Observational study on hospital building heritage and microbiological air quality in the orthopedic operating theater: the IM.PA.C.T. Project

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Key words: Operating theaters, orthopedic surgery, air sampling, ventilation system, hospital building heritage
Parole chiave: Sale operatorie, chirurgia ortopedica, campionamento dell’aria, sistemi di ventilazione, strutture ospedaliere

Abstract

Background. The study investigated 35 orthopedic OTs [17 with mixed flow (M-OTs), 18 with turbulent flow (T-OTs)].
Methods. The OTs were divided into two categories based on recurring architectural and construction solutions, collected by a survey form: type-A (recently built or renovated rooms), and type-B (other OTs). Assessment of microbial air contamination (colony forming units (cfu)/m$^3$ obtained by active sampling via Surface Air System) was then performed.
Results. In 97% of the OTs, a Total Viable Count (TVC) was within the limits recommended by ISPESL 2009; all A-type OTs, and 94% of B-type passed. The TVC of type-A OTs [median 15 cfu/m$^3$, range 3–158] was lower than that of type-B OTs [median 28 cfu/m$^3$, range 6–206], although the difference was not significant. The number of people in type-A [mean 8.6, range 6–11] was lower than in type-B [mean 9.6, range 7–13] OTs, and when adjusted to the volume of the OT (person/m$^3$), showed a significant correlation with TVC ($\rho = 0.383$, $p <0.05$).
Conclusions. In conclusion, the structural factors examined do not appear to significantly affect the microbiological air quality at the specific sampling point. However, further investigations are required to identify the factors that have the greatest effect on TVC.

Introduction

The surgical unit, intended as an organizational structure designed for the execution of highly invasive procedures, can be defined as a complex adaptive system, i.e. “an open system, formed by numerous elements that interact in a non-linear way and that constitute a unique entity, organized and dynamic, capable of evolving and adapting to the environment” (1). The complexity of both pre and post-operative phases, the relative unpredictability of operating times, and the coordination of many people with different professional skills are the major difficulties in the management of surgical activities and

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in particular, their safety and quality. One of the possible negative outcomes of surgery is Surgical Site Infection (SSI) which, even today, is associated with excess morbidity, mortality, and welfare costs (2-5). Notably, SSI related to orthopedic surgery, such as total joint replacement surgery, is reported to be the most serious complication, causing longer post-operative stay, additional surgical procedures, higher mortality, and additional costs (6).

In recent decades, the role of air as a vector of SSI, especially for surgery unrelated to microbial infection, has been the subject of much interest and debate (4, 7). Guidelines for the design and ventilation of operating theaters (OTs) have been published and threshold values proposed (4, 5, 8-11). However, the levels of microbiological air pollution in the OTs described in the literature often exceed the recommended thresholds (7), even compared with a general decrease in the average reduction of microbial values over time (4, 12).

The correlation between the level of microbial air contamination and the number of people/hour present in the OTs is known (13), as well as the number of door openings/hour. These findings underline how important it is to increase the awareness of the operators of the risks associated with incorrect behavior (14, 15).

Studies have also observed microbial air contamination even in empty OTs, suggesting inadequacy of maintenance programs for ventilation systems (7, 16), and potentially of the plant equipment. Therefore, investing only in the training of health professionals may not be enough to increase the safety and quality of OTs (17). Indeed, the evolution of biomedical techniques and technologies require the public client to continually review organizational-welfare models. This implies the need to identify new distribution solutions, construction materials and finishings, recovering and adapting spaces often created for other purposes. It follows that the compositive solutions for the spaces proposed by the designers may not be satisfactory, being focused solely on the functional aspects, without considering the hygienic/sanitary needs.

The IM.PA.C.T. Project (IMproving the health of PApatients supporting dynamIC healTh system and new technologies) is a study promoted by the Apulia Region Government (Southern Italy) aimed to investigate numerous aspects of health care, including the evaluation of air contamination in the OTs of public hospitals in Italy, using different sampling systems.

This study investigates if there is a relation between OT design and microbial air contamination and consisted of three main aims: i) to evaluate if the OTs’ building design (shape, dimensions, layout and construction technology) influenced microbial air pollution; ii) to investigate the relationship between the OTs’ plant characteristics (design and maintenance) and microbial air contamination; and iii) to analyze the correlation between the number of operators accessing OTs and microbial air pollution.

This part of the IM.PA.C.T. Project, coordinated by the Department of Biomedical Sciences and Human Oncology of the University of Bari “Aldo Moro” (Apulia, Italy), was conducted in collaboration with the Department of Civil, Building and Environmental Engineering of Sapienza University of Rome, Italy through a multidisciplinary and transversal approach.

Material and methods

1. Study design

The study involved 35 orthopedic OTs distributed in the 30 hospitals of the Apulian Region that joined the IM.PA.C.T. Project.

Attention to the construction aspects of the study plan chronologically followed the general research approach, and started
with a census of the hospitals of the region and a request for voluntary participation. In the case of existing building heritage, the approach initially considered the building itself, evaluating the complete original building plan, determining if over the years it has undergone changes and updates, and understanding which components influence microbial contamination of the air. In the specific case of the OTs, this process lead to the determination of the different technological systems that make up this complex microsystem, the partitions that delimit the spatiality of the room, and systems for the provision of services, in particular air-associated services (18).

Detailed information was collected regarding the number of staff in the OTs (13, 19-21), comparing the function, distribution, and efficiency of the OTs, and the total viable count (TVC) with the number of components of the surgical team. The count of the people present in the OTs was performed by the operator in charge of microbiological sampling, and was only of staff that remained inside the OT for the entire duration of the intervention.

1.1 Data collection and survey form

The survey form was structured in five sections aimed at:
- the identification of the hospital, including data concerning the structure, the Surgical Unit (SU) within which the OT was located, the year of construction, and the distribution data of the SU.
- gathering more detailed information, including metric data on the OTs, year of construction and/or renovation, and morphological-typological data.
- describing the finishing materials used in the OTs (walls and floors).
- collecting data on electro-medical equipment and furnishings in the OTs.
- investigating the Heating, Ventilation and Air Conditioning (HVAC) system, analyzing its characteristics in terms of the number of air supply/extraction points and their relative positioning, types of filters, thermo-hygrometric parameters and air changes, as well as maintenance aspects of the HVAC system.

The form was sent to hospitals prior to microbial air sampling, to allow the health and technical departments to retrieve all the necessary information.

1.2 Integrated survey (photographic/documental/direct)

Concurrent with air sampling, the initial photographic survey campaign was conducted of all the OTs involved in the study. This made it possible to identify the correspondence between the responses of survey forms and the actual state of the OTs, in particular the morphological and typological aspects. Subsequently, a documental survey of the OTs was carried out, thanks to the collaboration of the technical offices that made available the building and plant plan drawings.

This initial phase was followed by the identification of the main and recurrent characteristics of the OTs of the hospitals examined, which was necessary to select a sample to perform the direct surveys. These provided a more detailed photographic campaign and a survey using a terrestrial laser scanner (TLS) (22). The use of the TLS was necessary due to both the geometric complexity of the OTs, given the large and numerous electromedical equipment and furniture present inside the rooms, which would have complicated the traditional relief, and the limited time to perform the measurement, considering that the daily surgical activity was to proceed as planned.

The survey was carried out using the Scan to BIM (Building Information Modeling) methodology, integrating the survey using a TLS in the informative model (23). The 3D scans were performed with the FARO® Focus3D X330 instrument (FARO...
Technologies, Lake Mary, FL, USA), by executing four capture points for each OT to generate the point cloud and digitally reproduce the rooms. The four capture points were necessary to overcome the numerous “gray areas”, inevitable because of the large number of elements in the OTs, some of which were not removable, i.e. operating table and electromedical equipment, despite the contained surfaces of the rooms (Fig. 1) (24).

The point cloud resulting from the TLS survey was then elaborated with Faro Scene software, eliminating the inaccuracies and “noise” deriving from the survey, and subsequently imported into the RECAP software for the management of the cloud itself and the interoperability with the Autodesk REVIT program, within which the BIM models were created. The parametric model of the analyzed OT was constructed preserving the point cloud and the photogrammetric data as a “scaffold” for three-dimensional objects (25). These models were overlaid with the plant plans derived from the technical documentation provided by the hospitals, for the reproduction of the HVAC system ducts, which otherwise were not inspectable.

This survey and the detailed analysis of the BIM models produced (see Fig. 2), allowed identification of the integration between the building and plant systems (26).

2. Classification of operating theaters

Considering the factors that can influence the operability and microbial contamination of OTs in consultation with the ISPESL guidelines (11), the geometry of the rooms, the equipment present, the furnishings, the staff, and the positioning of the air inlets and outlets, the OTs were stratified according to:

- the type of HVAC system: Turbulent Flow (T-OTs), Mixed Flow (M-OTs), or Unidirectional Flow (U-OTs);
- the type of shape, considering the design of the OT space is one of the variables that can potentially create or increase the risks of contamination in the surgical area (27). The shape of the OT also influences the geometry and positioning of the air supply and extraction points in the room, which must be optimized to minimize damaging effects such as short circuits between intake and suction, the formation of unventilated zones, and local cooling caused by high residual air velocity (28).
- the method of construction; using prefabricated functional modules such as a set of construction elements created through an industrial production, to be inserted in the construction of a building to integrate with the plants and contain ducts or group together utilization devices, or perform the two functions at the same time (29), and in-situ construction.

Fig. 1 - Survey with a terrestrial laser scanner in an operating theater and point cloud processing, within Autodesk RECAP software.
Considering the many building variables involved and the factors that are not easily controllable, OTs were divided into two macro-categories (Fig. 3):

- type-A OTs: newly built or renovated OTs with prefabricated functional modules;
- type-B OTs: all the others OTs not included in the first category.

This categorization was made by a team of experts, taking into account different building and plant variables (size, shape, positioning of the HVAC extraction points, distribution of furniture and electromedical equipment), including the hypothesis that newly built/renovated OTs would favor a better management of the surgical team’s work and the OTs functional layout.

The first type of OT (type-A OTs) were characterized by regular geometries in plan and room height, symmetrical layout of the extraction points of the HVAC system, the presence of electro-medical ceiling equipment, and integrated cabinets in the covering surfaces.

The second type of OT (type-B OTs) were defined by a considerable geometrical complexity in the floorplan or room height, with the presence of beams, pillars, and cavities in various positions inside the room, which consequently lead to the positioning of the extraction points of the HVAC system not being symmetrical.
3. Microbial air monitoring

For each OT, indoor air was sampled twice during our study, at rest (to verify the efficiency of the environmental cleaning systems and conditioning system) and in operation (15 minutes after the surgical incision) during the first surgical procedure (hip and knee arthroplasty) of the day. For this study, the OT's characteristics were correlated with the microbial results, obtained by active sampling on a solid substrate (Surface Air System, SAS Super ISO 180; PBI International, Milan, Italy) (30). For each sampling, 1000 L of air was aspirated by the SAS, which was placed approximately 1 m above the floor and 1 m from the operating bed, in accordance with the literature (4). The number of colony forming units (cfu) was adjusted using the conversion table provided by the manufacturer, and the value was expressed in cfu/m$^3$. The total viable count (TVC) was recorded in duplicate to ensure sampling accuracy. Plate Count Agar (PCA, Merck, Grenoble, Italy; Becton Dickinson, Rome, Italy) was used and incubated at 36 ± 1°C for 48 h.

4. Statistical analyses

The data obtained were entered into a database and the possible associations between average TVC values and the different building and plant parameters examined were analyzed, using the Student t-test. To assess the relationship between TVC and the number of people present in the room and/or number of people per m$^3$, Spearman’s correlation was used. The analyzes were performed with IBM SPSS Statistics version 25 (IBM Corp., Armonk, NY, USA). P-values <0.05 were regarded as statistically significant.

Results

The majority of the OTs (65.7%, 23/35) belonged to small healthcare facilities (<300 beds). In these facilities, a lower TVC median value was found [median 21 cfu/m$^3$, range 3–206] compared with the OTs of larger healthcare facilities (> 300 beds) [median 38.5 cfu/m$^3$, range 5–154] ($p = 0.632$) (Table 1).

The examination of the type of HVAC system allowed identification of 17 OTs with Mixed flow (M-OTs), and 18 OTs with Turbulent flow (T-OTs). No Unidirectional flow OTs (U-OTs) were detected. No microbial contamination was detected in OTs at rest. Furthermore, in operation, significant differences were not detected between the TVC in the M-OTs [median 15 cfu/m$^3$, range 5–154] and the T-OTs [median 24.5 cfu/m$^3$, range 3–206] ($p >0.05$).

Regarding the maintenance of the air conditioning systems, in the OTs where maintenance frequency was equal to or less than quarterly, lower TVCs were observed [median 19 cfu/m$^3$, range 3–206], compared with the other OTs [median 41.5 cfu/m$^3$, range 7–154] ($p >0.05$).

The investigation of the HVAC plant extraction points identified two types of arrangements: symmetric and asymmetric. In OTs with symmetric arrangement, a lower TVC median value was observed [median 21 cfu/m$^3$, range 3–158], compared with the ones with asymmetric arrangement [median 27 cfu/m$^3$, range 6–206] ($p >0.05$).

For the analysis of the dimensional aspects of the OTs, the minimum area recommended by the ISPESL Guidelines (37.4 m$^2$) (11) was considered. Notably, 37% of the examined OTs had a surface area 37.4 m$^2$ and median TVC values of 26 cfu/m$^3$ [range 5–118]. The OTs with a surface ≤37.4 m$^2$ showed median TVC values of 22 cfu/m$^3$ [range 3–206] ($p >0.05$).

Given the average height of an OT was 3.10 m, and the median floor area of type-A OTs was 38 m$^2$, they have a median volume of 117 m$^3$ [range 81–150] (Fig. 4). Interestingly, larger dimensions were observed in the B-type OTs [median 132
Table 1 - Stratification of the analyzed operating theaters and related aerial microbial contamination

<table>
<thead>
<tr>
<th>Hospital Size (number of beds)</th>
<th>TVC (cfu/m³)</th>
<th>Student t-test</th>
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<tr>
<td></td>
<td>n.</td>
<td>Mean</td>
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<tr>
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<th>Type of HVAC system flow</th>
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<th>Student t-test</th>
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<td>n.</td>
<td>Mean</td>
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</tr>
<tr>
<td>M-OTs</td>
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<tr>
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<th>HVAC extraction arrangement</th>
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<tr>
<td>asymmetric</td>
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<td>total</td>
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<th>OT surface area (m²)</th>
<th>TVC (cfu/m³)</th>
<th>Student t-test</th>
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<td>40.5</td>
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<tr>
<td>&gt;37.4</td>
<td>18</td>
<td>44.4</td>
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<tr>
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<table>
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<th>Type of construction of OT</th>
<th>TVC (cfu/m³)</th>
<th>Student t-test</th>
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<td>Type-A</td>
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<tr>
<td>Type-B</td>
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<td>total</td>
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CFU: Colony Forming Units; HVAC: Heating, Ventilation and Air Conditioning; M-OTs: Operating Theater with Mixed flow; OT: Operating theater; T-OTs: Operating Theater with Turbulent flow; TVC: Total Viable Count

Figure 4 - Stratification of operating theater volumes according to construction type. Mean values are highlighted.
m³, range 90–193], with a mean volume of 130.79 m³ and surface area of 42.2 m². The following analyses were performed on 31 of the 35 OTs enrolled, as the dimensional values for four OTs could not be acquired.

At lower volumes, the type-A OTs are associated with much more regular geometries in plan and in height, without ledges and alcoves, or various spatial articulations involving a series of distributive and functional complexities, including those related to the optimal organization of the HVAC system, for the location of the air extraction points, and the functional distribution of furniture and equipment. In particular, the arrangement of the extraction points was not always optimized in the type-B OTs, unlike those of type-A OTs. Importantly, the geometric complexity of the OTs has repercussions on the difficulty of positioning the necessary equipment, often leading to the arrangement of these in such a position as to occlude air outlets, as evident in the type-B OTs. Inside type-A OTs, the furniture was often integrated into the ceiling or walls, allowing more free space inside the room.

Concerning the TVC, it was within the threshold recommended by the ISPESL guidelines (11) (180 cfu/m³ for T-OTs) in 97% of the monitored OTs. Stratifying the data according to OT type, 100% of the type-A OTs were within guideline limits and 94% of the type-B ones (Fig. 5).

The median TVC of the type-A OTs was 15 cfu/m³ [range 3–158] and 28 cfu/m³ [range 6–206] for the type-B OT. However, the difference between the TVC mean values (Table 1) did not reach a level of statistical significance ($p = 0.414$).

Type-A OTs were mainly mixed-flow (86.6%), while type-B OTs were mainly turbulent-flow (81.25%). Among the TVC detected according to the types of flow, stratified by type of construction, no significant differences were observed (M-OTs type A vs M-OTs type B $p = 0.20$; T-OTs type A vs T-OTs type B $p = 0.97$).

Figure 6 shows the number of people present in the type-A OTs [mean 8.6, range 6–11] and type-B OTs [mean 9.6, range 7–13]. Overall, the number of people in the OTs showed a significant correlation with the TVC ($\rho = 0.464$, $p = 0.04$). To quantify the actual encumbrance of the OTs determined by the presence of operators, the number of people present was adjusted for the volume of the OTs (person/m³). Notably, the value obtained shows a significant correlation with the TVC ($\rho = 0.383$, $p = 0.017$) (Fig. 7).

![Fig. 5 - Total viable count (cfu/m³) stratified by operating theater construction type.](image-url)
Discussion

The initial observation of the TVC evaluated at rest being zero confirmed the effectiveness of the sanitation measures of the OTs and of the HVAC systems. Similarly, regarding the contamination of OTs in operation, the microbial air quality was good, with the TVC within the threshold recommended by ISPESL (11) in 97% of monitored OTs (180 cfu/m³ for T-OTs). Specifically, 100% of the type-A OTs and 94% of type-B were within recommended guidelines. A single case was found above the threshold values. This outlier could be linked to the number of staff in the OT (11 people), the room size (48.97 m²), and the large number of tools, furnishings, and
electromedical equipment present in that particular OT.

Lower TVC values were detected in the OTs belonging to hospitals with <300 beds, and those with M-OTs, that performed maintenance on a quarterly basis, had symmetrical arrangement of the HVAC extraction points, and surface areas > 37.4 m². The stratification of the OTs by type of flow of the HVAC system was performed according to an analysis of the scientific literature of the sector, which recommended unidirectional flow for orthopedic OTs until a few years ago (31). The debate on the effectiveness of these systems is still open, and there is no unequivocal scientific evidence (32-35), despite the recent WHO guidelines agreeing on not considering it a preventive measure to reduce the risk of SSI in arthroplasty surgery (5).

In the present study, U-OTs were not detected and the difference between TVC mean values in M-OTs and T-OTs was not statistically significant. Furthermore, the difference in the TVC between symmetric or asymmetric arrangement of the HVAC extraction points was not statistically significant but represents interesting data to be linked to the dimensional aspects of the OTs, which should be interpreted as a whole.

Regarding the definition of optimal dimensions for an operating room, it is known that the surgical team normally operates in a circular space of approximately two meters radius. With the evolution and increasing use of technology, equipment, and other professionals involved in surgery, OT room dimensions of 30 m², for a long time considered a suitable area, has been found to be insufficient. Studies have led to a standardization of OTs to promote greater interchangeability and flexibility, adapting to different specialties, and ensuring greater economies of scale (36).

The national reference (37) indicates “the rooms and spaces must be related to the type and volume of the activities provided”, thus leaving a certain discretion to the designers and delegating to regional legislation the task of detailing the data. Most of the Italian Regions have adopted two benchmarks: 30 m² for medium-complexity interventions and 36 m² for high-complexity interventions (36). Moreover, the references for the guidelines are rather vague on the subject. For example, the ISPEL guidelines (11) report that “the surface of the operating room should be adapted to the type of activities provided and the technology used” and refer to the standards of the American Institute of Architects (8) citing only the data of 37.4 m² as a minimum surface area. The AIA instead, defines a minimum surface area of 37.4 m² for newly constructed or renovated OTs, while for specialized OTs (including cardiovascular, orthopedic, and neurological surgery) the minimum standard is 55.74 m². From a dimensional point of view, the operating suites of the Puglia region analyzed showed dimensions in line with the recommendation of the literature (8, 11), without a significant difference in terms of TVC values between those smaller or larger than the threshold.

Regarding the shape of the OT, the OTs of the examined healthcare facilities demonstrated variable geometries and internal characteristics. Compositional solutions often focus attention on functional aspects, neglecting to combine them with aspects minimizing contamination risks in the surgical area (27). The effort of the designer must be to understand the potential sources of risk in OTs, to deal with the hospital staff who live the daily routine, and to arrive at a design synthesis that minimizes the negative effects of environmental contamination, both on patients and on operators (27).

In the present research, the stratification that best interpreted the building and plant complexity of the OTs of the existing hospital heritage was that structured by method of building. The OTs built with prefabricated functional modules presented
regular geometries in floor plan and in height, symmetrical arrangement of the extractions of the HVAC system, presence of electro-medical ceiling equipment and cabinets integrated into the covering surfaces. In the other OTs there was a greater variety of building solutions, with notable geometric complexity in the floor plan and height, including the presence of beams, pillars and cavities in various positions inside the room, which consequently led to the asymmetrical arrangement of the of HVAC system extraction points, as well as a frequent occlusion of the same by the furniture and/or equipment present in the OTs and not integrated into the walls. Between the two types of OTs different mean TVC values were observed, even if these differences were not statistically significant.

Procedural and management aspects of OT function are also important. One of the most significant aspect of these was the maintenance frequency of the HVAC plant. It was shown that the OTs with the lowest median TVC were those in which quarterly controls are performed. Similarly, the correlation between TVC and the number of people in the OT has previously been reported in the scientific literature (19). This association has also been evaluated by adjusting the number of occupants for the volume of air available, to reduce the likelihood of any confounding factors, and the correlation was confirmed.

Although the correlation between the number of people/volume and TVC is significant ($\rho = 0.383$, $p = 0.017$), and a linear correlation can be described in agreement with previous studies (13), in our study the highest TVC values were found when the number of people/m$^3$ was near the mean value (0.06–0.10) (Fig. 7), suggesting that other factors can influence microbial contamination, in addition to the presence of people. These factors (for example, equipment in the room, cleaning procedures, work organization, cleaning of HVAC filters, and number of air changes) will be further investigated.

Our study has two main weaknesses, that air sampling was carried out only twice for each OT, and only 15 minutes after the start of the first surgery of the day. Although the protocols followed technical regulations (30) regarding the need to perform sampling in proximity to the patient, the sampling could have been extended. Other critical points include the lack of awareness of personnel regarding the specific building issues, in accordance with other investigations (38). Furthermore, given the geometric complex conformation of the OTs (such as the presence of alcoves), it would have been advisable to provide more ad hoc sampling to evaluate the TVC overtime and to compare the real situation of the HVAC systems. Therefore, future research should increase the number of OTs analyzed and the number of air samples collected in those OTs, including a follow-up of patients up to 6–12 months after surgery, to check for the presence of SSI.

Despite these limitations, the study made it possible to elucidate the relationship between the quality of the air inside and the components of the building and the plant in the OT. From this point of view, it is essential to improve both training of healthcare workers and microbiological control practices on environmental matrices (water, air and surfaces) (11, 14, 39, 40) remains fundamental, even as early as university. Importantly, working in multidisciplinary and multi-professional teams requires the use of the same language and the ability to share technical and health skills. In this regard, we must mention DIN 1946 (41), the German regulations governing ventilation techniques in the OT, which prescribe the presence of a hygienist doctor in the multidisciplinary hospital planning team, including in the design and construction phases and in the management and maintenance of air conditioning systems.
Conclusion

Overall, the OTs showed satisfactory environmental quality levels. The quality of the air at rest confirmed the effectiveness of the sanitation measures of the OTs and of the HVAC systems. In operation, TVC values were within the recommended threshold. Moreover, the building structural factors did not appear to affect the microbiological air quality. Further investigations will help to assess other aspects of the study and critical issues that have emerged thus far.

Abbreviations

- CFU: Colony Forming Units
- BIM: Building Information Modeling
- HVAC: Heating, Ventilation and Air Conditioning
- M-OTs: Operating Theater with Mixed flow
- OT: Operating theater
- SAS: Surface Air System
- SSI: Surgical Site Infection
- SU: Surgical Unit
- TLS: Terrestrial Laser Scanner
- T-OTs: Operating Theater with Turbulent flow
- TVC: Total Viable Count
- U-OT: Operating Theater with Unidirectional flow

Declarations of Interest

None.

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