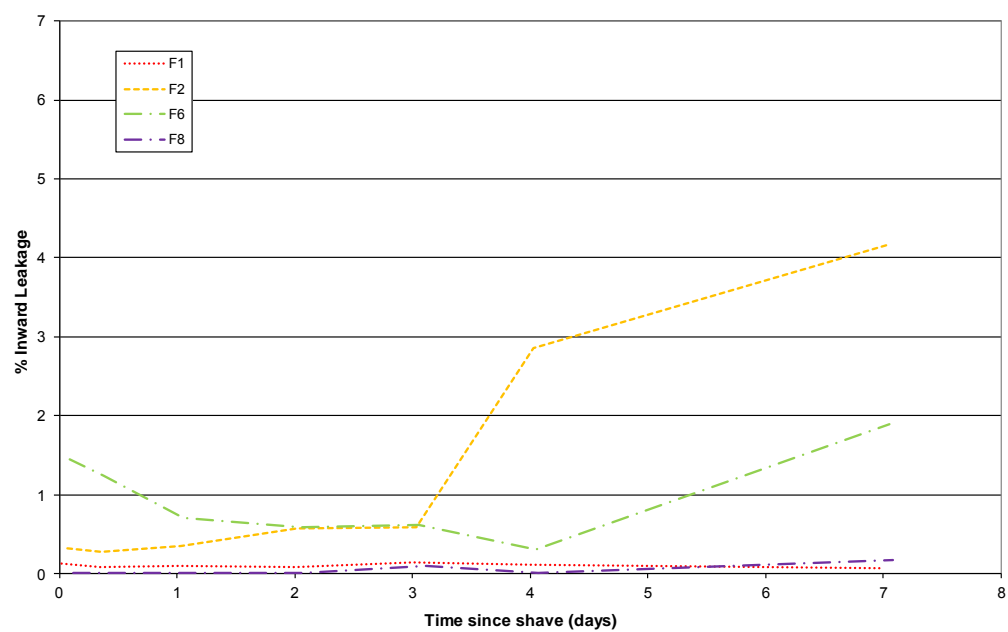
Figure 21 Inward leakage results for test subject V13**Figure 22 Inward leakage results for test subject V14**

Figure 23 Inward leakage results for test subject V15**Figure 24 Inward leakage results for test subject V16**

3.1.3 Percentage Inward Leakage Results by Individual Facepiece - discussion

Initial examination of the results by individual facepiece, (Figures 1 to 9) reveals that some of the facepieces show similar trends. These facepieces have been grouped together for discussion.

3.1.3.1 F2 and F7

Some of the graphs presented in Figures 1 to 9 show that for several test subjects percentage inward leakage has increased significantly by the end of 4 days. F2 and F7 (Figures 2 and 7) are both examples of this trend. With F2 the inward leakage is very low in the clean-shaven state (time zero) for all seven test subjects. For one test subject inward leakage has increased by 1 day of stubble growth and this continues to rise steeply and similarly with another three test subjects through 2 and 3 days to at least day 4, with inward leakage of around 3%, up to nearly 6%. Likewise with F7 for four test subjects there is a significant increase in inward leakage from day 3 which continues to rise with a total of seven test subjects showing increasing inward leakage by day 4. However, there were some test subjects whose stubble did not appear to increase inward leakage, with facepieces F2 or F7. Fit tests with V11 and V14 notably showed a stable level of inward leakage on all test days for both of these facepieces.

3.1.3.2 F1, F4, F6 and F9

For facepieces F1, F4, F6 and F9 there is a general steady increase in inward leakage over the course of the 7 days for about 50% of test subjects. However, with other test subjects, wearing the same facepiece model with stubble does not appear to be detrimental to protection, there being no notable change in inward leakage over the 7 days of testing.

F1 and F6 show mainly fairly consistent leakage results across most test subjects but each facepiece has a single example of where inward leakage dramatically increases. With F1 this is the final data point only which could indicate a donning or mask fault, (for example a faulty exhalation valve may be difficult to spot, but one was detected whilst preparing for another test with another example of F1, it was not used for testing). More significant is V5 with F6 where inward leakage increases substantially after day 2 and continues to rise to 25.6% at day 7. This degree of inward leakage is so much greater than any other examples that plotting all graphs to this scale would lose the detail.

3.1.3.3 F3 and F5

F3 and F5 both show that in the early stages (at day 1) for 3 test subjects (V5, V6, V15) there is a sharp rise in inward leakage which then falls back to clean-shaven level at day 2. This could indicate interference from stubble and therefore should not be dismissed but such data may be caused by a facepiece or donning fault, which is supported by the fact that inward leakage does not continue to rise but instead falls back to the previous test level. Later tests show continuing marked variations for these test subjects. Overall there is only one test subject, V8, where inward leakage increases steadily with stubble growth with F5.

3.1.4 Effect of Faceseal Type

Section 2.3 gives a summary description of the faceseal types included in this study, Table 1 identifies facepieces according to faceseal type.

3.1.4.1 Faceseal Type 1 smooth finish FFP3

F1, F2 and F3 all have a smooth surfaced faceseal. All of these facepieces show that a good level of protection is achieved with all of our test subjects in the clean-shaven state. However, there is a difference between these facepieces with the faceseal material with F1 being more flexible. This may be having some effect on the inward leakage as stubble grows with F1 being more accommodating of

stubble than the more rigid facesal material of F2 and F3. F2 especially shows significant inward leakage with stubble on some test subjects, whilst with other test subjects no effect was measured.

After testing on stubble on some test subjects, dimple indentations were visible on the facesal on both F2 and F3 models. An example of this is given in the photograph Figure 25, below which is Figure 26 a photograph of an unused facesal.

Figure 25 Photograph of facesal F3 after being worn by a test subject with stubble



Figure 26 Photograph of facesal F3 in unused condition



3.1.4.2 *Faceseal Type 2 knitted fabric FFP3*

F4 and F5 are the knitted fabric type of faceseal. An example of this type of faceseal is shown in the photograph, Figure 27. On a clean-shaven face the amount of inward leakage is generally higher than with Type 1 faceseal. As stubble grows some sustained increase in inward leakage occurs with V2, V8 and V9 but for the other 10 test subjects inward leakage remains similar to that in the clean-shaven state.

Figure 27 Photograph of an example of a Type 2 faceseal

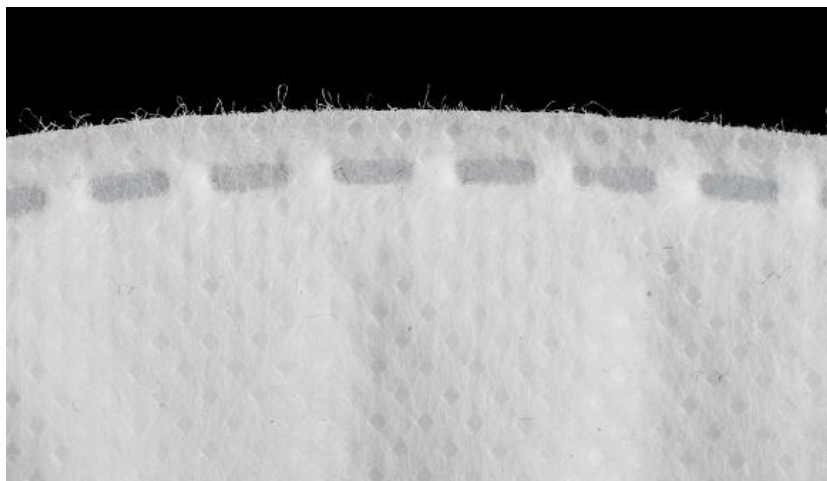


3.1.4.3 *Faceseal Type 3 edge of filtering material FFP3*

This type of faceseal occurs with F6 and F7. An example of this type of faceseal is shown in the photograph Figure 28. Whilst in the clean-shaven state the amount of inward leakage is low, there is a general increase with F7 with many test subjects beginning at day 2 and increasing more sharply from day 3 to significant levels, between two and five percent.

V5 does experience substantial and sustained increase in inward leakage with F6 after day 2, which reaches 25% by day 7, but for most test subjects the level of inward leakage, although variable, remains at a fairly constant level of about 1% over the 7 days.

Figure 28 Photograph of an example of a Type 3 faceseal



3.1.4.4 *Faceseal Type elastomeric half mask*

F8 and F9 are both half masks with elastomeric type seals. When clean-shaven all test subjects measured very low levels of inward leakage with these types of half mask. F9 shows gradually increasing inward leakage over 7 days with most test subjects with a couple of peaks with V11 and V13, and a significant rise in inward leakage at day 7 with V7.

3.1.5 Results by Test Subject

Presentation of the results by test subject (Figures 10-24) shows the results from face pieces worn by each individual. Presentation in this way allows the performance of each mask to be easily compared and it enables trends to be identified and cross-referenced.

As already mentioned with some test subjects stubble growth did not have a measurable effect on inward leakage for the facepieces tested. V11 and V14 are examples of this, with V1 showing a similar effect with all but one facepiece F7.

However, the situation is less straightforward with some of the other test subjects. After 24 hours V13's stubble is demonstrating a substantial effect on inward leakage with F2 and there is also a peak with F9 at day 3, however there is little effect on F7. This is puzzling as with other test subjects F7 shows significantly increased inward leakage with the same time period of stubble growth. As mentioned in the above section, V5 also shows very high inward leakage, but with one facepiece only, F6, an effect not repeated with other test subjects.

It is difficult to see any trends occurring by test subject. The limited number of facepieces tested (4) will have some influence and if all test subjects had been tested with all facepiece types this would have increased the likelihood of identifying test subject trends, if they exist. The overall picture from observation of the graphs is that the effect of stubble on the percentage inward leakage is unpredictable and specific to a particular facepiece wearer combination.

3.1.5.1 *Individual test exercise results*

The results given in the main body of the report are overall percentage inward leakage results averaged over all test exercises. Appendix A gives details of individual exercise test results. These give a fuller picture of the exercises which are most affected by stubble. For many of the tests the exercise which resulted in the greatest inward leakage was the talking. This is typical of fit test results generally, and is partly due to wearer generated particles being falsely counted as inward leakage by the Portacount⁷. Although the extent of wearer generated particles varies between individuals, for each individual it will be constant and therefore should not impact on the results of this work, further discussion is in section 2.1. Figure 29, F7 V11, demonstrates this effect with talking consistently resulting in higher measured inward leakage than any other exercise.

The exercises which measured the greatest inward leakage due to stubble were more likely to involve head movements or bending. Facepiece F6 with test subject V2 (Figure 30) is an example of where inward leakage is very much increased on the "head up and down" and "head side to side" exercises from day 3 onwards, reaching more than 2% on day 7 with head up and down. Another example is F8 with V8 (Figure 31) where the overall performance is good but at both day 4 and day 7 during the "head up and down" exercise the inward leakage is notably high being nearly 2% at day 4.

Figure 29 Facepiece F7 test subject V5 inward leakage results by fit test exercise

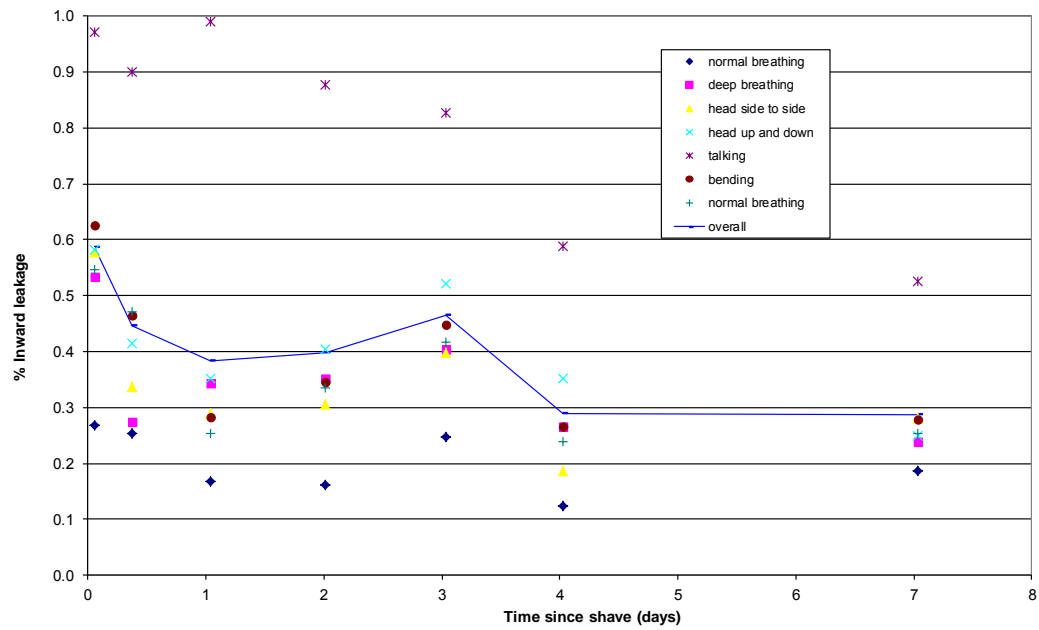


Figure 30 Facepiece F6 test subject V2 inward leakage results by fit test exercise

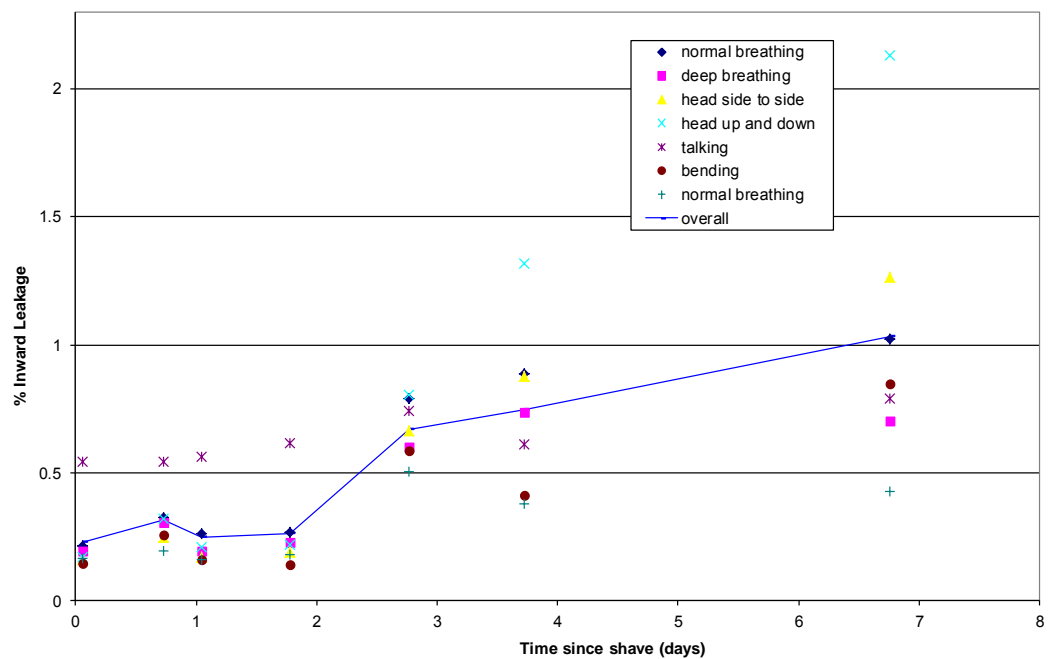
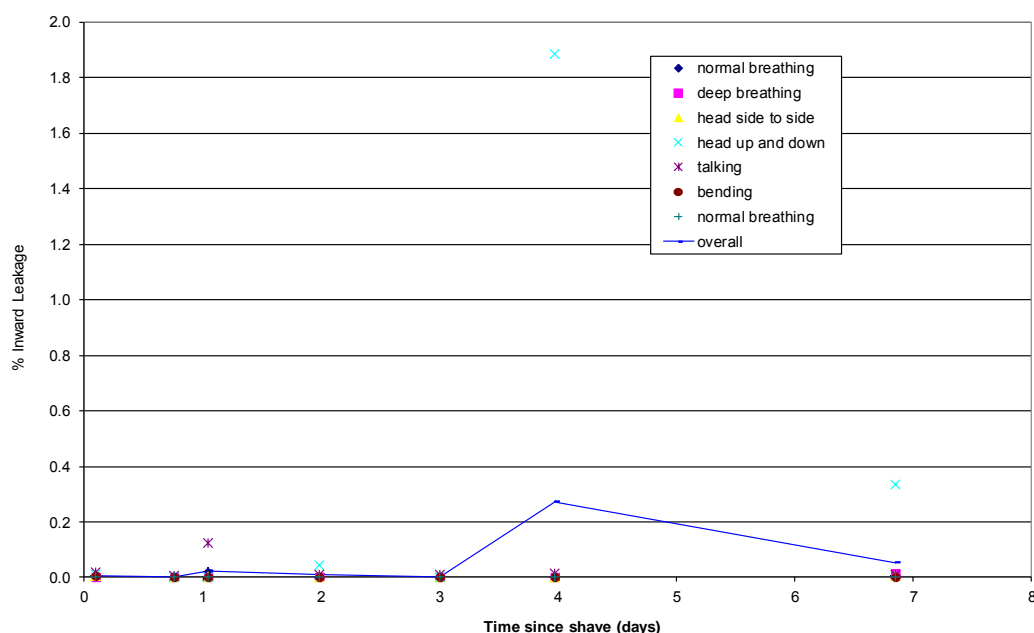


Figure 31 Facepiece F8 test subject V8 inward leakage results by fit test exercise

3.1.6 Statistical Analysis of Inward leakage results

The following summary is drawn from the full statistician's report which is given in Appendix E. The purpose of the statistical analysis was to investigate whether growth of stubble during the 7-day trial period affected the percentage inward leakage of the facepieces. The analysis also provided information on the main sources of variability.

Inward leakage for each facepiece tested was measured on each volunteer on up to eight occasions. These repeated measures were analysed using the standard multilevel change curve (or growth curve) model approach. This type of regression analysis takes into account the design of the study, models the shape of the trajectory for each volunteer over time, and also models how these trajectories vary over time.

The dependent variable in the analysis was percentage inward leakage, while the independent (or predictor) variables included in the model were facepiece type, time elapsed since shaving, and the interaction between facepiece and time elapsed. Facepiece was included in the model as a fixed effect since their effects were of interest, and time elapsed was included as a random effect. Including time as a random effect enabled the model to take into account individual differences in inward leakage and to estimate the variability. Quadratic and cubic effects of time elapsed were tested in the model to investigate whether the percentage inward leakage trajectories were non-linear.

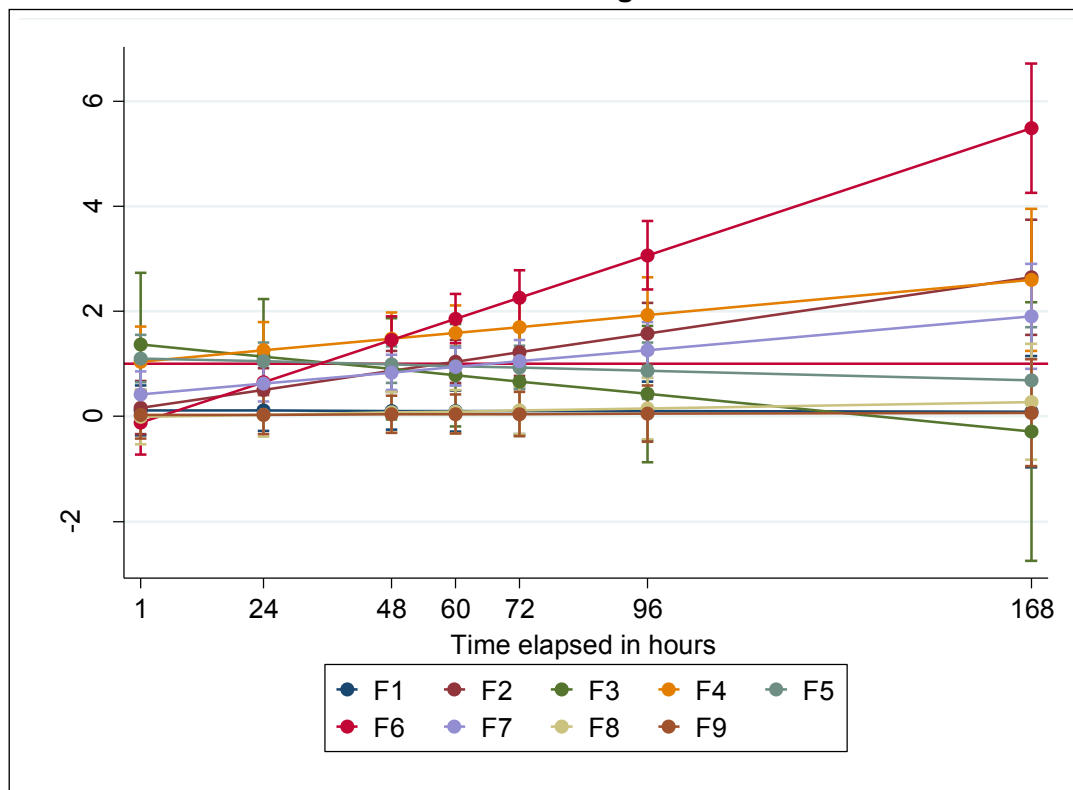
The intra-class correlation coefficient in the empty model was 3.3%, indicating that the variability in percentage inward leakage between volunteers (3.3%) was relatively small compared to the variability in percentage inward leakage within volunteers (96.7%). In the final model, which included terms for facepiece, time elapsed and the interaction between facepiece and time elapsed, the conditional intra-class correlation coefficient was 1.5%. This shows that much of the between-volunteer variability was accounted for by the model.

The terms included in the model were all statistically highly significant ($p < .001$). There was no evidence of non-linearity in the percentage inward leakage trajectories over time, so the model

assumed a linear change in percentage inward leakage over time. The percentage inward leakage for each facepiece over time predicted by the model is given in Figure 32. This shows that there were differences between facepieces overall, and that these differences between facepieces were affected by time since shaving. The percentage inward leakage increased more rapidly over time with F6 than the other facepieces. The predicted inward leakage for F8 was very low, even by day 7, and F8 was the only facepiece with all the observed values of percentage inward leakage below 1%. However, because of the large variability within volunteers, the 95% confidence intervals for predicted values were wide and for every facepiece tested, the upper bound of the 95% confidence interval exceeded 1% by day 7. The 95% confidence interval signifies that there is 95% confidence that the true value of inward leakage is within the range of values represented by the confidence interval. Consequently, the results suggest that by the seventh day, the predicted inward leakage for all facepieces tested could exceed 1%.

The statistical model enabled the calculation of the intra-class correlation coefficient (ICC), which denotes how much of the total variability in the percentage inward leakage occurs between individuals, and how much occurs within individuals. The ICC in the empty model was 3.3%, indicating that the variability in percentage inward leakage between volunteers (3.3%) was relatively small compared to the variability in percentage inward leakage within volunteers (96.7%). In the final model, which included terms for facepiece, time elapsed and the interaction between facepiece and time elapsed, the conditional intra-class correlation coefficient was 1.5%. This shows that much of the between-volunteer variability was accounted for by the terms in this model.

Figure 32 Predicted percentage inward leakage by facepiece over time elapsed since shaving



The statistical analysis showed that there were differences between masks, with some masks performing better than others. In addition, these differences between masks changed over time. However the within individual variability in percentage inward leakage was not well explained by the model, resulting in wide confidence intervals around the predicted values. If the characteristics of an individual's stubble growth were included in the analysis, they may help to explain the within individual variability and so determine which facepieces are more appropriate for an individual to use. However, it is not practical to be prescriptive about an individual's characteristics in this way when recommending facepieces, which are intended for general use. Consequently the statistical analysis indicates that by day 7, the percentage inward leakage may reach an unacceptable level in some individuals with any of the facepieces tested. For some of the facepieces tested this happened sooner, with the percentage inward leakage increasing from the first day after shaving.

3.1.7 Photographs

Appendix B contains photographs of our test subjects at the day 2 stage of stubble growth and Appendix C shows test subjects at day 7 of stubble growth.

3.1.8 Stubble measurements

As described in the methodology, test subjects were asked to shave sample areas for assessment of amount, length and width. This proved quite difficult for some individuals, particularly those not used to wet shaving and/or using a single blade razor. Whilst some test subjects managed to cleanly shave an area of their face, for others this shave cut only some of the stubble and/or cut the stubble short. For this reason the results of the measurements did not provide any meaningful data.

The results of the measurements taken are given in a Table in Appendix D.

3.2 SUMMARY DISCUSSION OF RESULTS

Tests have been carried out on a relatively small number of facepieces (9) and using a relatively small number of test subjects (15) each testing only 4 facepieces. With this limited number of tests, potentially trends may be discernible if results are similar, however where there is a wide variation in results more tests would need to be carried out in order to gain a fuller picture of the effect of stubble on the inward leakage of facepieces worn by the general population.

Trends of increasing inward leakage as stubble grows have been noted with some facepieces which affected a significant proportion (50%) of our test subjects who were tested with these facepieces. With other facepieces significant increased inward leakage occurred with only one of our test subjects, and likewise for some individual test subjects inward leakage increased with only one facepiece, which was surprising as with other test subjects' stubble inward leakage did increase with that same facepiece. What we have is a snap-shot of effects which suggest that some individuals may be able to use some facepieces with stubble growth having little effect on the protection they receive whilst another facepiece will show a substantial loss in protection with that same wearer and stubble growth. Whilst individual facepieces differ in their response to stubble, in the limited number of tests carried out there is no trend related to faceseal type.

There was an increased effect of stubble on certain test exercises, specifically those involving head movements. This may indicate that where this type of movement is a consequent requirement of the work activity there may be more risk to the worker than is apparent from the overall results.

The example photographs given in Figures 33 and 34 give a visual representation of the amount of stubble which has resulted in significantly increased inward leakage by 2 days (V3 and V13) in these

tests. In other words this amount of stubble is compromising the fit with some test subjects of at least one of the FFP3 tested. Also given are Figures 35 and 36 which show stubble which has demonstrated little effect on inward leakage, even at 7 days growth. This suggests that visual assessment of the amount of stubble is not necessarily a guide to the effect that stubble has on the face fit. In some cases, what appears to be a small amount of stubble growth may lead to a significant increase in inward leakage and conversely more visible stubble growth may result in little effect on inward leakage. (Appendix B gives a full set of photographs of day 2 stubble growth for every test subject and Appendix C gives a full set of photographs of day 7 stubble growth, again for all test subjects.)

This study looked at the effect of the early stages of stubble growth (up to 7 days) on the protection afforded by the facepieces. The half masks used in this study show a better performance than the FFP3, but in other studies^{3,4,5,6} elastomeric type facepieces(half masks and full facemasks) show that they can be significantly affected by more substantial facial hair growth. This would suggest that FFP may well perform very poorly against longer term facial hair growth.

FFP1 and FFP2 are lower classes of filtering facepiece which are less efficient at filtering hazardous substances. They are designed to be used where a lower level of protection is needed but are easier for users to wear as breathing resistance is lower. They are of similar construction to FFP3 and have similar face seals although they are most commonly of Type 3 (edge of filtering material). Therefore the results from Type 3 tests are likely to be equally applicable to FFP1 and FFP2.

Figure 33 Test Subject V3: 2 days stubble growth



Figure 34 Test Subject V13: 2 days stubble growth



Figure 35 Test Subject V1: 7 days stubble growth



Figure 36 Test Subject V12: 7 days stubble growth



4. CONCLUSIONS

This testing indicates that with the selected filtering facepieces and half masks, the protection given to the wearer may be reduced where stubble is present. This effect may begin within 24 hours from shaving, and increases as stubble grows up to at least seven days. This suggests that there is a potential for some loss of protection generally with similar facepieces, which includes a wide range of facepiece types, affecting at least some wearers. The statistical analysis showed that by the seventh day, the predicted inward leakage may reach an unacceptable level (greater than 1%) for all of the facepieces tested. For some facepieces this occurred sooner.

The loss of protection with stubble can be quite specific to the facepiece and test subject combination and such occurrences can lead to high amounts of inward leakage. Although it may be possible for individual wearers to grow some stubble without loss of protection, for some masks, it would not be practical to conduct the necessary testing on each individual wearer/mask combination in order to confirm this. Neither is it possible to predict whether a given individual and mask combination is likely to be relatively insensitive to stubble growth.

Work activities may have a further influence on protection. Specifically where there is a frequent need to move and hold the head position at extremes, for example in some types of construction work, this may compromise the protection to a greater extent than more sedentary work.

The statement in the European Standard EN 529 (annex D.4.2) which advises that tightfitting facepieces should not be selected where there is unshaven hair would seem a reasonable guide. The definition of unshaven given is “In this context unshaven means hair which has not been shaved within the previous 8 hour period prior to the work shift” and this would seem appropriate.

5. REFERENCES

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6. APPENDICES

6.1 APPENDIX A: DETAILED GRAPHS

Detailed graphs showing inward leakage by individual test exercise. These are grouped by facepiece as trends are more apparent within facepiece type.

Points to note:

- The Y-axis is scaled to just accommodate the data from the tests presented in each Figure and therefore varies from one Figure to another. This is in order to maximise the detail.
- For test subjects V1 and V2 an additional final fit test was carried out after shaving which is shown in this detailed data. It is not shown in the Figures in the main report results in order not to confuse

Figure 37 Facepiece F1 test subject V2 inward leakage results by fit test exercise

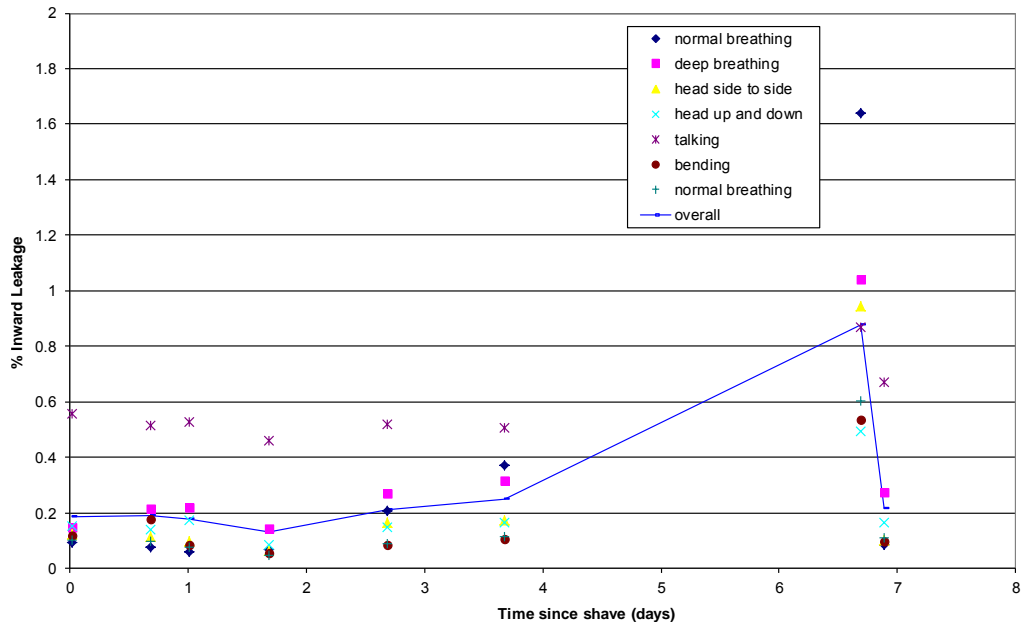


Figure 38 Facepiece F1 test subject V4 inward leakage results by fit test exercise

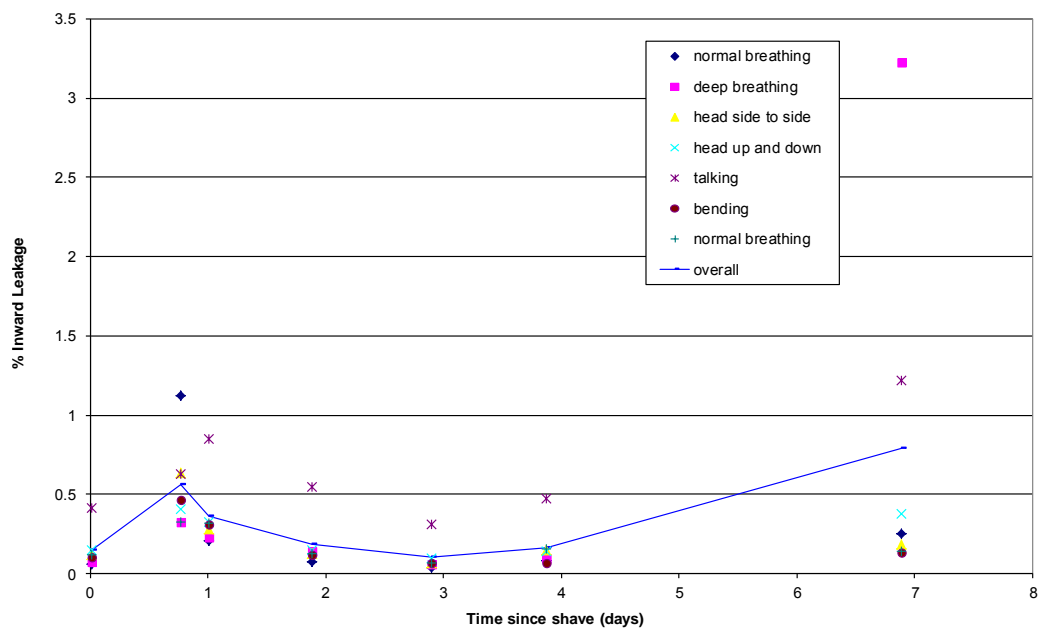


Figure 39 Facepiece F1 test subject V5 inward leakage results by fit test exercise

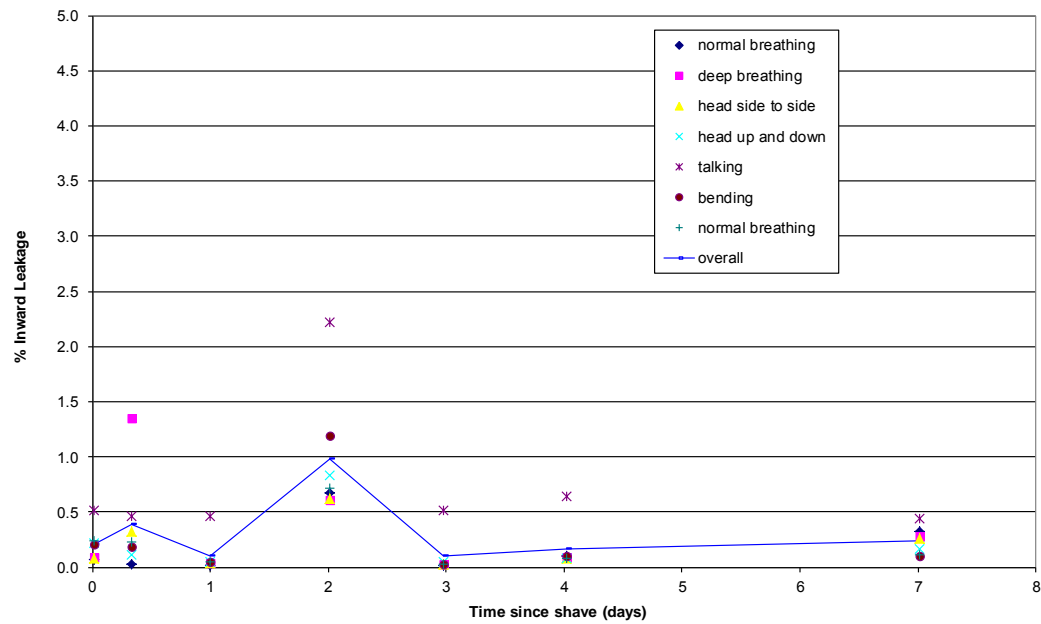


Figure 40 Facepiece F1 test subject V7 inward leakage results by fit test exercise

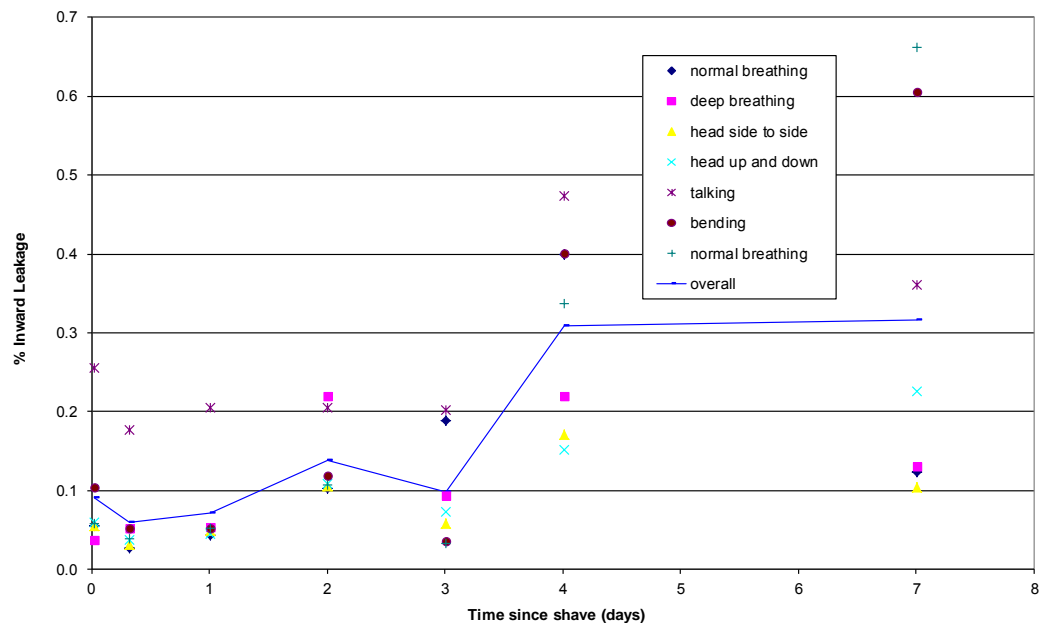


Figure 41 Facepiece F1 test subject V8 inward leakage results by fit test exercise

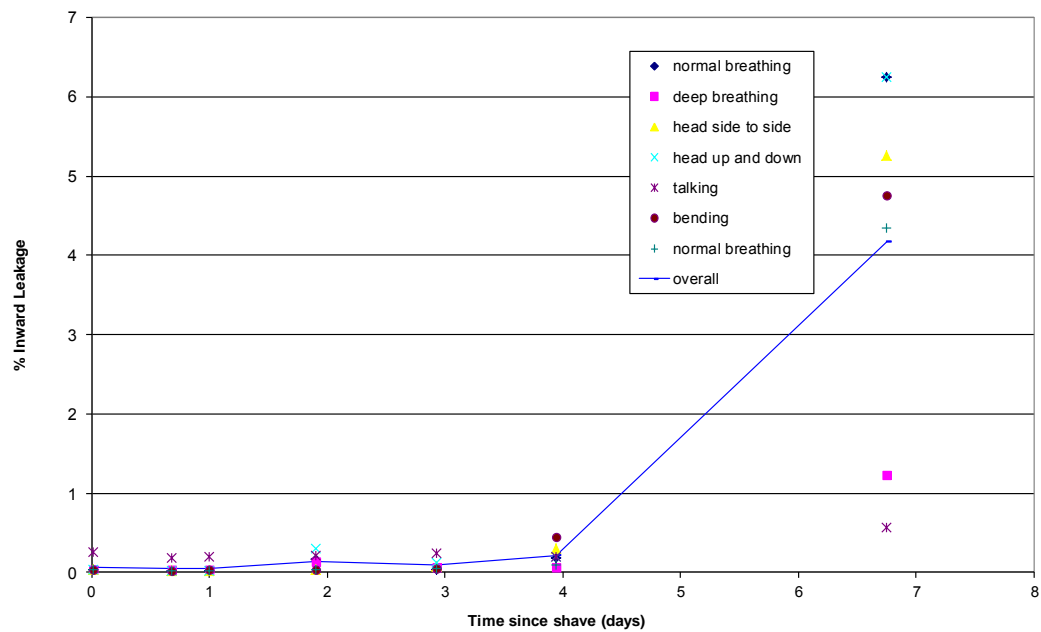


Figure 42 Facepiece F1 test subject V9 inward leakage results by fit test exercise

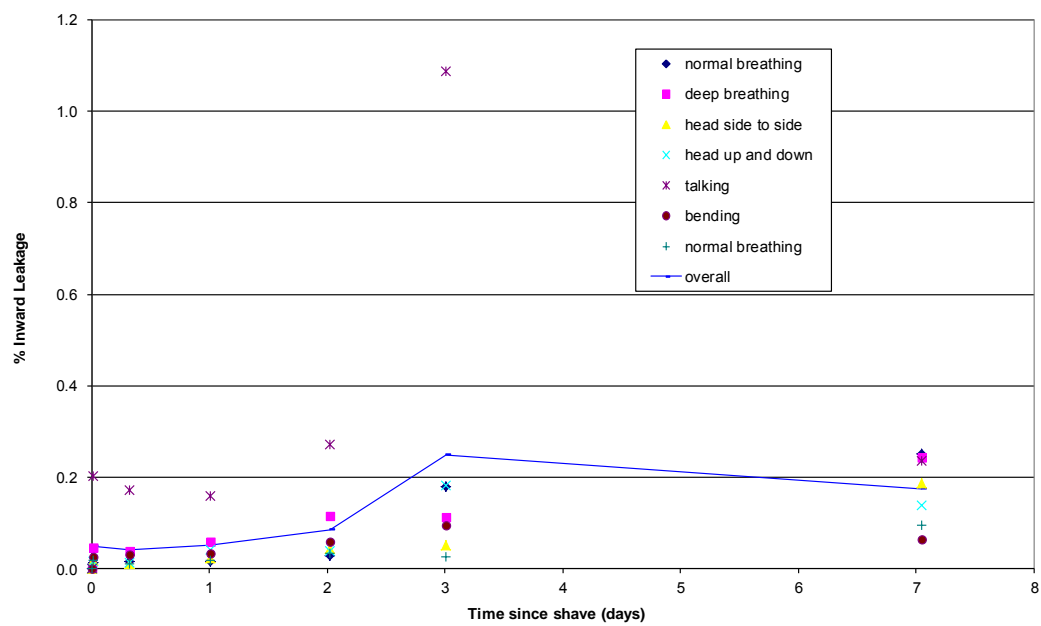


Figure 43 Facepiece F1 test subject V15 inward leakage results by fit test exercise

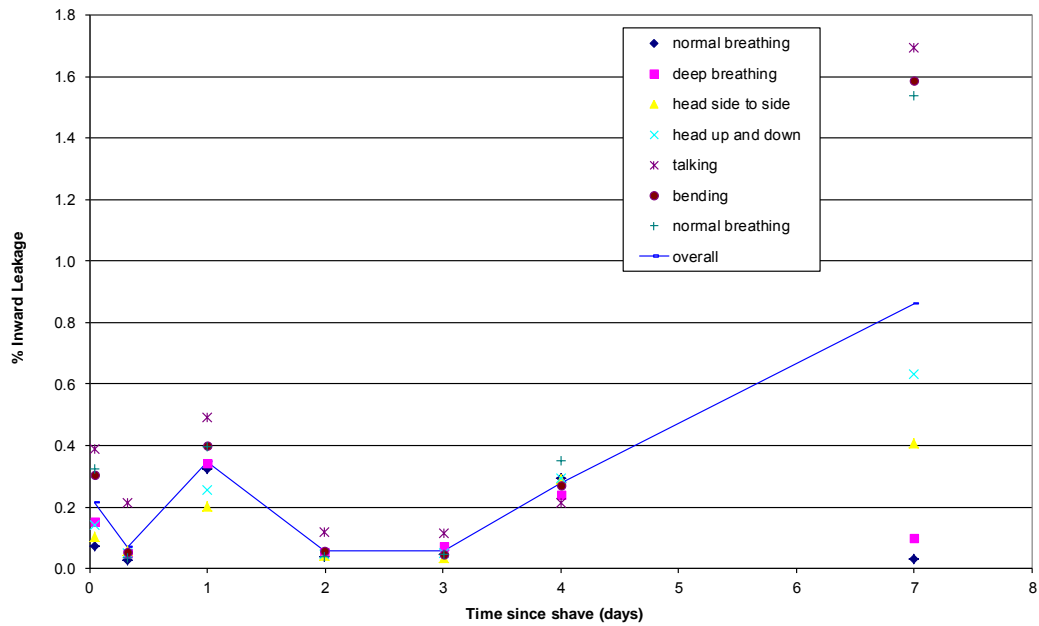


Figure 44 Facepiece F1 test subject V16 inward leakage results by fit test exercise

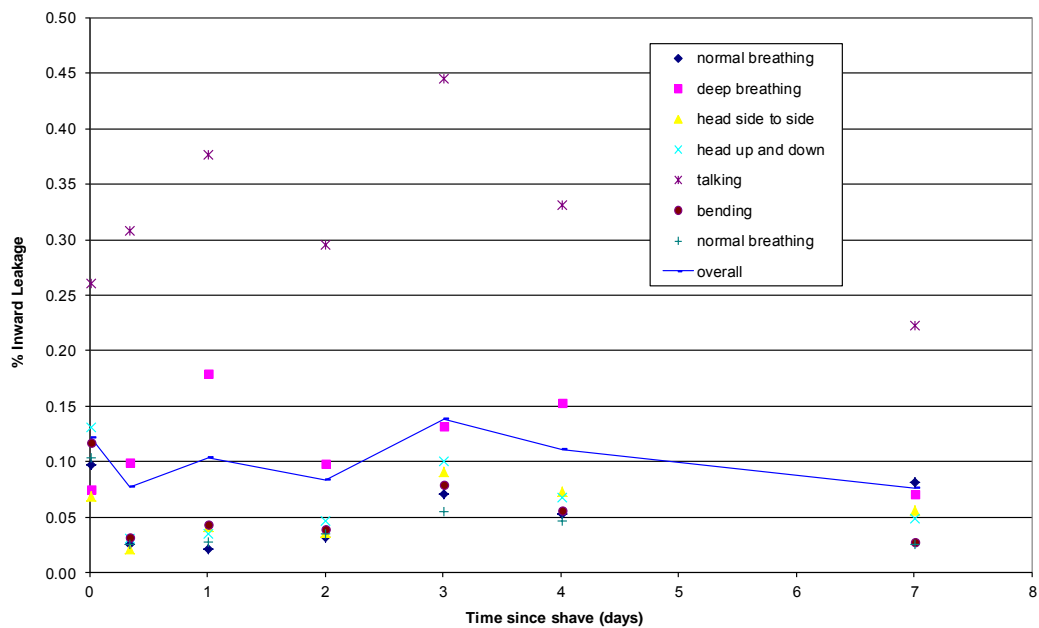


Figure 45 Facepiece F2 test subject V1 inward leakage results by fit test exercise

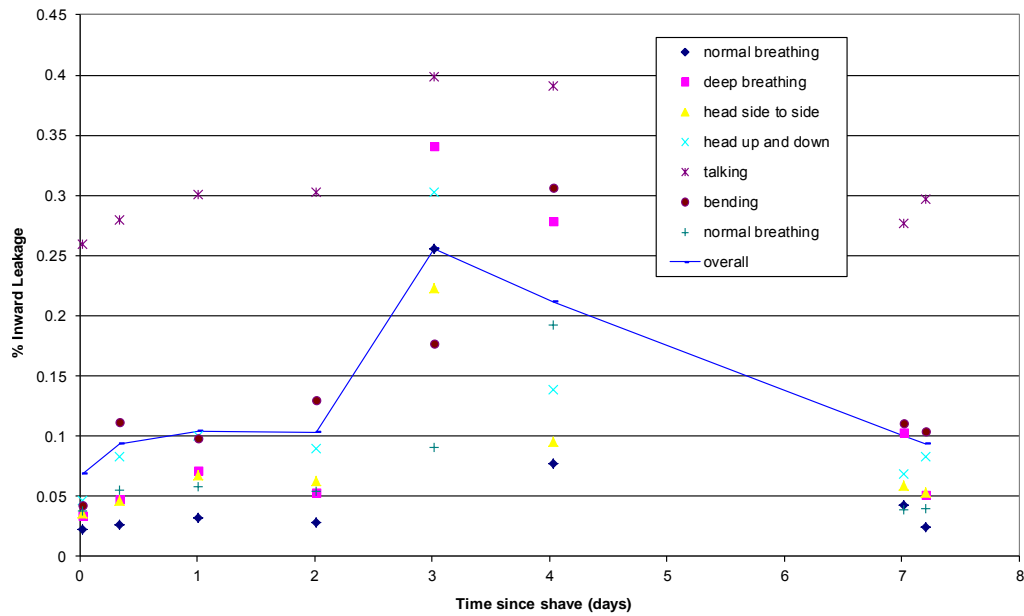


Figure 46 Facepiece F2 test subject V3 inward leakage results by fit test exercise

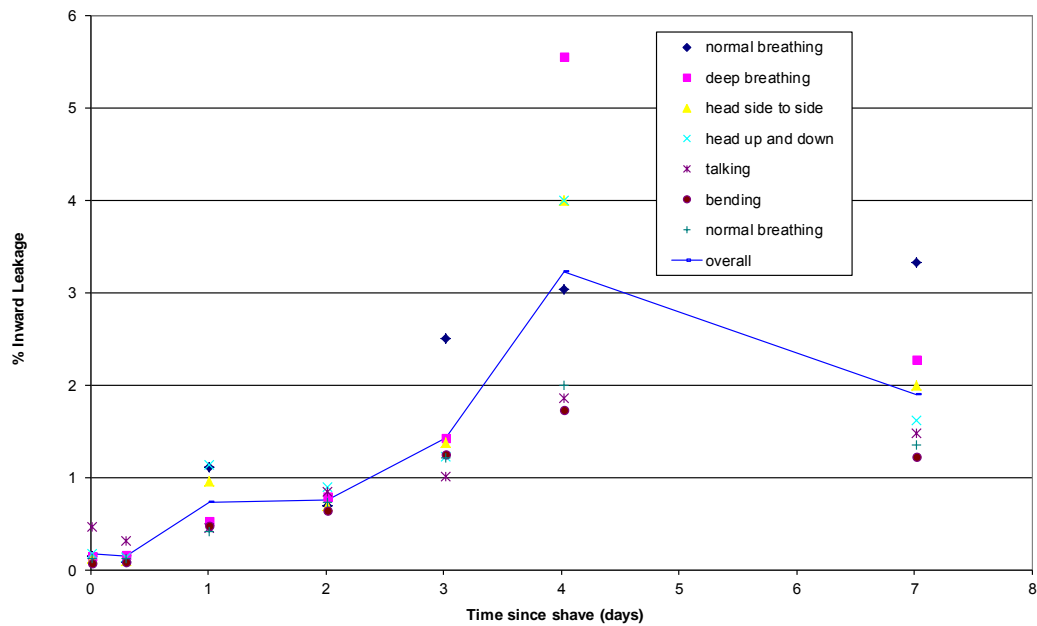


Figure 47 Facepiece F2 test subject V11 inward leakage results by fit test exercise

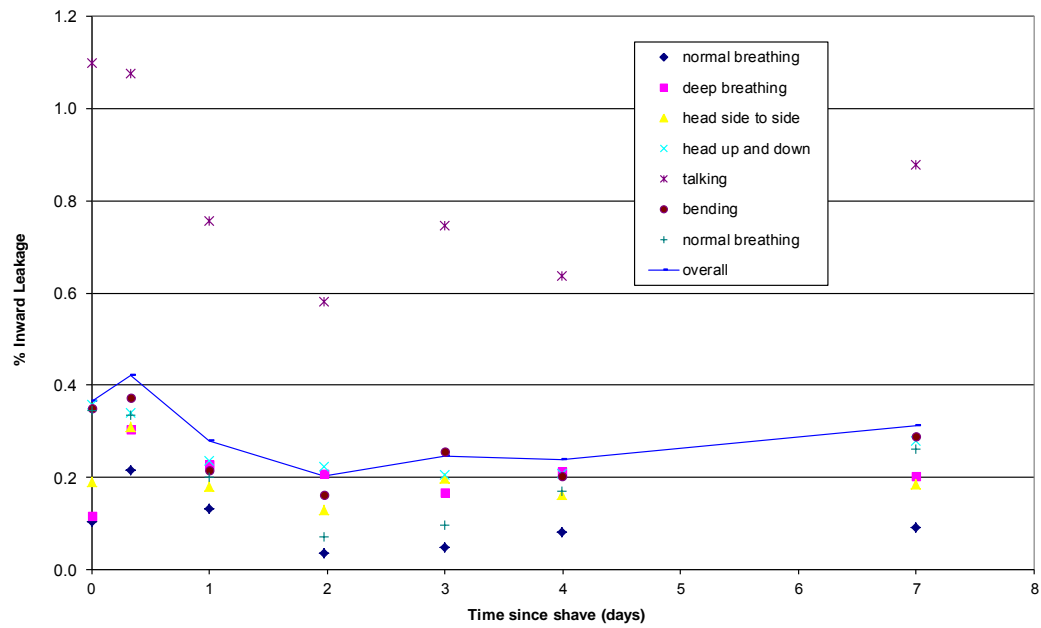


Figure 48 Facepiece F2 test subject V12 inward leakage results by fit test exercise

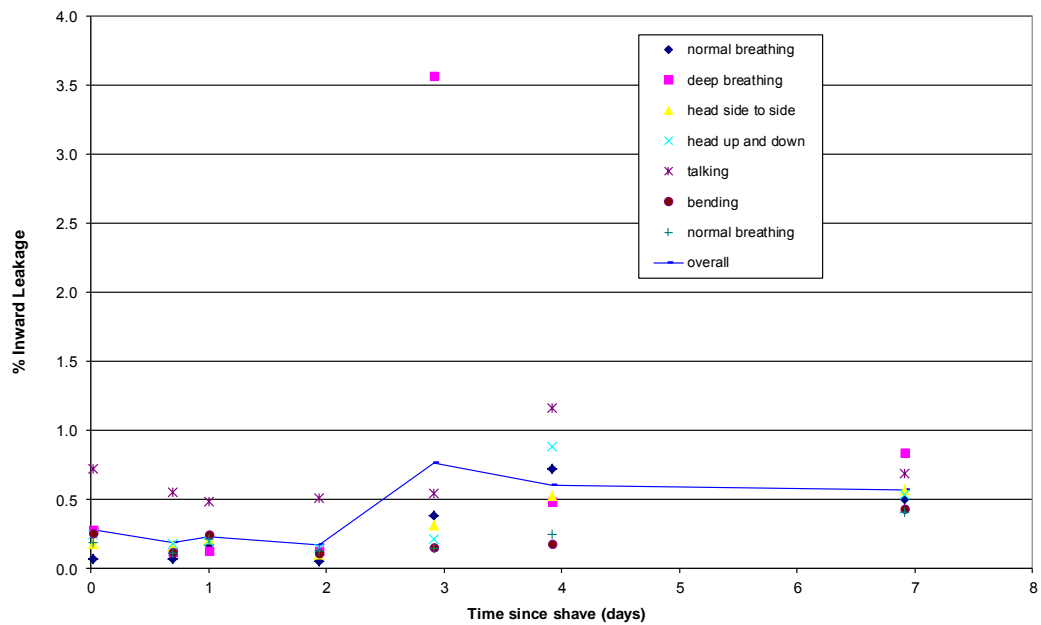


Figure 49 Facepiece F2 test subject V13 inward leakage results by fit test exercise

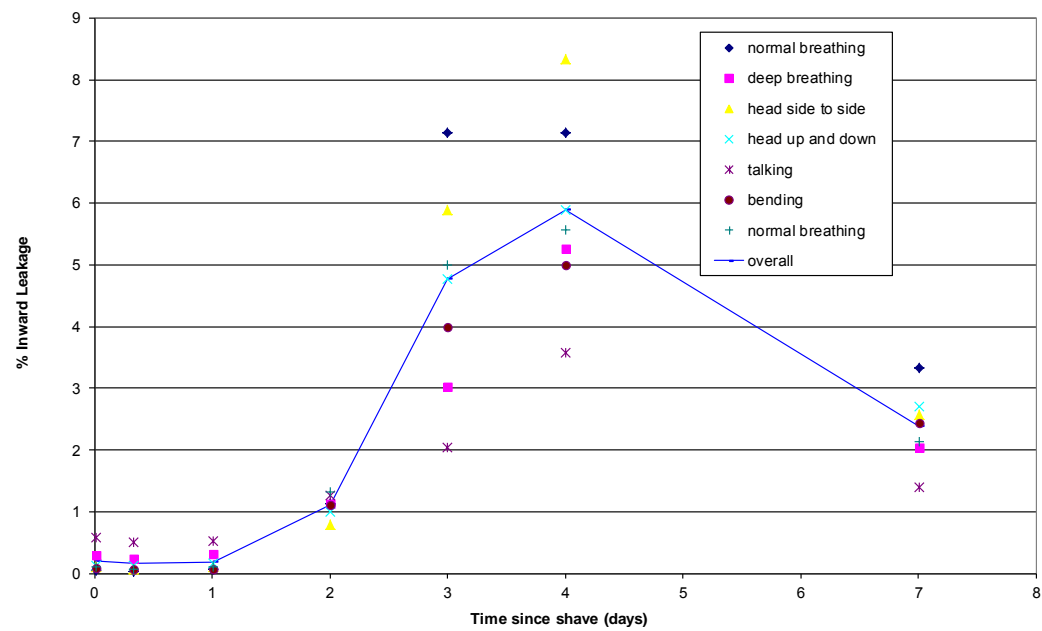


Figure 50 Facepiece F2 test subject V14 inward leakage results by fit test exercise

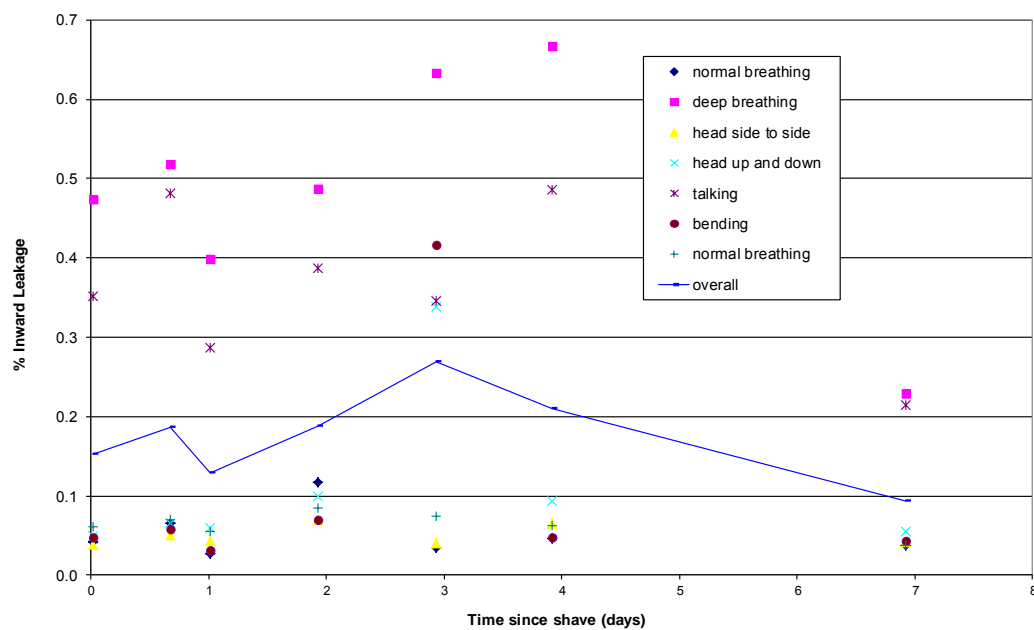


Figure 51 Facepiece F2 test subject V16 inward leakage results by fit test exercise

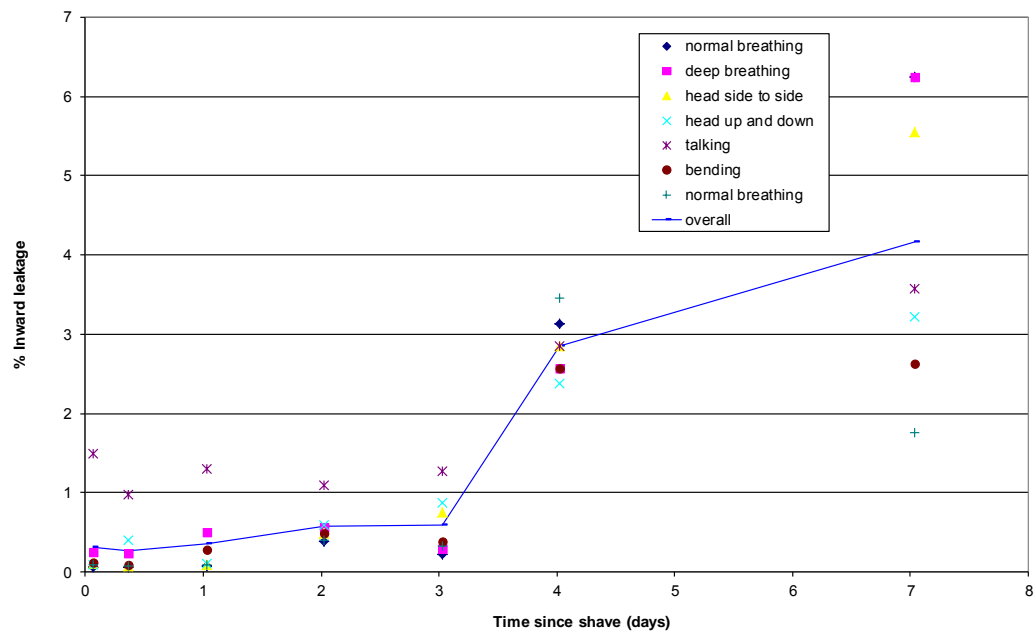


Figure 52 Facepiece F3 test subject V6 inward leakage results by fit test exercise

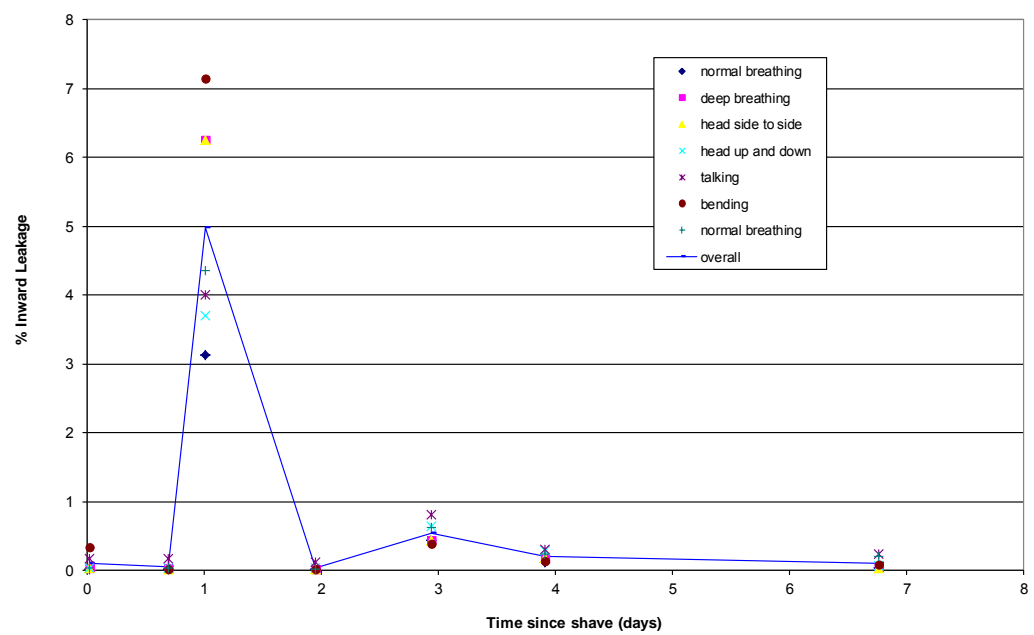


Figure 53 Facepiece F4 test subject V2 inward leakage results by fit test exercise

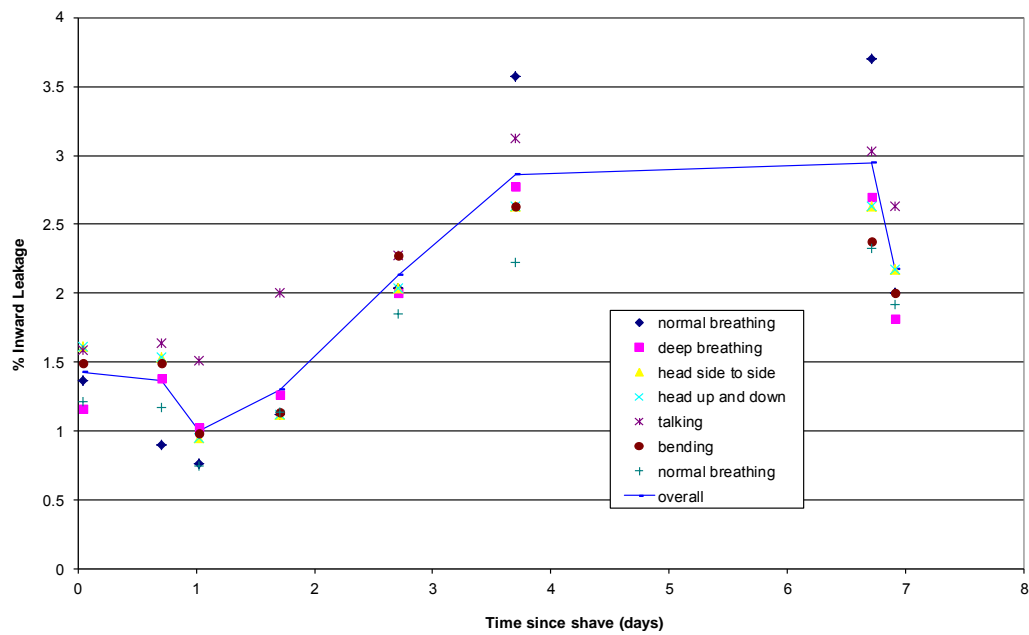


Figure 54 Facepiece F4 test subject V9 inward leakage results by fit test exercise

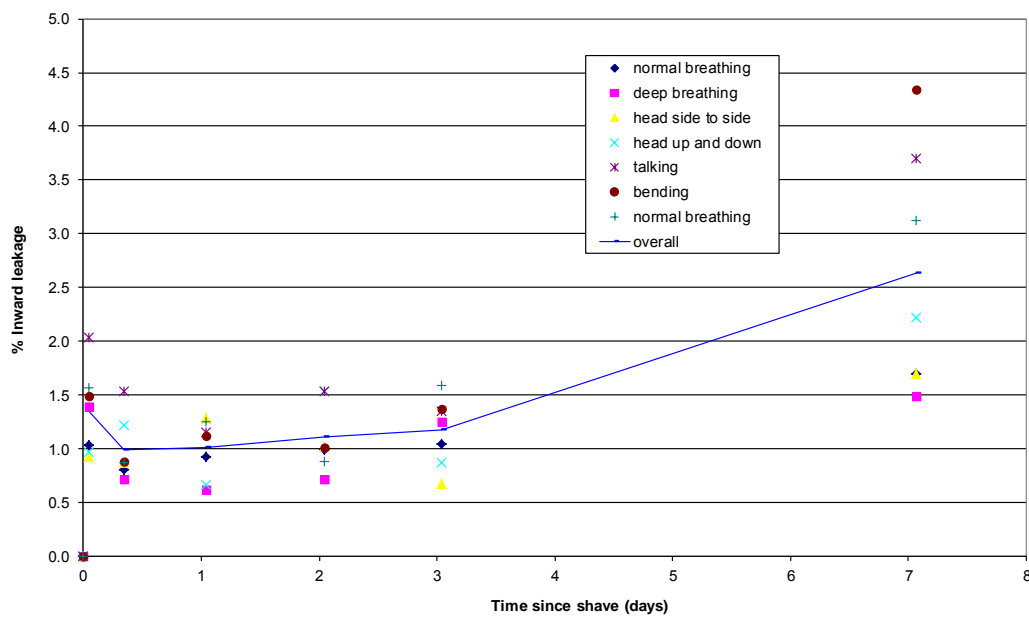


Figure 55 Facepiece F4 test subject V11 inward leakage results by fit test exercise

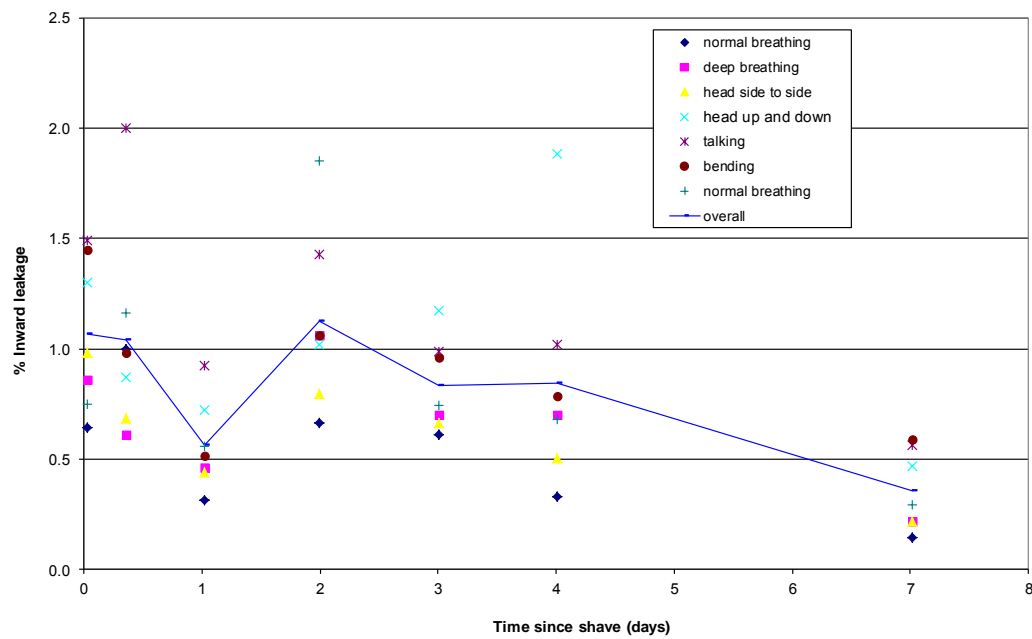


Figure 56 Facepiece F4 test subject V14 inward leakage results by fit test exercise

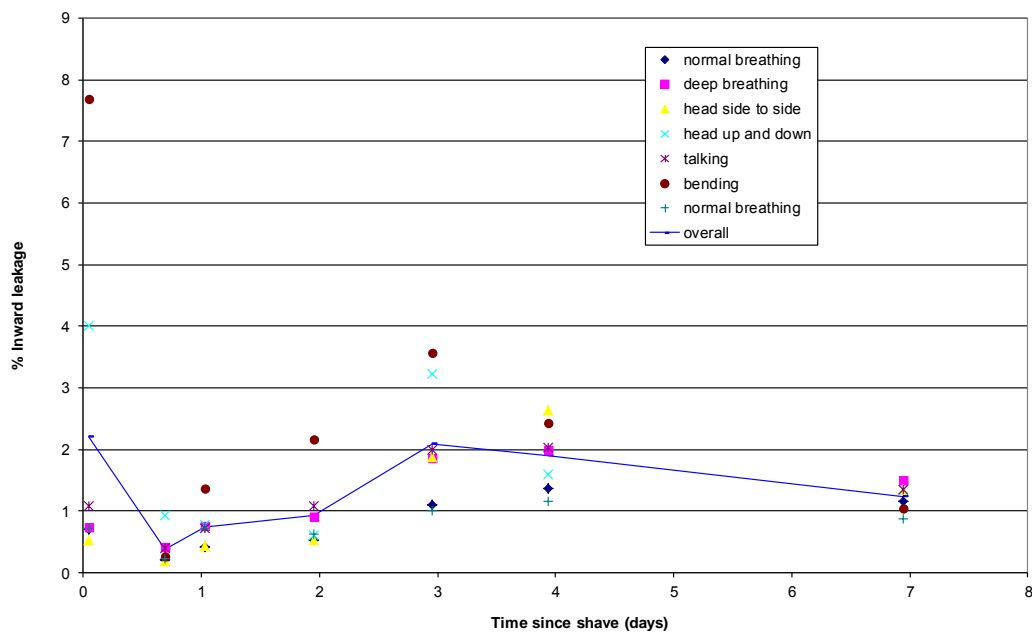


Figure 57 Facepiece F5 test subject V1 inward leakage results by fit test exercise

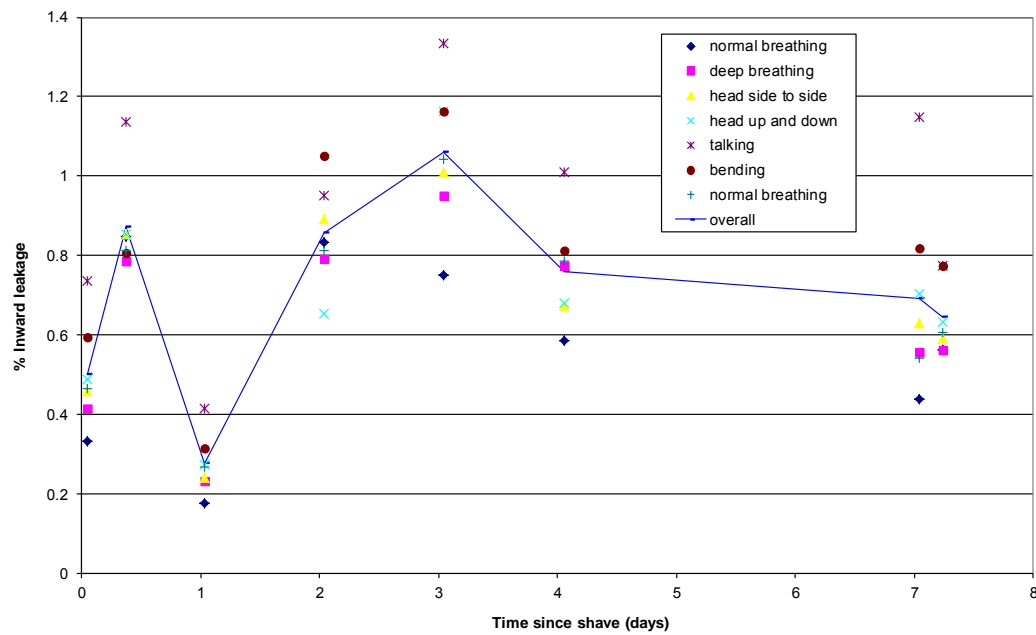


Figure 58 Facepiece F5 test subject V3 inward leakage results by fit test exercise

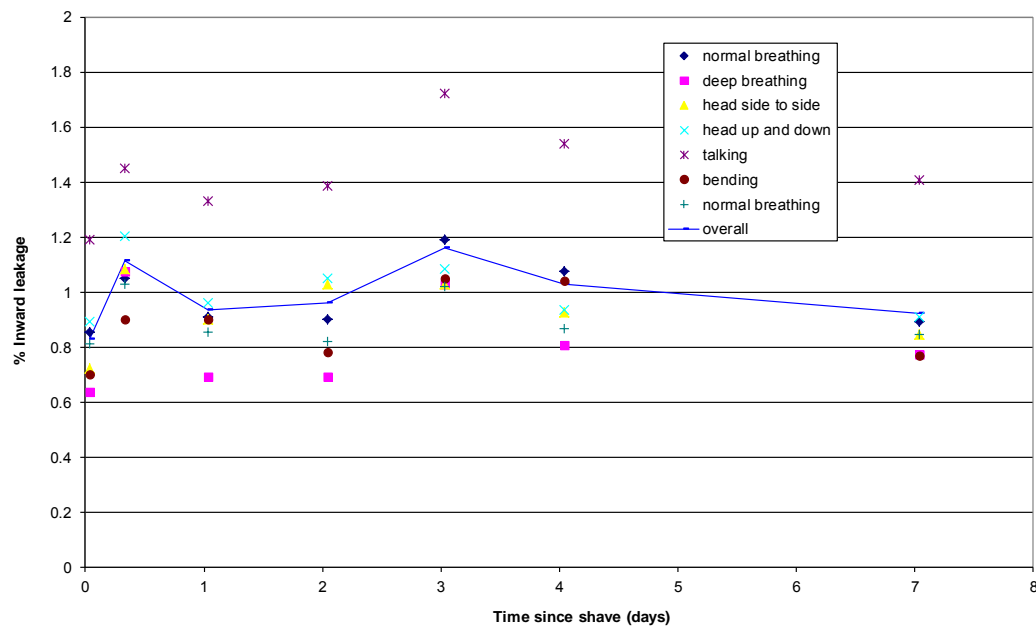


Figure 59 Facepiece F5 test subject V4 inward leakage results by fit test exercise

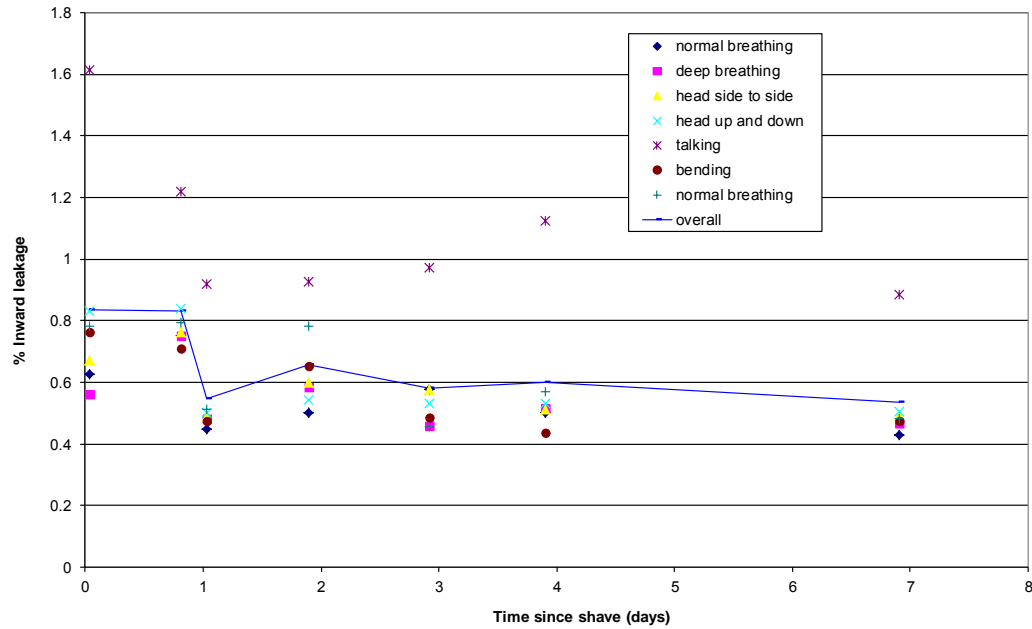


Figure 60 Facepiece F5 test subject V5 inward leakage results by fit test exercise

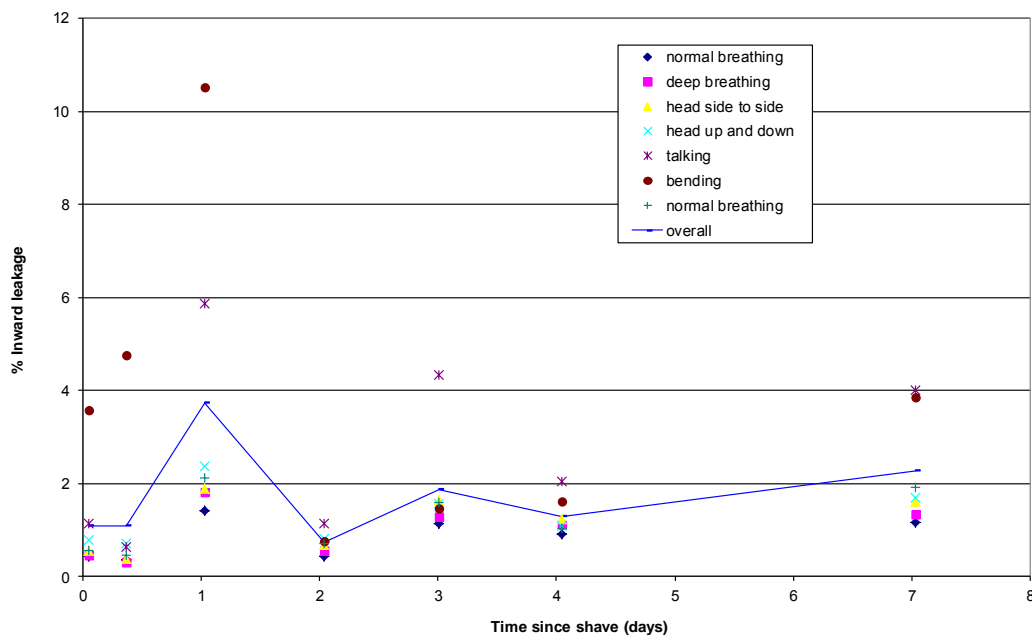


Figure 61 Facepiece F5 test subject V7 inward leakage results by fit test exercise

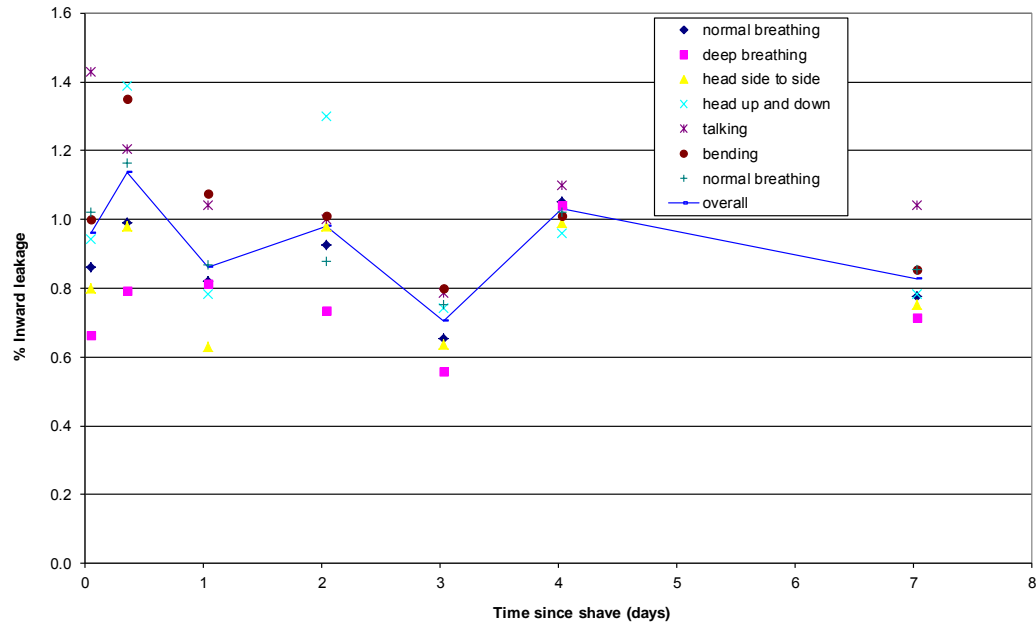


Figure 62 Facepiece F5 test subject V8 inward leakage results by fit test exercise

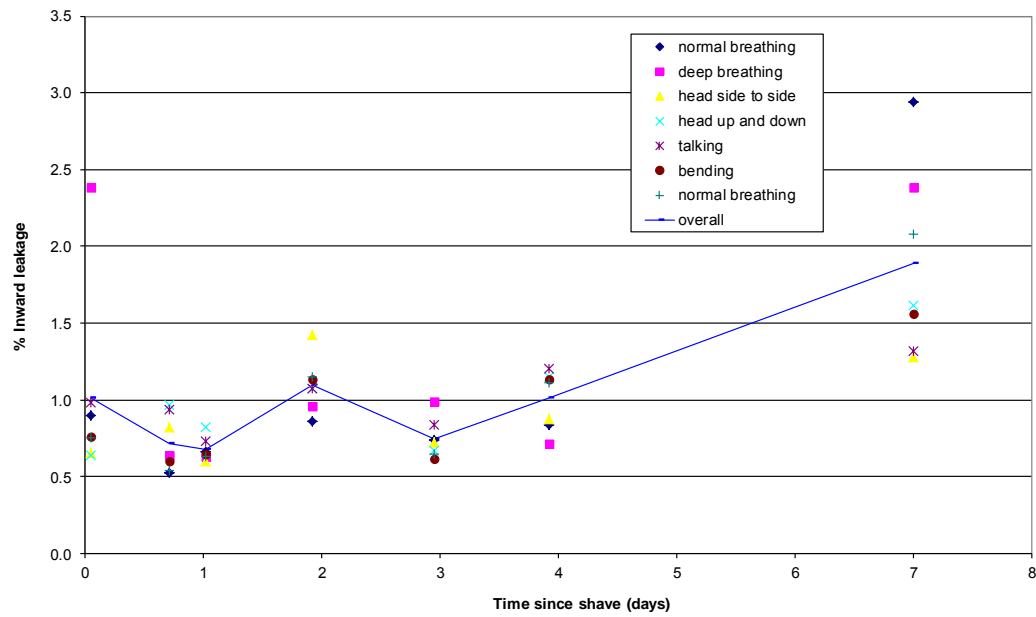


Figure 63 Facepiece F5 test subject V12 inward leakage results by fit test exercise

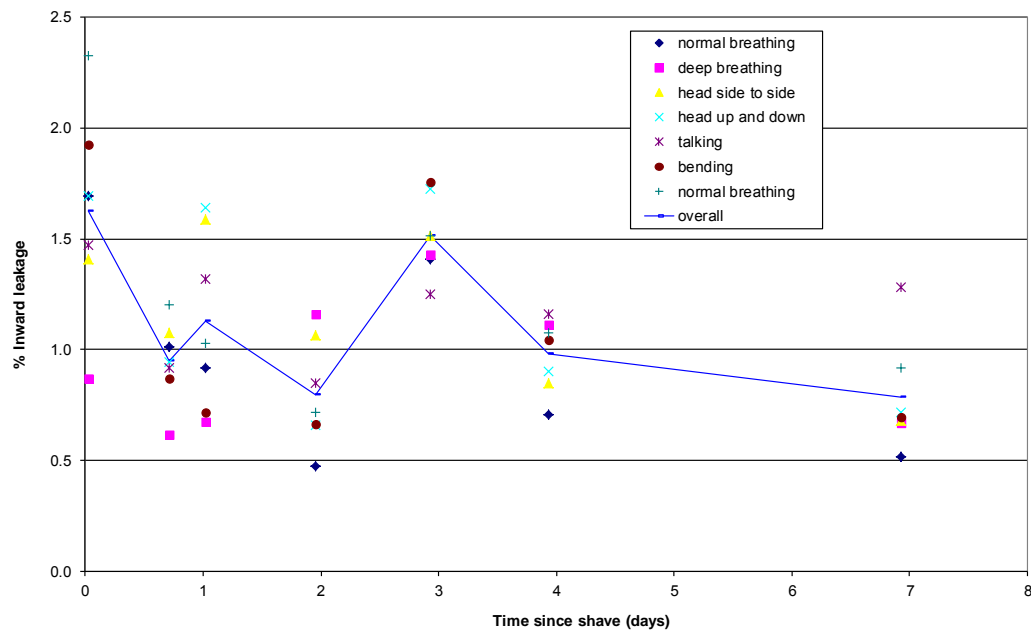


Figure 64 Facepiece F5 test subject V13 inward leakage results by fit test exercise

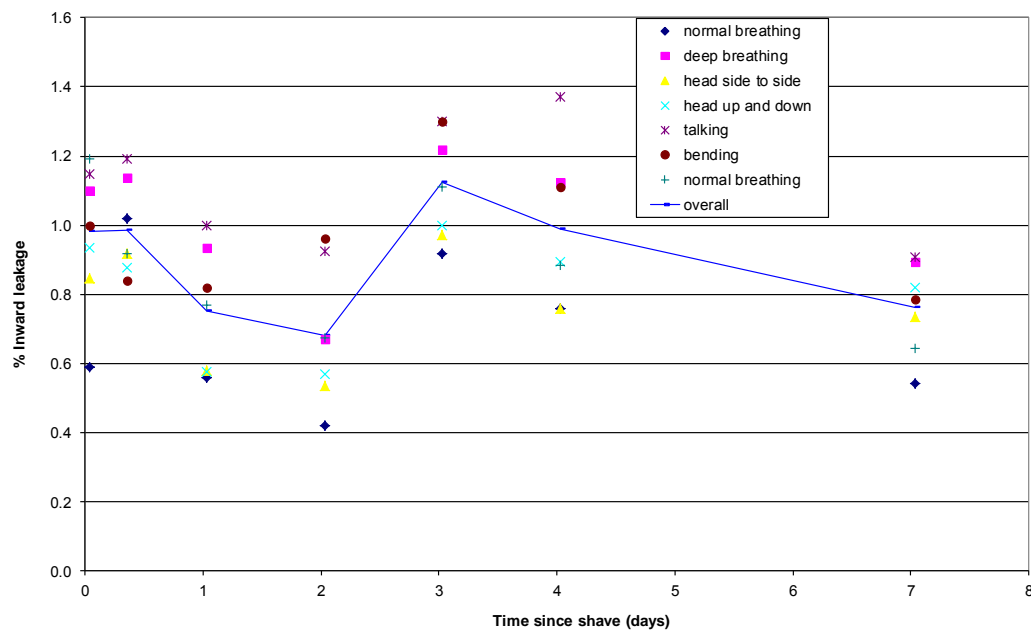


Figure 65 Facepiece F5 test subject V15 inward leakage results by fit test exercise

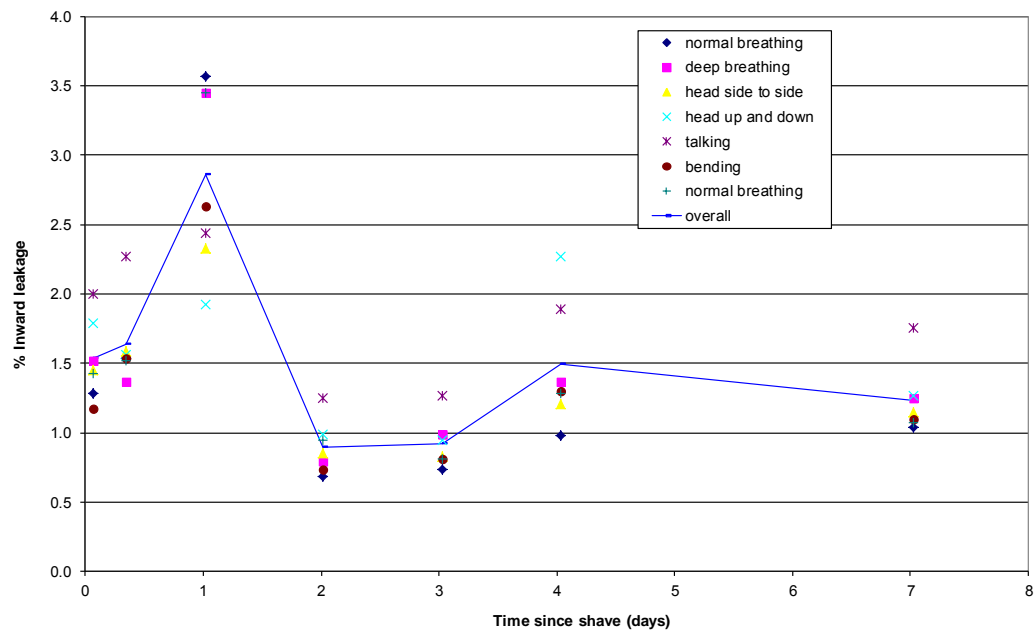


Figure 66 Facepiece F6 test subject V2 inward leakage results by fit test exercise

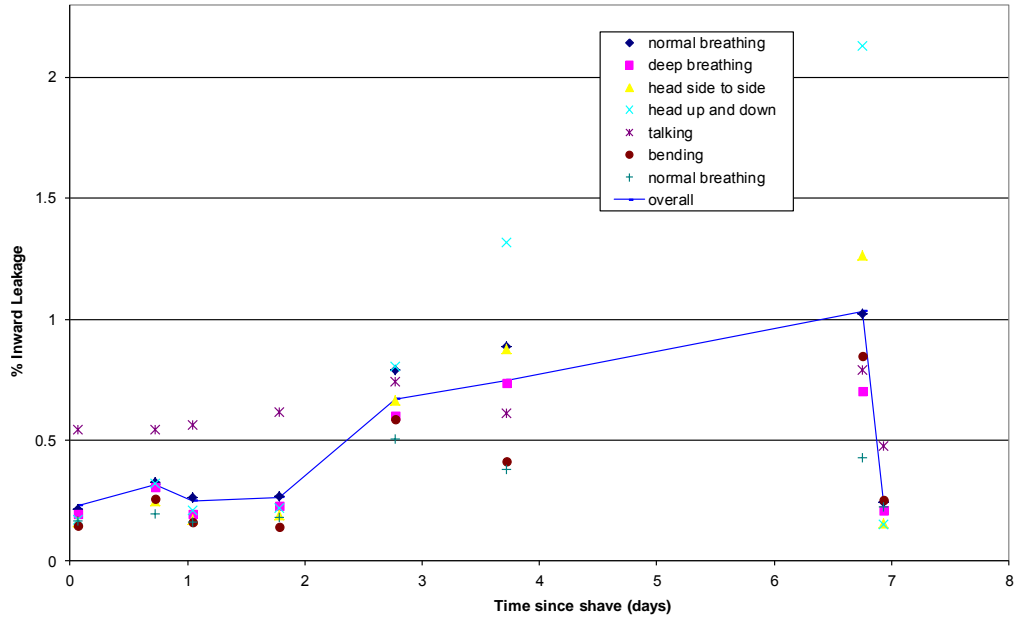


Figure 67 Facepiece F6 test subject V3 inward leakage results by fit test exercise

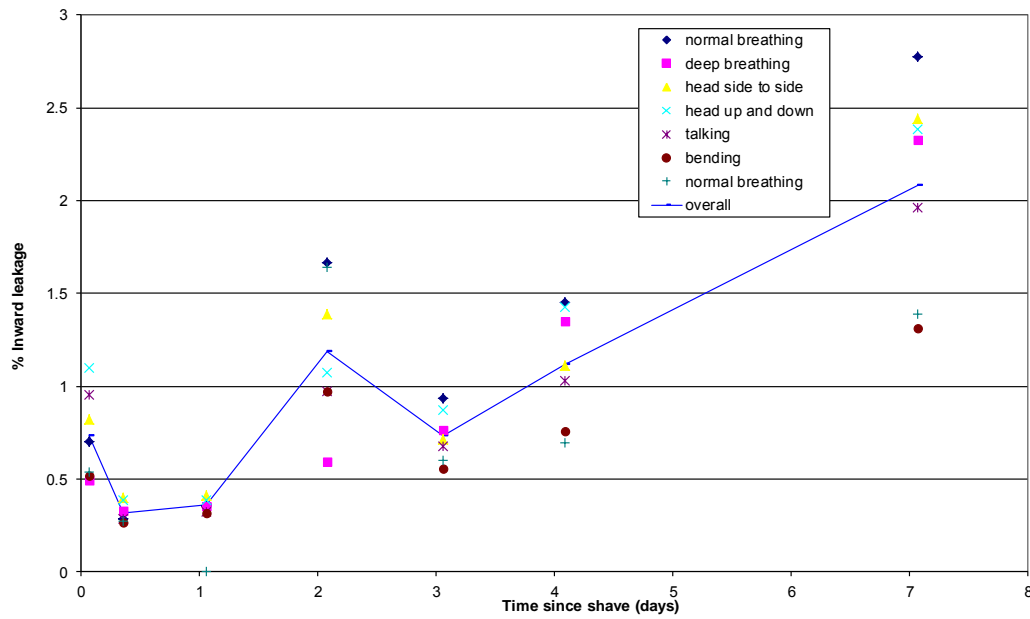


Figure 68 Facepiece F6 test subject V5 inward leakage results by fit test exercise

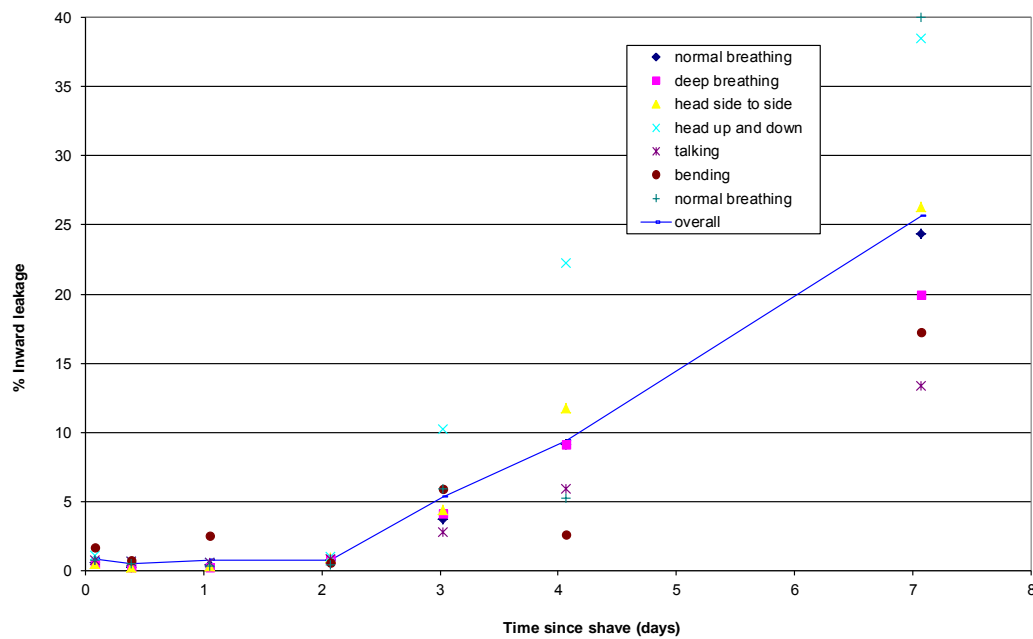


Figure 69 Facepiece F6 test subject V12 inward leakage results by fit test exercise

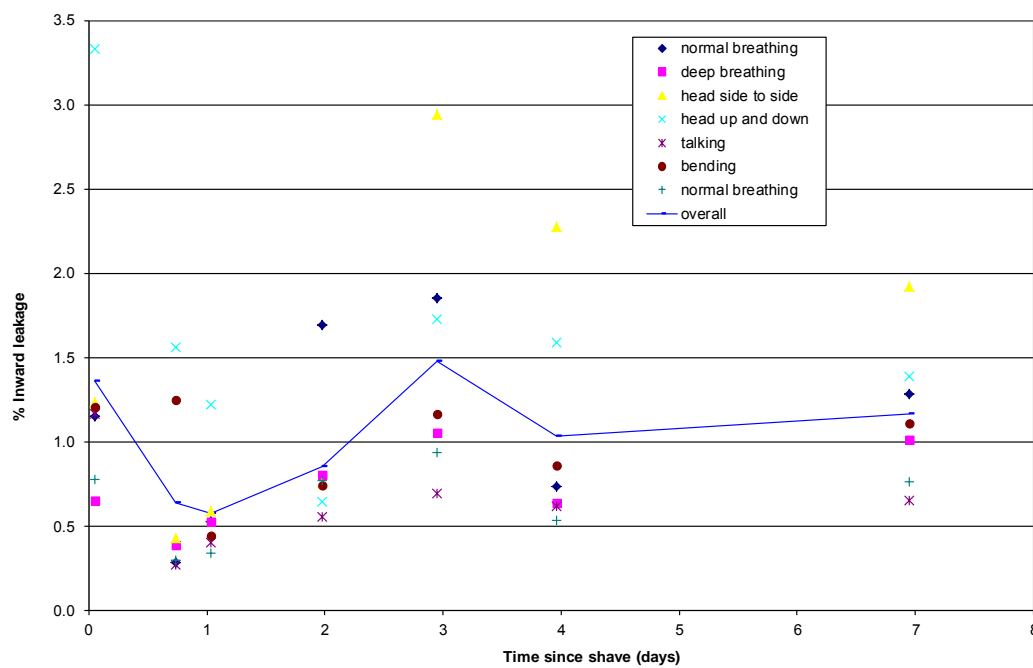


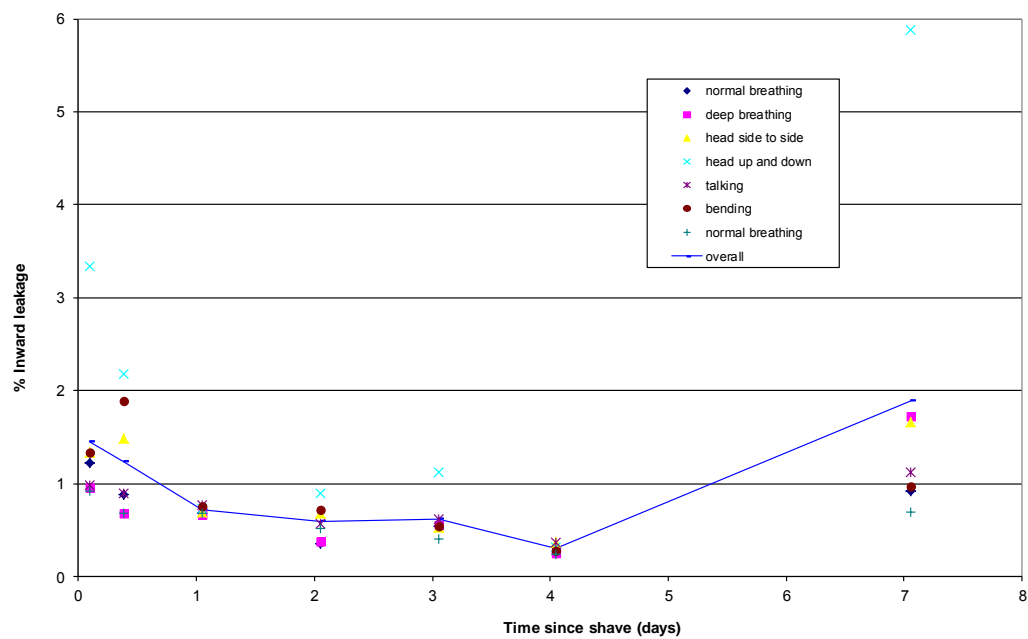
Figure 70 Facepiece F6 test subject V16 inward leakage results by fit test exercise

Figure 71 Facepiece F7 test subject V1 inward leakage results by fit test exercise

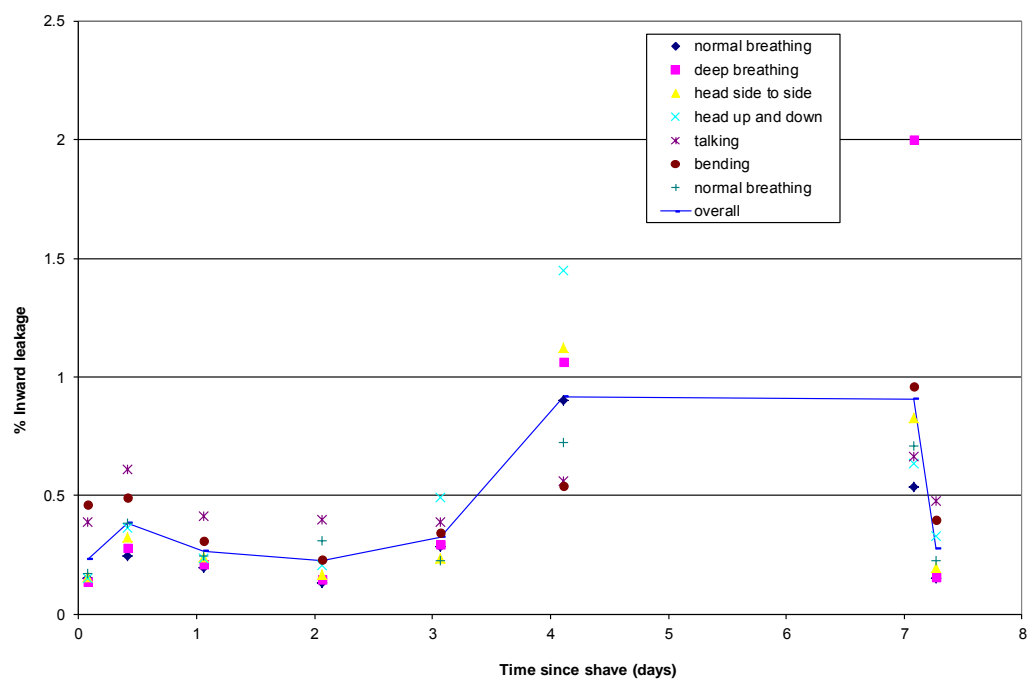


Figure 72 Facepiece F7 test subject V4 inward leakage results by fit test exercise

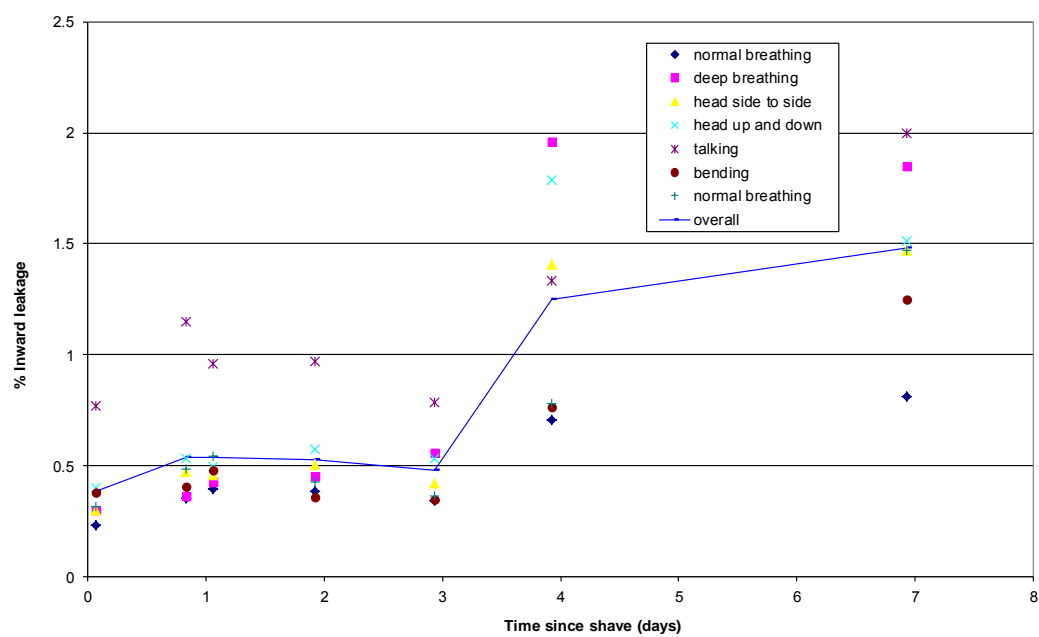


Figure 73 Facepiece F7 test subject V6 inward leakage results by fit test exercise

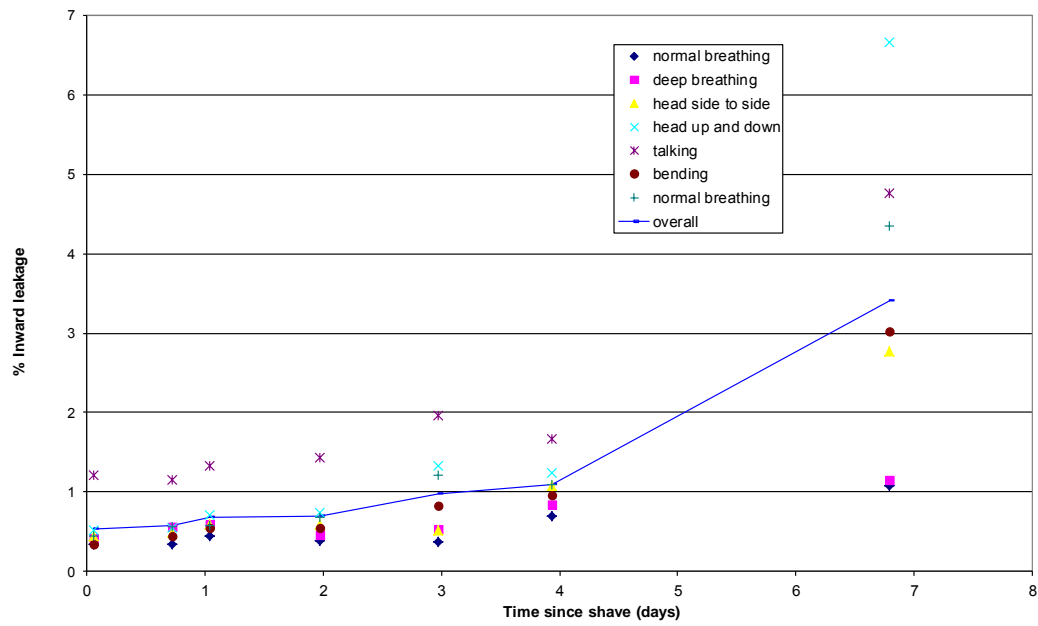


Figure 74 Facepiece F7 test subject V7 inward leakage results by fit test exercise

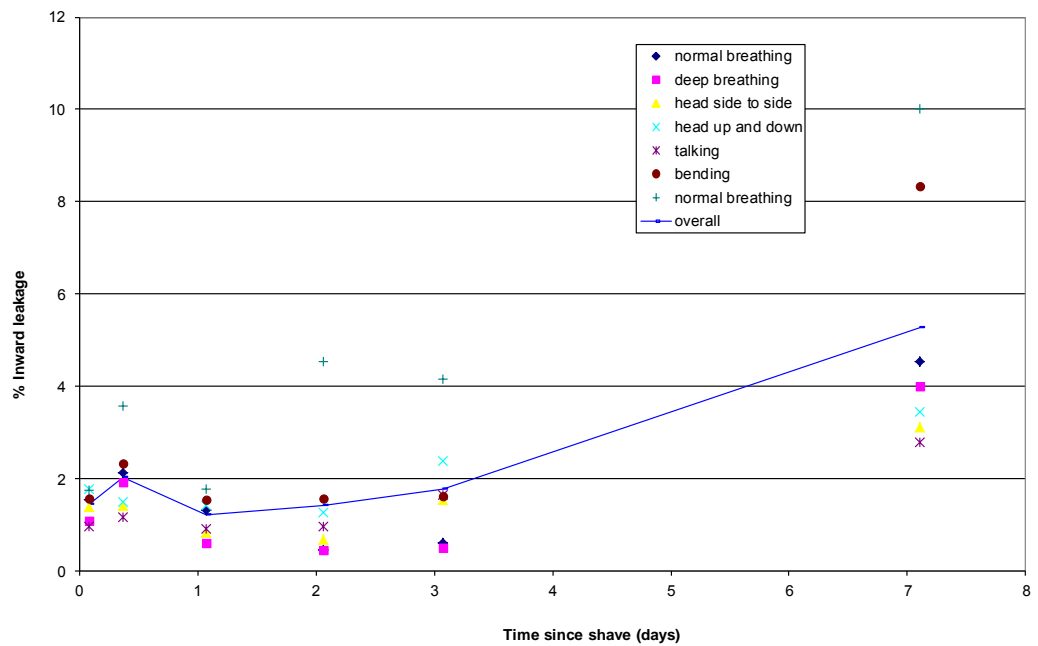


Figure 75 Facepiece F7 test subject V8 inward leakage results by fit test exercise

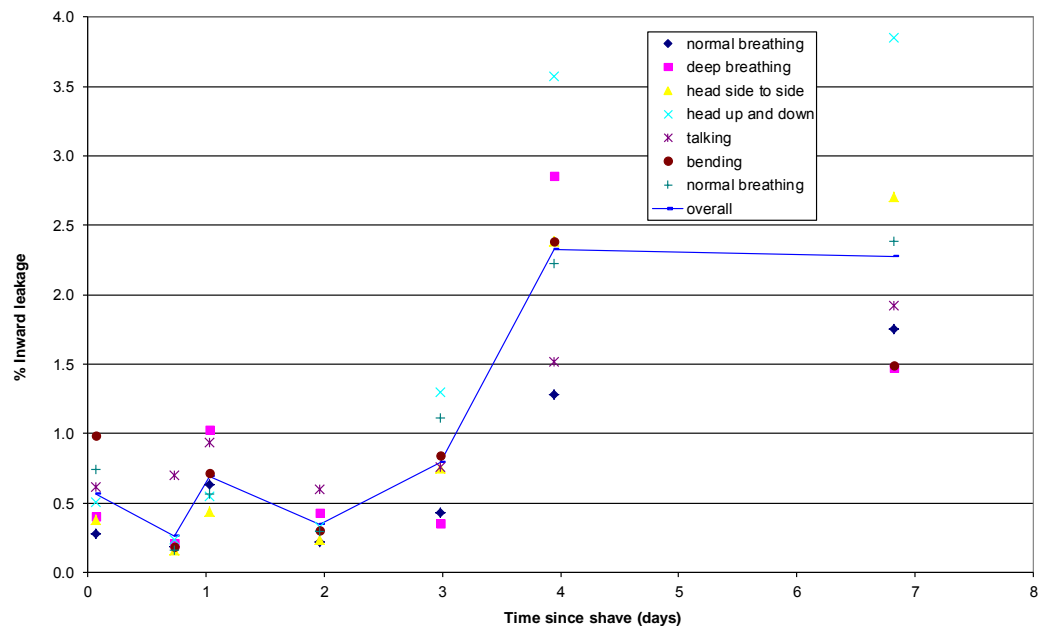


Figure 76 Facepiece F7 test subject V9 inward leakage results by fit test exercise

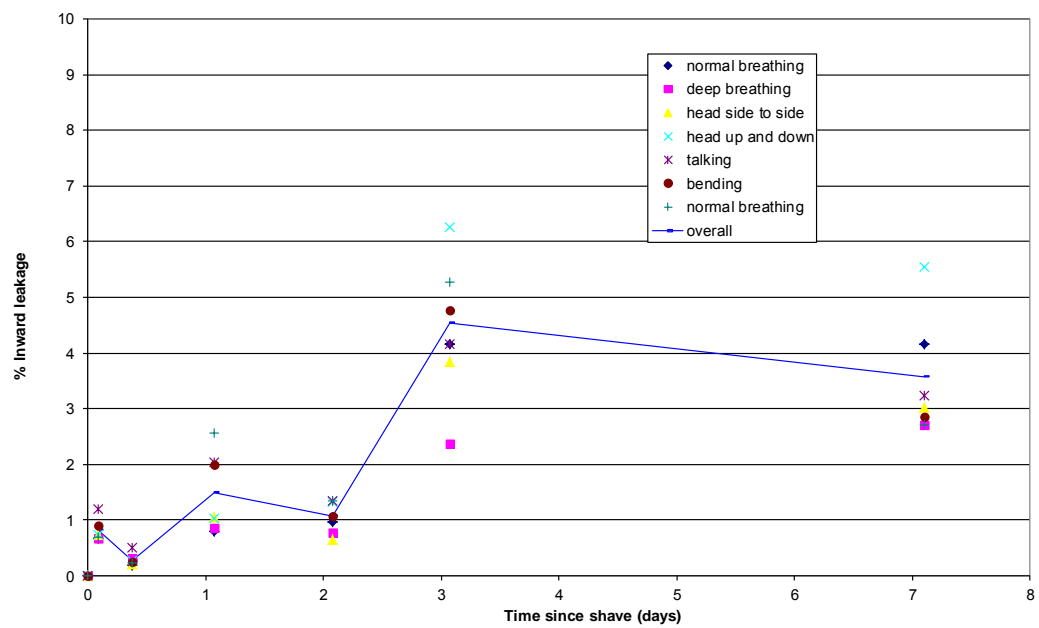


Figure 77 Facepiece F7 test subject V11 inward leakage results by fit test exercise

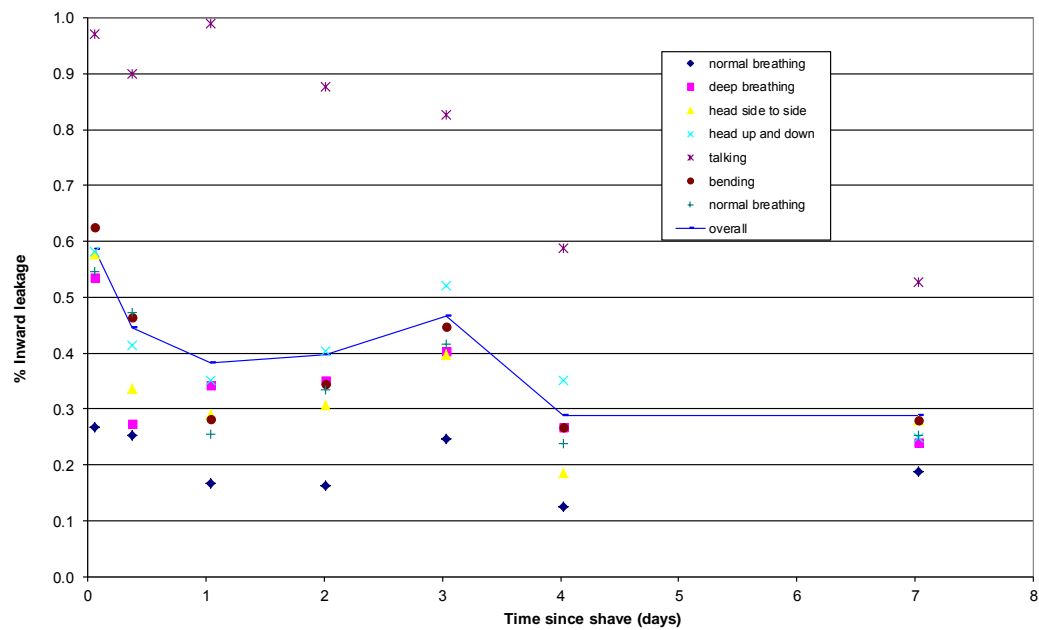


Figure 78 Facepiece F7 test subject V13 inward leakage results by fit test exercise

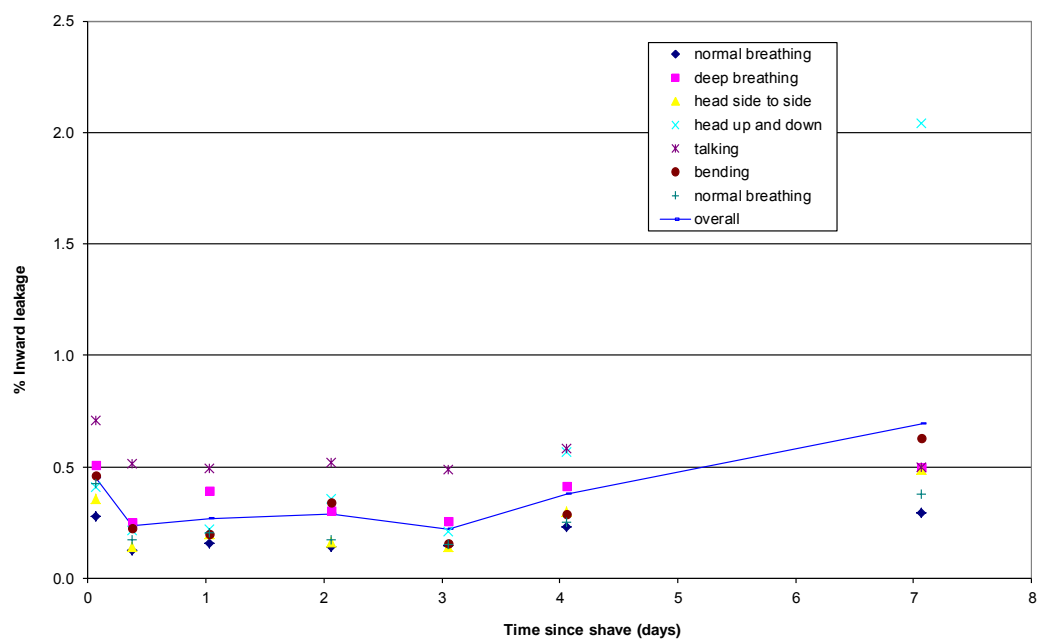


Figure 79 Facepiece F7 test subject V14 inward leakage results by fit test exercise

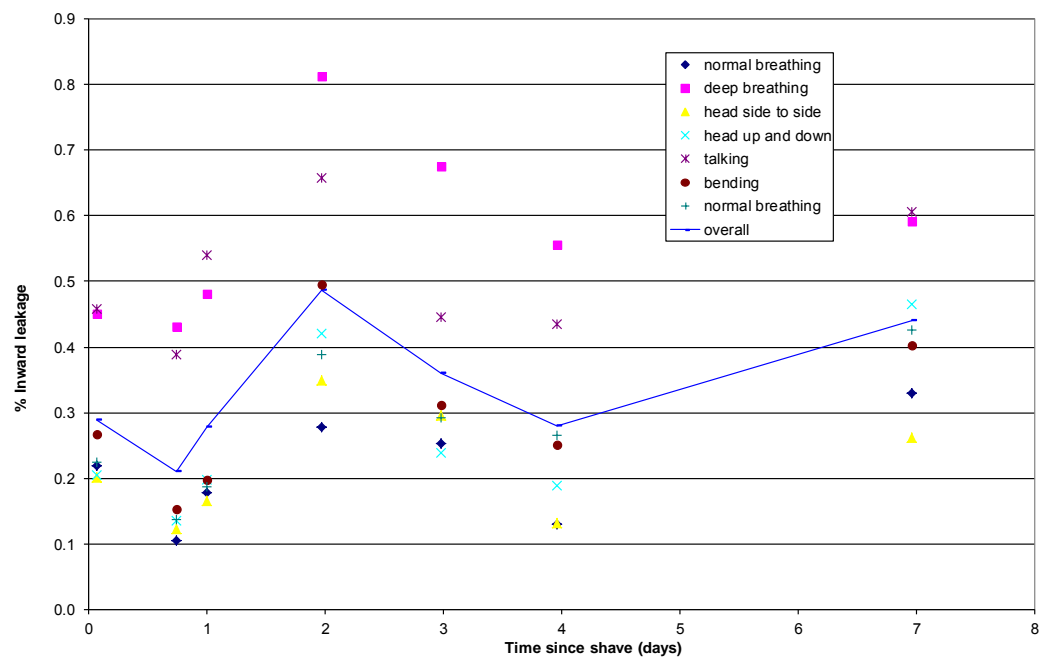


Figure 80 Facepiece F7 test subject V15 inward leakage results by fit test exercise

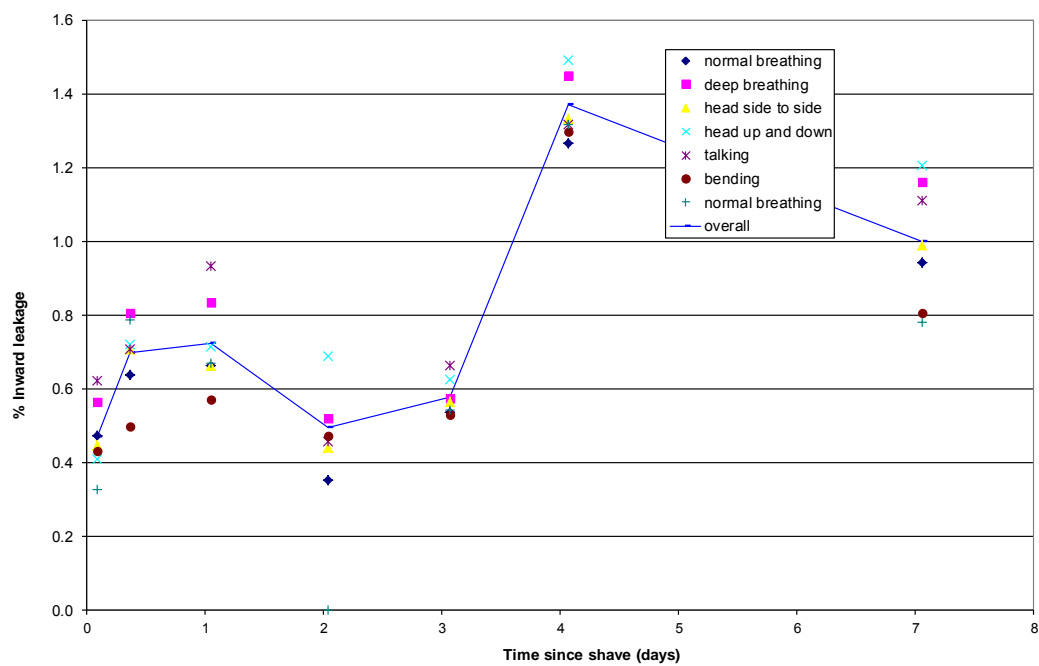


Figure 81 Facepiece F8 test subject V1 inward leakage results by fit test exercise

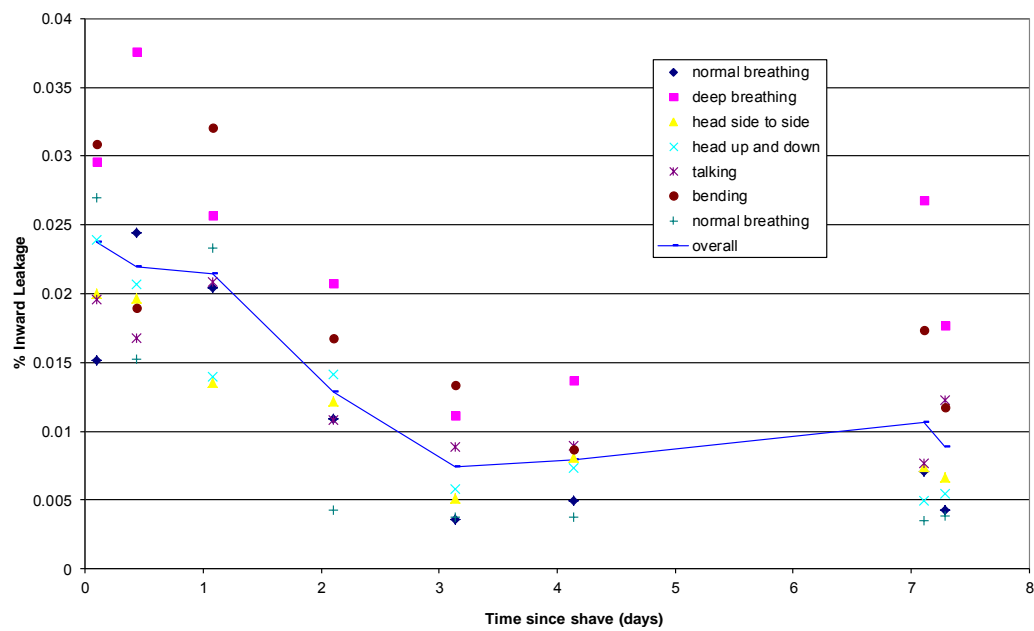


Figure 82 Facepiece F8 test subject V4 inward leakage results by fit test exercise

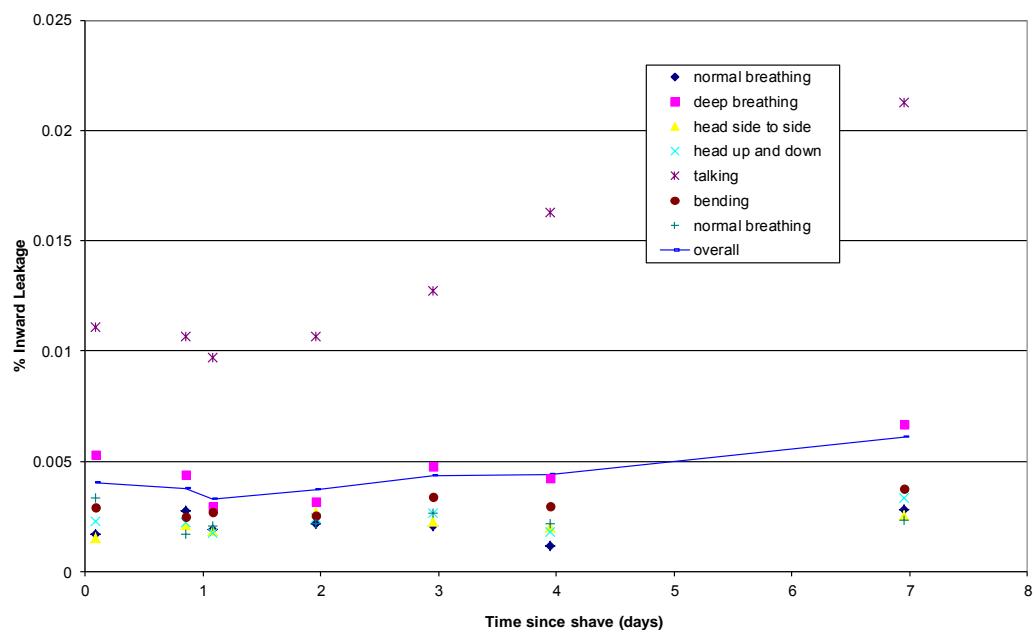


Figure 83 Facepiece F8 test subject V6 inward leakage results by fit test exercise

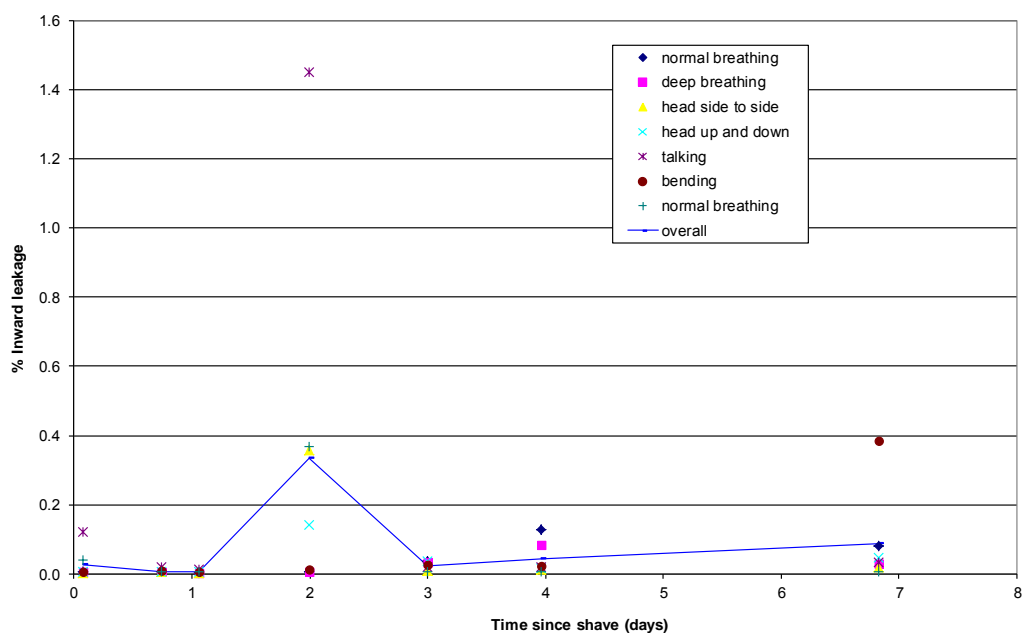


Figure 84 Facepiece F8 test subject V8 inward leakage results by fit test exercise

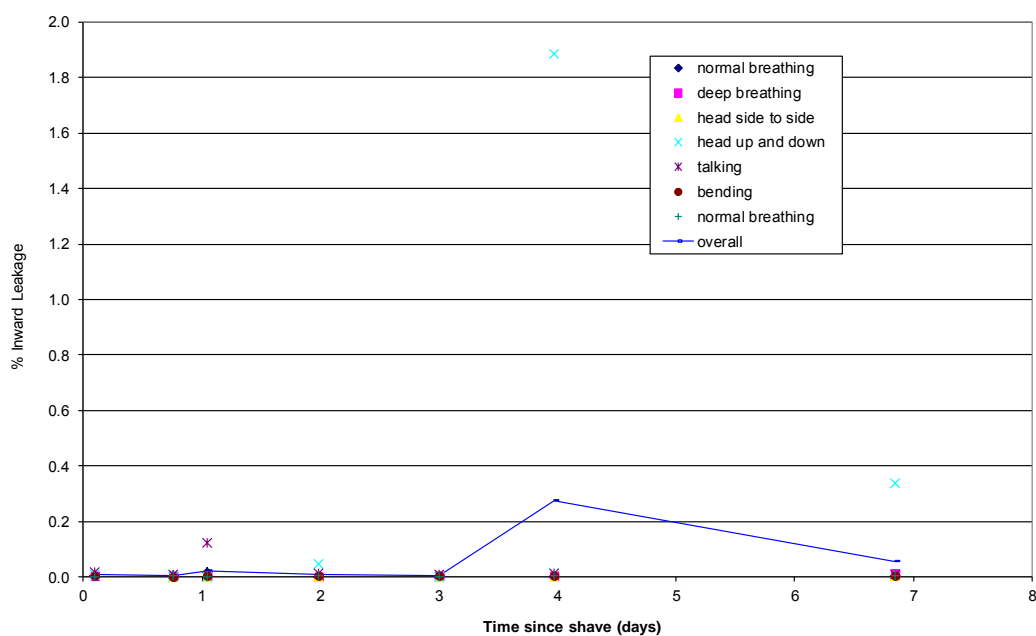


Figure 85 Facepiece F8 test subject V9 inward leakage results by fit test exercise

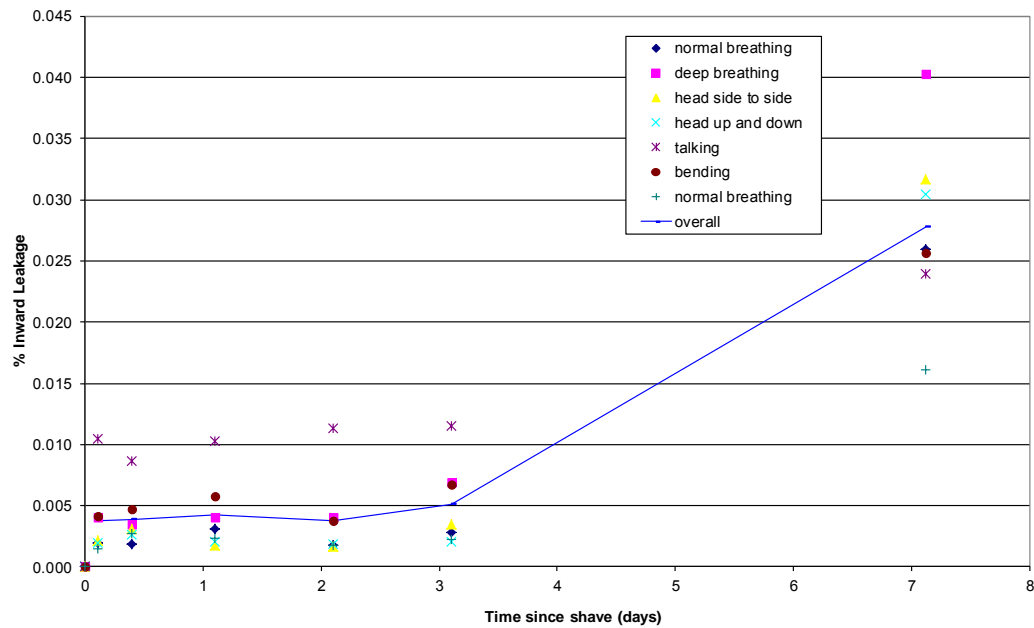


Figure 86 Facepiece F8 test subject V14 inward leakage results by fit test exercise

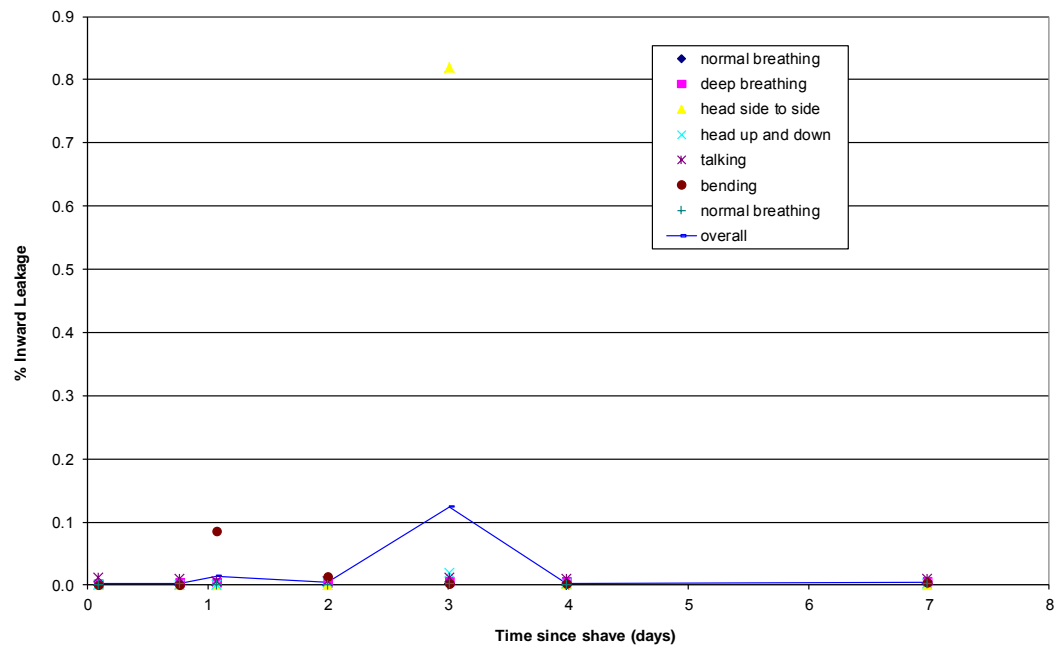


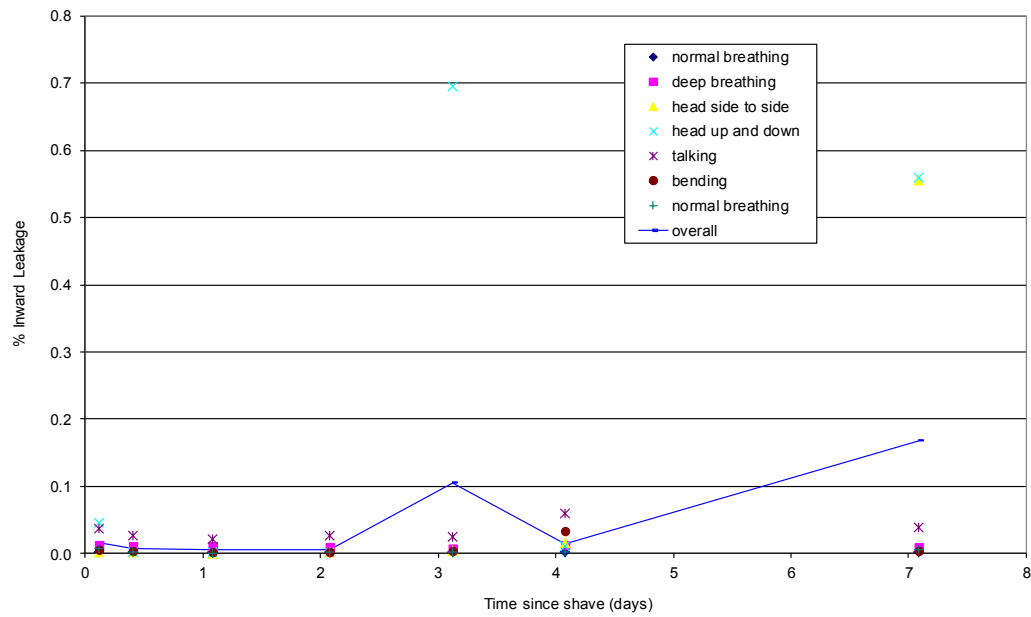
Figure 87 Facepiece F8 test subject V16 inward leakage results by fit test exercise

Figure 88 Facepiece F9 test subject V2 inward leakage results by fit test exercise

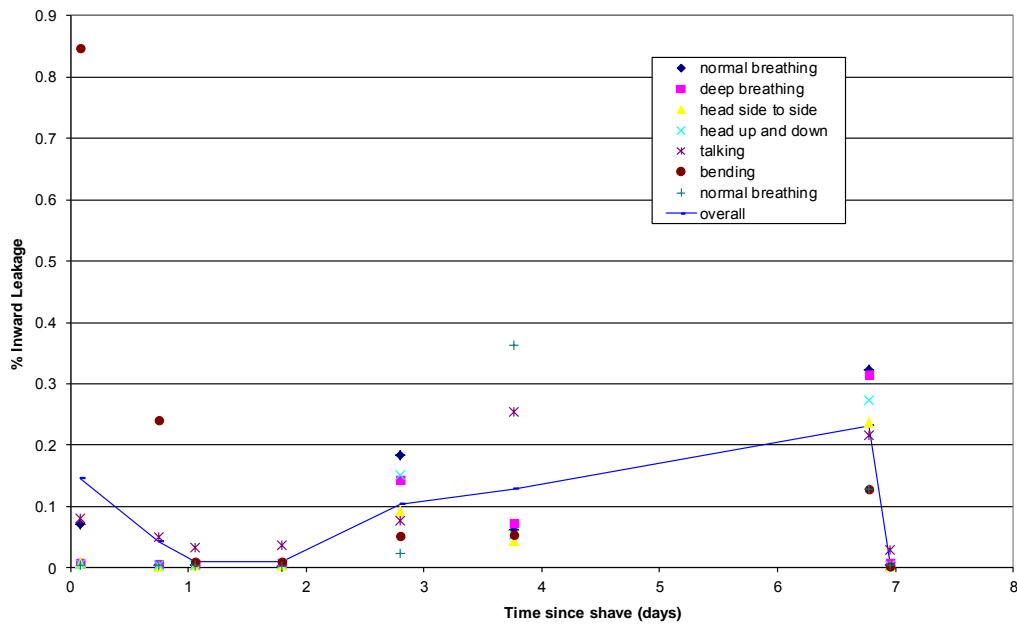


Figure 89 Facepiece F9 test subject V3 inward leakage results by fit test exercise

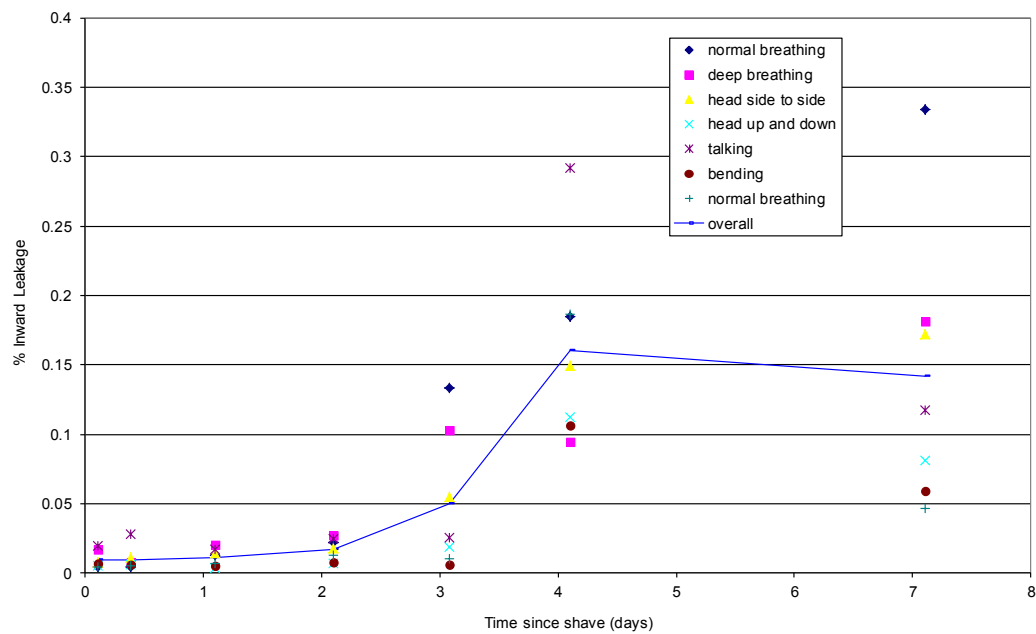


Figure 90 Facepiece F9 test subject V5 inward leakage results by fit test exercise

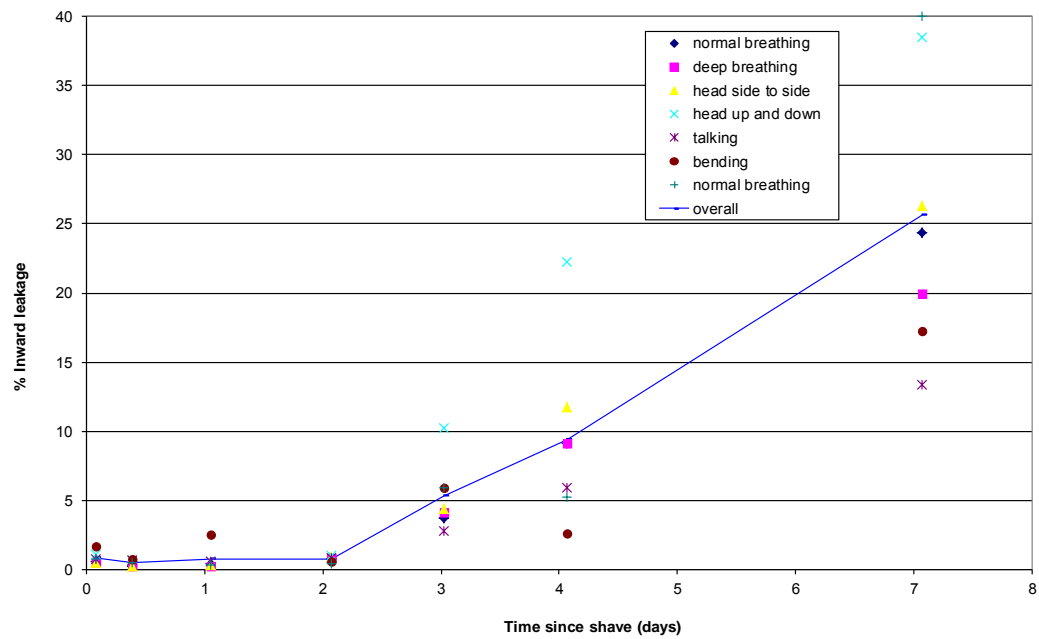


Figure 91 Facepiece F9 test subject V6 inward leakage results by fit test exercise

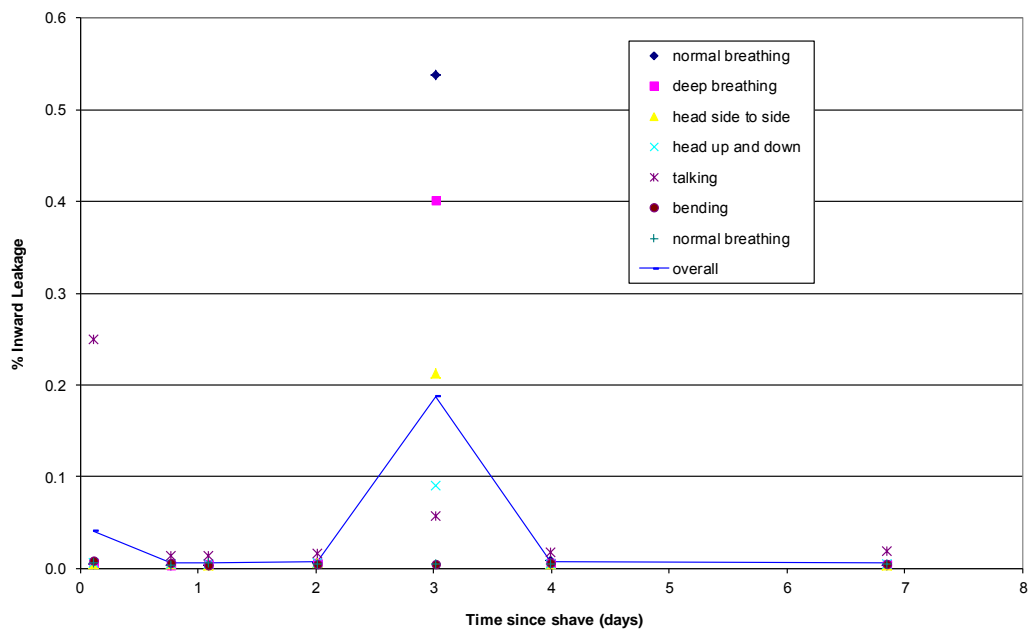


Figure 92 Facepiece F9 test subject V7 inward leakage results by fit test exercise

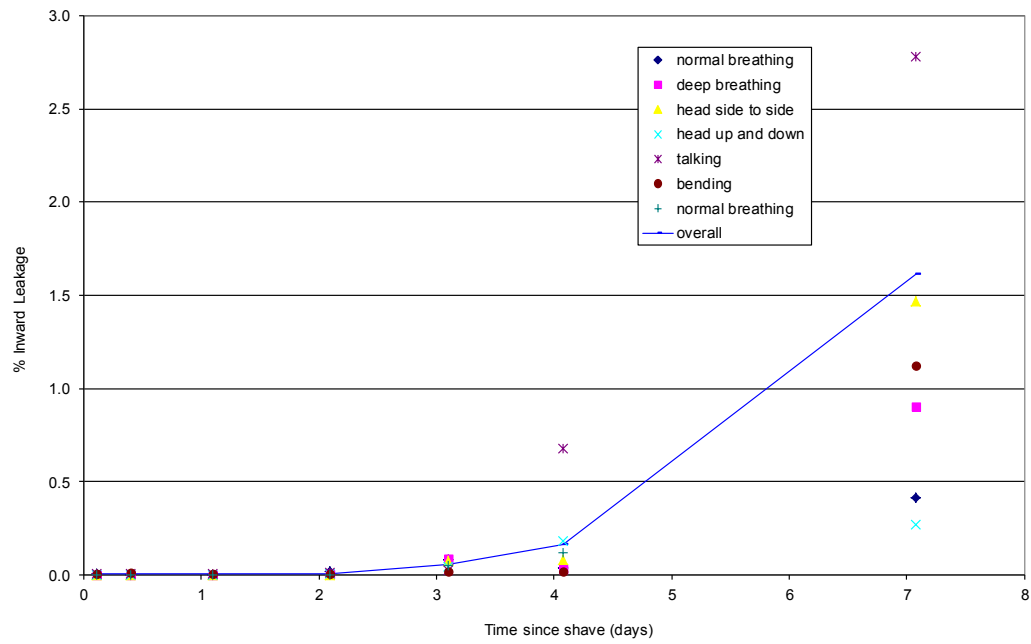


Figure 93 Facepiece F9 test subject V11 inward leakage results by fit test exercise

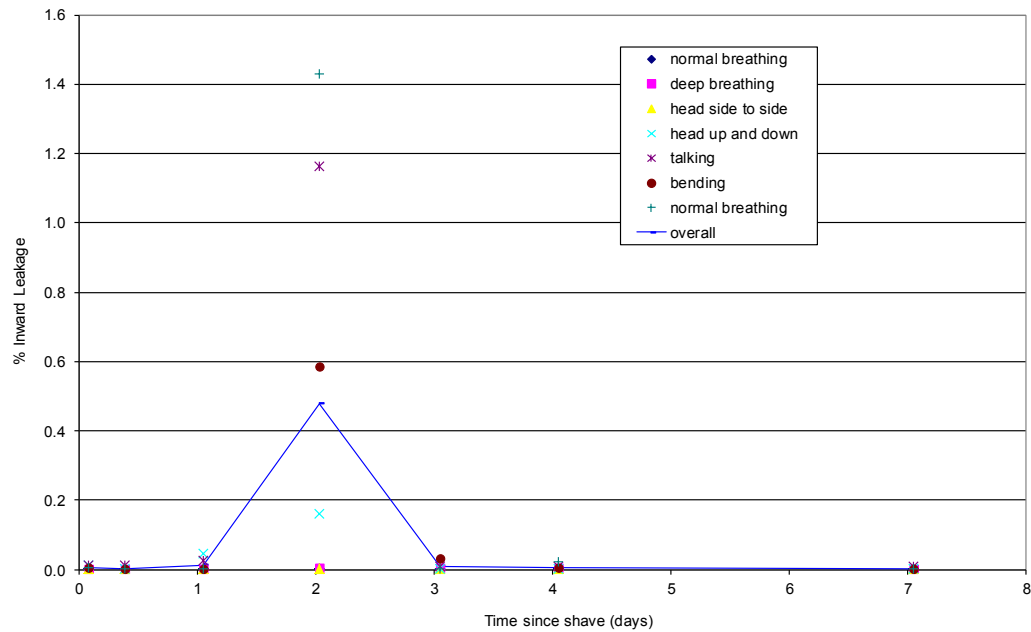


Figure 94 Facepiece F9 test subject V12 inward leakage results by fit test exercise

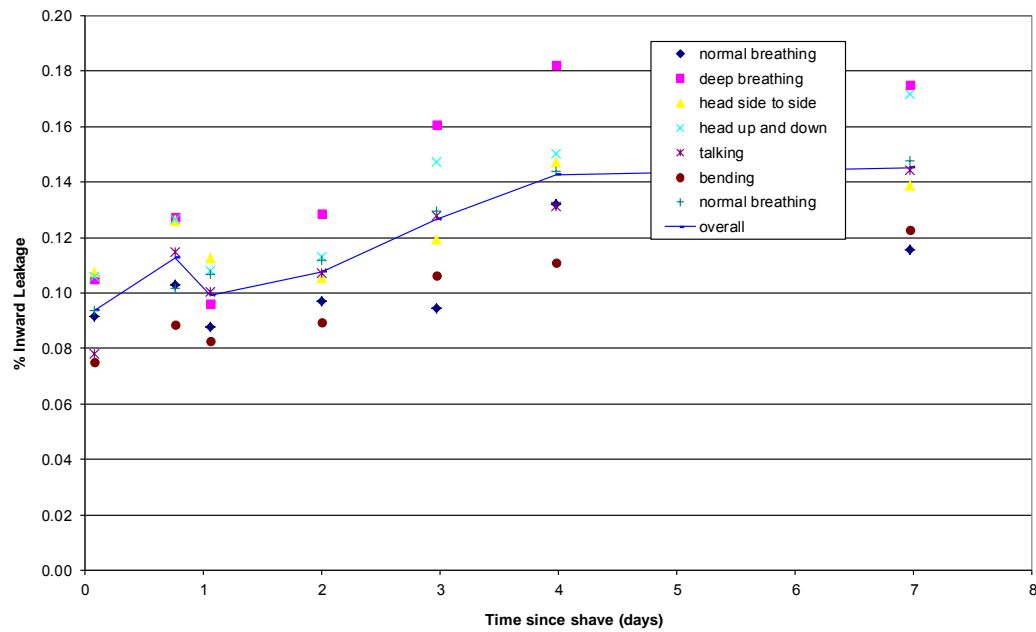


Figure 95 Facepiece F9 test subject V13 inward leakage results by fit test exercise

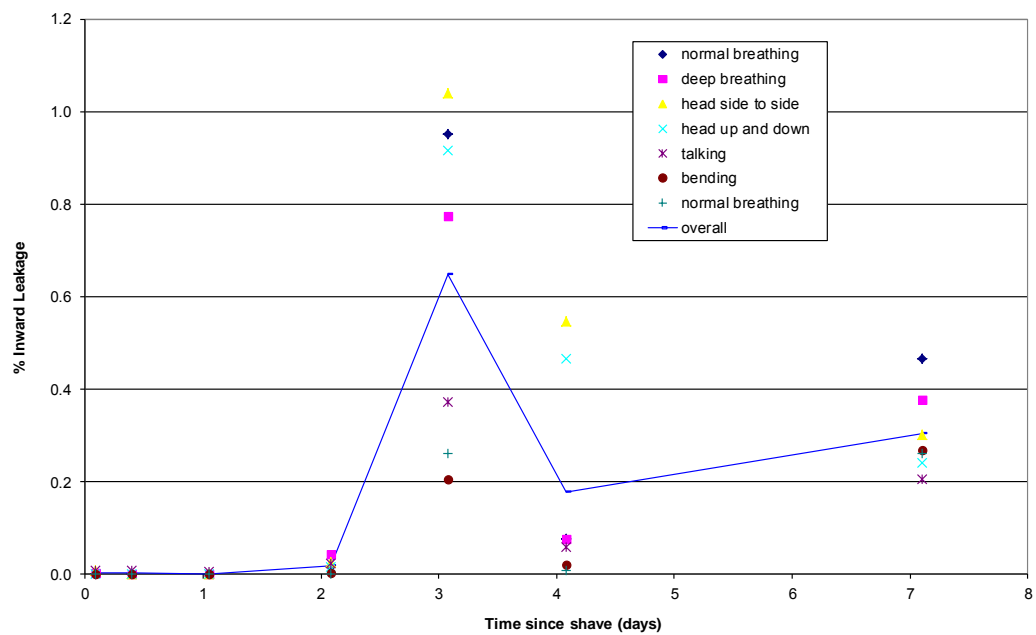
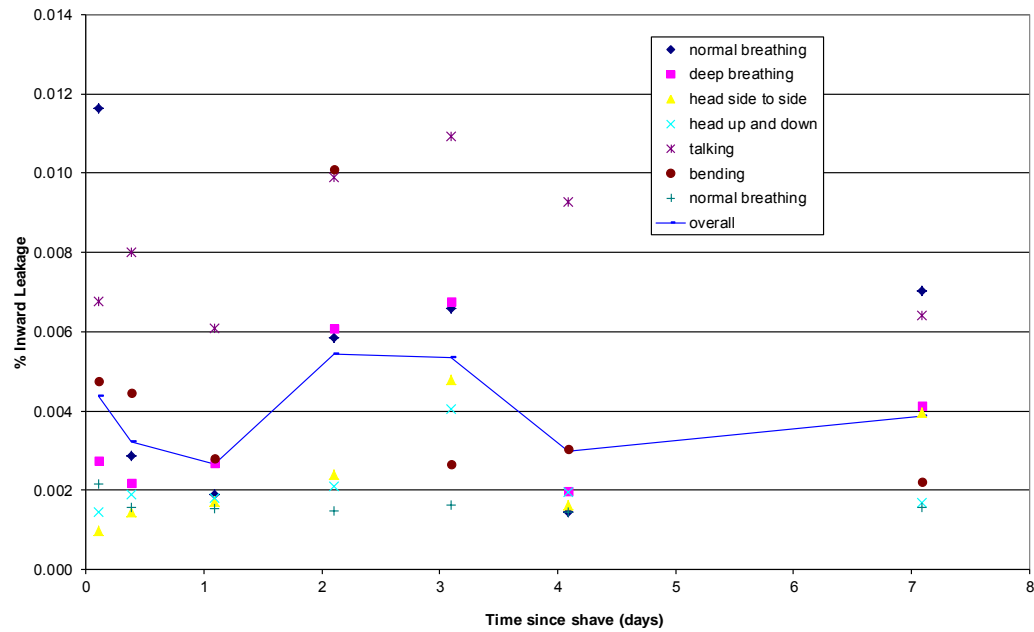


Figure 96 Facepiece F9 test subject V15 inward leakage results by fit test exercise



6.2 APPENDIX B: PHOTOGRAPHS 2 DAYS

Photographs of test subjects showing stubble growth at 2 days after shaving

Figure 95 Test Subject V1: 2 days stubble growth



Figure 96 Test Subject V2: 2 days stubble growth



Figure 97 Test Subject V3: 2 days stubble growth



Figure 98 Test Subject V4: 2 days stubble growth



Figure 99 Test Subject V5: 2 days stubble growth



Figure 100 Test Subject V6: 2 days stubble growth



Figure 101 Test Subject V7: 2 days stubble growth



Figure 102 Test Subject V8: 2 days stubble growth



Figure 103 Test Subject V9: 2 days stubble growth



Figure 104 Test Subject V11: 2 days stubble growth



Figure 105 Test Subject V12: 2 days stubble growth



Figure 106 Test Subject V13: 2 days stubble growth



Figure 107 Test Subject V14: 2 days stubble growth



Figure 108 Test Subject V15: 2 days stubble growth



Figure 109 Test Subject V16: 2 days stubble growth



6.3 APPENDIX C: PHOTOGRAPHS 7 DAYS

Photographs of test subjects showing stubble growth at 7 days after shaving

Figure 110 Test Subject V1: 7 days stubble growth



Figure 111 Test Subject V2: 7 days stubble growth



Figure 112 Test Subject V3: 7 days stubble growth



Figure 113 Test Subject V4: 7 days stubble growth



Figure 114 Test Subject V5: 7 days stubble growth



Figure 115 Test Subject V6: 7 days stubble growth



Figure 116 Test Subject V7: 7 days stubble growth



Figure 117 Test Subject V8: 7 days stubble growth



Figure 118 Test Subject V9: 7 days stubble growth



Figure 119 Test Subject 11: 7 days stubble growth



Figure 120 Test Subject V12: 7 days stubble growth



Figure 121 Test Subject V13: 7 days stubble growth



Figure 122 Test Subject V14: 7 days stubble growth



Figure 123 Test Subject V15: 7 days stubble growth



Figure 124 Test Subject V16: 7 days stubble growth



6.4 APPENDIX D: STUBBLE MEASUREMENTS

volunteer	area shaved cm2	comments	mass mg	mass/area mg/cm2	mean length of stubble mm	mean width of stubble mm
V1	7.5	close shave	10.9	1.5	2.8	0.17
V2	4.25	chin area - denser growth	19	4.5	2.4	0.14
V3 left side	12		10.6	0.9	2.3	0.14
V3 right side	12	closest shave	15.9	1.3	2.3	0.13
V4 left	7.5		4.7	0.6	1.7	0.14
V4 right	10.5	closest shave	11.9	1.1	1.2	0.14
V5 left	9		16.4	1.8	2.7	0.14
V5 right	6	closest shave	14.8	2.5	2.2	0.12
V6 right	10.5	close shave	14.3	1.4	2.8	0.16
V7 left	9		12.7	1.4	2.4	0.13
V7 right	12	closer shave than left	8.4	0.7	2.0	0.11
V8 left	6		7.6	1.3	2.2	0.13
V8 right	6		7.2	1.2	2.3	0.12
V9 left	12	sparse shave	12.2	1.0	2.4	0.13
V9 right	8	sparse shave	10.1	1.3	2.1	0.13
V11 left	12	under chin - denser growth	12.6	1.1	3.0	0.13
V11 right	12	under chin - denser growth	17.4	1.5	3.0	0.14
V12 left	9	sparse shave	9.4	1.0	2.1	0.12
V12 right	6	sparse shave	7.2	1.2	2.0	0.11
V13 left	9	sparse shave	5.21	0.6	2.1	0.12
V13 right	9	sparse shave	2.55	0.3	1.7	0.09
V14 left	6	hairs curl	8.3	1.4	2.3	0.13
V14 right	7.5	hairs curl	9.8	1.3	2.0	0.09
V15 left	8	sparse shave	6.5	0.8	2.1	0.15
V15 right	4	sparse shave	2.7	0.7	2.0	0.11
V16 left	12	close shave	13	1.1	2.8	0.14
V16 right	12	close shave	14	1.2	2.5	0.13
mean				1.3	2.3	0.13
standard deviation				0.75	0.40	0.02

6.5 APPENDIX E: STATISTICIANS REPORT

Stubble Evaluation

Data were analysed on percentage inward leakage in nine face pieces tested by 15 volunteers over a seven day period; each volunteer tested 4 different face pieces. The data collected are longitudinal data, since the measures of inward leakage on each individual were repeated on a number of occasions.

The following plot gives a complete summary of the % inward leakage by time elapsed since shaving for each individual and mask tested. Although it only becomes decipherable if enlarged to 200%, it gives an overall impression of the variability over time within some individuals.



Statistical analysis

A multilevel regression model was used for this longitudinal data set, using the *growth curve model* (or change curve model) approach. This models the shape of the trajectory for each volunteer over time, and also models how these trajectories vary over time.

The first question addressed was, what is the intra-class correlation coefficient (ICC)? The ICC indicates how much of the total variability in the % inward leakage occurs between individuals, and

conversely how much occurs within individuals. The ICC was very small – only 3.3% of the variability in % inward leakage occurred between individual volunteers, and 96.7% occurred within volunteers.

The multilevel model fitted to that data was:

Dependent variable - % inward leakage

Independent (explanatory) variables – face piece, time elapsed since shaving, and the interaction between face piece and time elapsed. All these terms in the model were statistically highly significant ($p < 0.001$)

- Face piece was included as a fixed effect, since we are interested in the effects of these and they are population level effects.
- Time elapsed was fitted as a random effect since this enables the model to account for individual differences in inward leakage. Essentially random effects estimate the variability.

The change curves were checked for non-linearity, but the terms for quadratic and cubic effects were not statistically significant in the model. So the model assumed linear change over time.

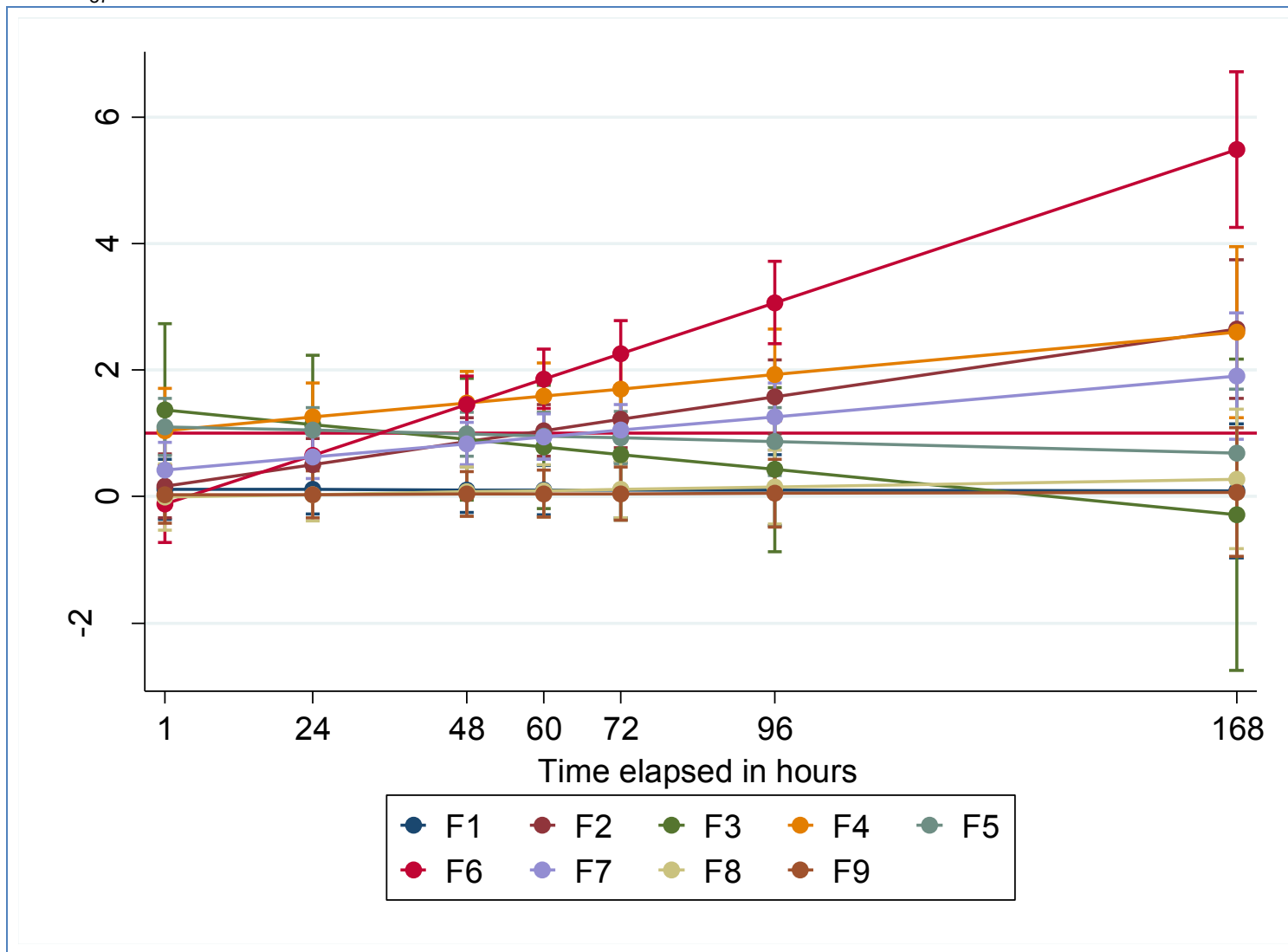
The table of predicted values of % inward leakage, and the Figure showing these predicted values plotted against time of observation, are shown below. In addition, the predicted values for the individual face pieces are also shown on separate plots, since it is difficult to see the individual face pieces on the main Figure. Essentially they show that there is a large amount of variability around the predicted values.

The predicted values, and/or their confidence intervals were greater than or equal to 1% inward leakage for all face pieces except F1 and F9. F8 also performed well until the final observation at 168 hours, when a very large confidence interval exceeded 1 % inward leakage.

Table of predicted values of % inward leakage

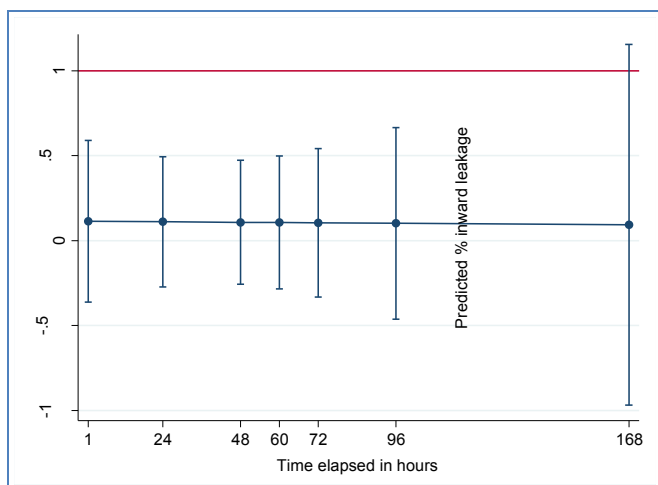
Face piece	Time						
	1	24	48	60	72	96	168
F1	0.114	0.111	0.108	0.107	0.105	0.102	0.093
	(-0.362 to 0.590)	(-0.272 to 0.495)	(-0.257 to 0.473)	(-0.284 to 0.498)	(-0.331 to 0.541)	(-0.462 to 0.666)	(-0.96 to 1.154)
F2	0.168	0.509	0.865	1.044	1.222	1.578	2.646
	(-0.340 to 0.676)	(0.100 to 0.919)	(0.481 to 1.250)	(0.635 to 1.452)	(0.769 to 1.674)	(0.996 to 2.159)	(1.553 to 3.739)
F3	1.372	1.144	0.905	0.786	0.666	0.428	-0.288
	(0.009 to 2.735)	(0.052 to 2.235)	(-0.055 to 1.865)	(-0.188 to 1.759)	(-0.374 to 1.707)	(-0.868 to 1.724)	(-2.750 to 2.175)
F4	1.040	1.254	1.478	1.590	1.702	1.926	2.597
	(0.367 to 1.712)	(0.711 to 1.798)	(0.978 to 1.978)	(1.068 to 2.112)	(1.131 to 2.272)	(1.203 to 2.648)	(1.241 to 3.952)
F5	1.105	1.048	0.987	0.957	0.927	0.867	0.686
	(0.654 to 1.557)	(0.685 to 1.411)	(0.641 to 1.334)	(0.585 to 1.330)	(0.511 to 1.344)	(0.328 to 1.406)	(-0.330 to 1.702)
F6	-0.116	0.655	1.459	1.861	2.263	3.068	5.480
	(-0.722 to 0.489)	(0.167 to 1.142)	(1.011 to 1.907)	(1.392 to 2.330)	(1.750 to 2.777)	(2.415 to 3.720)	(4.251 to 6.710)
F7	0.423	0.627	0.839	0.945	1.052	1.264	1.902
	(-0.009 to 0.855)	(0.279 to 0.974)	(0.504 to 1.174)	(0.583 to 1.308)	(0.645 to 1.458)	(0.735 to 1.793)	(0.906 to 2.897)
F8	-0.006	0.033	0.074	0.094	0.115	0.156	0.278
	(-0.526 to 0.513)	(-0.385 to 0.451)	(-0.316 to 0.464)	(-0.318 to 0.507)	(-0.341 to 0.571)	(-0.429 to 0.741)	(-0.825 to 1.381)
F9	0.0286	0.0346	0.0408	0.0439	0.0470	0.0533	0.0720
	(-0.427 to 0.484)	(-0.332 to 0.401)	(-0.307 to 0.388)	(-0.328 to 0.416)	(-0.369 to 0.463)	(-0.485 to 0.592)	(-0.943 to 1.087)

Data shown are predicated values with 95% confidence intervals in parentheses

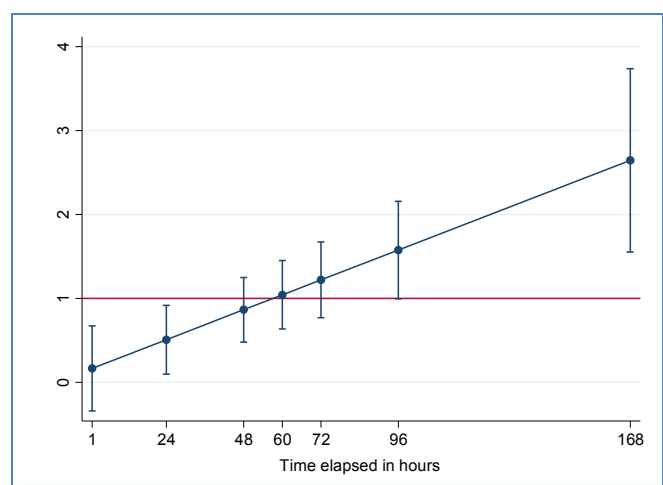


Plot of predicted values of % inward leakage against time elapsed from shaving

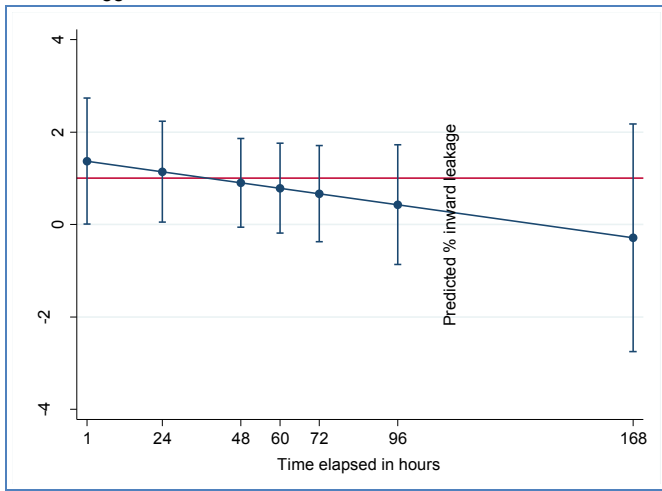
Plots for individual face pieces



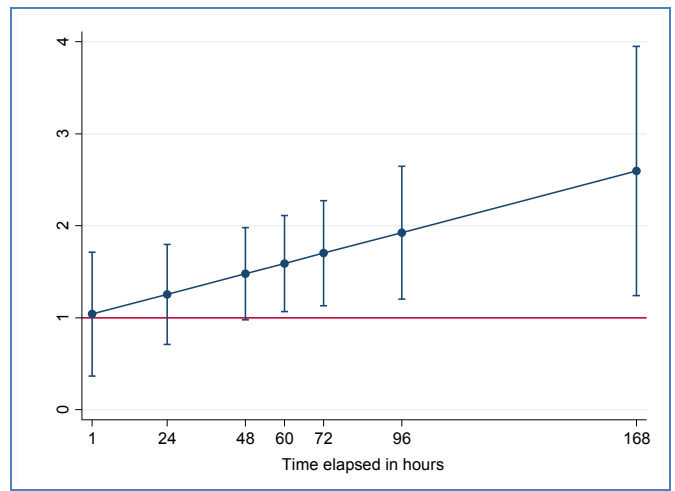
F1



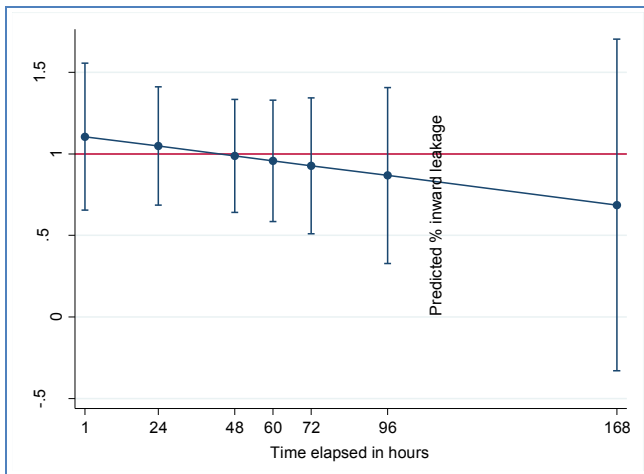
F2



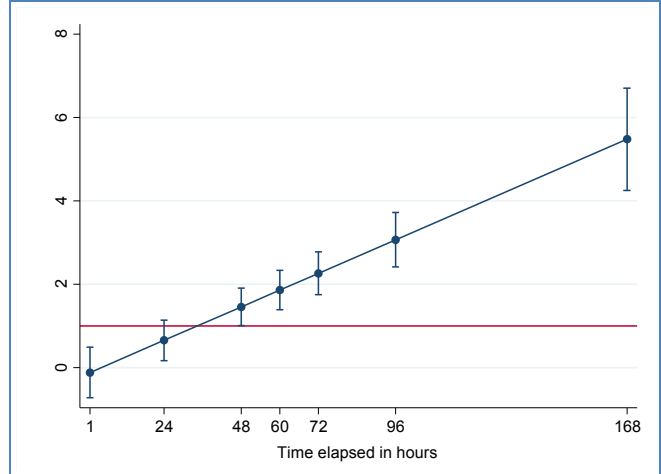
F3



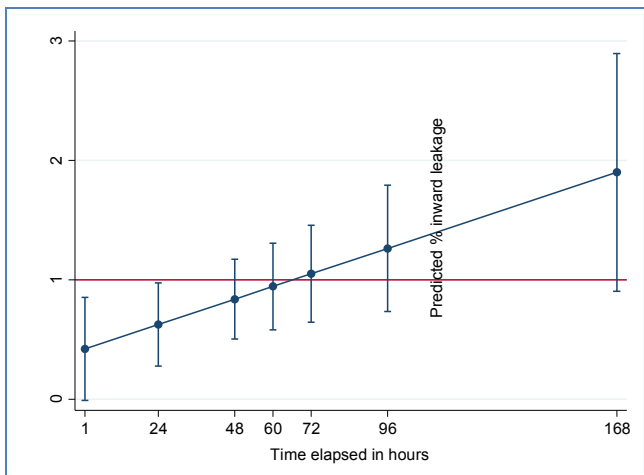
F4



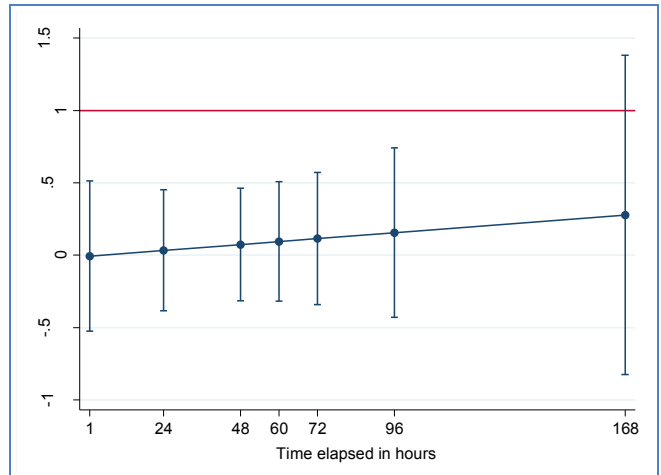
F5



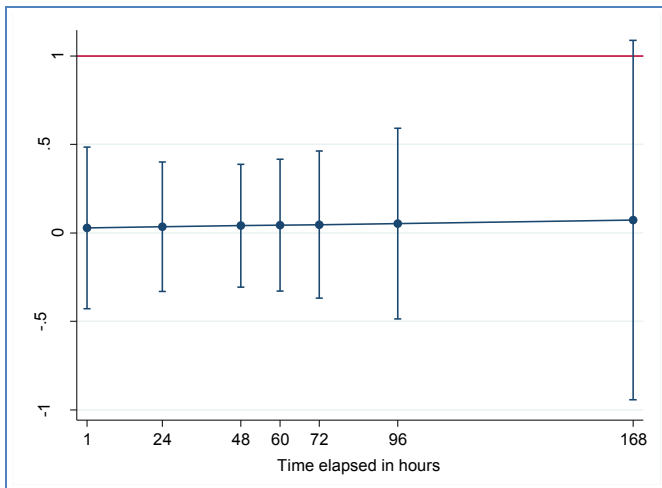
F6



F7



F8

**F9**

The effect of wearer stubble on the protection given by Filtering Facepieces Class 3 (FFP3) and Half Masks

HSE Inspectors routinely come across workers with various degrees of stubble growth using respiratory protective masks, despite guidance to the contrary. This research studied the effect of 0-7 days stubble growth on the protection given by FFP3 filtering facepieces and half masks.

Fifteen male volunteers took part, each testing four masks. For most, three different design FFP3 and one half mask were tested, selected from seven models of FFP3 and 2 half masks. Fit tests were carried out immediately after shaving and repeated six times during the following week, without further shaving.

Results showed that the effect on protection was quite specific to the mask/wearer combination. Protection could be significantly reduced where stubble was present, beginning within 24 hours from shaving, and generally worsening as facial hair grew. Statistical analysis predicted this could reach an unacceptable level for all of the masks tested.

While some individual wearers did grow some stubble without significantly reducing protection with some masks, this was unpredictable and it would not be practical to conduct the necessary testing to confirm this for every individual wearer.

The current guidance advising being clean-shaven in the area of the mask seal is justified.

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