Prevention of airborne disposal from staff in the O.R. reducing the risk of infection: What are the benefits of using clean air suits or scrub suits?

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ABSTRACT
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, what are clean air suits and scrub suits?
This article seeks to highlight the most relevant information of this products and try to define the benefits of using them for preventing airborne disposal from the surgical staff, reducing the risk of infection.
No scientific data support the practice of using scrub suits as a means for preventing transmission of infection, but on the other side we have a vast amount of studies regarding the effectiveness of clean air suits. However this won´t invalidate the use of scrub suits, just validating that this type of studies has to be done for scrubs suits.

Keywords: Clean air suits, scrub suits, infection control, operating room.

1. INTRODUCTION

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 the operating rooms (OR´s) and more importantly, what are the main differences between these two type 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 an useful resources of preventing or controlling transmission of infection?
The clean air suits are considered a 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 and the scrub suits don´t have any regulation for their use in any hospital area.
Routes of infection are contact or airborne. In the last case, dispersed human skin particles are often carriers of infection. A healthy individual can disperse to the air approximately 5000 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 this 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, specifically for clean air suits. The clean air suits are used mostly in the Scandinavian countries and are not very spread in other European countries or over 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 as an obligatory item in the OR such as the surgical gowns and drapes? Will there be any reference regarding the scrub suits?

2. HISTORY OF SURGICAL CLOTHING

The figure 1 represents a painting of Thomas Eakins *The Gross Clinic* from 1875 and portray the reality of late nineteenth century surgical theatre. This portrait brings the viewer into the amphitheater of the surgical classroom in the late nineteenth century. The painting represents a team of five surgeons and one anesthesiologist treating a young man with osteomyelitis of the femur removing a piece of dead bone from a man's leg. Here, surgeons crowd around the anesthetized patient in their frock coats. The patient lies on his right side with his knees drawn up, wearing only a pair of socks. To twentieth one century viewers, *The Gross* Clinic may seem to portray a very backward ideal of medicine. This is just prior to the adoption of a hygienic surgical environment. In fact, this was the perception even in the late 1880's after the adoption of aseptic procedures.

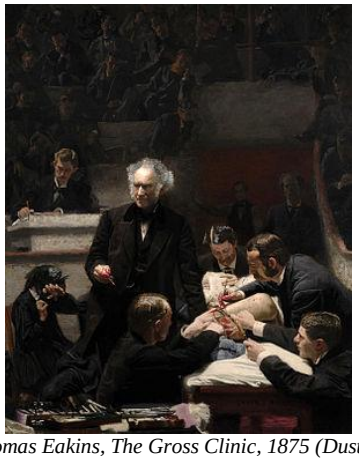

Figure 1 - Thomas Eakins, The Gross Clinic, 1875 (Dustin Kidd 2004)

The Gross Clinic is thus often contrasted with Eakins's later painting *The Agnew Clinic* from1889 (Figure 2), which represents a cleaner, brighter, surgical theater 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 Portrait of Professor Gross* are wearing street clothes. The felt-lined instrument tray of the earlier painting has been replaced with the sterile covered case. Eakins was able, and indeed forced, to give greater detail to the audience members in the later painting because of the introduction of artificial lighting into the surgery.

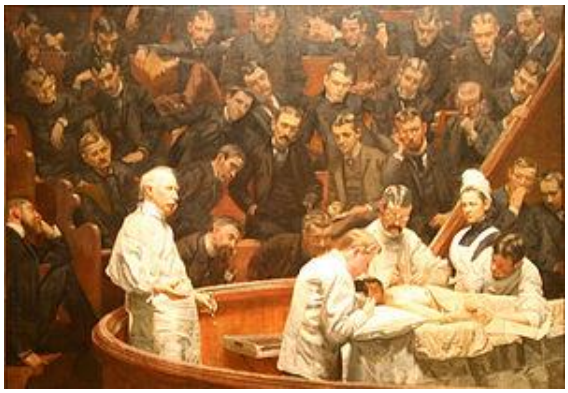

Figure 2 - Thomas Eakins, The Agnew Clinic, 1889 (Dustin Kidd 2004)

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 sterilize dressings and surgical tools. The figure 3 shows surgery circa 1906-1908. At that time , some surgeons had begun to wear surgical masks.

Figure 3 - Surgery at the beginning of the XX century (White 2008)

In the following years the 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 to use in the operating room. The woven textiles, such as carded cotton were considered most suitable for this application, often referred as muslin. This material was easy to purchase, easy to work, economic and seemed to have the characteristics to be considered an acceptable barrier for this type of application.
The cotton muslin fabric is a lightweight, absorbent and soft fabric, but extremely porous, having no resistance to liquid penetration and release small particles, causing linting. Linting is the release of fiber fragments and other particles during handling and use of the fabric. So, it turns out that cotton fabrics are not suitable for the O. R. and that the micro-particles released by wearing the uniforms has became a mean of transmission of micro-organisms into the wound and that in the wet state, the fluids pass through the fabric in contact with the skin of the healthcare professional (Abreu, 2004).
Every person lose about 5 000 to 55 000 skin scale/minute. About 10 to 20 % of these scales contain live bacteria. Loose cotton scrub or clean air suits helps in detaching. Higher the temperature and humidity, more will be the detaching.
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.

3. CLEAN AIR SUITS

The clean air suits are considered a 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 minimize 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".
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)", 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)" and 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)" identifie the relevant characteristics of clean air suits, specifies test methods for evaluating the identified characteristics and sets performance requirements for finished products (Table 1). In addition this standard sets requirements for manufacturing and for processing and specifies information to be supplied by the manufacturer. Unlike the gowns usually worn in the operation room, 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.

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	$\leq 2{,}0$ [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)	$\leq 3{,}5$
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 10^8 cfu (colony forming unit)/g talc and 30 minutes vibration time
[b] For the purpose of this standard, log_{10} cfu ≤ 2 means maximum 300 cfu

This standards were revised this year to an unique standard (pr EN 13795, 2010) and the clean air suits appear, but will emerge soon in an entirely new standard for this type of products, "Clean air suits, used as medical devices for clinical staff - General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels". This document will supersede those parts of prEN 13795 (2010) that deal with clean air suits.
The conception of the clean air suit should be sufficient to enclose the dispersed bacteria-carrying particles in the suit and not dispersed through the openings of the suit at the neckline, sleeves, waist, leg and boot openings. So, this part has to 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 (Figure 1 and 2). If the clean air suit is a two piece ensemble (shirt and trousers), the shirt has to be put into the trousers.

Figure 1 – Single-Use Clean air suit from Mölnlycke Health Care

Figure 2 – Reusable Clean air suit from Lojigma Int.

Following studies demonstrated that a reduction in airborne bacteria arising from the perineum, thighs and feet could be accomplished by using specially designed trouserlike garment that was sealed at the feet and waist and made from tightly woven fabrics that restricted 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 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 the effectiveness has been established by Verkala et al, 1998 and Blomgren et al, 1990.
The test 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 laminar vertical system.

4. 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 "pajamas" that consists of pants and shirt.
Since the turn of the XX century, clothing known as surgical scrub suits has been worn by health care workers in the OR. Today, a wide variety of this type of suits is being used for many applications in healthcare also outside the OR (Belkin, 1997), but scrub suits don´t have any regulation for their use in any hospital area. This 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 practice of surgical staff who scrubbed their hands before performing surgery or assisting in surgical procedures. The first mention of scrubs was published in the final of the XIX century stating that it is safer and better that all should put on a complete change of costume rather than simply put a sterilised coat and pair of trousers over the ordinary clothing as has been recommended by the German school.
In the late 1950s of the XX century, concern for the level of airborne contamination comes out as possible influence on the occurrence of surgical wound infection (Belkin, 1997). Once the bacteria are airborne, their subsequent journey to the wound depends also of 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 that a person wearing a standard cotton scrub suit actually sheds more bacteria than without clothing (Kulkani, 2008).
A scrub development later took place that included changes in the color, design and materials of which they were made and also expanded outside the OR to other healthcare facilities (Figure 3 and 4).

Figure 3 – Single Use Scrub suit from Mölnlycke Health Care

Figure 4 - Reusable Scrub Suit from Lojigma Int. Lda.

4.1 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 if it is a single-use or a reusable scrub and should not be hung or put in a locker for wearing in 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 it´s 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 suits is tightly related with 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).

5. FINAL REMARKS

No scientific data support the practice of using scrub suits as a means for preventing transmission of infection, but on the other side we have a vast amount of studies regarding the effectiveness of clean air suits. However this won´t invalidate the use of scrub suits, just validating that this type of studies has to be done.

In the next future the Textile Engineering Department of the University of Minho and an enterprise interested in this study, between comparison of scrub suit and clean air suit with the same fabrics (nonwoven, when single-use and micro-polyester if reprocessed and reused afterwoods) will be done, testing the same performance measurements. Perhaps this comparison will bring more explicitness. Also the cost-effectiveness, since the scrub suits are less expensive than the clean air suits, is an important issue for the healthcare system in the different countries, when it guarantee the same prevention of infection. Cost deliberation include purchase price, maintenance and management.

At last, the scrub suits are certainly more effective as the use of normal underwear beneath the surgical gown and the obligation to use this suits under the gowns is undoubtedly a positive attitude of the hospital administrations.

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