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A Clinical Test to Measure Airborne Microbial Contamination on the Sterile Field During Total Joint Replacement

Method, Reference Values, and Pilot Study

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Background: Airborne microbe-carrying particles in the operating-room environment during total joint replacement are a risk factor for periprosthetic joint infection. The present study focuses on a simple environmental test, based on practices used in aseptic cleanrooms, to quantify the deposition of microbe-carrying particles onto the sterile field.

Methods: Settle plates are exposed Petri dishes. A settle plate test system and sampling plan were developed from current practices used in aseptic manufacturing. A pilot study evaluated this system in an orthopaedic operating room during 22 total knee and hip arthroplasties. The microbial deposition total (MDT), expressed in colonies/m^2, is proposed as an outcome variable to report airborne sterile-field contamination as measured with settle plates. Two reference MDT levels were developed: (1) an upper limit of 450, corresponding with the ultraclean air definition of 10 colonies/m^3, and (2) a target level of 100, corresponding with 1 colony/m^3. These levels also correspond with widely used limits in aseptic cleanrooms and controlled environments.

Results: High MDT standard deviations were noted. Ninety-one percent (95% confidence interval, 71.0% to 98.7%) of wound zone MDT levels were within the upper limit. Twenty-seven percent (95% confidence interval, 12.9% to 48.4%) of wound zone levels were within the target level.

Conclusions: Settle plates are a feasible technique to test environmental levels of microbe-carrying particles on sterile fields during total joint replacement for scientific and environmental quality studies.

Clinical Relevance: This settle plate operating-room environmental test can be used in future research to validate the presence of actual ultraclean-air conditions during periprosthetic joint infection outcome studies. Surgeons also can use this test to measure intraoperative airborne microbe-carrying-particle sterile-field contamination and compare it with ultraclean-air reference levels for environmental quality-control programs.

The presence of airborne microbe-carrying particles[1] during surgical operations increases the likelihood of periprosthetic joint infection[2]. Periprosthetic joint infection after total joint replacement negatively affects all healthcare system stakeholders as a result of increased readmissions[3], economic costs[4,5], and patient mortality[6]. Currently, there is no standard technique in the United States to measure intraoperative airborne microbe-carrying-particle contamination during total joint replacement, nor are there guideline levels for interpretation[7,8]. However, the United Kingdom[9] and Germany[10] specify techniques and reference values to address microbe-carrying-particle levels. Hence, the scientific study of airborne microbe-carrying particles in the operating room has been identified as a "research gap."[11] The present study examines a test method, outcome variables, and reference values to fill this void.

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Sir John Charnley[12-14] associated improved operating-room air quality with decreased rates of periprosthetic joint infection in patients undergoing total joint replacement. The Medical Research Council (MRC) of the U.K.[15,16], in a study of 8,052 total hip arthroplasty and total knee arthroplasty procedures, showed that the lowest periprosthetic joint infection rates (0.1%) were associated with the use of prophylactic antibiotics and body-exhaust suits in a rigorous ultraclean air environment (<1 colony/m^3). The history of operating-room contamination control recently was summarized by Whyte[17,18].

These sources demonstrate the importance of airborne contamination control in preventing periprosthetic joint infection. An average concentration of ≤10/m^3 at the wound was recommended by Whyte et al.[19] and has now become the accepted standard for ultraclean-air systems in the U.K.[9]. Other standards for air contamination fallout have been suggested since then; Friberg et al.[20] recommended 350/m^2/hr. German standard DIN 1946-4[10] also addresses operating-room microbiological air quality and suggests a limit of 1 colony/50 cm^2/hr. Pasquarella et al.[21] described the index of microbial air contamination (IMA) method for measuring air quality and recommended 0 to 5 colonies/plate/hr for total joint replacement. Those and other[22] international references demonstrate that measuring and limiting air-contamination levels are recommended in multiple health-care systems; however, diverse methods and data formats make comparisons of reference values difficult.

Basic-science principles related to microbial air contamination are that (1) microbes are dispersed into the air by personnel in the operating room and usually are carried on skin particles[23], more specifically designated as microbe-carrying particles[1], and (2) microbe-carrying particles have an average size of approximately 12 to 14 μm[24] and are deposited onto surfaces under the influence of gravity. Techniques used to directly assess microbe-carrying-particle fallout into a wound include wound swabs[25], wound washout[26], and contact sampling methods[27,28]. However, those methods are subject to losses during microbial transfers, are complicated by requirements such as antibiotic neutralization, and require skilled microbiological assistance. Indirect assessment of airborne contamination outside the wound is more practical and can be classified into methods for monitoring either viable particles or all particles (including nonviable ones)[29].

Nonviable technologies include laser particle counters and biofluorescent particle counters. These devices do not require incubating microbe-carrying particles and give real-time results; however, they are expensive, require specialized technical support, require a sterile isokinetic connection to the sampled area, and correlate poorly with microbiological samplers[30-33]. Two general classes of viable airborne-particle sampling methods[34], termed "active" and "passive," have been used to measure microbial contamination in industrial cleanrooms[35] and in the total joint replacement operating-room environment[36,37]. Active sampling includes volumetric methods (e.g., a slit sampler); these methods are relatively expensive, necessitate skilled technical assistance, require painstaking attention to detail[38], do not correlate well between models[39,40], and require a connection to the sterile field with a sterile tube to obtain an accurate measurement at the wound site. Passive sampling involves the use of a settle plate, which is a Petri dish opened to the ambient environment. As microbe-carrying particles sediment directly onto the medium surface, the colony count is not subject to design[39] or ventilation variables that affect active samplers. Previous studies have investigated the placement of settle plates in various locations, including corridors[41], nonsterile operating-room areas adjoining sterile fields[21,41], and sterile fields distant[42] or close[36,41,43] to the wound. Settle plates are inexpensive, and sampling tasks can be carried out by the surgical team.

Recommendation of a specific microbe-carrying-particle monitoring technique for orthopaedic applications in the total joint replacement operating room environment is beyond the scope of the present report. Therefore, the present study instead focused on the simplest viable particle method: settle plates. The purpose of the present pilot study was twofold. The first purpose was to develop an environmental test procedure based on similar nonsurgical aseptic technical processes. The second purpose was to develop concepts for 2 applications relevant to orthopaedic surgeons: (1) how settle plate data can be used in future studies investigating the risk of periprosthetic joint infection and (2) how data can be utilized as a clinical tool to monitor and control operating room environmental quality.

Materials and Methods

Test Procedure

The sampling plan and the settle plate locations were adapted from aseptic processing practices recommended for pharmaceuticals and compounded medications[29,44-46]. Two areas in the total joint replacement operating room are visualized as "products" of aseptic processing: (1) the extremity drape area, and (2) the instrument table area. Sampling the sterile extremity drape or "wound zone" assesses 2 risks: (1) direct contamination of the surgical wound with airborne microbe-carrying particles and (2) indirect wound contamination from contact with gloves and instruments. Back-table microbe-carrying-particle values assess the risk of contact contamination via instruments.

Two types of Petri dishes were used; both are available in triple-wrapped sterile packaging suitable for operating-room use, are only available in trypticase soy agar media, and have a nominal diameter of 9 cm. Fifteen of the initial 16 procedures involved the use of plates that required refrigeration (BD BBL 221236; BD Biosciences). Occasional condensation inside packaging required discarding inventory before use and led a change for the remaining 7 procedures to plates that are gamma-irradiated and stored at room temperature (TS 146001; MilliporeSigma)[47]. The approximate cost per plate is 2 USD.

Three plates were exposed on the back-table sterile field (back-table zone) at the opening of the procedure. One additional plate on the back table was kept closed as a

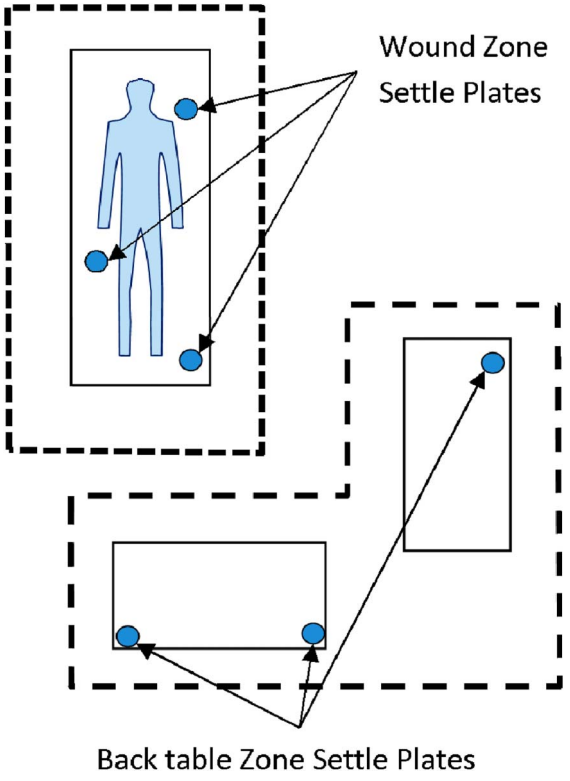

Fig. 1

Diagram illustrating the pilot study sampling plan. Plates are placed at roughly equal intervals in each zone. Back-table-zone plates are placed at the outer edge bordering the high-traffic area. Wound-zone plates are distributed equally along the extremity draping. The zone area per plate is approximately 0.8 m^2 in the back-table zone and 0.3 m^2 in the wound zone.

negative control. A second set of 3 plates was exposed on the sterile field created when the hip or knee was draped (wound zone). Figure 1 portrays this layout. These plates were secured to drapes inside autoclavable stainless steel holders. Each holder had a wire-frame cover that protected the agar surface yet allowed free airflow. All plates were closed after the fascia was closed, and the exposure time was recorded. All plates were incubated for 48 hours at 35°C in the hospital microbiology laboratory walk-in incubator. All plates were read with use of a desk-mounted 2× magnifier and 4× to 10× handheld magnifying glasses to differentiate a colony from surgical debris. All visible microbial colonies were counted manually. Colony speciation does not add useful information about airborne contamination levels and was not performed. Colony counts were recorded on paper data sheets then were transferred to a spreadsheet program (Excel; Microsoft) for analysis and plotting.

Pilot Study

The Sparks Regional Medical Center institutional review board approved a pilot study of the passive sampling technique. Patient consent was not required as the sampling device did not contact the patient and no patient-specific data were collected. The initial phase evaluated the difference in microbe-carrying particle levels between total knee arthroplasty procedures involving the use of surgical helmet systems and similar lower-extremity trauma procedures such as open reduction and internal fixation of ankle fractures without the use of helmet systems. Twenty-eight procedures were monitored over a period of 8 months; these procedures were selected on the basis of the availability of supplies and research personnel. The helmet and no-helmet groups showed a large overlap in terms of low microbe-carrying-particle levels; however, 2 extreme outliers were noted in the no-helmet group. This finding led to the conclusions that clinically relevant future studies must (1) stratify microbe-carrying particle levels for nonparametric analysis and (2) link procedure-specific levels to each patient's outcomes. The project then refocused on developing test instruments, supplies, and protocols to allow observational studies to relate surgical outcomes to the intraoperative sterile field microbe-carrying-particle exposure. An additional 19 total joint replacement procedures were monitored over 3 months to achieve these goals. At the conclusion of the study, 47 procedures had been monitored: 33 total joint replacement procedures and 14 trauma surgery procedures. The trauma surgery procedures and 7 robotic unicondylar knee replacements were excluded from the analysis because of marked differences in terms of setup, draping, and equipment. Four additional total joint replacement procedures were excluded because the negative control was positive, indicating possible mishandling of the plates. Twenty-two total joint replacement procedures were then available for analysis.

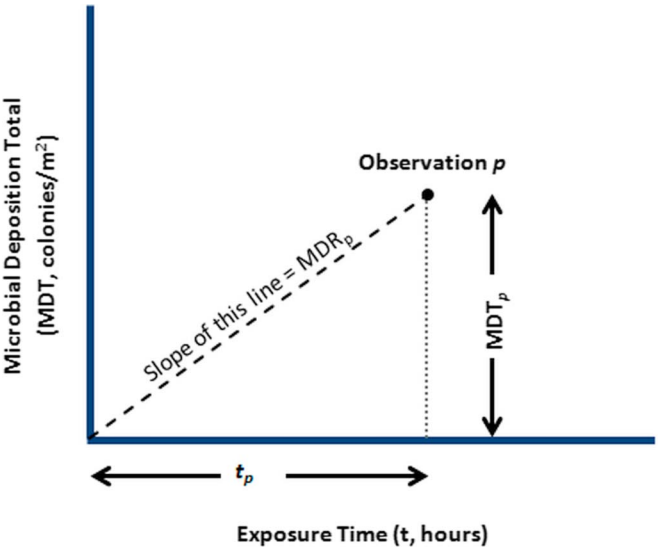

Fig. 2

A plot of MDT versus t, demonstrating the relationship between MDT and MDR for an observation p. $MDR_p = MDT_p/t_p$ = slope of line from origin to observation p. MDR = microbial deposition rate (colonies/m^2/hr), MDT = microbial deposition total (colonies/m^2), and t = plate exposure time (hours).

TABLE I Benchmark Values, MDT Calculations, and Reference Levels

Source	Benchmark Value	Sample Location	Conversion Equation (see Appendix)	Calculation Variables*	MDT	Reference Level[54,55] (MDT)
Whyte et al.[15,19]	1 colony/m^3	Wound	4	x = 1, t = 1.4 hr†	81	Target (100)
Charnley[14]	0.624 colony/plate‡	Wound zone	2	A = 0.00601 m^2§	104	
Whyte et al.[15,19]	10 colonies/m^3	Wound zone	4	x = 10, t = 1.4 hr†	368	Alert (450)
Friberg et al.[20]	350 colonies/m^2/hr	Wound zone	3	t = 1.4 hr†	490	

*x = volumetric air contamination (colonies/m^3), t = procedure duration (hr), A = surface area (m^2). †t = 1.4 hours was arbitrarily chosen to calculate all benchmark MDT values using Equations 3 and 4 (see Appendix). It is based on the average total joint procedure duration of 84 minutes as reported by Charnley[14]. ‡The study states that 80-cm plates were used, but at that time only 90-cm plates were in use[62]. §A 90-cm Petri dish is assumed to have an 87.5-cm-diameter effective surface (area [A] = 0.00601 m^2).

The operations were performed in 2 operating rooms built to current U.S. standards[48] and commissioned in 2012. The ventilation system has an HEPA (high-efficiency particulate air) filter that supplies air through cleanroom-type laminar airflow diffusers grouped over the surgical table, positive pressurization, and low wall air returns. All surgeons used identical draping, equipment, and implant systems. Scrubbed personnel used surgical helmet systems (Flyte Steri-Shield Personal Protection System; Stryker), low-permeability surgical gowns, and double gloving. Protocols included prophylactic antibiotics, limited room traffic, minimal door openings, and other Association of periOperative Registered Nurses (AORN) recommendations[49]. Passive counts were measured according to the protocol described above.

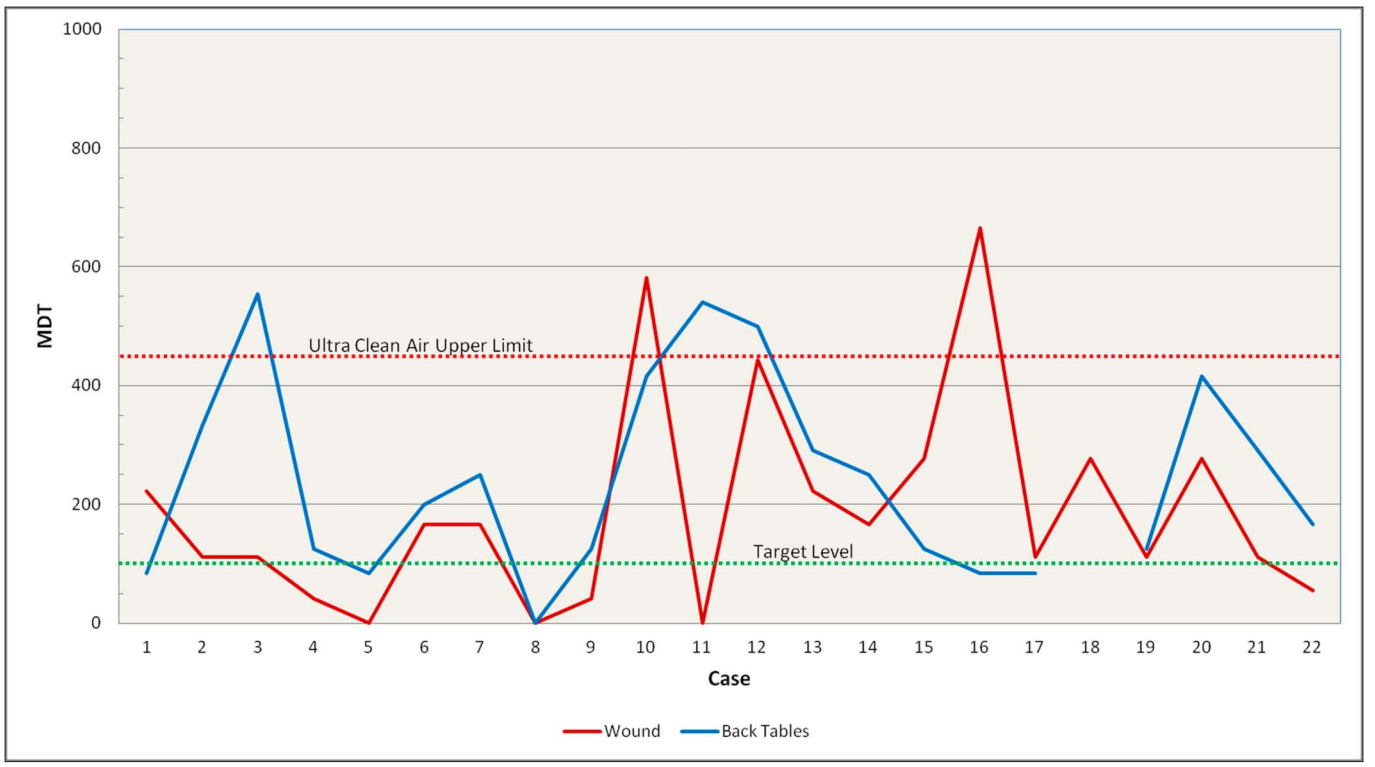

Fig. 3

Line graph illustrating sequential MDT results for the 22 procedures and MDT reference values (expressed in colonies/m^2). The wound-zone values represent the sterile field exposure time from extremity draping until fascia closure. The back-table-zone values represent the sterile field exposure time from patient draping until fascia closure (Cases 1 to 9) and from room opening until fascia closure (Cases 10 to 22). The ultraclean-air upper limit of 450 and the target level of 100 are shown as dashed lines. A plot of MDT zone data and reference values such as that shown here also could be used as a control chart for operating-room environmental quality control systems.

TABLE II Mean Exposure Time and MDT for Pilot Project Zones

Zone	N	Exposure Time* *(hr)*	MDT*
Back table	21	1.29 ± 0.48	240 ± 166
Wound	22	1.02 ± 0.39	189 ± 179

*The values are given as the mean and the standard deviation.

Scientific Application: Conversion of Observations to a Single Outcome Format

Settle plate observation variables include colony count, plate area, and exposure duration. The most commonly utilized outcome expression in passive sampling is the microbial deposition rate (MDR) (Fig. 2)[50,51]. Another outcome expression was developed and named during the present project: the microbial deposition total (MDT). This outcome represents the settle plate colony count normalized to a standard surface area (Fig. 2). If the test procedure stipulates that the plate is opened at the start and closed at the end of the surgical procedure, then the MDT will represent the total surface contamination accumulated during that observation period. Whyte and Eaton[51] derived a relationship between MDR and volumetric data from active sampling. The Appendix includes 4 equations (Equations 1, 2, 3, and 4) that relate active and passive sampling outcome data formats. The average MDT was calculated for each case in both zones with use of Equation 2.

Statistical Analysis

Confidence intervals were calculated with use of the Wald method (QuickCalcs; GraphPad Software, www.graphpad.com/quickcalcs). Other descriptive statistics were calculated with use of Excel.

Clinical Application: Environmental Quality Control

Statistical process control (SPC) has been used in industrial manufacturing for many years to control the quality of the product and, more recently, has been used in surgery[52,53]. SPC requires an underlying probability distribution to set boundaries for acceptable observations. Data that were generated during the pilot study showed a high percentage of 0 colony observations, and this finding made distribution selection difficult. Therefore, an alternative technique to provide desirable and outlier levels was employed.

Calculation of MDT Reference Values

A literature search was performed for English-language reports containing air contamination monitoring benchmark levels and related periprosthetic joint infection outcomes relevant to the total joint replacement operating room. Only 2 studies met these criteria (Table I). An additional sham surgery study was included in Table I because of the paucity of data. The benchmark values in those studies had different units and could not be directly compared, so they were converted to MDT format for correlation.

Cleanroom control protocols stratify sample results into multiple levels[35,54] denoting increasing contamination risk and are useful for surgical applications. The "target level" is defined as "…a goal for routine operations," and the "alert level" is defined as "…giving early warning of a drift from normal conditions, which, when exceeded, should result in increased attention to the process."[55]

The MDT benchmarks in Table I were grouped and used to calculate proposed reference levels (analogous to cleanroom levels) for scientific and clinical applications. Charnley's data[14] and the MRC lowest reported level[15,19] of 1 colony/m^3 are averaged and rounded, resulting in an MDT of 100. Two values (the higher MRC[15,19] and Friberg[20] MDT levels) correspond with the defined upper limit of ultraclean air conditions of 10 colonies/m^3; when averaged and rounded, the result is 450. Thus, a target MDT of 100 and upper limit MDT of 450 are reference values consistent with achievement of optimal ultraclean air conditions in the operating room.

Results

Scientific Application

The MDT values for the 22 procedures (20 total knee arthroplasties and 2 total hip arthroplasties) are shown in Figure 3. During the first 9 procedures, the back-table results did not capture field exposure during the room opening phase; this was corrected in later procedures. One procedure had no back-table data because of a protocol error. All 22 procedures had wound-zone data. Descriptive statistics are shown in Table II. Complete data are available in Table E-1, and excluded case data are shown in Table E-2 (see Appendix).

Environmental Quality-Control Application

MDT reference lines of 100 and 450 are shown in Figure 3. The MDT levels for the individual procedures were generally below 450, which is the upper limit of ultraclean air conditions. The back-table-zone MDT exceeded this upper limit in 3 cases, and the wound-zone MDT exceeded this upper limit in another 2 cases. Wound-zone observations showed that 6 procedures (27.3%; 95% confidence interval [CI], 12.9% to 48.4%) had wound MDT levels of <100 (1 colony/m^3) and 20 procedures (90.9%; 95% CI, 71.0% to 98.7%) had wound MDT levels of <450 (10 colonies/m^3). The mean MDT for both the wound and back-table zones was <450. An analysis of excluded cases showed no meaningful change in these trends as a result of their omission.

The high variation in observations is not unusual in environmental monitoring programs[29,56]. Control charts address this variability and plot sequential observations along with target and alert levels. Figure 3 also can be visualized as a control chart to monitor and adjust operating room airborne contamination as described in the controlled-environment technical literature[29,57]. Unusual or repetitive patterns would require further attention to testing and aseptic protocols.

Discussion

Research Application of Settle Plates

In general, current controlled-environment technology is aimed at managing the risk of product contamination by

keeping microbe-carrying-particle volumetric or rate levels and product-exposure variables below calculated limits[35,46]. However, the surgical problem appears different: airborne contamination of the sterile field or wound with current operating-room aseptic technology is certain. The present study proposes a new concept, namely, that the total microbe-carrying-particle surface load on the sterile field at the end of a surgical procedure is the outcome variable of interest. The variable MDT represents this load when the Petri dish exposure period coincides with sterile field creation and wound closure.

Airborne environmental contamination during total joint replacement surgery and its effects on periprosthetic joint infection rates were studied by Charnley[14] and the MRC[15] but remain a "research gap"[11] that is demonstrated by the lack of published research since that time. Table III provides a summary of data from the literature; the reported or recommended microbe-carrying-particle levels have been converted to MDT levels and the references sorted from high to low MDT number. The MDT levels in the present study are in general agreement with those in the literature.

This settle plate method can also be used as a research tool to validate the in situ performance of ultraclean air systems and operating room protocols to protect the sterile field. Miner et al.[58] and Hooper et al.[59] reported increased periprosthetic joint infection rates with clean air systems, yet those studies provided no information to validate that ultraclean air conditions were achieved in the critical zone around the wound and sterile fields. Passive sampling also could be used to evaluate specific equipment such as surgical helmet systems[60] that may be less effective than the body exhaust gowns used by Charnley[14].

Environmental Quality Control Application of Settle Plates

Reference MDT levels of 100 as a target value and 450 as an upper limit have been suggested in the present study. These values are derived from the Charnley[14] and MRC[15] studies that measured sterile zone environmental air quality associated with low periprosthetic joint infection rates. These values roughly correspond to widely accepted microbiological cleanroom volumetric definitions (1 colony/m^3 and 10 colonies/m^3) as described in the aseptic processing literature[44,45].

One limitation of the present study is that it does not address other sources of contamination that could have an influence on periprosthetic joint infection rates. These other sources include transfer, strike-through[61], barrier defects, and incision skin edges. Other limitations included the small number of procedures in the study and the absence of procedure outcome data on periprosthetic joint infection; however, the purpose of the present study was not to test a scientific hypothesis but rather to investigate a straightforward, inexpensive sampling system and to explore data-interpretation methods for future research or clinical projects. Another limitation was that the study was performed at 1 institution, but as there is a "research gap"[11] regarding intraoperative microbe-carrying-particle levels and the risk of periprosthetic joint infection, the present study remains useful to provide a tool for starting scientific dialogue to fill this gap.

Overview

Settle plate measurement of airborne microbial contamination has been used since the earliest days of modern arthroplasty to quantify the effect of operating-room environmental conditions on the sterile field. The zoned sampling system based on current aseptic manufacturing principles, the MDT variable, reference

TABLE III Literature Values and Conversion to MDT Format

Source	Reference Type	Benchmark Value	Sample Location	Conversion Equation (see Appendix)	Calculation Variables*	MDT
Hoffman et al.[38]	Hospital Infection Society working party report	1 colony/m^3	Within 300 mm of wound	4	x = 1, t = 1.4 hr†	81
Deutsches Institut für Normung (DIN) 1946-4[10]	Technical specification	1 colony/50 cm^2/hr	Sterile zone border	3	50 cm^2 = 0.005 m^2, t = 1.4 hr†	280
Health technical memorandum 03-01[9]	Technical specification	10 colonies/m^3	Within 300 mm of wound	4	x = 10, t = 1.4 hr†	368
Whyte et al.[19]	Recommendations based on MRC study[15]	20 colonies/m^3	Sterile areas away from wound	4	x = 20, t = 1.4 hr†	581
Collis and Steinhaus[43]	252 total hip arthroplasties performed in conventional ventilation and gowns	4.8 colonies/plate/hr	Wound zone	1,3	A = 0.00601 m^2, t = 1.4 hr†	1,118
Pasquarella et al.[21]	Recommendation based on review	5 IMA (index of microbial air contamination) = 5 colonies/90-mm plate/hr	At border of sterile zone	1,3	A = 0.00601 m^2, t = 1.4 hr†	1,165

*x = volumetric air contamination (colonies/m^3), t = procedure duration (hr), A = Petri dish surface area (m^2). †t = 1.4 hours to match benchmark calculations in Table I.

levels linked to aseptic processing standards, and a description of the control chart method to manage operating-room environmental quality are all new tools to address microbe-carrying-particle sterile-field contamination during total joint replacement.

Appendix

eA Equations that relate active and passive sampling outcome data formats and tables showing raw data from the pilot study are available with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJSOA/A62). ■

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