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TOPICAL ANTIPENETRANT (TAP)

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QUANTITATIVE FIT FACTOR EVALUATION OF SCHISTOSOME TOPICAL ANTIPENETRANT (TAP)

1. Introduction

The U.S. Army Engineering Research, Development and Engineering Center (ERDEC) conducted a quantitative fit factor evaluation of the effect of Schistosome Topical Antipenetrant (TAP) on protective mask face seal leakage. This testing was requested by the U.S. Army Medical Materiel Development Activity. The human use protocol for this test was reviewed by the ERDEC Human Use Committee and determined to be greater than minimal risk due to the classification of Schistosome TAP as an investigational drug. The protocol was then submitted to the U.S. Army Surgeon General's Human Subjects Research Review Board (HSRRB). The HSRRB approved this protocol on 3 May 1993 (Log No. A-5860). This protocol then received local ERDEC administrative approval on 6 May 1993 (ERDEC Log No. 9304A). Testing was conducted on two dates; 8 and 22 May 1993.

2. Body

2.1 Purpose

The purpose of this test was to evaluate the effects of Schistosome TAP on the facial fit or seal of the US M17 and M40 chemical-biological protective masks. The facial fit or seal of a mask is determined by measuring mask fit factors on a population of individuals. A fit factor is defined as the ratio of an aerosol challenge concentration relative to the concentration measured within the mask.

Three test conditions were evaluated. The control condition consisted of the standard M17 and M40 masks with no Schistosome TAP applied on the face. The other two conditions were wet Schistosome TAP and Schistosome TAP which had been applied to the face and neck and permitted to dry for 30 minutes. The Schistosome TAP was applied to the lower face and upper neck area as specified in the product literature.

2.2 Test Subjects

The 143rd Ordnance Battalion located at Aberdeen Proving Ground, MD provided 48 male soldiers of whom 16 volunteered to support this testing. Only male volunteers were used due to logistical considerations. A blood serum pregnancy test is required for females 48 hours prior to participation because of the investigational status of Schistosome TAP. Since the volunteers are not specifically identified until less than 24 hours prior to the start of testing it was decided that females would not be used. All subjects recruited for this study

received a medical examination. The purpose of this examination was to determine if the subject was suitable for use with the Schistosome TAP. Each subject was examined for facial irritation or lesions and questioned about their allergy history.

The volunteers were sized by the test personnel for fit in both the M17 and M40 masks. The M17 is available in 4 sizes; extra-small, small, medium and large. The M40 has 3 sizes; small, medium and large. Two facial measurements were recorded for each individual; the face length or menton-nasal root depression distance and the face width or bizygomatic diameter. This data is presented in Appendix A.

2.3 Corn Oil Aerosol Test Method

A 10 ft by 10 ft by 32 ft test chamber was used for this study. A polydispersed aerosol challenge is generated by atomizing liquid corn oil using an array of 8 Laskin nozzle nebulizers. The Laskin nozzle generates a coarse aerosol mist by using low pressure filtered air to shear off particles of corn oil. The resulting airflow generated by the nozzle carries the mist upwards into a separate chamber of the nebulizer where the airstream is deflected by a calibrated impactor plate to remove the larger particles. This produces an aerosol consisting of the desired particle size range. A uniform challenge concentration of approximately 25 mg/m³, having a mass median aerodynamic diameter (MMAD) of 0.4 - 0.6 micrometers, is maintained within the test chamber through controlled dilution with room air by a 300 cfm filter/blower system.

A computer-automated laser photometer system is used to quantify the amount of aerosol leakage within the protective equipment. The laser photometer, Model 8587 manufactured by TSI Inc., measures the amount of light scattered by the aerosol in the sample stream and converts it to a voltage. The output is digitized and processed by the microcomputer system. The photometer unit used in the test system responds to a five-decade range in aerosol concentration. At the beginning of a test, the photometer is automatically adjusted to full scale to measure the chamber concentration. Both the initial chamber and subsequent mask concentrations are determined by integration. The ratio of the outside challenge concentration to the concentration measured inside the mask is defined as a mask fit factor. The fit factor, therefore, represents an expression of the performance of the protective equipment. The larger the value, the greater the protection provided by the protective equipment. This system is capable of measuring fit factors up to 100,000.

At the conclusion of a test trial, the computer calculates an overall (average) fit factor by taking the inverse of the arithmetic mean of the individual exercise penetrations values measured during the course of the test. In addition, exercise

fit factor values are computed from the inverse of the individual exercise penetration values. The overall fit factor value along with the individual exercise fit factor values are stored on a computer diskette for subsequent analysis.

2.4 Test Procedure.

Prior to testing, the volunteers were assisted by ERDEC test personnel in donning the protective masks. A single air sampling probe was inserted in the facepieces of each protective mask with an attached 10-foot length of flexible silicone tubing. Once the mask was correctly donned and adjusted, the subjects entered the aerosol chamber where they connected the end of the sample tubing to a port on the chamber wall. Air was then sampled from the eye cavity region of the mask at a continuous rate of 2.2 liters per minute through the photometer detector unit.

During a test the subjects performed the following ten exercises, each 1 minute in duration:

- Standing still (normal breathing)
- Deep breathing
- Head movement, side to side
- Head movement, up and down
- Talking (recite "Rainbow" passage)
- Sight rifle
- Reach for floor and ceiling
- On hands and knees looking left and right
- Facial expressions
- Standing still (normal breathing)

The above exercise routine is designed to stress the face seal of the respirator under simulated "generic" use conditions and has been used in prior studies at ERDEC for the fit factor testing.

After completion of the test trial the subjects disconnected their sample lines and exited the chamber. The protective masks were then doffed and the subjects were instructed to wash their faces to remove any residual Schistosome TAP. Test personnel then sanitized the protective masks for the next use.

2.5 Data Analysis

2.5.1 Fit Factor Calculation Method

The protection provided by a respirator assembly against a challenge agent is expressed as the ratio of a concentration inside the respirator over a challenge concentration; this ratio is called the penetration. The reciprocal of this ratio is called the fit factor. Both terms are presented by the following equations:

$$P = \frac{C_{\text{respirator}}}{C_{\text{challenge}}}$$

and

$$FF = \frac{C_{\text{challenge}}}{C_{\text{respirator}}} = \frac{1}{P}$$

where P = Penetration

$C_{\text{respirator}}$ = average concentration of challenge agent inside the respirator (mg/m³)

$C_{\text{challenge}}$ = average challenge concentration (mg/m³)

FF = Fit Factor

2.5.2 Average Leakage Concentration per Exercise

The results of a fit factor test are usually expressed by a graph showing the instantaneous ratio of the in-respirator and challenge concentrations in the form of penetration or fit factor versus time. The duration of each of the exercises in this example is 60 seconds. Within one exercise, the computer collects data at the rate of two data points per second. Hence, the average penetration for one exercise can be expressed as:

$$P_{\text{exercise}} = \sum_{i=1}^n \frac{P_i}{n}$$

where n = the number of data points collected per one minute exercise (n = 120)

and P_i = the individual measured penetration data point

2.5.3 Overall Fit Factor

In the same way, the overall fit factor, which represents the fit factor over the duration of the test, is expressed as:

$$FF_{overall} = \left(\sum_{i=1}^m \frac{P_{exercise\ i}}{m} \right)^{-1}$$

where m = number of exercises in one complete test

2.5.4. Statistical Analysis

All fit factor data presented in this report were statistically analyzed using binomial proportions of percentage of success. Continuous methods of analysis could not be used due to the truncation of data at a fit factor of 100,000. The analysis was based on a total of approximately 16 fit factor trials conducted on each condition. The 1667 and 6667 fit factor levels correspond to standard pass/fail criteria levels established under the U.S. Joint Service Operational Requirements for testing of the M40 military mask system and were derived from combat threat analyses of the chemical/biological battlefield environment.

2.6 Results

The results for the M40 mask are summarized in Table 1. The complete set of data, which includes the individual exercise and the overall fit factors is listed in Appendix B. The pass/fail rates for each configuration at various fit factor levels are provided in Appendix C. A graphical comparison of the three mask wear configurations is displayed in Appendix D.

Table 1. Summary of fit factor results for the M40 mask

M40 Mask	Fit Factor						
	500	1667	3000	5000	6667	10000	20000
No TAP	100%	100%	100%	94%	94%	94%	81%
Wet TAP	100%	100%	100%	100%	100%	100%	100%
Dry TAP	100%	100%	100%	100%	100%	100%	100%

The results for the M17 mask are shown in Table 2. and are given in terms of percent difference based on the baseline configuration of the M17 worn without any Schistosome TAP applied to the face. The absolute M17 data are not provided in this report due to the Secret classification of M17 data under the Operation Rock Ready security classification guide. Table 3 displays the M40 results in terms of percent difference in order to assist interpretation of Table 2.

Table 2. Summary of fit factor percent differences for the M17 mask

M17 Mask	Fit Factor						
Concept	500	1667	3000	5000	6667	10000	20000
No TAP	0%	0%	0%	0%	0%	0%	0%
Wet TAP	+6.3%	+6.3%	+6.3%	+6.3%	+5.4%	+10.7%	+10.7%
Dry TAP	+6.3%	+6.3%	+6.3%	+6.3%	+12.5%	+25.0%	+12.4%

Table 3. Summary of fit factor percent differences for the M40 mask

M40 Mask	Fit Factor						
Concept	500	1667	3000	5000	6667	10000	20000
No TAP	0%	0%	0%	0%	0%	0%	0%
Wet TAP	0%	0%	0%	+6.3%	+6.3%	+6.3%	+18.8%
Dry TAP	0%	0%	0%	+6.3%	+6.3%	+6.3%	+12.5%

3. Conclusions

Subject participation was a significant problem in the conduct of this study. The 16 subjects used represent only half of the desired goal of 32 subjects. As a result of this, the pass/fail rates for both masks exhibit large intervals at the 90% confidence limits for reliability. The results for all three configurations fall within the expected range of the confidence limits. The conclusion that can be reached from the data by itself is that there were no significant differences between any of the three configurations. Schistosome TAP had no significant effect on the protective capabilities of either the M17 or the M40 masks.

However, despite the small amount of data, there are several factors which permit some definite conclusions to be attained. First of all, the results are very consistent with previous studies performed on both the M17 and M40 masks. A major deviation in the current pattern would have to take place before any significant differences would become evident. Furthermore, the data for both masks show a minor trend of increased protection when Schistosome TAP is worn. This protection enhancement effect was demonstrated in an earlier study of the

M17 mask.¹ In this study, lanolin was applied around the entire face corresponding to the mask periphery. The results on 37 subjects who were tested for a total of 118 trials showed an overall improvement in protection. The percent improvement is shown in Table 4.

Table 4. Summary of effect of lanolin on M17 fit factors

	M17	500	1000	3000	5000	6667	10000
Baseline		0%	0%	0%	0%	0%	0%
Lanolin		0%	0%	+3%	+8%	+11%	+17%

This minor increase in protection is most likely the result of a reduction in the number of microscopic face seal leaks which occur during normal mask wear. Topical lotions and creams probably have little effect on larger mask seal breaks.

Based on this previous study of the M17 mask and the consistency of the trend for increased protection with both the M17 and M40 masks while using Schistosome TAP, it can reasonably be stated that the application of Schistosome TAP, whether it is wet or has been allowed to dry, does not have an adverse impact on mask face seal leakage.

4. References

M17 Mask Follow-On Evaluation (U); Secret Report
Fritch, William H.; Gardner, Paul D.; Hughes, Francis P.;
Bretlich, Richard W.; Laye, Randolph G.
April 1989; Report No. CRDEC-TR-049

¹M17 Follow-On Evaluation (U); Secret Report

APPENDIX A

Subject Facial Anthropometric Data

Subject No.	Face Length	Face Width	M17 Size	M40 Size
1	114 mm	142 mm	M	M
2	120 mm	145 mm	M	M
3	117 mm	133 mm	S	M
4	125 mm	136 mm	M	M
5	121 mm	142 mm	M	M
6	120 mm	142 mm	M	M
7	120 mm	140 mm	M	M
8	111 mm	142 mm	S	M
9	129 mm	139 mm	M	L
10	120 mm	137 mm	M	M
11	120 mm	150 mm	L	L
12	122 mm	140 mm	M	M
13	127 mm	133 mm	S	M
14	115 mm	142 mm	S	M
15	115 mm	145 mm	M	M
16	116 mm	145 mm	S	M

Notes:

Subject 4 withdrew after 3 tests.
 Subject 8 was judged by the mask sizer to be a little large for the small M40 mask, but too small for the medium mask.
 Subject 10 had a long slender face.
 Subject 14 was judged by the mask sizer to be a little large for the small M40 mask, but too small for the medium mask.
 Subject 15 was judged by the mask sizer to be a little large for the small M17 mask, but too small for the medium mask.

APPENDIX B

M40 Fit Factor Data
No Schistosome TAP

MASK	SUBJECT	CONCEPT	TRIAL	AVEFIT	EXRCS1	EXRCS2	EXRCS3	EXRCS4	EXRCS5	EXRCS6	EXRCS7	EXRCS8	EXRCS9	EXRCS10
M 40 6	1	2	1	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0
M 40 5	2	2	1	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0
M 40 4	3	2	1	60350 6	74092 1	60988 3	68018 6	64234 1	65340 5	85663 7	69808 8	60709 4	51124 5	40577 3
M 40 8	4	2	1	88818 3	100000 0	72901 1	95128 7	98763 8	87740 1	100000 0	90403 4	70243 8	85899 6	100000 0
M 40 12	5	2	1	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0
M 40 14	6	2	1	36619 7	39908 3	35689 9	40928 0	42117 1	28607 4	36575 3	34434 8	36670 9	36482 8	38749 1
M 40 4	7	2	1	13185 9	93152 0	24163 0	20591 6	1749 5	37462 8	49133 5	100000 0	100000 0	100000 0	100000 0
M 40 7	8	2	1	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0
L 40 1	9	2	1	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0
M 40 9	10	2	1	41181 1	53879 9	61379 2	63489 5	59524 4	54982 9	30354 6	51984 0	46806 8	17957 3	34623 0
L 40 14	11	2	1	12020 4	100000 0	100000 0	1752 9	100000 0	100000 0	18633 0	12021 5	16041 3	81754 4	100000 0
M 40 14	12	2	1	45240 4	47573 1	45218 4	47964 9	44740 8	51178 8	25247 9	47044 7	53286 0	53530 9	59324 4
M 40 6	13	2	1	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0
M 40 12	14	2	1	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0
M 40 9	15	2	1	83074 9	76842 0	70729 4	80861 1	80157 5	93209 1	87273 7	84222 0	84797 5	89772 5	87822 6
M 40 5	16	2	1	3822 2	100000 0	100000 0	100000 0	100000 0	428 4	90806 6	100000 0	100000 0	6846 6	15427 7

M40 Fit Factor Data
Wet Schistosome TAP

MASK	SUBJECT	CONCEPT	TRIAL	AVEFIT	EXRCS1	EXRCS2	EXRCS3	EXRCS4	EXRCS5	EXRCS6	EXRCS7	EXRCS8	EXRCS9	EXRCS10
M 40 6	1	4	1	93145.5	100000.0	100000.0	100000.0	100000.0	57807.4	100000.0	100000.0	100000.0	100000.0	100000.0
M 40 9	2	4	1	43839.0	52241.9	51951.2	26244.9	57029.3	47703.5	45717.7	47340.6	46399.4	36652.7	46983.2
M 40 4	3	4	1	60849.9	57864.0	67799.2	68699.5	63218.8	65088.1	62422.1	51010.5	64452.9	52918.1	60887.3
M 40 8	5	4	1	30439.6	67261.9	59700.0	66650.9	66181.6	30267.2	55344.1	56087.1	59176.7	6143.6	55435.9
M 40 6	6	4	1	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0
M 40 4	7	4	1	84459.4	100000.0	93023.1	52176.7	87992.2	72840.7	75438.7	100000.0	100000.0	98664.2	100000.0
M 40 4	8	4	1	62635.1	75168.8	69786.3	65365.7	71202.5	43924.9	72677.4	60206.0	58402.1	60622.1	62792.0
L 40 17	9	4	1	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0
M 40 14	10	4	1	34924.3	34201.7	34201.8	40370.6	34282.3	34857.3	32447.3	32303.2	35625.5	34526.4	37849.9
L 40 1	11	4	1	98273.8	100000.0	100000.0	100000.0	100000.0	85059.1	100000.0	100000.0	100000.0	100000.0	100000.0
M 40 10	12	4	1	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0
M 40 12	13	4	1	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0
M 40 8	14	4	1	90432.8	100000.0	84501.4	85690.0	95046.7	88490.6	100000.0	86603.7	89465.3	81396.6	100000.0
M 40 11	15	4	1	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0	100000.0
M 40 9	16	4	1	45776.9	52845.8	51717.4	54387.6	54739.9	40745.5	50175.2	46279.4	54708.4	55702.1	24257.1

M40 Fit Factor Data
Dry Schistosome TAP

MASK	SUBJECT	CONCEPT	TRIAL	AVERIT	EXRCS1	EXRCS2	EXRCS3	EXRCS4	EXRCS5	EXRCS6	EXRCS7	EXRCS8	EXRCS9	EXRCS10
M 40 5	1	6	1	44008 9	41731 0	42805 9	46431 9	26124 6	45524 6	31407 8	68674 8	100000 0	37621 2	65999 5
M 40 5	2	6	1	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0
M 40 14	3	6	1	36015 8	37311 0	39947 6	40540 4	39657 7	35378 5	32897 1	31203 4	36480 7	35764 4	33705 5
M 40 14	4	6	1	44669 8	42019 7	42806 6	47676 7	43928 4	43548 0	44869 1	43100 1	44789 2	45110 6	49949 9
M 40 12	5	6	1	88091 6	100000 0	100000 0	100000 0	100000 0	50678 0	100000 0	95977 0	96378 8	90038 1	84143 3
M 40 10	6	6	1	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0
M 40 7	7	6	1	51265 3	100000 0	15307 0	100000 0	100000 0	59598 6	59803 1	100000 0	27598 7	100000 0	100000 0
M 40 11	8	6	1	14336 4	100000 0	37640 5	23040 4	2096 1	11053 3	100000 0	100000 0	100000 0	100000 0	100000 0
L 40 12	9	6	1	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0
M 40 5	10	6	1	30616 4	100000 0	100000 0	100000 0	100000 0	100000 0	39903 5	88069 5	41739 4	5587 1	26788 0
L 40 1	11	6	1	97945 4	100000 0	100000 0	100000 0	100000 0	82680 4	100000 0	100000 0	100000 0	100000 0	100000 0
M 40 6	12	6	1	39062 8	34441 4	100000 0	18522 0	25022 3	32553 0	88366 8	59656 8	22615 9	100000 0	100000 0
M 40 9	13	6	1	61224 9	68259 6	70865 1	49686 6	58110 8	62184 5	63403 0	65260 2	67433 1	50936 2	64133 0
M 40 14	14	6	1	41565 7	46938 1	42361 7	39994 3	40459 8	42141 6	38537 4	39157 6	41996 2	39031 9	46938 1
M 40 5	15	6	1	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0
M 40 5	16	6	1	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0	100000 0

APPENDIX C

Schistosome TAP PF Test
M40 Mask (Baseline)

NUMBER OF SUBJECTS = 16

PASS/FAIL RATE BY MASK SIZE

SMALL	PASS = 0	FAIL = 0
MEDIUM	PASS = 13	FAIL = 1
LARGE	PASS = 2	FAIL = 0
TOTAL	PASS = 15	FAIL = 1

RANGED PROTECTION FACTOR

PROTECTION FACTOR	PERCENTAGE	CONFIDENCE LIMITS @ 90% RELIABILITY	
500	100%	86.6%	100%
1667	100%	86.6%	100%
3000	100%	86.6%	100%
5000	94%	77.8%	99.3%
6667	94%	77.8%	99.3%
10000	94%	77.8%	99.3%
20000	81%	63.0%	92.8%

Schistosome TAP PF Test
M40 Mask w/ Tap Wet

NUMBER OF SUBJECTS = 15

PASS/FAIL RATE BY MASK SIZE

SMALL	PASS = 0	FAIL = 0
MEDIUM	PASS = 13	FAIL = 0
LARGE	PASS = 2	FAIL = 0
TOTAL	PASS = 15	FAIL = 0

RANGED PROTECTION FACTOR

PROTECTION FACTOR	PERCENTAGE	CONFIDENCE LIMITS @ 90% RELIABILITY	
500	100%	85.8%	100%
1667	100%	85.8%	100%
3000	100%	85.8%	100%
5000	100%	85.8%	100%
6667	100%	85.8%	100%
10000	100%	85.8%	100%
20000	100%	85.8%	100%

Schistosome TAP PF Test
M40 Mask w/ Tap Dry

NUMBER OF SUBJECTS = 16

PASS/FAIL RATE BY MASK SIZE

SMALL	PASS = 0	FAIL = 0
MEDIUM	PASS = 14	FAIL = 0
LARGE	PASS = 2	FAIL = 0
TOTAL	PASS = 16	FAIL = 0

RANGED PROTECTION FACTOR

PROTECTION FACTOR	PERCENTAGE	CONFIDENCE LIMITS @ 90% RELIABILITY	
500	100%	86.6%	100%
1667	100%	86.6%	100%
3000	100%	86.6%	100%
5000	100%	86.6%	100%
6667	100%	86.6%	100%
10000	100%	86.6%	100%
20000	94%	77.8%	99.3%

APPENDIX D

M40 OVERALL FIT FACTOR PERFORMANCE

