Comparison of showering protocols effectiveness for human volunteers' skin decontamination

Report of the ORCHIDS project volunteer study performed at Gurcy-le-Châtel (France) from Sept 6 to 10, 2010.

Agreement Number 2007203 ORCHIDS

Technical Report 5 (Deliverable 9) – ANNEX B

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This report from the IRBA reflects understanding and evaluation of the current scientific evidence as presented and referenced in this document.

CONTENTS

INTRODUCTION

Background

The “ORCHIDS” project is an EU funded research project aimed at providing evidence-based guidelines for decontamination following a mass casualty incident. It includes *in vitro* and *in vivo* studies, the latter being performed on animals following exposure to toxic chemicals or on human volunteers exposed to non-toxic surrogates of these compounds. *In vitro* studies have shown that shorter showering durations (0.5 to 1 min) could improve the effectiveness of decontamination. An optimised showering protocol for skin decontamination of toxic chemicals and radioactive or biological agents might consist of a 0.5 to 1 min wash with water at 35 - 40°C, containing 0.5% detergent, and use of a wash cloth (cotton flannel) followed with 0.5 – 1 min rinse (water at 35 - 40°C).

Aims and objectives

Volunteer studies using non-toxic chemical simulants were performed to compare the effectiveness of showering protocols: Methyl salicylate (MeS) and a fluorescent chemical, Invisible Red S (FP), were used as surrogates of sulphur mustard and biological or radiological particulates. Two types of trials were conducted:

(1) “ORCHIDS” *vs* “French Reference Protocol (FR)” which differed in the showering duration: 1.5 min *vs* 6 min, water temperature: 35°C *vs* 25°C, water washing flow-rate 10 L/min *vs* 30 L/min and use of a wash cloth *vs* without (see Table 1 overleaf);

(2) use of wash cloth by the volunteer (“ORCHIDS”) or by a rescuer (“ORCHIDS +”) with the “ORCHIDS” showering protocol.

Showering Conditions	ORCHIDS	FR
Water flow rate (L/min)	10 (wash) 10 (rinse)	30 (wash) 10 (rinse)
Water Temperature (°C)	35-38	25-28
Detergent solution **(Argos 700* from Argos hygiène®)**	0.5%	0.5%
Duration: - **Wash** - **Rinse** **Total**	 1 min 30 sec 1 min 30 sec	 3 min 3 min 6 min
Wash cloth	+ (cotton flannel)	-
Pre-showering decon **(not performed in this trial)**	-	*e.g.* Fuller's Earth

***Table 1**: Conditions of the showering protocols compared in this study: "ORCHIDS" and "FR"*

*Argos 700 is a concentrated detergent solution containing non ionic and anionic surfactants.

MATERIALS AND METHODS

Volunteers and ethics

The study (reference ID RCB: 2010-A00569-30) was conducted in accordance with the principles of the Declaration of Helsinki and approved by the Ethics Committee Sud Est V (Grenoble, France). It included 86 fully informed male volunteers aged from 18 to 55 years.

Prior to inclusion in the study, each volunteer completed a medical questionnaire which was reviewed by a registered health professional to exclude those adults with pre-existing skin conditions (*e.g.* severe acne) or other health issues (*e.g.* allergy) that could potentially affect their safety during the trial.

The volunteers were recruited mainly from Etablissement Public d'Insertion de la Défense (EPIDE) (Montry). A few volunteers came from Seine-et-Marne Fire & Rescue Services (SDIS77), Institut de Formation en Soins Infirmiers St Joseph (Paris) and Centre d'expérimentations aériennes militaires (Cazaux).

Simulant contaminants

The study involved the use of either one of the following chemicals as simulant contaminants:

- A 4 mg/ml ethanol solution of a fluorescent chemical (Tris(3-(2,2,3,3,4444-heptafluorobutyryl)bornane-2-onato-O,O')europium) or "invisible red S" which was provided by Capricorn Chemicals, UK. When deposited on the skin, the fluorescent compound formed fluorescent particulates (FP) which were about 5 µm in diameter. Consequently, use of FP is more representative of radiological or biological particulate agents than chemicals. The maximum excitation and emission wavelengths for the FP were 365 nm and 616 nm, respectively.
- Undiluted methyl salicylate (MeS) (Sigma)

Groups of volunteers

The volunteers were randomly assigned to a group and ranked (Table 2).

Trial Simulant	ORCHIDS	FR	ORCHIDS +	Controls	Total
Trial 1 (FP)	12	11	-	5	28
Trial 2 (FP)	13	-	13	6	32
Trial 3 (MeS)	7	7	-	6+6	26
Total	32	18	13	23	86

Table 2*: Number of volunteers included in each of the 4 groups: ORCHIDS, FR, ORCHIDS + and non decontaminated controls for the 3 trials.*

Each volunteer had to follow a specific procedure which consisted of the following:

FP trial:

Disrobing, fluorescence measurement (background), contamination with simulants, fluorescence measurement (total contamination), decontamination, fluorescence measurement (residual contamination), sampling on the skin depot sites, rerobing, questionnaire (questions about instructions, comfort (temperature), compliance, privacy issues etc.)

MeS trial:

Disrobing, contamination with simulants, 5 min waiting, decontamination, off-gassing, sampling on the skin depot sites, rerobing, questionnaire (questions about instructions, comfort (temperature), compliance, privacy issues etc.)

Contamination with simulants

FP trial:

20 µl of a 4 mg ml^{-1} FP solution (0.08 mg) were topically applied to 19 sites on the volunteer (14 on the front and 5 on the back) (1.52 mg total): forehead (1), cheeks (2), shoulders (2), arms (2), hands (2), abdomen (1), legs (6), back (3).

MeS trial:

10 µl of undiluted MeS (11.8 mg) were topically applied to 10 sites (7 on the front and 3 on the back) (118 mg total): cheeks (2) + internal sides of the arms (2) + legs (4) + back (1) + abdomen (1).

Decontamination

The decontamination process was performed in a specific shelter (Utilis®) provided by the Fire Service (SDIS57) (Figure 1).

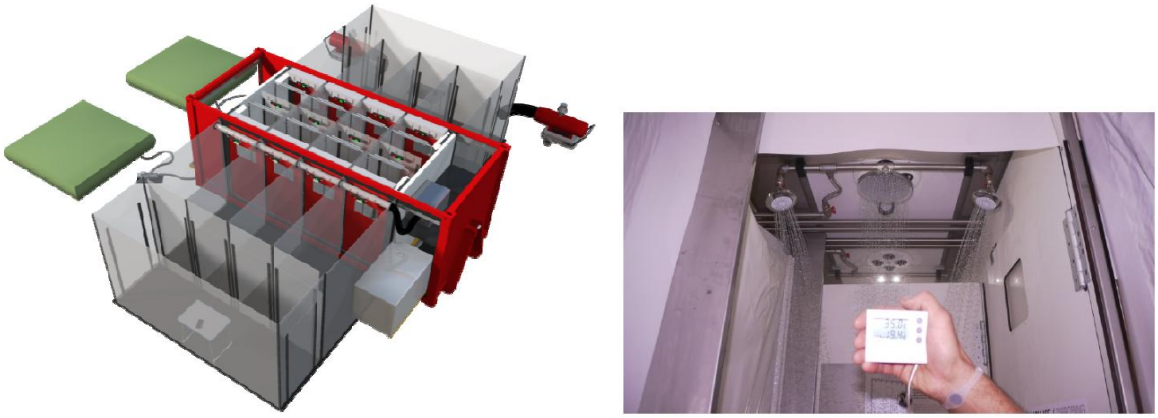

Figure 1*: Schematic top view of the decontamination unit (left) and shower nozzles in the washing unit (right). The decontamination unit consisted of 4 shower lanes which comprised 4 delimited spaces: entrance (instructions-disrobing), washing, rinsing, and exit (drying instructions).*

During the trials, the environmental conditions were 15-20°C, 30-60% Relative Humidity.

Instructions

The following brief instructions were given to each volunteer just before entering the washing and rinsing spaces:

"ORCHIDS" protocol:

> Here is a wash cloth; Use it to wash all your body. In the 1st cabin (green light on), shower and wash for 1 min. Go into the 2nd cabin when the light turns from red to green, rinse.

"FR" protocol:

> Go in the 1st cabin, wash for 3 min, wash all your body with your hands. After 3 min, when the light is green, go into the 2nd cabin, rinse for 3 min. Then leave the cabin.

Measurements

Quantification of FP on the skin surface was directly performed by UV fluorescence photography of volunteers and subsequent image analysis (Image Pro Analyzer v6.2, Media Cybernetics, UK). Quantification was conducted by comparison against known standard FP intensities on filter paper[1].

Extraction of contaminants from the skin

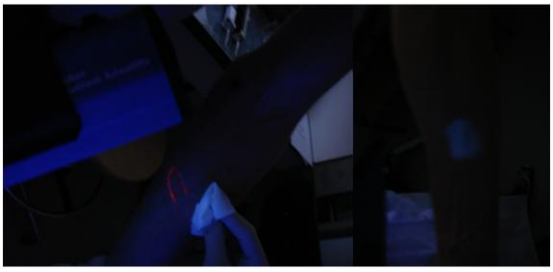

Figure 2*: Wiping of residual FP (left) and MeS (right) from the skin.*

Following decontamination (or without decontamination for the non-decontaminated controls) residual MeS and FP were recovered from the skin deposit sites by wiping with Wypall tissue (Kimberley-Clark®) wetted with ethanol (Figure 2). MeS was analysed in samples by HPLC-UV.

MeS off-gassing from the skin

Figure 3*: MeS off-gassing measurements.*

As shown on Figure 3, MeS off-gassing from the volunteers' skin was measured in a closed cabin for 3 min (left). An Ion Mobility Spectrometer (LCD3.2 detector, Smiths Detection) was placed on the ground (right) on the left side of volunteers (middle).

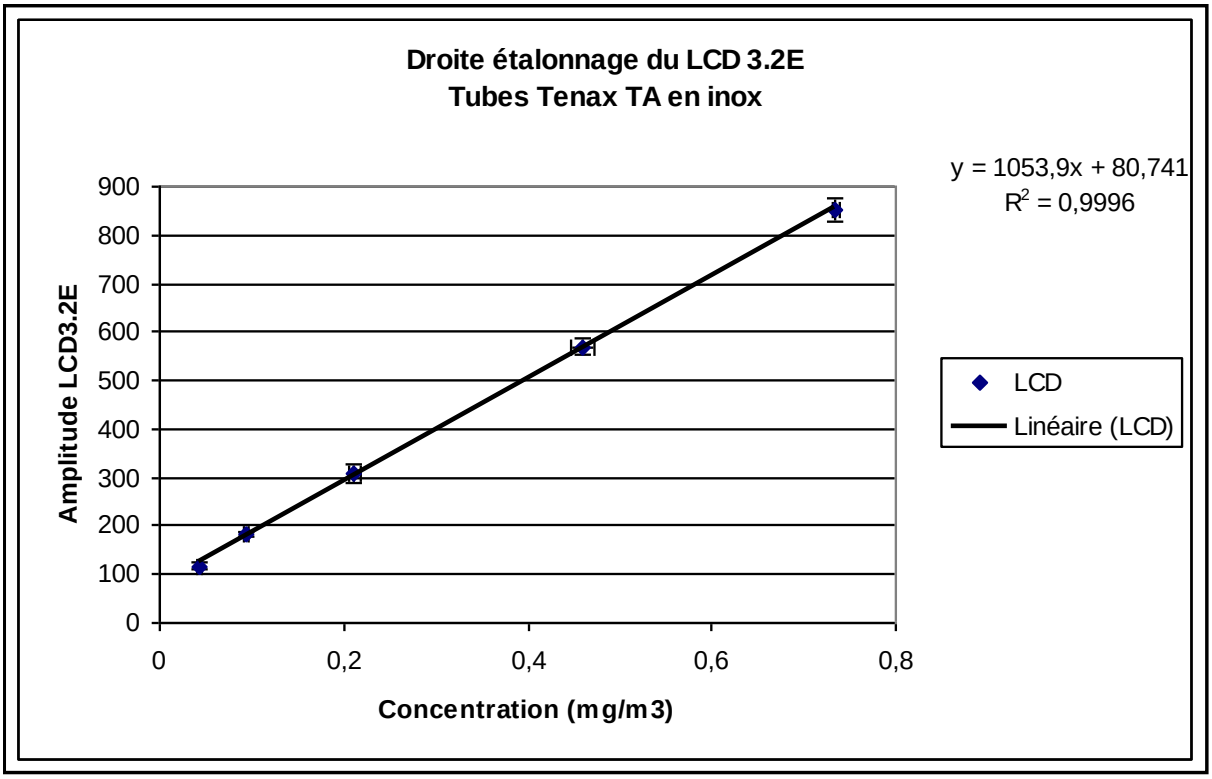

***Figure 4**: Calibration curve LCD3.2 signal in function of the MeS concentration in the air (mg/m^3).*

As can be seen on Figure 4, the calibration curve (LCD signal = f(MeS)) was linear from 0.02 mg m^{-3} to at least 1 mg m^{-3}. This corresponded to LCD signals of ~ 100 to 900.

Decontamination efficacy and statistical analysis

The decontamination efficacy (DE) was evaluated from the amount of FP or MeS recovered from the skin deposit:

Decontamination efficacy (DE %) =: (Q0-Q1) x 100/Q0

Where
Q0 = amount of chemicals before decontamination
Q1, = amount of chemicals after decontamination.

Decontamination efficacy data was assessed for normality and subjected to significance analysis using parametric, 1-way ANOVA testing using SPSS v18.

RESULTS

1 Trials with fluorescent particles

1.1 ORCHIDS *vs* French Reference Protocol

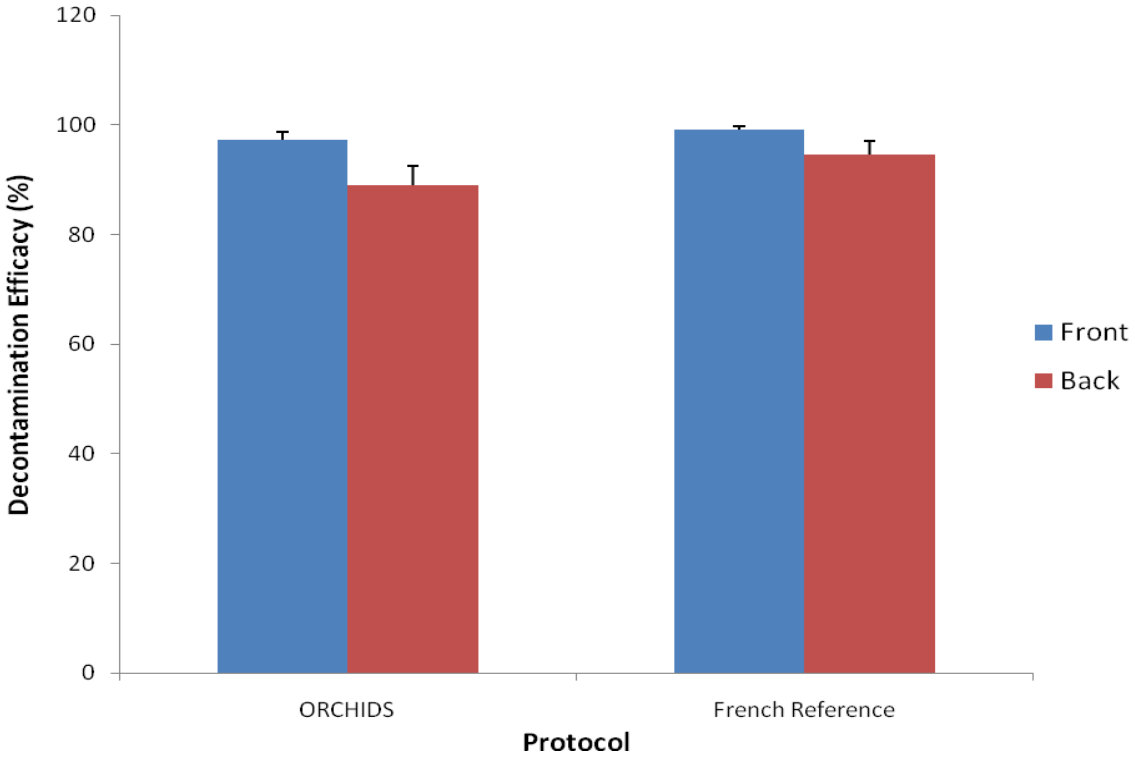

***Figure 5**: Decontamination efficacy (DE) according to the "ORCHIDS" and "FR" decontamination protocols (blue bars: front deposit sites; red bars: back deposit sites) (HPA data).*

The ORCHIDS and FR decontamination protocols were of similar efficacy (> 85%) (Figure 5).

1.2 ORCHIDS *vs* ORCHIDS +

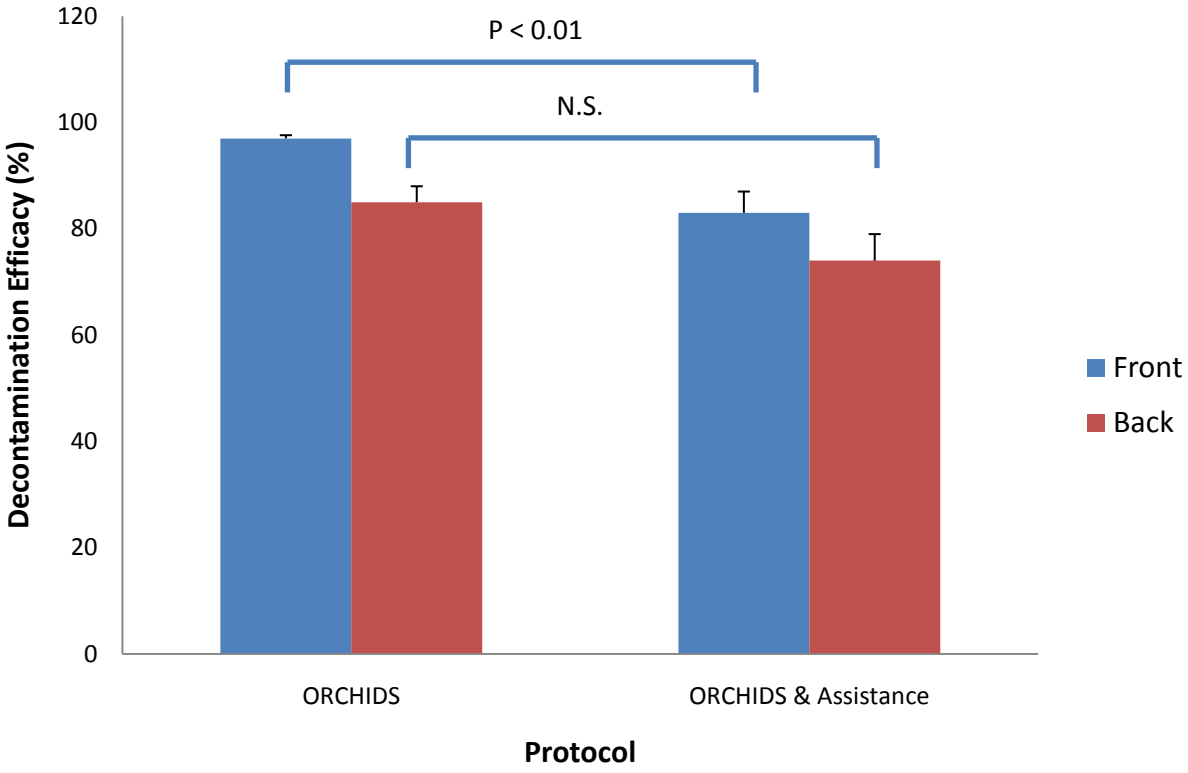

***Figure 6**: Decontamination efficacy (DE) according to the "ORCHIDS" and "ORCHIDS +" (i.e. ORCHIDS & Assistance) decontamination protocols (blue bars: front deposit sites; red bars: back deposit sites) (HPA data).*

The ORCHIDS + protocol (front washing) was found to be significantly less effective than the ORCHIDS protocol ($p<0.01$) (Figure 6).

2 Trials with methyl salicylate

2.1 Methyl salicylate recovered from the skin deposit sites

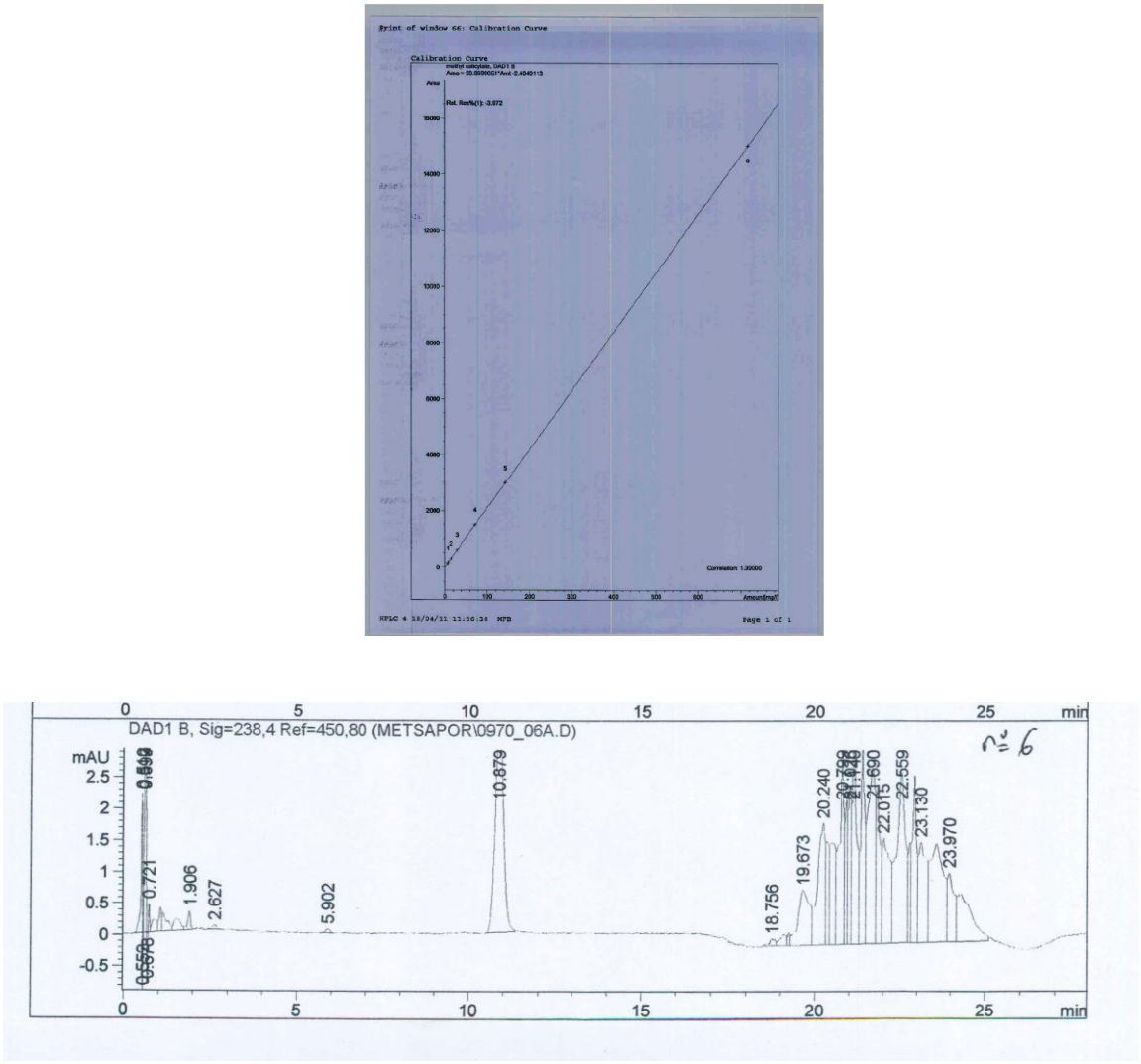

***Figure 7**: Calibration curve obtained from MeS standards in ethanol following HPLC-UV analysis (top) and typical chromatogram of a wipe extract (MeS retention time of 10.8 min) (bottom).*

As shown in Figure 7, following HPLC-UV analysis, the calibration curve representing the area under the MeS peak in function of the MeS concentration was linear from 0.1 to 1000 mg L^{-1}.

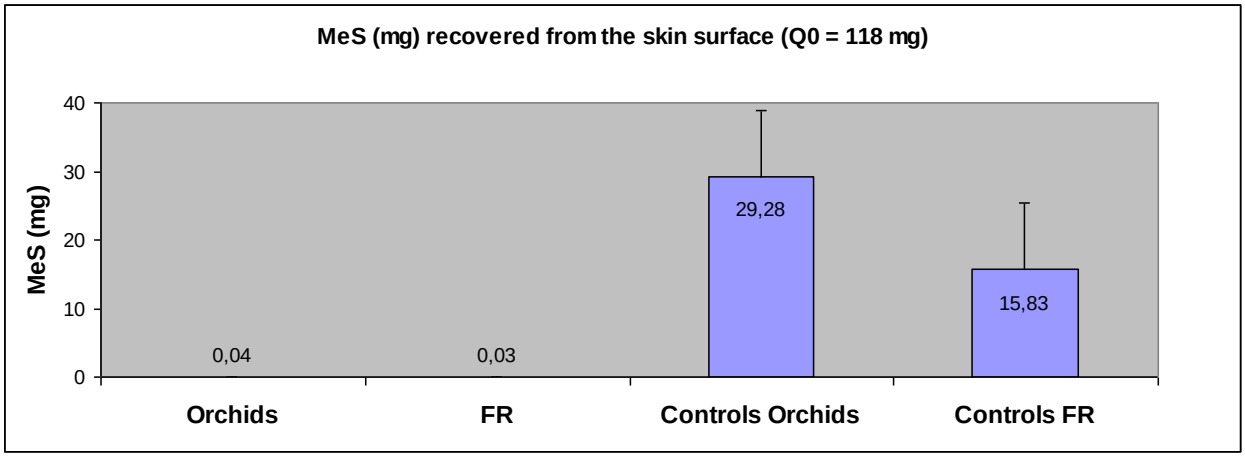

***Figure 8**: MeS (mg) recovered from the skin surface following decontamination (or without decontamination for the controls) according to the ORCHIDS and FR protocols.*

MeS recovered from the skin surface of the non-decontaminated ORCHIDS and FR control groups was 25% and 13% of Q0, respectively (Figure 8)**.** This indicates significant MeS loss following skin exposure. This could mainly be due to MeS evaporation, and to a lesser degree, to skin absorption and to a loss following skin wiping and extraction of MeS from the wipes (10 to 20 min post-exposure).

MeS recovered from the ORCHIDS control group (*i.e.* 10-15 min post-exposure) was consistently about twice that of the FR control group (*i.e.* 15-20 min post-exposure). This suggests that MeS loss due to evaporation was relatively significant. Following decontamination (ORCHIDS or FR protocols), over 99.9% of MeS deposit was lost (Figure 9).

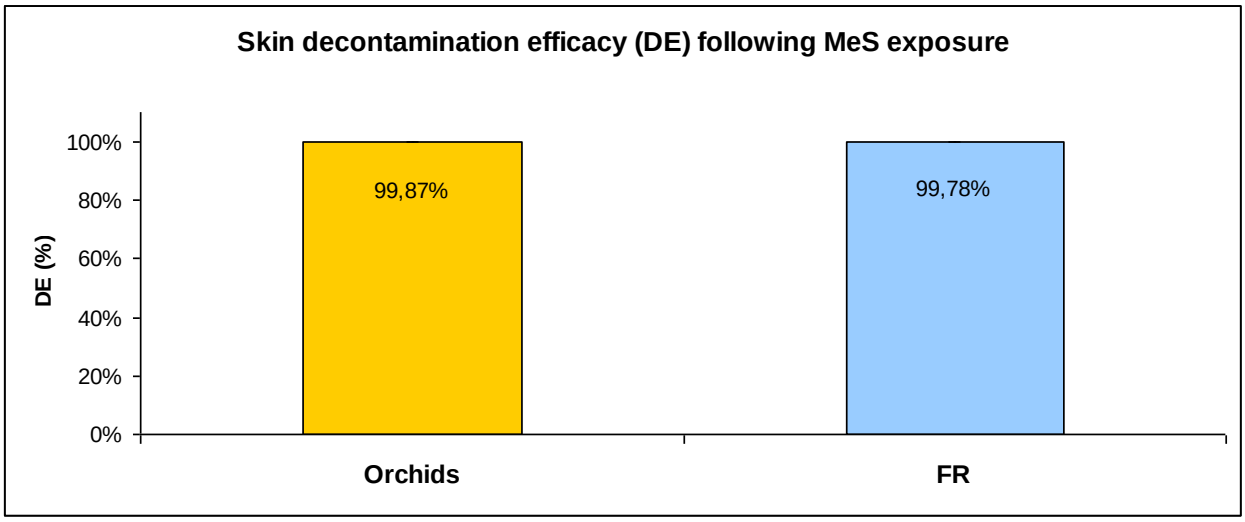

***Figure 9**: Decontamination efficacy (DE) following skin decontamination of MeS according to the ORCHIDS and FR protocols.*

The decontamination efficacies of both ORCHIDS and FR protocols were not significantly different (> 99.7%).

2.2 Methyl salicylate off-gassing

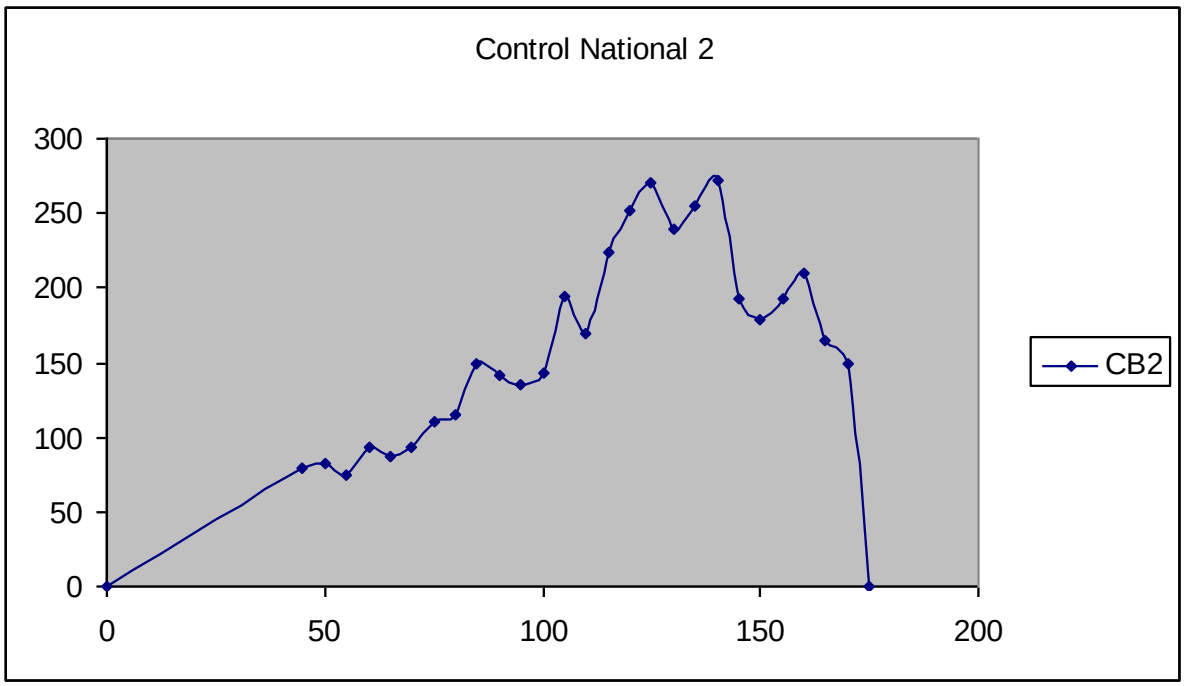

***Figure 10**: Typical LCD signal-time profile during the 3 min measurement for a non-decontaminated control. The time 0 sec corresponds to the volunteer's entry in the cabin; the time 180 sec corresponds to the volunteer's exit from the cabin.*

For the non-decontaminated controls, MeS off-gassing was relatively low but detectable. It was similar for the ORCHIDS and FR control groups (Figure 10).

Following decontamination, MeS off-gassing could not be detected by using the LCD3.2 or PID detectors.

DISCUSSION

In vitro studies have previously indicated that reducing the shower duration (from 6 to 1.5 min), alteration of the shower water temperature (between 25 and 35°C) and introduction of a cotton cloth during the washing process could be proposed as guidelines in future decontamination protocols.

In trials performed with valid, autonomous volunteers, contaminated with either methyl salicylate or fluorescent particles as non-toxic simulants of toxic chemicals , it was shown that: (1), the “ORCHIDS” and “FR” decontamination protocols were of similar effectiveness, and (2), washing of volunteers by a responder did not significantly improve the “ORCHIDS” protocol decontamination effectiveness.

The latter result was quite unexpected. It might be due to the inability of the responder to handle a wash cloth whilst wearing specific protective equipment such as butyl gloves, and/or from a less effective mechanical removal of contaminants when performed by a responder as compared with the volunteer him or herself. Despite this, however, the responder’s aid during the shower process might be of value for washing less easily accessible body sites (*e.g.* casualty’s back, bottom of legs *etc*.).

Further volunteer studies performed with simulants of toxic agents and additional *in vivo* animal studies are required to validate and optimise casualty decontamination protocols after a mass casualty incident. Future volunteer studies should focus on the evaluation of instruction provision, more specifically:

1) the understanding and application of instructions by the volunteers during the showering process,

2) the evaluation of the hair decontamination efficacy,

3) the validation of decontamination protocols for more vulnerable victims such as children, elderly or disabled, as well as designing and validating specific protocols for the wounded.

Introduction of technical improvements such as real-time quantitative analysis and videos could also significantly improve the outcomes from the volunteers’ studies.

Acknowledgements: special thanks should be addressed to all the staff members who contributed to this volunteer study (Figure 11).

Figure 11*: Staff members for the volunteer study performed at Gurcy-le-châtel (Sept 2010, France)*

REFERENCES

1. Amlôt R, Larner J, Matar H, Jones DR, Carter H, Turner EA, Price SC, Chilcott RP: Comparative analysis of showering protocols for mass-casualty decontamination. *Prehosp Disaster Medicine* 2010: 25(5): 435-439