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Source strength as a measurement to define the ability of clean air suits to reduce airborne contamination in operating rooms

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SUMMARY

Background: Surgical site infections after total hip and knee replacement are linked to the quality of the operating room (OR) air. Applying tight occlusive clothing, effective ventilation and correct working methods are key concepts to obtain low bacterial concentrations in the OR air. The dry penetration test referred to in European standard EN 13795-2:2019 is a screening method for materials used in surgical clothing. Source strength, defined as the dispersal of bacteria-carrying particles from persons during activity, is a functional test of clothing systems and has been calculated in a dispersal chamber and in ORs. Results from both tests can be used when comparing surgical clothing systems.

Aim: This study relates results of dry penetration tests to source strength values for five surgical clothing systems available on the Swedish market.

Methods: Experimental data are reported on the function of these products, expressed as source strength calculated from results in a dispersal chamber and in ORs during orthopaedic operations.

Findings: All materials tested with dry penetration $\leq$50 colony-forming units (cfu) had source strength values $<$3 cfu/s for one person in the dispersal chamber, whereas the material of one product when laundered $>$50 times had source strength in the dispersal chamber of up to 8 cfu/s.

Conclusion: The dry penetration test could predict the performance of clean air suits of the same design, but more studies are needed to obtain a more valid correlation. Requirements of source strength should be included in standards.

Introduction

Total hip and knee replacements are among the most common orthopaedic surgical procedures, and are expected to increase further as the population ages [1,2]. In the USA alone, there were over 50,000 hip replacements and 72,000 knee replacements in 2014 [3]. Deep surgical site infections after

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total hip and knee replacements are a feared, costly and disabling complication. However, these infections continue to occur; one study of 69,993 US Medicare patients undergoing total knee replacement reported that 1400 (2%) infections developed [4].

A source for deep surgical site infections after implant surgery is thought to originate from bacteria-carrying particles in the air of the operating room (OR) which deposit in the open wound and on surgical equipment [5,6]. Efforts to improve OR air quality include optimizing the performance of the ventilation system to dilute the air, and correct working methods such as minimizing door-openings. Additional reduction of the concentration of bacteria-carrying particles in the OR air can be achieved by occlusive clothing which reduces dispersal of particles from the surgical team [7,8].

The performance of occlusive operating clothes on the market varies between brands. Objective information is necessary to guide infection control professionals and procurers.

The dry penetration test (EN 1SO 22612:2005), referred to in European standard EN 13795-2:2019, is a screening method for materials used in operating clothes, and can be used when selecting and comparing products [9,10]. Source strength, defined as the dispersal of bacteria-carrying particles from persons during activity, is a functional test which has been calculated in a dispersal chamber and in ORs. The dry penetration test is a material test, while the source strength test is a functional test of the performance of the clothing system. Source strength requirements are not defined in standards but are mentioned in an informative annex to EN 13795-2:2019 [10].

This study compared the results of dry penetration tests for five OR garments available on the Swedish market. Experimental data are reported on the function of the same products, expressed as source strength, calculated from results in a dispersal chamber and in ORs during orthopaedic operations. The aim was to compare the dry penetration test results with the source strength results, and explore whether there is correlation.

Materials and methods

Clean air suits

A clean air suit is a suit, used as a working garment for OR staff, intended and shown to minimize bacterial contamination of the OR air from the wearer by blocking the penetration of skin scales through the material. A clean air suit is defined as a medical product, tested and CE-marked according to requirements of European standard EN-13795-2: 2019 [10]. A clean air suit consists of a coverall or a set of blouse and trousers and a hood. In the investigations described below, all clean air suits were of the same design, with tightly fitting neck, short sleeves and long trousers closed by cuffs. All persons in the dispersal chamber or in the OR wore surgical hoods of various designs and materials. The materials described in Table I have been used in clean air suits in Swedish hospitals. Material a is single use, whereas Materials b, c, d and e are re-usable.

Dry bacterial penetration

The dry bacterial penetration test is designed to simulate the penetration of bacteria-carrying skin scales through materials when dry [9]. It is used as a screening method for the functional performance of OR clothing materials. The value of dry bacterial penetration for OR clothing materials is a requirement of SS-EN 13795-2:2019 [10]. The test method is described in EN ISO 22612:2005 [9]. Talcum particles with median particle size of 4.5 μm (maximum range ≤2—17 μm) are used. The talcum particles are sifted for 30 min through the material to be tested, and spore-forming bacteria are used as marker organisms. Results are given as mean of 10 test pieces.

Dispersal chamber

Dispersal chambers for testing design and materials of marketed OR clothing are located in Europe at Chalmers University of Technology, Gothenburg (Sweden) and in Politecnico di Milano, Milan (Italy). A dispersal chamber is a qualified and validated chamber with a volume of approximately 2 m^3, with tightly sealed walls and door, and with a specified inflow of high-efficiency-particulate-air-filtered air at positive pressure (≈10 Pa) and controlled outflow (see Figure 1). A description of the Swedish dispersal chamber located at Chalmers University of Technology used in this study is given in Reinmüller and Ljungqvist [11].

Measuring airborne particles in the dispersal chamber and in operating rooms

Active air sampling was performed in the dispersal chamber with a slit-to-agar-sampler of 0.05—0.1 m^3/min, with 50%

Table I
Material characteristics of the five tested products with regards to composition, structure, material, warp thread, weft thread and dry penetration values obtained from the manufacturer

Material	Composition %	Structure	Weight (g/m^2)	Warp threads/cm	Weft threads/cm	Dry penetration
a	Polypropylene	Spunbonded	35	-	-	8
b[a]	Cotton 69/polyester 30/carb 1	Plain weave	150	47	26	44
b[b]	Cotton 69/polyester 30/carb 1	Plain weave	150	47	26	109
b[c]	Cotton 69/polyester 30/carb 1	Plain weave	150	47	26	171
c[a]	Polyester 99/carb 1	Twill	165	54	51	11
d[a]	Olefin 98/antistat 2	Twill	125	34	26	13
e[a]	Polyester 99.5/carb 0.5	Plain weave	135	61	34	33

[a] Laundered once.
[b] Laundered 50 times.
[c] Laundered 100 times.

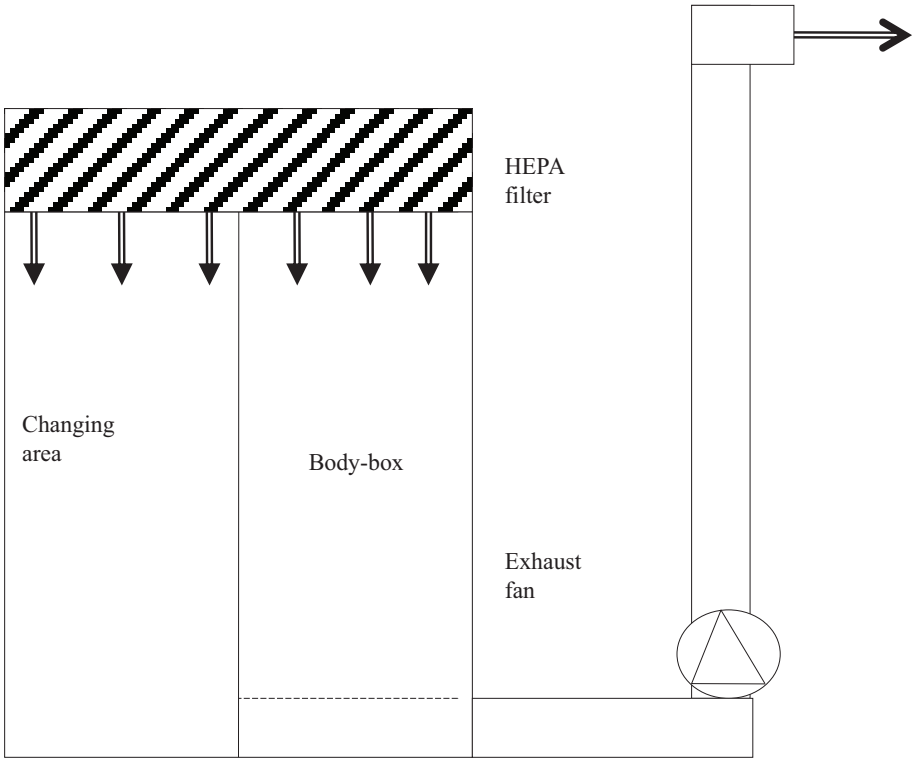

Figure 1. Principal design of a dispersal chamber. A male test person performs a set of standardized movements when wearing a product. The concentration of airborne particles is measured in the exhaust duct of the dispersal chamber, where the air is turbulent mixed. HEPA, high-efficiency particulate air.

deposition for equivalent aerodynamic particle size $\leq$2 μm. Active sampling in the ORs with a Sartorius MD8 air sampler with a gelatine filter pore size $\leq$3 μm was performed according to Ljungqvist *et al.* [12]. After incubation, the bacteria-carrying particles [colony-forming units (cfu)] were counted, and concentrations were given as aerobic cfu/m^3. The air flow rates in the chamber were adjusted to give expected bacterial counts between 2 and 30 cfu per sample [13].

A comparative study of the two measuring methods is described by Ljungqvist *et al.* [12], where measurements were performed in ORs during ongoing orthopaedic surgery. The results show that the filter sampler and slit-to-agar sampler give concentration values (cfu/m^3) in the same range. The Mann–Whitney *U*-test showed no significant difference between results from the two measuring methods.

Source strength

Source strength (q_s) is defined as the number of emitted bacteria per second (cfu/s) from a person wearing a specified garment, and is calculated using Equation (A) as follows:

$$q_s = (c \times Q)/n \quad \text{(A)}$$

where q_s is source strength calculated as emitted bacteria-carrying particles per second (aerobic cfu/s); c is measured concentration of bacteria-carrying particles per air volume (aerobic cfu/m^3); Q is measured total air flow (m^3/s); and n is number of people present in the OR excluding the patient.

The steady-state bacterial concentration per volume (c, cfu/m^3) depends on the number of persons present (n), the bacteria-carrying particles dispersed from them, source strength (q_s, cfu/s) and air flow into the OR (Q, m^3/s). It is independent of the size of the room and is calculated as follows:

$$c = (n \times q_s)/Q \quad \text{(B)}$$

Equation (B) can be used to predict air flow rates and type of clothing needed for a predetermined level of air cleanliness. Figure 2 shows some examples.

Source strength in a dispersal chamber

A male test person, aged 20–50 years, with no visible skin disorder performed a test cycle consisting of a standardized series of movements for 10 min [13]. During this period, inert and bacteria-carrying particles were measured in the outflow air. This test was repeated at least four times and with five test persons. Based on the measured cfu concentrations and the air volume flow, the mean value source strength for one person, was calculated using Equation (A).

Source strength during clean operations

Functional tests of clean air suits were carried out in ORs with a known number of people present and known air flow. Measurements of bacterial concentrations (cfu/m^3) were carried out in eight to 10 hip or knee joint replacement procedures with five to 10 persons present, all wearing the same type of clean air suit. During each procedure, at least

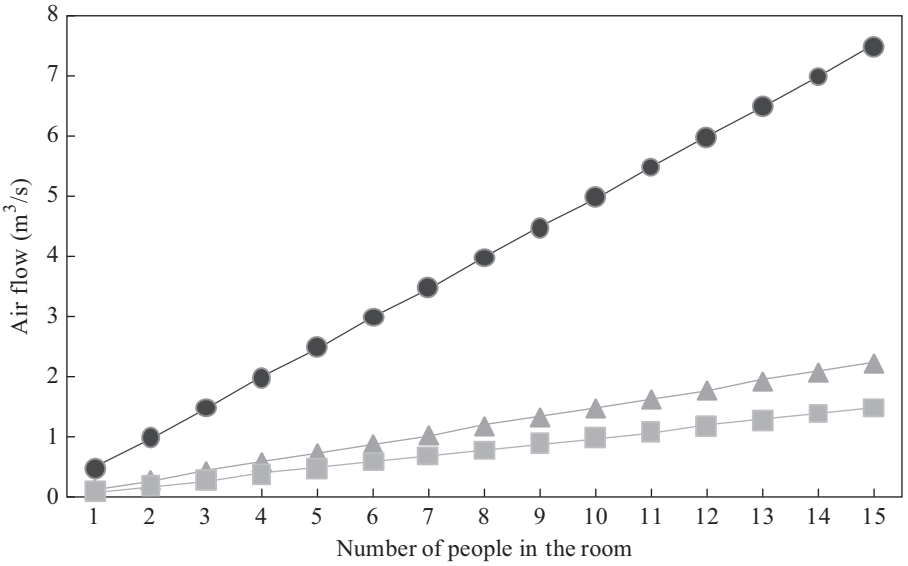

Figure 2. The source strength formula [Equation (A)] is used to estimate the effect of different clean air suits in operating rooms, and can be calculated when air flow rates and number of people present are known.

five active air samplings, each sampling 0.5–1 m^3 of air, were performed, after incision and before closure of the wound. The test results were reported as bacterial concentrations (cfu/m^3), and the source strength per person was calculated using Equation (A) (mean/median and min–max values).

Results

Dry penetration and materials

Table I lists the materials used for clean air suits in Sweden with composition, structure, weight and dry penetration. The results of dry penetration were obtained from the manufacturers of the materials/garments, and performed in commercial accredited textile laboratories, mainly in Germany. Re-usable materials were tested as new and as laundered up to 100 times. All materials tested fulfilled the requirement of dry penetration ≤50 cfu in EN 13795-2 for high-performance clean air suits except Material b when laundered >50 times.

Source strength in the dispersal chamber

The results of source strength (cfu/s for one person) tested in the dispersal chamber are presented in Figure 3. These investigations were carried out at Chalmers University of Technology in Gothenburg, Sweden. The results are published in laboratory reports [14–17].

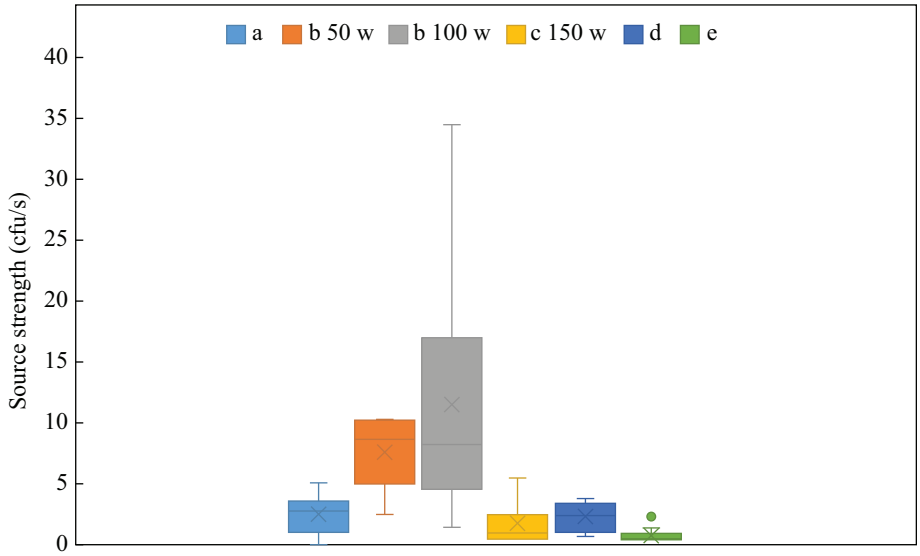

Figure 3. Source strength results in the dispersal chamber. Twenty measurements per material were recorded and the number of washes is expressed as w. Materials a–e are described in Table I. cfu, colony-forming units.

Material a had mean source strength of 2.5 (range 0–5.1). Material b, laundered 50 and 100 times, showed greater variability, with mean source strengths of 7.8 (range 2.5–10.3) and 10.9 (range 1.4–34.5), respectively. Material c, laundered 100 and 150 times, had mean source strength of 2.0 (range 0.5–7.5), and Materials d and e had mean source strengths of 2.3 (range 0.7–3.8) and 0.8 (range 0.5–2.3), respectively.

Source strength in operating rooms

Mean source strengths (cfu/s for one person) during hip and knee replacement operations were 1.2–1.5 [18–20], 3.4–5.3 [8, 12 ,20], 1.2–1.8 [8, 20] and 0.4 [21], for Materials a, b, d and e, respectively. Data for Material c are not available.

Figure 4 shows correlation between dry penetration and source strength in the dispersal chamber and in ORs. The correlation coefficients for dry penetration values and source strength values estimated during dispersal chamber tests and in ORs during ongoing surgery were 0.96 and 0.89, respectively. The high correlation coefficient value for dry penetration and source strength in the dispersal chamber may depend on standardized movements in the dispersal chamber.

All materials tested with dry penetration ≤50 cfu had source strength values <3 cfu/s in the dispersal chamber, except Material b when laundered <50 times which had a source strength value in the dispersal chamber of ≤8 cfu/s. Source strength results in ORs were approximately half the values of those in the dispersal chamber.

Discussion

Clean air suits are used to minimize the dispersal of microorganisms from the operating staff to patients' surgical sites and equipment, thereby helping to prevent postoperative surgical site infections. In this study, five different surgical clothing systems were examined for their ability to prevent the dispersal of bacteria-carrying skin scales from the wearer. The functionality of the products examined was expressed as source strength, which is a value that can be calculated using Equation (A) when the number of people, the bacterial concentration and the total air volume flow in a room are known. The study data indicate that there are correlations between dry penetration values and source strength values, but due to limited data, it is difficult to achieve reliable mathematical expressions between these parameters. Further studies are needed to establish the relationship between dry penetration and source strength.

Dry (microbial) penetration is the value used in European standard EN-13795-2 when defining the performance of a clean air suit. Standards should be relied on in the process of procurement for health care, and to help compare prices for products of similar or adequate quality. European standard EN 13795-2 for clean air suits can assist the communication between manufacturers and third parties regarding material or product characteristics and some information about performance requirements [10]. EN 13795-2 can ensure the same level of safety from single-use and re-usable clean air suits throughout their lifetime. According to EN 13795-2, the measure for comparison is dry penetration of the material. The dry penetration test provides a means for assessing resistance to penetration through barrier materials of bacteria-carrying particles. The EN ISO 22612 test was designed to simulate the penetration of bacteria-carrying skin scales through fabrics. The dry penetration limit of ≤100 cfu in EN 13795-2 is based on results of materials used for the manufacturing of clean air suits in clinical use today, both re-usable and single use. Annex D of EN 13795-2, 'Guidance to users for selecting products', introduces two barrier performance levels ('standard performance' and 'high performance') for clean air suits, thereby acknowledging the fact that different products may be required depending on the microbial cleanliness of the OR required for the procedure. The study data show that the dry penetration test can be used to classify the five tested materials into standard performance and high performance, and to define limits for how many launderings a re-usable material can withstand before it is worn out. EN 13785-2:2019 presents the requirements for clean air suits in the normative part. The

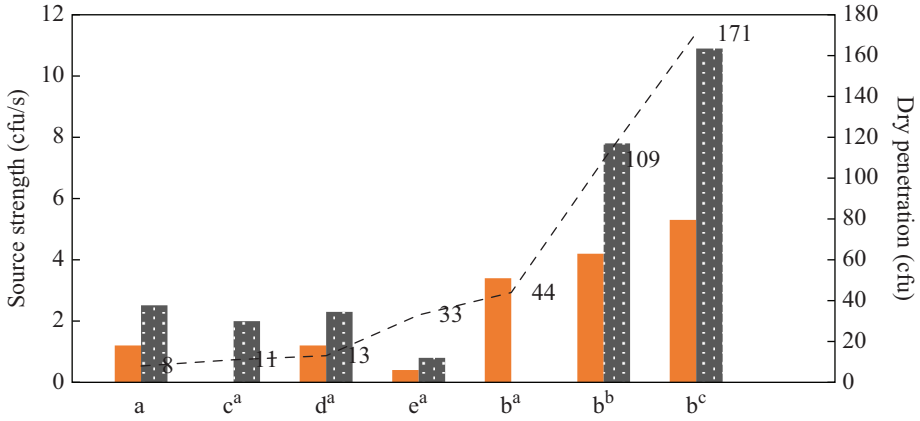

Figure 4. Dry penetration results of single-use, new and laundered re-usable materials, and their relations to source strength in the dispersal chamber and operating rooms. Materials a–e are described in Table I. Orange bars, source strength in operating rooms; black stippled bars, source strength in dispersal chamber; dashed line, dry penetration; cfu, colony-forming units. [a] Laundered once. [b]Laundered 50 times. [c]Laundered 100 times.

demands for high performance of dry penetration (≤50 cfu) were fulfilled for all clothing systems tested in this study, but not for the clothing system of mixed material.

There are no requirements for functionality of the OR garment when it is worn by operating staff in the normative part of the European standard [10]. Annex E of EN 13795-2, 'Functional design', suggests that dispersal experiments can be performed to test the design and material of a clean air suit. The concept source control is suggested as a measure of functionality of the clean air suit when worn by operating staff. The dispersal chamber test is not sensitive enough to evaluate minor changes in design and accessories, such as wearing a face mask or not, but may show the importance of quality and design of head coverings.

If the value of source strength is known for an OR garment, together with the supply air flow and the number of people present in the OR, estimations of the bacterial concentrations can be calculated using Equation (B). It is suggested that in the next version of the European standard, requirements for source strength should be included in the normative part to inform infection control professionals and procurers to select, evaluate and compare products on the market. It is suggested that manufacturers should provide information on both dry penetration and source strength for their respective products. Dispersal chamber measurements of source strength would enable further classification of clean air suits into standard- or high-performance groups. Measurements of operating garment source strength in ORs during standardized surgical procedures, such as hip replacements (clinical or simulated), can be used for clinical assessment of the products (Figure 2).

However, the value of source strength obtained, regardless of the method used, must be interpretated with caution. Source strength depends on the design of a garment and of the material used, but also on the wearer and the type of activity performed. When comparing designs, the clothing should be made of the same material.

The study data show that the clothing systems of synthetic material fulfilled the source strength of ≤1.5 cfu/s for clean air suits during ongoing surgery with high staff activity (hip joint surgery) according to SIS TS 39:2015 [22], and had source strength values ≤3 cfu/s in the test chamber.

Investigations of source strength for surgical clothing systems in dispersal chambers have been published in technical reports by Ljungqvist and Reinmüller [14—17]. Between-individual variability of dispersal from skin is known to be high, but the number of tests and test persons in the dispersal chamber is sufficient to give reproducible results for homogenous materials. Reliable results are achieved as the source strength results for similar clothing systems are in the same range over group of test subjects and time. Due to the number of test persons and the number of tests, the mean value source strength value is less affected by individual variations. The dry penetration test is a material test and depends only on the quality of the material.

Re-usable woven materials (Material b) deteriorate with laundering, particularly in mixed materials, whereas single-use (Material a) and monofibre (Materials c, d and e) materials are more homogenous and stable. This is clear from Material b, where dry penetration and source strength increased with the number of laundering cycles (Figure 4). The manufacturers and reprocessors should report the maximum number of washes allowed for the materials to remain within the requirements for high or standard performance, and ensure that each garment is removed from circulation when it reaches that number.

Results based on measurements of source strength in ORs (Figure 4) are less accurate as the number of launderings of the re-usable garments is unknown, and the air flow is not always known. The rationale for the difference in source strength of the same garment between the dispersal chamber and the OR is that movements in the chamber were more vigorous than in the ORs. Furthermore, test persons in the chamber were male, and most staff in the ORs were female; females disperse fewer skin micro-organisms [23].

In conclusion, the dry penetration test for clean air suits used in European standard EN 13795-2:2019 was tested for five OR garments available in Sweden. Reported source strength measurements conducted in a dispersal chamber and in the ORs were used to evaluate the performance of the same five clean air suits. This study found that the dry penetration test could predict the performance of clean air suits of the same design. More studies are needed to establish the correlation between dry penetration and source strength.

Conflict of interest statement
None declared.

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