

Suitable Control Choices

Exploring the roles of clean air suits and scrub suits in infection control

Experts in infection control are often asked about issues related to the use of scrubs and clean air suits in the operating room (OR). So far there is no clear explanation or mandatory obligation why the surgical team has to wear clean air suits or scrub suits in ORs and, more importantly, what the main differences are between these two types of clothing. There is a general perception that the two are equal or very similar.

So, what are clean air suits and scrub suits? Where did the concept and employ originate? Are they necessary from an infection control point of view? Are they useful in preventing or controlling transmission of infection?

Clean air suits are considered Class I medical devices according to the definition and classification rules of the consolidated EU directive 93/42/EC as amended by 2007/47/EC, while scrub suits don't have any regulation for their use in a hospital.

Infection sources

Routes of infection are contact or airborne. In the case of the latter, dispersed human skin particles are often carriers of infection. A healthy individual can disperse to the air approximately 5,000 bacteria-carrying skin

particles per minute during walking – and males disperse more than females.

The particles are 5 μm to 60 μm in size and the average number of aerobic and anaerobic bacteria carried is estimated to be about 5 per skin particle. The airborne particles contaminate the surgical site directly by sedimentation or indirectly by first setting on instruments or other items that are then brought into contact with the surgical wound. Fabrics with interstices larger than 80 μm do little to prevent the dispersal of skin scales.

This article seeks to highlight the most relevant information of these products and try to define the benefits of using them for preventing airborne disposal from the surgical staff, reducing the risk of infection.

This issue is more important now, because in the next year the European Commission will release a standard, EN 13795-2, specifically for clean air suits. The clean air suits are used mostly in the Scandinavian countries and are not widespread in other European countries or around the world. As a result, will this standard influence the use of clean air suits or perhaps increase the consumption of this product in Europe, turning it into an obligatory item in the OR, like surgical gowns and drapes? Will there be any reference regarding scrub suits? ▶



History of surgical clothing

A painting by Thomas Eakins, *The Gross Clinic*, 1875, portrays the reality of late Nineteenth Century surgical theatre. Surgeons crowd around the anaesthetised patient in their frock coats. Given it is painted just prior to the adoption of a hygienic surgical environment, to Twenty-First Century viewers, *The Gross Clinic* depicts a very backward ideal of medicine.

The Gross Clinic is thus often contrasted with Eakins's later painting *The Agnew Clinic*, 1889, which represents a cleaner, brighter surgical theatre and illustrates the evolving understanding of surgical hygiene and clothing during the intervening 14 years. In comparing the two, we see the advancement in our understanding of the prevention of infection. Notice that the surgeons are dressed in the white, specifically medical clothing, whereas those of *The Gross Clinic* are wearing street clothes. The felt-lined instrument tray of the earlier painting has been replaced with a sterile covered case.

At the turn of the Twentieth Century, some doctors still resisted the new 'germ theory', but others had begun to wear face masks and rubber gloves in surgery. Some surgeons wore surgical gowns and used heat treatments to sterilise dressings and surgical tools.

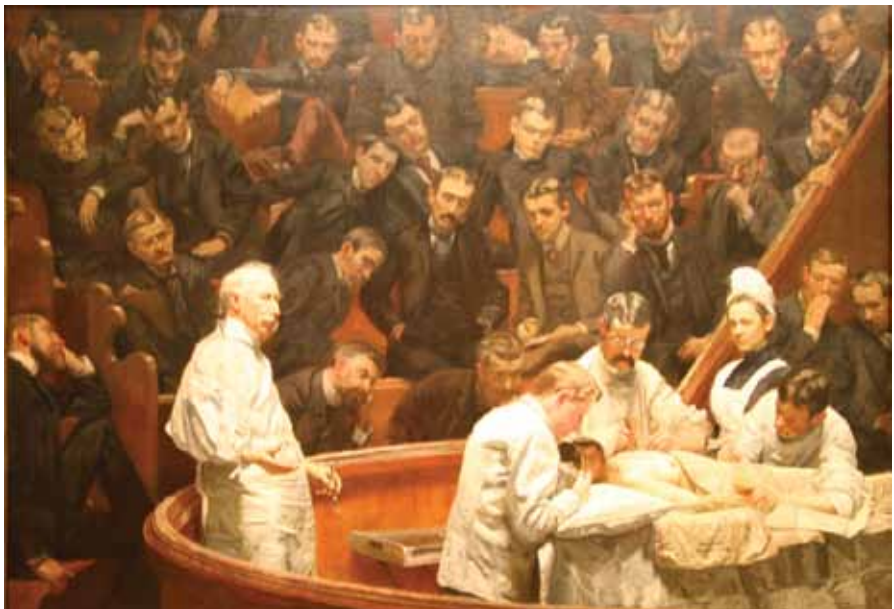
By around 1906-1908, some surgeons had begun to wear surgical masks.

In the following years medical staff strengthened the concern of the adequacy of textile materials for making surgical clothing, giving more attention to the protection and comfort of the patient and surgical team.

Throughout the Twentieth Century, a number of materials were used in the manufacture of surgical clothing for use in the OR. Woven textiles such as carded cotton, often referred to as muslin, were considered most suitable for this application. This material was easy to purchase, easy to work, economic and seemed to have the characteristics considered to be an acceptable barrier.



Thomas Eakins, *The Gross Clinic*, 1875 (Dustin Kidd 2004)



Thomas Eakins, *The Agnew Clinic*, 1889 (Dustin Kidd 2004)

“Eakins's later painting *The Agnew Clinic*, illustrates the evolving understanding of surgical hygiene and clothing during the intervening 14 years”

The cotton muslin fabric is a lightweight, absorbent and soft fabric, but extremely porous, having no resistance to liquid penetration, and it releases small particles, causing linting. Linting is the release of fibre fragments and other particles during handling and use of the fabric.

It therefore turns out that cotton fabrics are not suitable for the OR and that the micro-particles released by wearing the uniforms has become a means of transmission of microorganisms into the wound, and that in a wet state, the fluids pass through the fabric in contact with the skin of the healthcare professional (Abreu, 2004).

Every person loses about 5,000 to 55,000 skin scales/minute. About 10 to 20% of these scales contain live bacteria. Loose cotton scrub or clean air suits help in detaching. The higher the temperature and humidity, the higher the detachment rate.

While some hospital administrations stood still in time, others went in search of new materials and fabrics, which led to the development of numerous attempts to solve the problem penetration and density of the fabrics. This attempt led to the development of two different fabrics: reusable textiles and single-use nonwoven fabrics (Abreu, 2004) used to produce the clean air suits and scrub suits.

Clean air suits

Clean air suits are considered Class I medical devices according to the definition and classification rules of the MDD 93/42/EEC.

The definition of clean air suit is “a suit intended and shown to minimise contamination of the operating wound by the wearer’s skin scales carrying infective agents via the operating room air thereby reducing the risk of wound infection.”

The following standards identify the relevant characteristics of clean air suits, specify test methods for evaluating the identified characteristics and set performance requirements for finished products (Table 1):

- EN 13795-1 (2002) – ‘Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment – general requirements for manufacturers, processors and products (Part 1)’

Table 1 – Performance requirements for clean air suits (EN 13795-3:2006)

Characteristic	Test method	Unit	Requirement
Resistance to microbial penetration	EN ISO 22612	cfu	≤2,0 ^{a,b}
Cleanliness-Microbial	EN ISO 11737-1	cfu/100 cm ²	<2 ^b
Cleanliness-Particular matter	EN ISO 9073-10	IPM (index for particulate matter)	≤3,5
Linting	EN ISO 9073-10	Log ₁₀ (lint count)	≤4
Bursting strength-Dry	EN ISO 13938-1	kPa	≥40
Tensile strength-Dry	EN 29073-3	N	≥20

^a Test conditions: challenge concentration 108 cfu (colony forming unit)/g talc and 30 minutes vibration time

^b For the purpose of this standard, log₁₀ cfu ≤2 means maximum 300 cfu

“clean air suits are shown to minimise contamination of the operating wound by the wearer’s skin scales carrying infective agents via the operating room air”

- EN 13795-2 (2004) – ‘Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment – test methods (Part 2)’
- EN 13795-3 (2006) – ‘Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment – performance requirements and performance levels (Part 3)’

In addition, these standards set requirements for manufacturing and for processing and specify information to be supplied by the manufacturer.

Unlike the gowns usually worn in the OR, the clean air suit is designed to reduce the operating room air contamination by the personnel. The clean air suit should be used in addition to surgical gowns and not as a substitute.

These standards were recently revised to an unique standard – pr EN 13795, 2010 – and the clean air suits appear, but will emerge soon in an entirely new standard for these types of products: ‘Clean air suits, used as medical devices for clinical staff – General requirements for manufacturers, processors and products, test methods, performance requirements ▶

“the correlation between a low surgical wound infection rate and a high microbiological air cleanliness during the operation has been demonstrated”



Figure 1 - Single-use clean air suit

Figure 2 - Reusable clean air suit

and performance levels'. This document will supersede those parts of pr EN 13795 (2010) that deal with clean air suits.

The concept of the clean air suit is that it should be sufficient to enclose the dispersed bacteria carrying particles in the suit and not disperse them through the openings of the suit at the neckline, sleeves, waist, leg and boot openings. These parts should therefore be closed, preferably by cuffs.

If a clean air suit with a wide neckline is used, the gap should be closed by wearing a hood that covers all uncovered body parts (Figures 1 and 2). If the clean air suit is a two piece ensemble of a shirt and trousers, the shirt has to be tucked into the trousers.

Following studies demonstrated that a reduction in airborne bacteria arising from the perineum, thighs and feet could be accomplished by using a specially designed trouser-like garment that is sealed at the feet and waist and made from

tightly woven fabrics that restrict the dissemination of skin particles.

The correlation between a low surgical wound infection rate and a high microbiological air cleanliness during the operation has been demonstrated in total joint replacement operations (Lidwell *et al*, 1983) and hip or knee joint replacement (Lidwell *et al*, 1984). The ultraclean air conditions have been shown to be obtained either by using special ventilation systems or special clean air suits by Bergman *et al*, 1985 and Blomgren *et al*, 1990.

Clean air suits to reduce dispersal of bacteria carrying skin particles from the human body out into the air and their effectiveness has been established by Verkala *et al*, 1998 and Blomgren *et al*, 1990.

The testing of a clean air suit is quite expensive, because it's important to do the test in a dispersal chamber (very expensive) or in an OR with a laminar vertical system.

Scrub suits

The definition of scrub suit is quite wide ranging. Outside the OR, scrubs have been adopted as a replacement for the more traditional uniform worn by healthcare staff. Inside the OR, it's used under the surgical gown and frequently denominated as 'pyjamas' that consist of pants and shirt.

Since the turn of the Twentieth Century, clothing known as surgical scrub suits has been worn by healthcare workers in the OR. Today, a wide variety of these types of suits is being used for many applications in healthcare, outside the OR too (Belkin, 1997) – but scrub suits don't have any regulation for their use in any hospital area.

They should be viewed as a uniform over which a sterile gown is worn. The use of scrubs began in the OR around 1900 and was preceded by the surgical cap and gown (Doberneck, Kleinman, 1984). The word 'scrub' was derived from the practise of surgical staff scrubbing ▶

their hands before performing surgery, or assisting in surgical procedures.

The first mention of scrubs was published at the close of the Nineteenth Century, when it was stated that it is safer and better to put on a complete change of clothing rather than simply put a sterilised coat and pair of trousers over the top of ordinary clothing, as had been recommended by the German school.

In the late 1950s, concern for the level of airborne contamination came out as a possible influence on the occurrence of surgical wound infection (Belkin, 1997). Once the bacteria are airborne, their subsequent journey to the wound also depends on the scrub suit used by the surgical team and other personnel present in the OR.

It had already been demonstrated that dissemination of skin bacteria occurred as a result of friction between areas of heavy skin colonisation and that many more bacteria were liberated by movement involving the lower extremities (Bernard *et al*, 1965).

Tests have demonstrated that a person wearing a standard cotton scrub suit actually sheds more bacteria than without clothing (Kulkani, 2008).

Scrub suits in the OR

The Association of Operating Room Nurses (AORN) suggests that scrubs in the OR promote high level cleanliness and hygiene within the practice setting. Further, it recommends that all scrub attire should be placed in appropriately designed containers for washing or disposal, depending on whether it is a single-use or a reusable scrub, and should not be hung or put in a locker for wearing another time (AORN, 1995).

Traditional scrubs are generally not made of a barrier type, a liquid resistant material and therefore may not provide adequate protection, but on the other hand, if used under the surgical gown the protection has to be guaranteed by the gown and not by the scrub suit, so the use of scrub suit is closely related to the prevention of infection.

OR gowns with front and sleeves made of material that is resistant to liquid penetration reduces the risk of transfer of bacteria between patients in the operating theatre via scrub suits (Hoborn, 2005).

Conclusions

No scientific data supports the practise of using scrub suits as a means of preventing the transmission of infection, but we do have a vast number of studies regarding the effectiveness of clean air suits. This won't, however, invalidate the use of scrub suits, but, rather, highlights the fact that more study in this area is necessary.

In the near future, the Textile Engineering Department of the University of Minho and an enterprise interested in a comparative study of scrub suits and clean air suits will join forces to measure the performance of suits made with the same fabrics – nonwoven, when single-use and micro-polyester if reprocessed and reused afterwards.

Perhaps this comparison will bring more clarity. Also, cost-effectiveness, which is an important issue for the healthcare systems around the world will be explored, since the scrub suits are less expensive than the clean air suits. This needs to be weighed up against which garments may guarantee infection prevention. Cost deliberations will include purchase prices, maintenance and management.

Finally, the scrub suits are certainly more effective than the use of normal underwear beneath a surgical gown, and the decision to use these suits under gowns is undoubtedly a positive step for hospital administrations to take. ■

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“ OR gowns with front and sleeves made of material resistant to liquid penetration reduces the risk of transfer of bacteria via scrub suits ”