



# Operating theatre ventilation systems and microbial air contamination in total joint replacement surgery: results of the GISIO-ISChIA study

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## SUMMARY

**Background:** Recent studies have shown a higher rate of surgical site infections in hip prosthesis implantation using unidirectional airflow ventilation compared with turbulent ventilation. However, these studies did not measure the air microbial quality of operating theatres (OTs), and assumed it to be compliant with the recommended standards for this ventilation technique.

**Aim:** To evaluate airborne microbial contamination in OTs during hip and knee replacement surgery, and compare the findings with values recommended for joint replacement surgery.

**Methods:** Air samplings were performed in 28 OTs supplied with unidirectional, turbulent and mixed airflow ventilation. Samples were collected using passive sampling to determine the index of microbial air contamination (IMA). Active sampling was also performed in some of the OTs. The average number of people in the OT and the number of door openings during the sampling period were recorded.

**Findings:** In total, 1228 elective prosthesis procedures (60.1% hip and 39.9% knee) were included in this study. Of passive samplings performed during surgical activity in unidirectional airflow ventilation OTs (U-OTs) and mixed airflow OTs (M-OTs), 58.9% and 87.6% had IMA values >2, respectively. Of samplings performed during surgical activity in turbulent airflow OTs (T-OTs) and in turbulent airflow OTs with the surgical team wearing

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Steri-Shield Turbo Helmets (TH-OTs), 8.6% and 60% had IMA values  $\leq 2$ , respectively. Positive correlation was found between IMA values and the number of people in the OT and the number of door openings ( $P < 0.001$ ). In addition, correlation was found between active and passive sampling ( $P < 0.001$ ).

**Conclusion:** These findings challenge the belief that unidirectional systems always provide acceptable airborne bacterial counts.

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## Introduction

Following a study by the Medical Research Council that demonstrated an association between air microbial contamination and deep surgical site infection (SSI) in hip and knee arthroplasty,<sup>1</sup> it has been recommended that total joint replacement surgery should be performed in ultraclean operating theatres (OTs) with maximum air microbial contamination values of 10 colony-forming units per cubic metre (cfu/m<sup>3</sup>) when measured by active sampling,<sup>2–6</sup> and 350 cfu/m<sup>2</sup>/h<sup>7</sup> or 2 cfu/9-cm plate/h<sup>8</sup> when measured by passive sampling. However, in 2008, a German retrospective study unexpectedly showed significantly higher SSI rates after hip prosthesis implantation when using unidirectional airflow ventilation compared with turbulent ventilation.<sup>9</sup> However, this study did not evaluate the air microbial quality of the OTs, assuming it to be compliant with the recommended standards for unidirectional airflow ventilation systems because of regular validation by the health authority. A subsequent meta-analysis demonstrated that the presence of unidirectional airflow ventilation was a risk factor for developing severe SSIs in hip and knee prosthesis operations.<sup>10</sup> None of the studies included in the meta-analysis contained an assessment of air microbial contamination.

As it is unwise to assume that an ultraclean air system will always provide low bacterial air counts, even when functioning correctly, the authors measured the microbial contamination in ultraclean OTs where hip and knee replacements were performed, compared the findings with the recommended values, and checked compliance with recommended air quality standards.<sup>4,8</sup> Microbial contamination was also measured in turbulent airflow OTs (T-OTs) that were used for prosthesis implantation. Two variables were investigated for a possible association with microbial air contamination: the number of people in the OT and the number of door openings during surgical activity.

This study is part of the multi-centre ISChIA (Infezioni del Sito Chirurgico in Interventi di Artroprotesi)—GISIO-SItI (Italian Study Group of Hospital Hygiene of the Italian Society of Hygiene, Preventive Medicine and Public Health) project, which relies on multiple active surveillance of SSIs, antibiotic prophylaxis and air microbial contamination in OTs.

## Methods

This study was performed from March 2010 to February 2011 in 14 hospitals (seven in northern Italy, three in central Italy and four in southern Italy and islands). Hospitals were invited to join the ISChIA project and participation was voluntary. Hospitals that agreed to participate in the study were invited to attend a meeting to involve the key stakeholders as

representatives of the final users of the project (hospital managers, epidemiologists, surgeons, nurses, microbiologists).

Microbial air sampling was performed in the patient area of OTs, within 1 m of the operating table, at rest, before surgical activity began and during the surgical procedure, starting at the time of surgical incision. Samples were collected using passive sampling and, where an air sampler was available, active sampling. Settle plates, 90 mm in diameter, containing tryptic soy agar were left exposed to the air for 1 h, 1 m from the floor, to determine the index of microbial air contamination (IMA).<sup>11</sup> Active sampling was performed using a Surface Air System Sampler (SAS, International Pbi, Milan, Italy), with 55-mm diameter RODAC plates containing tryptic soy agar, flow rate of 180 L/min, and suction volume set to 1000 L (five consecutive samplings of 200 L during 1 h of exposure of the settle plate). The active sampler was positioned at a height of 1 m beside the settle plate. The number of colony-forming units (cfus) was adjusted using the conversion table provided by the manufacturer, and the results were expressed as cfu/m<sup>3</sup>. After sampling, the plates were incubated at  $36^{\circ} \pm 1^{\circ} \text{C}$  for 48 h.

For surgical procedures lasting less than 1 h, air sampling was stopped when the first gauze was placed on the wound. Values measured in the sampling time were proportioned to 1 h.

The H+ Swiss guidelines (IMA)<sup>8</sup> and HTM 03-01 (cfu/m<sup>3</sup>)<sup>4</sup> were used to interpret the results.

The number of people in the OT and the number of door openings during the 1-h exposure period were also recorded.

## Statistical analyses

Statistical analyses were performed using Statistical Package for the Social Sciences Version 14.0 (SPSS Inc., Chicago, IL, USA). Descriptive analyses consisted essentially of frequency tables. Continuous variables were described as mean, standard deviation (SD), median and range. Categorical variables were compared using Chi-squared test, and continuous variables were compared using Student's *t*-test. Correlation between variables was evaluated using Spearman's correlation coefficient.  $P < 0.05$  was considered to indicate significance.

## Results

Twenty-eight OTs were included in this study: 16 (57.1%) were supplied with vertical unidirectional airflow ventilation, six (21.4%) were supplied with turbulent airflow ventilation, and six (21.4%) were supplied with mixed airflow ventilation (i.e. only the patient area was ventilated by vertical unidirectional airflow).

The size of OTs ranged from 90 m<sup>3</sup> to 180 m<sup>3</sup> [mean 116 (SD 20.4) m<sup>3</sup>], and the mean number of air changes per hour was 18 (SD 4.5). The heating, ventilation and air conditioning (HVAC) systems were equipped with high-efficiency particulate filters with efficiency  $\geq 99.97\%$  for particles  $\geq 0.3 \mu\text{m}$ .

In total, 1228 elective prosthesis procedures (60.1% hip and 39.9% knee) were included in the study. Forty-three percent of procedures were performed in unidirectional airflow OTs (U-OT), 8.6% were performed in mixed airflow OTs (M-OT), 20% were performed in T-OTs and 28.5% were performed in turbulent OTs with the surgical team wearing Steri-Shield Turbo Helmets (Stryker, Newbury, UK) (TH-OT).

In empty U-OTs, an IMA value of 0 was recorded for all passive samplings, and a median value of 3 cfu/m<sup>3</sup> (range 0–5) was recorded for active sampling. A median IMA value of 0 was recorded in M-OTs, with a maximum IMA value of 8, while the only active sampling gave a value of 18 cfu/m<sup>3</sup>. In T-OTs, median values of 1 IMA and 11.75 cfu/m<sup>3</sup> were recorded, with maximum values of 4 IMA and 23.5 cfu/m<sup>3</sup>.

Table I shows the descriptive statistics of air microbial contamination during surgical activity by surgical operation. Median IMA values ranged from 3, observed in U-OTs and TH-OTs, to 11, recorded in M-OTs during hip arthroplasty. The cfu/m<sup>3</sup> values ranged from 10 in U-OTs during knee arthroplasty to 280.5 in M-OTs during hip arthroplasty. The minimum IMA value observed by passive sampling was 0 and was recorded at least once in every OT type. The minimum value observed by active sampling was 0 cfu/m<sup>3</sup> and was recorded in U-OTs and T-OTs, but never in M-OTs. In U-OTs, the maximum values were 64 IMA and 290 cfu/m<sup>3</sup>, while in M-OTs, the maximum values were 94 IMA and 466 cfu/m<sup>3</sup>.

Mean air microbial values were significantly lower in U-OTs compared with M-OTs and T-OTs ( $P < 0.001$ ), both for IMA and cfu/m<sup>3</sup>, even when considering hip and knee prosthesis separately. Considering both procedure types together, the lowest mean IMA value (4.3) was observed in TH-OTs and was significantly lower compared with U-OTs (5.4;  $P < 0.001$ ).

The percentages of OTs within recommended threshold values of 2 IMA and 10 cfu/m<sup>3</sup> varied considerably between types of HVAC systems (Table I). The highest percentage of compliant OTs was observed among U-OTs, both for IMA (48.7% for knee arthroplasty and 37.8% for hip arthroplasty) and active sampling (61.4% for knee arthroplasty and 49.4% for hip arthroplasty). Air samplers in TH-OTs showed similar results as in U-OTs, while the percentages of compliant OTs were very low in T-OTs and M-OTs.

Table II shows IMA values by OT and type of HVAC system. High variability in microbial air contamination was observed among the OTs supplied with the same type of HVAC system and among operations performed in the same OT. M-OTs showed the highest level of variability (median IMA values between 5.5 and 40). T-OT No. 23 showed the widest range (IMA values from 3 to 156).

Most air samplings in U-OTs showed microbial contamination higher than the recommended threshold values of 2 IMA and 10 cfu/m<sup>3</sup>. Overall, 58.9% (311/528) of passive samplings and 46.4% (17/252) of active samplings performed in U-OTs yielded air microbial contamination values higher than 2 IMA and 10 cfu/m<sup>3</sup> respectively.<sup>4,8</sup> In total, 87.6% of IMA values recorded in M-OTs exceeded the recommended values.<sup>8</sup> The best compliance (210/350) with recommended IMA values for hip and knee replacement was recorded in TH-OTs (60.0%). In T-OTs, 8.6% of IMA values recorded were  $\leq 2$ . In the majority of

**Table I**

Air microbial contamination of operating theatres (OTs) by type of heating, ventilation and air conditioning (HVAC) system and surgical intervention

	Air microbial contamination							
	IMA				cfu/m <sup>3</sup>			
	U-OT	M-OT	T-OT	TH-OT	U-OT	M-OT	T-OT	TH-OT
<b>Knee arthroplasty</b>								
Number of OTs	15	5	4	2	3	2	3	—
Number of operations	158	34	61	237	88	5	19	—
Mean	4.3	12.6	10.2	4.2	20	231.8	70.9	—
Standard deviation	5.3	18.4	19.8	4	37.2	140.7	56.3	—
Median	3	6	8	3	10	277	69	—
Range	0–38	0–94	0–156	0–30	0–290	32–381	0–249	—
% of OTs within threshold values <sup>a</sup>	48.7	17.6	16.4	41.4	61.4	0	5.3	—
<b>Hip arthroplasty</b>								
Number of operating theatres	15	6	4	2	3	3	4	—
Number of operations	370	71	184	113	164	16	43	—
Mean	5.9	19.7	9.6	4.7	23.2	294.3	58.4	—
Standard deviation	7.2	20.3	11.1	4.9	33.2	125.8	39.2	—
Median	4	11	7	3	13	280.5	53	—
Range	0–64	0–85	0–133	0–30	0–201	2–466	0–237	—
% of OTs within threshold values <sup>a</sup>	37.8	9.9	6.0	37.2	49.4	0	2.3	—

IMA, index of microbial air contamination; cfu, colony-forming units; U-OT, unidirectional airflow operating theatre; M-OT, mixed airflow operating theatre; T-OT, turbulent airflow operating theatre; TH-OT, turbulent airflow operating theatre with surgical team wearing Steri-Shield Turbo Helmets.

<sup>a</sup> IMA threshold value  $\leq 2$ ; <sup>b</sup> cfu/m<sup>3</sup> threshold value:  $\leq 10$ .<sup>4</sup>

**Table II**

Index of microbial air contamination (IMA) by type of heating, ventilation and air conditioning (HVAC) system and operating theatre (OT)

HVAC	IMA					
	OT code	Number of operations	Mean	SD	Median	Range
U-OT	1	1	4.0	0	4	4
	2	32	6.9	5.7	5.5	0–24
	3	29	5.5	6.4	4	0–35
	4	19	9.1	6.4	7	2–25
	5	12	12.2	16.7	8.5	1–64
	6	23	6.0	4.1	5	0–15
	7	19	7.6	4.9	8	1–17
	8	21	9.8	7.4	9	2–32
	9	28	7.4	5.7	6	0–24
	10	29	9.4	7.8	7	2–41
	11	1	0.0	0.0	0	0
	12	23	12.8	11.5	9	4–60
	13	200	2.2	4.1	1	0–38
	14	22	6.4	4.1	6	0–18
	15	36	2.4	2.8	1.5	0–12
16	33	6.7	3.7	6	1–16	
Total	528	5.4	6.7	3	0–64	
M-OT	17	9	21.3	15.2	15	7–55
	18	36	9.9	7.7	7.5	0–33
	19	31	11.1	19.8	6	0–94
	20	2	13	7.1	13	8–18
	21	19	45.7	17.4	40	22–85
	22	8	4.8	3.4	5.5	1–11
	Total	105	17.4	19.9	9	0–94
T-OT	23	44	16.7	28.8	11	3–156
	24	59	9.4	7.2	7	0–38
	25	101	7.9	6.1	7	0–34
	26	41	7.2	5.5	6	0–30
	Total	245	9.7	13.8	7	0–156
TH-OT	27	231	4.3	4.6	3	0–30
	28	119	4.4	3.7	4	0–17
	Total	350	4.3	4.3	3	0–30

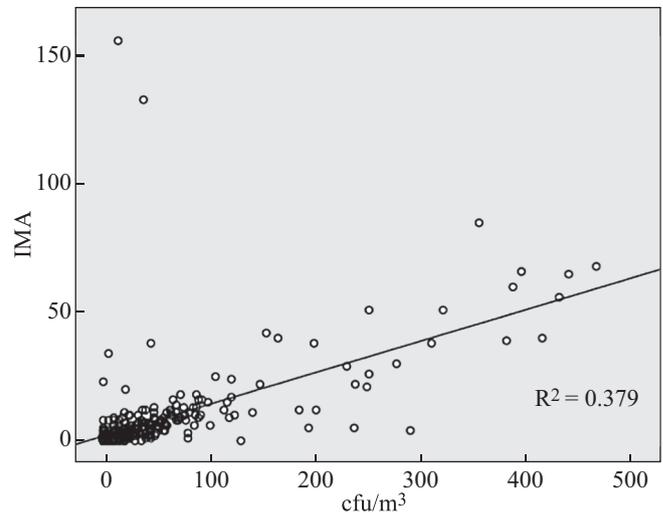
U-OT, unidirectional airflow operating theatre; M-OT, mixed airflow operating theatre; T-OT, turbulent airflow operating theatre; TH-OT, turbulent airflow operating theatre with surgical team wearing Steri-Shield Turbo Helmets; SD, standard deviation.

OTs (13/15 U-OTs, 3/6 M-OTs, 3/6 T-OTs and 2/2 TH-OTs), an IMA value compliant with the recommended value for hip and knee replacement was recorded at least once.<sup>4,8</sup>

Significant correlation was found between bacterial contamination recorded during surgical activity by active sampling and that recorded by passive sampling ( $P < 0.01$ ) (Figure 1).

The median number of door openings during the 1-h sampling period ranged from 3 for TH-OTs to 50.5 for T-OTs. In U-OTs, a maximum value of 100 was reached, while a value of 173 was recorded in a T-OT (Table III). A significantly higher mean number of door openings was observed during hip prosthesis procedures compared with knee prosthesis procedures (28.4 vs 15.1;  $P < 0.001$ ).

During surgical activity, the average number of people in the OT ranged from four (TH-OTs) to 19 (U-OTs). The lowest median value (five people) was observed in TH-OTs during knee



**Figure 1.** Correlation between microbial air contamination values measured by active sampling [colony-forming units (cfu)/m<sup>3</sup>] and microbial air contamination values measured by passive sampling [index of microbial air contamination (IMA)].

arthroplasty, while the highest median value (10 people) was observed in M-OTs during hip arthroplasty (Table III). A significantly higher mean number of people was recorded during hip prosthesis procedures compared with knee prosthesis procedures (7.8 vs 6.6;  $P < 0.001$ ).

Positive correlation was found between IMA values and the number of people in the OT (Spearman's correlation coefficient 0.377;  $P < 0.001$ ) (Figure 2) and the number of door openings (Spearman's correlation coefficient 0.345;  $P < 0.001$ ) (Figure 3).

## Discussion

This study, based on a large number of OTs in different Italian regions, found that a high proportion of U-OTs showed high microbial air contamination values during surgical activity, despite unidirectional airflow ventilation, and exceeded the recommended values for this type of technology. The situation was even worse in M-OTs, where air microbial contamination values were higher than in T-OTs.

HTM 03-01 recommends microbial air contamination values in working ultraclean OTs  $\leq 10$  cfu/m<sup>3</sup> within 300 mm of the wound,<sup>4</sup> whereas samples were taken behind the surgical team in this study. This difference could explain the high level of air microbial contamination recorded in this study. However, another study by Pasquarella *et al.* showed that microbial sedimentation on settle plates (IMA) positioned in the patient area and microbial sedimentation on nitrocellulose membranes placed on the operating table appeared to be consistent.<sup>12</sup> Therefore, the IMA values obtained could be considered to reflect contamination of the operating table.

The sampling position could justify the high air microbial contamination values recorded in the M-OTs as the air samples could have been taken outside the ventilation plenum of unidirectional airflow. However, in some cases, the values recorded in M-OTs were so high (higher than those recorded in conventionally ventilated operating theatres) that there should be no doubt about the poor management of these OTs.

**Table III**

Number of door openings and number of people in the operating theatres (OTs) by type of heating, ventilation and air conditioning system and surgical intervention

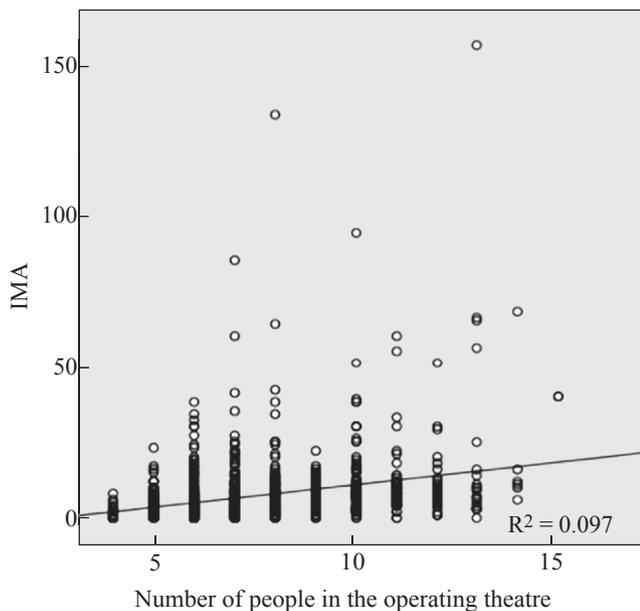
	Number of door openings				Number of people in OT			
	U-OT	M-OT	T-OT	TH-OT	U-OT	M-OT	T-OT	TH-OT
Number of OTs	16	2	3	2	16	6	4	2
Number of operations	508	9	186	336	524	98	240	336
Mean	23.1	27.6	58.8	2.7	7.2	9.9	9	5.4
Standard deviation	15.1	12.5	28.4	1.2	1.7	1.9	2	0.7
Median	21	33	50.5	3	7	10	9	5
Range	0–100	0–39	20–173	1–9	5–19	5–15	6–14	4–11
Knee arthroplasty								
Number of OTs	15	1	3	2	15	5	4	2
Number of operations	151	2	46	228	156	32	60	228
Mean	19.3	25.5	62.3	2.8	6.8	9.2	9.2	5.3
Standard deviation	12.9	13.4	28	1.2	1.6	1.3	2.3	0.8
Median	12	25.5	56	3	6	9	9	5
Range	5–59	16–35	22–139	1–9	5–14	7–12	6–14	4–11
Hip arthroplasty								
Number of OTs	15	2	3	2	15	5	4	2
Number of operations	357	7	140	108	368	66	180	108
Mean	24.7	28.1	57.6	2.7	7.3	10.2	8.9	5.5
Standard deviation	15.7	13.3	28.4	1.2	1.7	2	1.8	0.6
Median	23	33	50.5	3	7	10	9	5.5
Range	0–100	0–39	20–173	1–5	5–19	5–15	6–13	4–6

U-OT, unidirectional airflow operating theatre; M-OT, mixed airflow operating theatre; T-OT, turbulent airflow operating theatre; TH-OT, turbulent airflow operating theatre with surgical team wearing Steri-Shield Turbo Helmets.

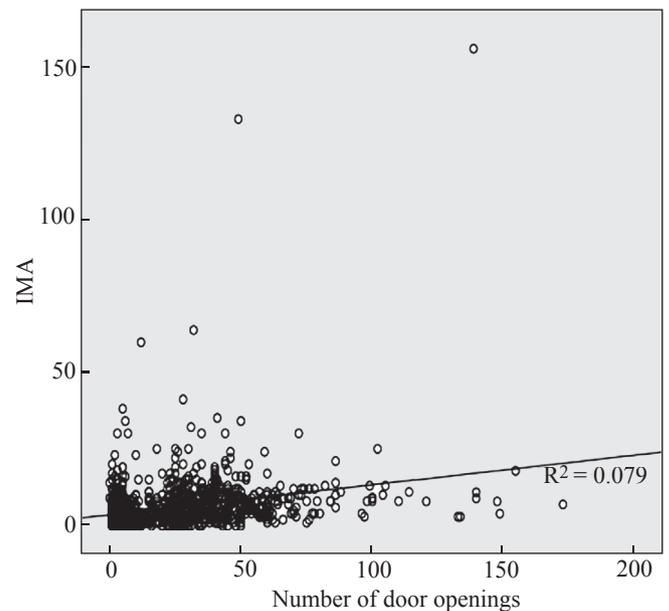
The air samplings performed in OTs at rest show the efficiency of unidirectional airflow ventilation, although the air was contaminated before surgical activity commenced in one M-OT.

These findings support the concept that one cannot assume that a unidirectional airflow system will always provide

acceptable bacterial counts,<sup>4,8</sup> even when engineered and monitored properly, and functioning correctly. Therefore, only procedures in which air quality complies with the achievable standard for this type of air flow should be considered in order to evaluate the efficacy of unidirectional airflow ventilation systems in reducing SSI.



**Figure 2.** Correlation between the number of people in the operating theatre and microbial air contamination values [index of microbial air contamination (IMA)].



**Figure 3.** Correlation between the number of door openings in the operating theatre and microbial air contamination values [index of microbial air contamination (IMA)].

Previously, Assadian *et al.*<sup>13</sup> criticized the assumption by Brandt *et al.*<sup>9</sup> that OT ventilation systems installed in enrolled hospitals would be effective as a result of routine controls by health authorities. A study has been conducted to assess the impact of unidirectional airflow ventilation on bacterial counts.<sup>14</sup> This included a limited number of surgical procedures performed in unidirectional airflow ventilation OTs (21 large laminar air flow and 19 small laminar air flow): the results indicated that having a unidirectional airflow ventilation system in place will not automatically provide low airborne counts in the surgical area.

The installation and management of ultraclean OTs is very expensive.<sup>15</sup> It is therefore an ethical duty to ensure that cleanliness levels match the ventilation system, and the economic investment is not undermined. This statement is also valid where turbulent ventilation systems are in place.

A surprising finding of this study was that 8.6% of T-OTs had IMA values  $\leq 2$ , and the median IMA value was 7; this is the same as observed in a recent study in T-OTs at the University Hospital in Parma.<sup>16</sup> With reference to the European Commission's guidelines on good manufacturing practice,<sup>17</sup> which classify the different environments based on airborne particles and microbial contamination measured by active and passive sampling, 50 cfu/90-mm settle plate over 4 h, which corresponds to 12.50 for 1-h exposure, is equal to 100 cfu/m<sup>3</sup>;<sup>16,17</sup> that means that an IMA value of 7 would correspond to less than 100 cfu/m<sup>3</sup>. In light of this, the recommended IMA value for working T-OTs,<sup>4</sup> dating back to the 1980s,<sup>18</sup> appears to be too high for modern T-OTs and could lead to underestimation of risk.

This study also included TH-OTs, which were supplied with turbulent airflow with the surgical team wearing Steri-Shield Turbo Helmets. In these OTs, similar levels of air microbial contamination as in U-OTs were recorded. This finding can also be justified considering the very low number of door openings during surgical activity and the number of people in the OT.

This study used both active and passive sampling methods as they have different purposes.<sup>19,20</sup> Active sampling provides information about the concentration of viable particles in the air, whereas passive sampling measures the rate at which viable particles settle on surfaces, thus providing a measure of the contribution of aerobiocontamination to the biocontamination of surfaces. In OTs, passive sampling estimates the risk posed by airborne micro-organisms to the surgical wound. This study found a significant correlation between the two methods, confirming previous observations.<sup>16,20</sup>

This study further confirmed that the number of door openings and the number of people in an OT during surgical activity can be regarded as key factors in increasing bacterial counts. The US Centers for Disease Control and Prevention guidelines for prevention of SSIs<sup>5</sup> recommend that doors should be kept closed except as needed for passage of equipment, personnel and the patient; and the number of people entering the OTs should be limited to the necessary personnel. However, the low rho-squared values (approximately 10%) indicate that other factors could be responsible for the variation in airborne microbe counts, as demonstrated by Scaltriti *et al.*<sup>21</sup>

The high degree of variability in microbial air contamination observed in the different OTs with similar forms of ventilation, with very low microbial air contamination levels in some surgical procedures, suggests that it is possible to achieve strict control of the factors affecting air quality.

A high number of OTs had contamination values exceeding recommended thresholds. These values were identified in the course of a specific project that exposed a situation which may otherwise not have come to light. As observed in the authors' previous study,<sup>22</sup> it is essential to increase healthcare workers' awareness of the risks associated with incorrect behaviours. Moreover, people responsible for infection control should promote periodic audits to ensure that OTs are managed properly (e.g. through microbiological monitoring) and that procedures are followed correctly.

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## Conflict of interest statement

None declared.

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