〈原　著〉

Effect of the Clean Bench Configuration Environment on Cleanliness during Intravenous Hyperalimentation Infusion Preparation

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Abstract

When mixing and compounding injectable agents, performing aseptic manipulations on a clean bench maintained according to the requirements of the US Federal Standard Class 100 ($\leq$100 pcs/ft^3) is crucial for the prevention of contamination by airborne particulates or microbes. Owing to air turbulence generated by the compounding manipulations and other factors, the level of cleanliness in the clean bench may be affected by the configuration environment. We configured clean benches in different environments with mean airborne particulate counts of (A) 1,000, (B) 30,000, and (C) 300,000/ft^3 and with the sash opened to 20 and 40 cm and measured the amount of particulate matter and microbes when preparing intravenous hyperalimentation infusions. For the particulate count, Class 100 was maintained in all configuration environments when the sash was opened to 20 cm, but Class 100 was not maintained in any of the environments when the sash was opened to 40 cm. When the sash was opened to 20 cm, no microbes were detected; however, at 40 cm, microbes were detected in all environments, with the level exceeding the NASA reference range ($\leq$0.1 pcs/ft^3) in environment C. Therefore, the configuration environment of the clean bench and size of the sash opening impact the level of cleanliness regarding the amount of particulate matter and microbes in a clean bench. This study prescribes conditions necessary for maintaining cleanliness in clean benches from an air cleanliness perspective when pharmacists are mixing and compounding injectable agents in hospital wards or pharmacies.

Key words: clean bench, airborne particulates, airborne microorganisms, compounding environment, aseptic formulation

Introduction

When injecting a patient with a drug, the sealed ampoule or vial is opened and the drug is extracted and compounded using a syringe or another device, with a risk of contamination from particulates such as glass pieces or microbes. Because the administration of contaminated pharmaceutical liquids can lead to thrombus or sepsis, comprehensive aseptic procedures and proper compounding environments are required when compounding injectables[1~8].

The United States pharmacopeia chapter 797: Pharmaceutical compounding-sterile preparations (USP-797)[9], the European Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice for Medical Products annexes[10], and the Japan Society of Hospital Pharmacists Guidelines for Injection Mixing 2004[11] describe the environments required for sterile compounding, including cleanrooms and clean benches. In the classifications (1-8) based on airborne particulates, as defined by the International Organization for Standardization (ISO) 14644-1 (Cleanrooms and associated controlled environments — Part 1: Classification of airborne cleanliness by particle concentration), environments for sterile compounding must conform to ISO Class 5 (Class 5). Classifications have traditionally used the United States Federal Stan-

Table 1 Prescriptions for the compounding of intravenous infusions in the current study

Product Name	Product Name (English)	Amount	Form
HICALIQ-2	HICALIQ-2	700 mL × 1 Bag	Soft bag
HICALIQ-3	HICALIQ-3	700 mL × 1 Bag	Soft bag
PROTEAMIN 12X injection	PROTEAMIN 12X Injection	200 mL ×　3B	Glass bottle
Elemenmic Injection	Elemenmic Injection	2 mL ×　1A	Ampoule
Heparin Sodium Injection 10,000 units/10 mL	Heparin Sodium Injection	2 mL	Vial

dard, and although $\geq 0.5\ \mu m/ft^3$ of airborne particulate had been used as an indicator, ISO standards are currently used. In addition to this classification, USP-797 and PIC/S require that airborne particulates and airborne microbes be used as monitoring indicators not only during off-times but also during work hours, and that environments obtain qualifications for sterile compounding.

However, the actual compounding of injectables is not limited to cleanrooms, and in numerous situations, compounding occurs using equipment such as clean benches installed in quasi-clean areas such as hospital wards. However, compared to a cleanroom where the entire room is a clean area, with a clean bench, cleanliness is only maintained within the space inside the glass door (sash) in the quasi-clean areas. Therefore, the level of cleanliness in a clean bench may vary depending on the configuration environment and the movements of the preparer during compounding. However, the available guidelines do not indicate how the configuration environment may impact the level of cleanliness of a clean bench. In addition, there is no unified index for specific clean bench configuration environments, and the instruction manual for each clean bench states that "the opening width of the front opening and closing glass door (Sash) should be maintained at approximately 20 cm" or is not described, so that they are configured according to each institution's standards.

Therefore, in the present study, we investigated the optimal environment for compounding injectables, using airborne particulate and microbe counts as indicators to clarify how the configuration environment influences the level of cleanliness of clean benches and the bacterial contamination of the compounded intravenous hyperalimentation (IVH) infusions.

Materials and Methods

1. Measurement of airborne particulates

1.1 Measurement conditions

(1) Clean bench configuration environment

A one-person, vertical, laminar flow-type clean bench (CCV type, Hitachi Industrial Equipment Systems Co., Ltd., Tokyo, Japan) was installed in a cleanroom with a mean of 1,000 particulates/ft^3 (environment A). By temporarily shutting down the air conditioning in the cleanroom, an environment with a mean of 30,000 particulates per ft^3 was established to simulate a general clean area, such as a hospital ward (environment B). The same clean bench was installed in a regular indoor environment with a mean of 300,000 particulates/ft^3 (environment C). The particulate counts in the configuration environments were measured before compounding the infusions to confirm that they were uniform.

(2) IVH infusion compounding methods

The IVH infusions were prepared by a single person wearing a specialized separated, polyester, dust-free garment, cap, mask, and sterile latex gloves. The compounding contents were two soft bag formulations, three glass bottles, one ampoule formulation, and one vial formulation (**Table 1**). The IVH infusion bag and disposable syringe were washed with sterile distilled water and sprayed with an ethanol disinfectant before being placed in the clean bench.

The soft-bag and glass bottle formulations were hung on the upper part of the clean bench, and the opened rubber stopper was disinfected using an ethanol cotton swab. The ampoule and vial formulations were individually apportioned using a disposable syringe, mixed in the glass bottles, and placed in the IVH infusion bags by administration from above. A 21 G Veress needle (TERUMO Co., Ltd., Tokyo, Japan) was used for the glass bottle formulations for air injection cannula. Compounding tasks such as disinfection and weighing of the ampoule and vial formulations were performed at least 15 cm inside the clean bench from
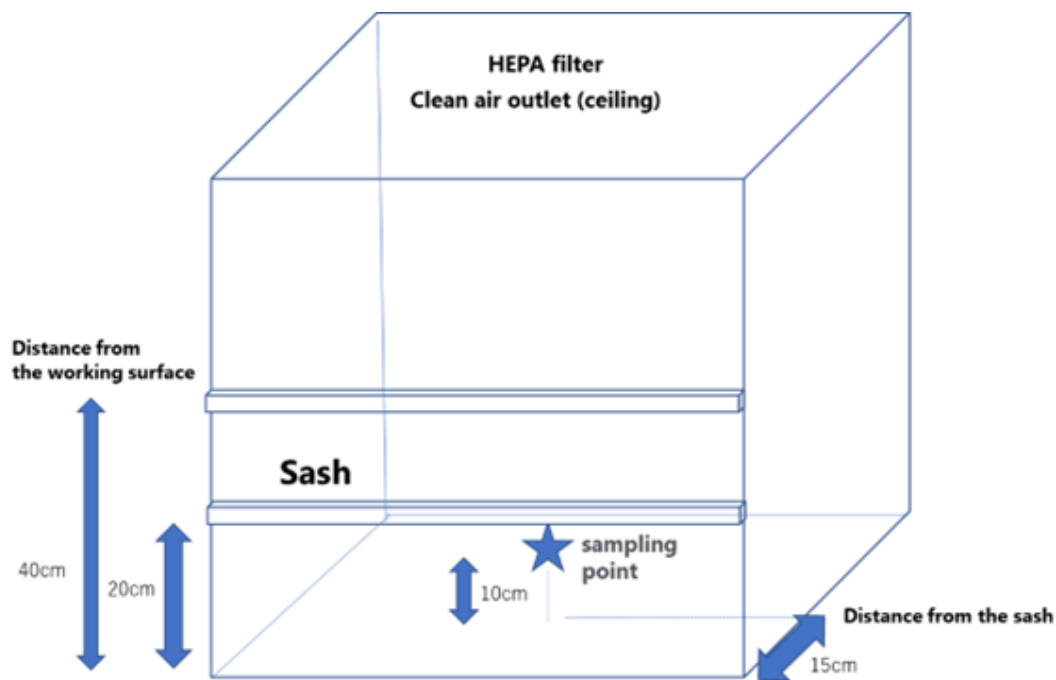
Fig. 1
Description of the compounding environment for the preparation of intravenous infusions
HEPA, high efficiency particulate air

Table 2　Existing standards for airborne particulates and airborne microorganisms

	Airborne particulate count		Airborne microorganism count
Name (Class)	ISO 14644-1 (Class 5)	Federal Standard 209D (Class 100)	NASA NHB5340.2
Units of measure	/m^3	/ft^3	/ft^3
Reference Values	$\leq$ 3,520 pcs	$\leq$ 100 pcs	$\leq$ 0.1 CFU

the sash[12]. IVH infusions were prepared four times in each environment (A, B, C) with the clean bench sash opened to 20 cm (sash20) and to 40 cm (sash40), the recommended opening width for this clean bench (**Fig. 1**).

1.2　Measurement standards

The ISO 14644-1 (Class 5) is currently used for airborne particulate count. However, in the Federal Standard (209D; Class 100) [13] used in the present study (which has different unit volumes but is essentially the same standard), the number of particulates $\geq$ 0.5 µm per 1 ft^3 is set to $\leq$ 100 (**Table 2**).

1.3　Measurement methods

The measurements were performed using an optical diffusion-type particle counter (Particle Counter KC-01, Sibata Scientific Technology Ltd., Tokyo, Japan) in-

stalled at a point 15 cm inside the clean bench from the sash and 10 cm above the working surface (**Fig. 1**; ★ surface).

The air in the clean bench was continuously aspirated at 500 mL/min and particulates of $\geq$ 0.5 µm were measured every 0.01 ft^3 (40 s) and converted to 1 ft^3. Measurements were carried out continuously from the beginning to the end of the IVH infusion compounding process. Measurements started after the pharmaceutical products and the equipment necessary for compounding were loaded into the clean bench and left in place for 80 s, and once the airborne particulate count was confirmed to be 0, compounding took 480-520 s. Four measurements were performed in each environment (A, B, C).

2. Measurement of airborne microbial count

2.1 Measurement conditions

Measurements were performed under the same conditions as for airborne particulate count.

2.2 Measurement standards

The airborne microbe standard was ≤ 0.1 colony forming units (CFU) per 1 ft³ based on the National Aeronautics and Space Administration (NASA) standard NHB5340[14] (**Table 2**).

2.3 Measurement methods

The measurements were performed using an air sampler (RCS air sampler, Biotest Ltd., Dreieich, Germany) equipped with a special medium (Agar strip for general bacteria, Biotest) installed at a point 15 cm inside the clean bench from the sash and 10 cm above the working surface (**Fig. 1**; ★ surface). The 320 L of air inside the clean bench during compounding was suctioned to collide with the medium, and the number of colonies (CFU) after culturing (32-37°C for 3 days) were counted and converted to the number of microbes per 1 ft³ using the following formula. Four measurements were performed in each environment (A, B, C).

Microbe count (CFU/ft³) = Number of colonies on medium (CFU) × 0.708/sampling time (min)

3. Measurement of the frequency of microbial contamination in the compounded IVH infusions

Microbial contamination in the IVH infusions compounded in environments A, B, and C were compared in terms of the frequency of colony development.

The chemical solution was suction-filtered (pore size: 0.45 μm) using an aspirator equipped with a 55-Plus Monitor (Millipore), and 2 mL of general bacterial culture medium was added to the base where the filter was installed and used as the Petri dish for culturing. Culturing was performed at 32-37° C for 3 days[15].

As a control, the same technique was used to prepare infusions at an infusion stand without a clean bench in environment C. Microbial contamination of the infusions was measured in the same manner. Measurements were performed four times in each environment, A, B, C, and the control.

4. Relationship between particulate and microorganism counts

Correlation coefficients were calculated to examine the relationship between the particulate and microbe counts in environments A, B, and C. Correlation coefficients were also calculated for sash20 and sash40.

5. Statistical Analysis

The Mann-Whitney U-test was used to compare particulate and microbe counts for sash20 and sash40 in environments A, B, and C (significance level < 0.5%). Spearman's product-moment correlation coefficients were calculated for the particle and microbe counts. All statistical analyses were conducted using EZR version 1.36 (Saitama Medical Center, Jichi Medical University, Saitama, Japan).

Results

1. Airborne particulate count

Figure 2 shows the particulate counts during infusion compounding. In sash20, the measurements were Class 100 or below in environments A, B, and C, whereas in sash40, the median particulate counts were over Class 100 for environment A (162.4/ft³), environment B (106.5/ft³), and environment C (100/ft³). In addition, while there was a difference in the particulate count between sash20 and sash40 in environment A (P < 0.05); the count between environments B and C was similar.

2. Airborne microbe count

Figure 3 shows the microbe counts during infusion compounding. No microbes were detected in environments A, B, or C with sash20. However, with sash40, the microbe count exceeded the NASA standard in environment C (the median was 0.17/ft³) and the microbe count was higher than that with sash20 (P < 0.05).

3. Frequency of microbial contamination in compounded IVH infusions

Table 3 shows the frequency of microbial contamination in the IVH infusions. With sash20, no microbes were detected in the infusions mixed in environments A, B, or C. However, with sash40, 25% (1/4 bags) exhibited microbial contamination in environment B and 25% (1/4 bags) in environment C. However, the frequency of contamination did not increase due to deterioration of the configuration environment. In addition, when compounding was performed in environment C without a clean bench, the frequency of microbial contamination was 75% (3/4 bags).

4. Relationship between airborne particulate and microbe counts

Figure 4 shows the relationship between the particulate and microbe counts. A weak, positive correlation was observed between the particulate and the microbe count (R^2 = 0.60). The correlation coefficients were cal-
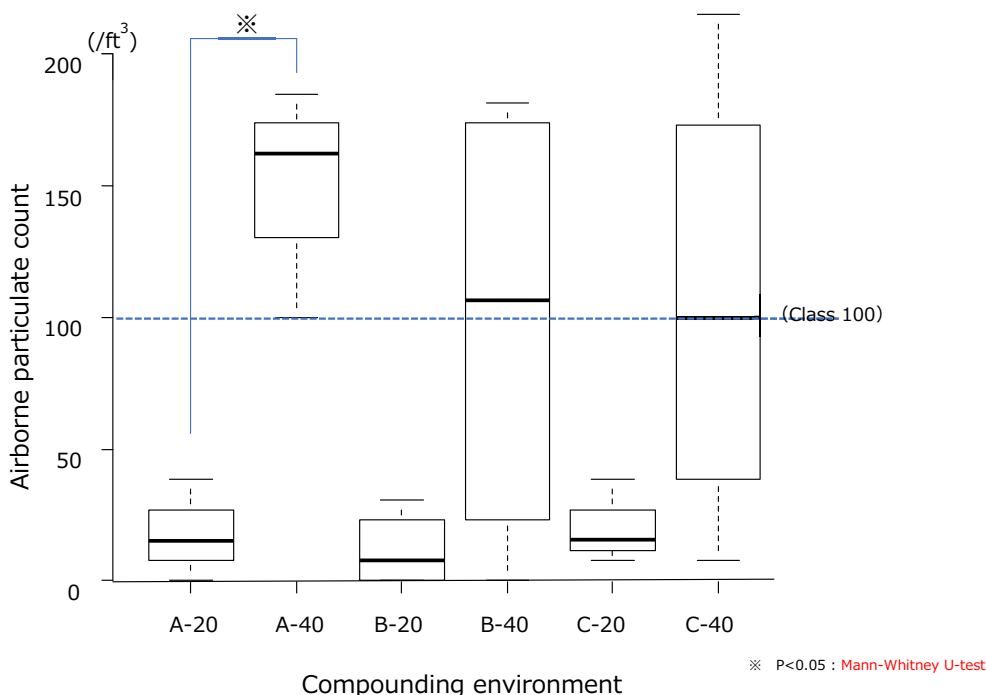
(clean bench configuration environment -- sash opening size)

Fig. 2
Airborne particulate count in the preparation of compounded intravenous infusions on clean benches with mean airborne particulate counts of (A) 1,000, (B) 30,000, and (C) 300,000/ft³, with the sash opened to 20 cm or 40 cm.
The box plots show indicate an $\sim$ 95% confidence interval of the median calculated as median $\pm 1.58 \times$ IQR/$\sqrt{}$ (n), with iqr being the difference between the third and first quartiles.

culated for the particulate and microbe counts for each sash size. No correlation coefficient was calculated for sash20 because no microbes were detected at any of the measurement points (**Fig. 4**, $\bigcirc$, $\triangle$, $\square$). For sash40, while no correlation was observed in environment A ($R^2 = -0.26$, **Fig. 4●**), strong positive correlations were observed in environment B ($R^2 = 0.77$, **Fig. 4▲**) and environment C ($R^2 = 0.89$, **Fig. 4■**).

Discussion

When mixing and compounding injectables, it is critical to do so using aseptic manipulations in an environment maintained at Class 100 to prevent contamination by airborne particulates and microbes. The results of the present study indicated that when IVH infusions were compounded at a point 15 cm inward from the sash, with the sash opened to 20 cm, the particulate count inside the clean bench was not affected by the configuration environment of the clean bench and Class 100 was maintained. However, when the

sash was opened to 40 cm, Class 100 was not met, even in environment A. In addition, the particulate matter count tended to increase as the configuration environment deteriorated (**Fig. 2**). In a study using a safety cabinet with an air barrier, Chiba et al.[16, 17] found that movements of the preparer's arms caused airborne particulates in the external environment to cross the air barrier and enter the cabinet. A clean bench is thought to maintain cleanliness by supplying a constant air volume (Q) to the workspace area (A), and the cleanliness of a clean bench is given by Q (m³/h) = passing air velocity V (m/s) × A (m²). Conversely, in the one-sided, vertical, laminar flow-type clean bench, the air supplied to the workspace is discharged only from the Sash opening surface, so that theoretically, the passing wind velocity in Sash40 is considered to be lower than that in Sash20. In addition, the present study used a clean bench without an air barrier. This is the first study to provide objective data demonstrating that increasing the size of the sash opening
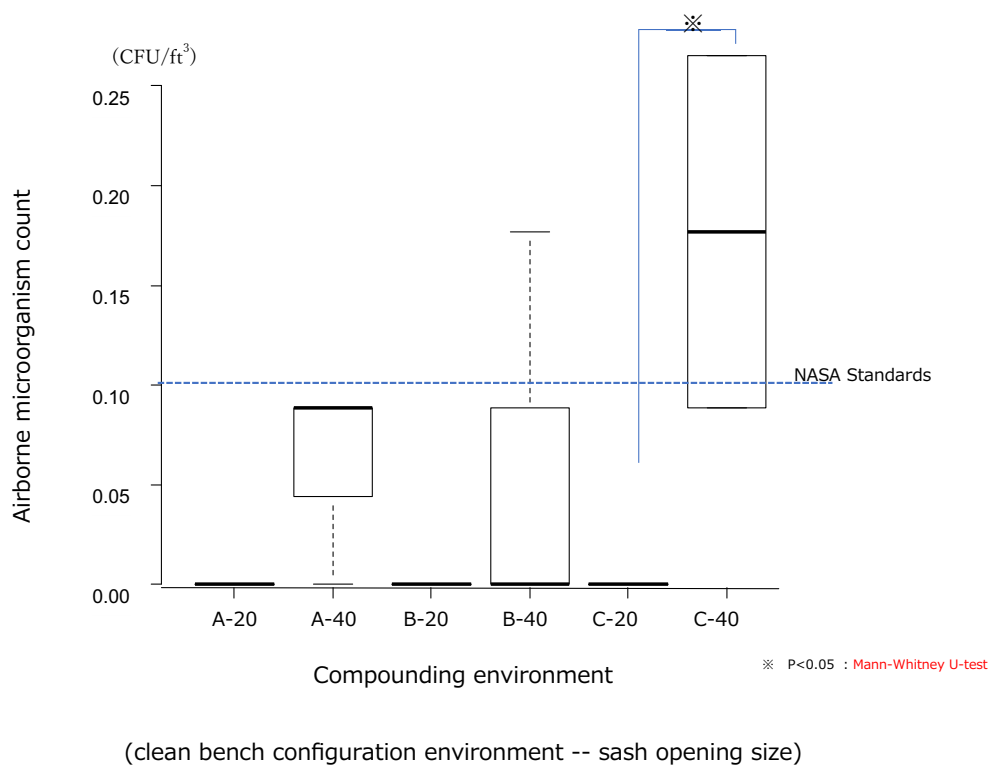
(clean bench configuration environment -- sash opening size)

Fig. 3
Airborne microorganism count on clean benches with mean airborne particulate counts of (A) 1,000, (B) 30,000, and (C) 300,000/ft³, with the sash opened to 20 cm or 40 cm.
The box plots show indicate an ～ 95%confidence interval of the median calculated as median±1.58× IQR/√ (n), with iqr being the difference between the third and first quartiles.

Table 3　Frequency of microbial contamination in compounded intravenous infusions on clean benches with mean airborne particulate counts of (A) 1,000, (B) 30,000, and (C) 300,000/ft³, with the sash opened to 20 cm or 40 cm

Compounded environment	A		B		C		
mean airborne particulate counts (/ft³)	1,000		30,000		300,000		
sash opened (cm)	20	40	20	40	20	40	clean bench unused
Counts of IVH infusions in which microorganisms were detected	not detected	not detected	not detected	1/4	not detected	1/4	3/4

affects the entry of airborne particulates from the external environment.

In addition, the microbe count was 0 CFU/ft³ in all environmental configurations with sash20, whereas microorganisms were observed in all environments with sash40, exceeding the NASA standard in environment C (**Fig. 3**). In environment C, where the NASA standard was not maintained, microbes were detected from infusions compounded without a clean bench and those compounded with a clean bench with sash40 (**Table 3**). This suggests that bacterial contamination of infusion solutions can occur in configuration environments with higher particulate and microbe counts,

even when compounding is performed using a clean bench.

The particulate and microbe counts inside the clean bench exhibited a weak positive correlation (R^2 = 0.60; **Fig. 4**) although environment A did not exhibit the higher correlation reported by Simones *et al*.[18, 19] With sash40, a strong correlation was observed between the particulate and microbe counts as the configuration environment deteriorated. In the present study, excluding in environment A, the indoor air conditioning was turned off and disturbances in airflow from the movement of people and objects were eliminated. In addition, when preparing for formulation, items and phar-
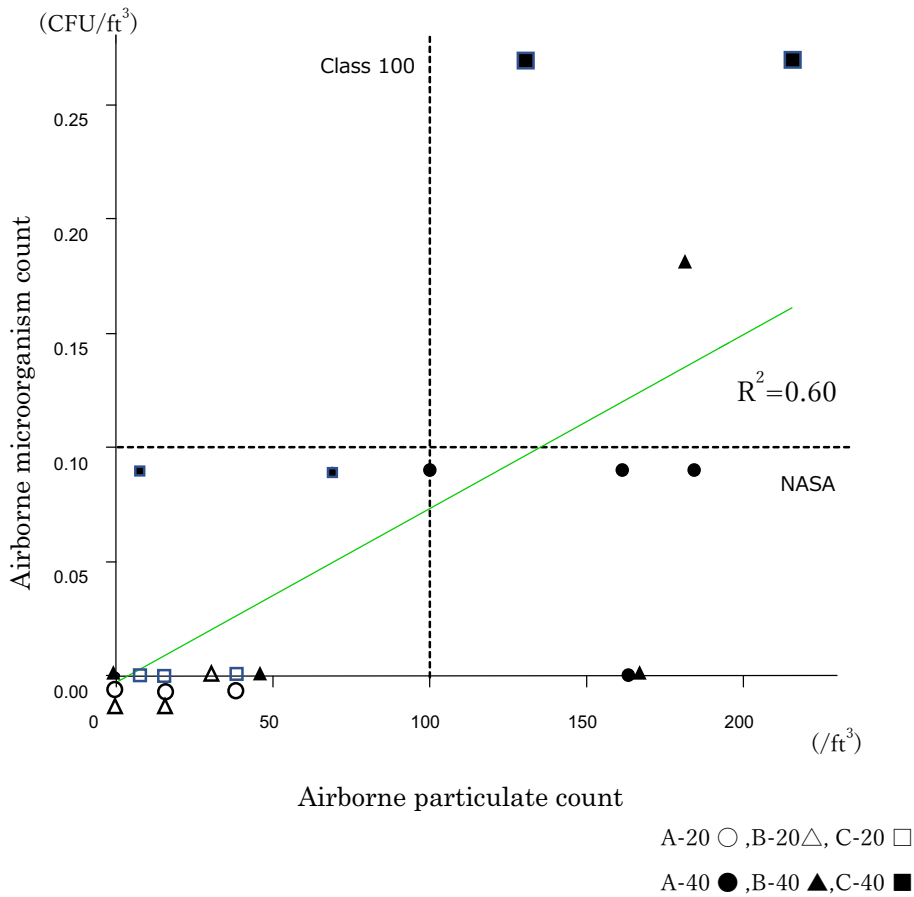
Fig. 4
Correlation between particulate and microorganism counts in the preparation of compounded intravenous infusions on clean benches with mean airborne particulate counts of (A) 1,000, (B) 30,000, and (C) 300,000/ft³, with the sash opened to 20 cm or 40 cm,
NASA, National Aeronautics and Space Administration

maceuticals such as syringes brought into the clean bench were disinfected with an ethanol disinfectant; the preparer wore a separated, polyester, dust-free garment that did not expose the skin; and aseptic compounding was performed. Consequently, we do not think that any bacteria adhered to the inside of the clean bench or that any particulate matter or microbes originated from the compounder's skin. Therefore, we presume that the microbes in the clean bench were particulate matter and microbes from the configuration environment that entered through the sash during the compounding work. Because the particulate and microbe counts exhibited a stronger correlation as the configuration environment deteriorated, in addition to using appropriate sterile compounding techniques[20, 21], it may be possible to prevent microbial contamination by compounding injectables in a suitable environment.

A limitation of this study is that in actual clinical set-

tings, the airflow in the clean bench configuration environment may be disturbed by people or objects, which is something that needs to be considered. In addition, the mixing and compounding of injectables may be complicated by the combination of different prescriptions, depending on an individual's pathology. The present study used a one-sided, vertical, laminar flow-type clean bench. In future, differences between models should be examined. However, the one-sided, vertical, laminar flow-type clean bench used in the present study is structurally supplied with air from the top of the clean bench to the work surface, and exhausted only through the sash opening. In addition, widely used clean benches comply with Japanese Industrial Standards (JIS) B9922[22] and meet the air velocity and air volume standards. Therefore, considering the movement of the airflow and the performance of the clean bench, we believe that the results of the present

study are also applicable to other one-sided, vertical, laminar flow-type clean benches.

According to the results of the present study, when performing sterile compounding in a clean bench at least 15 cm from the sash, the opening of the sash should be no more than 20 cm to prevent the configuration environment from having an impact while maintaining Class 100. As reported by Kata et al.[23] the compounding environment and standards for the mixing and compounding injectables differ from facility to facility. Therefore, it is necessary to protocol compounding environments and procedures for mixing and compounding injectables. The present study prescribes conditions necessary for maintaining cleanliness in clean benches from an air cleanliness perspective when pharmacists are mixing and compounding injectables in hospital wards or pharmacies.

Conflicts of interest declaration: There are no conflicts of interest to disclose with regards to this study.

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IVH 用輸液調製時のクリーンベンチ設置環境がクリーンベンチ内清浄度に及ぼす影響

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要　　旨
　注射薬を混合調製する場合は空気中の浮遊微粒子や微生物による汚染を防ぐために米国連邦規格 Class 100（100 個/ft3 以下）に維持されたクリーンベンチで，無菌操作を行うことが重要である．しかし，調製作業時の気流の乱れなどにより，クリーンベンチ内の清浄度が設置環境の影響を受ける可能性がある．我々は，クリーンベンチを平均浮遊微粒子数（A）1,000，（B）30,000，（C）300,000 個/ft3 の異なる環境下に設置し，かつ Sash を 20 cm および 40 cm に開口した条件で IVH 用輸液の混合調製を行った時のクリーンベンチ内の微粒子数および微生物数を測定した．微粒子数は Sash を 20 cm に開口した場合，いずれの設置環境でも Class 100 を維持していたのに対し，40 cm 開口した場合はいずれの設置環境においても Class 100 を維持できなかった．また，微生物数は Sash を 20 cm に開口した場合は，すべての測定点で微生物の検出はなかったが，40 cm に開口した場合は，すべての環境で微生物が検出され，（C）において NASA の基準範囲である 0.1 個/ft3 以下を超えていた．以上から，クリーンベンチ設置環境と Sash の開口幅がクリーンベンチ内の微粒子数および微生物数清浄度に影響を及ぼすことが示唆された．

Key words：クリーンベンチ，空気中浮遊微粒子，空気中浮遊微生物，調製環境，無菌調製

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