Cleanroom undergarments

Excessive effort or effective contamination reduction?

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Clothing under cleanroom garments is often still considered to be of minor importance [1]. The operators of cleanrooms are aware that humans are one of the largest sources of contamination. But by using cleanroom garments, many users assume that they have reduced this source. However, these considerations ignore the fact that a considerable contamination risk emanates precisely from ordinary cotton garments under cleanroom garments. In particular, if the employees are allowed to wear their personal clothing under the cleanroom garments, the cleanroom operator has no influence on the changing cycle, the degree of cleanliness, the washing conditions and the general condition of the underwear or rather undergarments.

Fig. 1: Testing with a contact plate

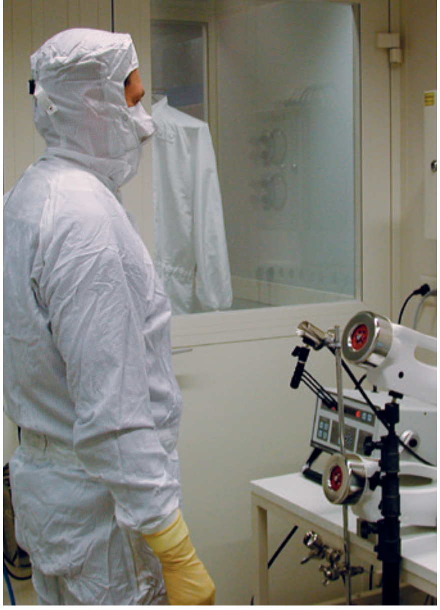

Fig. 2: Test setup

Fig. 3: Walking movement

Apart from recognising the importance of a so-called defined cleanroom undergarments, there are two main reasons that hinder the introduction of these: on the one hand, the increase in current costs, on the other hand, often a lack of employee acceptance. Due to the introduction of new materials, employee acceptance of this type of garments has risen significantly in the last two years. Both the wearing physiological properties and the optics / design could be improved. The argument of current operating costs increase should be countered by the rising risk of product contamination by a cleanroom unsuitable undergarments respectively the effectiveness of defined cleanroom suitable undergarments.

In spring of this year, Dastex therefore decided to carry out a new study on this topic in cooperation with the ITV Denkendorf (Institute for Textile and Process Engineering) and the company Labor L + S. Although the ITV had already demonstrated the efficiency of cleanroom suitable undergarments at the beginning of the 1990s [2–4], this new study was also intended to demonstrate the direct correlation between particulate and microbiological contamination as a function of the underwear or rather undergarments. At the same time, a new material for the undergarments, Light-Tech, was also to be tested.

In many semiconductor plants defined cleanroom compatible undergarments have already been able to established themselves. In contrast, in the microbiologically controlled areas, only a few companies (mainly large companies supervised by the FDA) have taken this consistent step, although W. Hecker had already expressly referred to the possible particle source „underwear" in a 1992 paper [5]. The results of this new study are a further proof of the importance and efficiency of an appropriate undergarment.

General conditions / Test setup

In a cleanroom at the ITV Denkendorf (comparable with a cleanroom class ISO 4 / ISO 5 or with a GMP area of the classes A/B), with vertical air flow at 0.45 m/sec, at 21 to 22 °C and approx. 45% relative humidity, the tests should be carried out under conditions as close as possible to those encountered in practice. The aim was to demonstrate different degrees of contamination depending on the selected undergarments, taking into account different movement sequences. The uniform cleanroom garments were made of ION-NOSTAT VI.2 and consisted of four parts: an overall with cuffs on arms and legs, a full protective hood with buttoned-in face mask (also made of ION-NOSTAT VI.2) and knee-high overboots. The garments were first professionally decontaminated twice at Micronclean Germany and then autoclaved. The undergarments were made of 100% cotton and 100% polyester and consisted of trousers and a long-sleeved T-shirt. These were each washed in a standard washing machine before the tests.

Initially, the measuring cleanroom of the ITV Denkendorf was subjected to an additional intensive cleaning, whereby all surfaces were wiped with a sterile alcohol mixture (Premier Klercide from Shield Medicare, 70% isopropanol and 30% WFI) and a sterile cleanroom cleaning wipe. This procedure was repeated daily. A possible cross-contamination should be excluded as far as possible. Two identical laser particle counters from Met One and air samplers from Biotest were used for the measurements. RODAC plates and RCS strips were used to determine the bacterial count. One particle counter probe and one air sampler each were placed at approximately workplace height (approx. 80 to 90 cm) and neck height (approx. 150 – 160 cm). An ITV employee carried out the experiments in the cleanroom. She operated the measuring devices and performed the respective contact plating. At each lock in, she received a freshly decontaminated and autoclaved set (4 parts, as described above) of cleanroom garments and 2 pairs of sterile powder-free nitrile gloves (for the so-called „double gloving"). The ITV employee always entered the airlock before the test person.

Experiment execution

The test person entered the airlock with the respective undergarments to be tested and first put on a pair of sterile, powder-free latex gloves. Then the full protective hood was put on, the textile face mask was buttoned up, the overall and the overboots were put on. Finally, a second pair of sterile, powder-free latex gloves was put on over the first (so-called „double gloving"). After entering the cleanroom, the cleanroom garments were first put on at three defined points (thigh on the right, forearm on the right and abdomen)

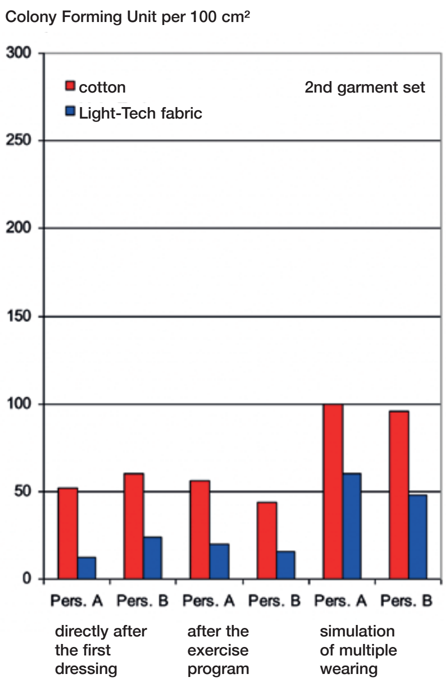

Fig. 5: Influence of undergarments on the microbiological contamination of cleanroom garments

Fig. 4: Gripping movement

«contact plated» (Fig. 1). Before the actual examination program was started, the test person moved a little in the cleanroom for one hour to achieve a certain used condition of the cleanroom garments.

Afterwards, the defined movement program was carried out directly in front of the measuring devices (Fig. 2). Following an IEST Recommendation Practice [6], three typical movements were simulated, walking (Fig. 3), a kind of gripping movement (Fig. 4) and bending down. The exercise programme (with breaks) lasted a total of 15 minutes. During the movement sequences, the particle concentrations of the cleanroom were continuously determined. At the same time, the airborne germs were collected during several phases of the programme.

Afterwards, the cleanroom garments were contact plated at six defined points (thigh on the right, forearm on the right, armpit on the right, abdomen, shoulder on the right and on the hood at the head top) (Fig. 1). After taking off the garments, the undergarments were also contact plated at four defined points (forearm right, armpit right, abdomen and shoulder right) for comparison.

The test person now left the cleanroom area for a few minutes and then re-entered the area as described above, but during this pass with the cleanroom garments that had been removed shortly before (but with new sterile gloves). This special test procedure was intended to simulate the repeated wearing of cleanroom garments. In microbiologically controlled areas, especially A/B areas, small and medium-sized companies (which are not usually supervised by the FDA) often put on and take off their sterile room garments several times a day. After a somewhat shorter «acclimatisation time» of approx. 15 minutes, the exercise programme was then started again and the garments and undergarments were again microbiologically tested (contact

Influence of undergarments on particulate contamination

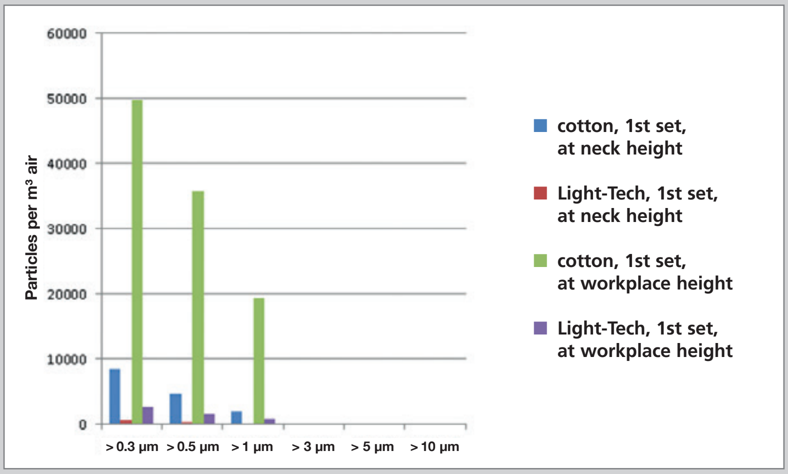

Fig. 6: starting from person 1 with the 1st garment set

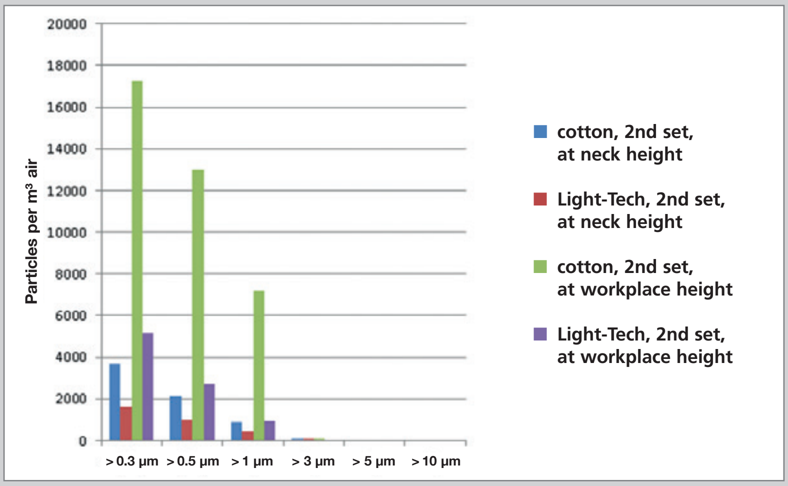

Fig. 7: starting from person 1 with the 2nd garment set

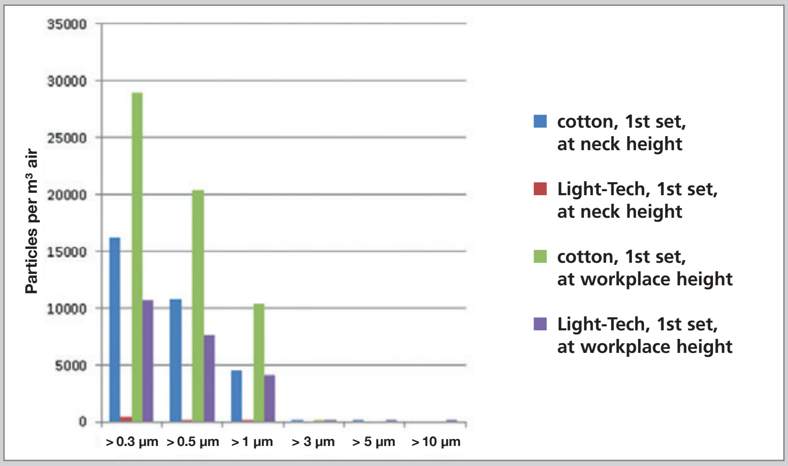

Fig. 8: starting from person 2 with the 1st garment set

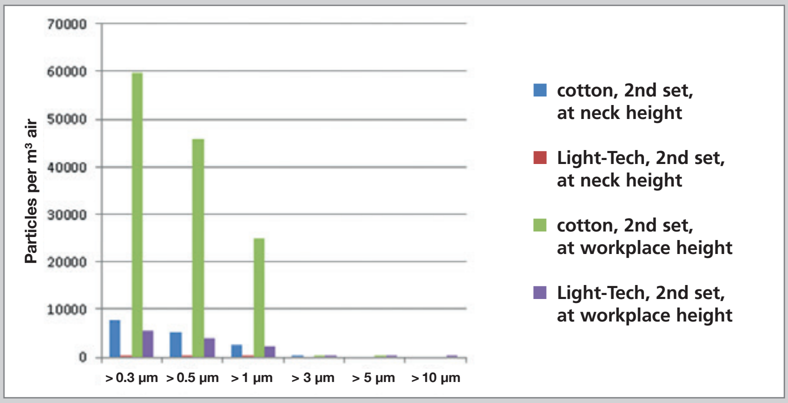

Fig. 9: starting from person 2 with the 2nd garment set

plated) as described above. For each test person, 2 completely fresh (i.e. decontaminated and sterilised) sets of cleanroom garments were pre-tested and retested.

Results

Both particulate and microbiological evidence of a clear reduction in contamination when wearing cleanroom compatible undergarments compared to simple cotton undergarments were provided. The germ reduction on the cleanroom garments was usually 50% and more. This reduction effect could be demonstrated directly after the first dressing, as well as after the exercise programme and after the second wearing (Fig. 5). It is also relatively obvious that cleanroom garments worn a second time have a significantly higher germ load than the garments after the first cycle of wear.

Particle reduction, especially at workplace height, is the best proof of the importance and efficiency of cleanroom compatible undergarments. On average, the reduction was well over 50%. In some cases, the values with the cleanroom compatible undergarments even reached only about 5% of the contamination level with cotton undergarments (Figs. 6 – 9). These statements also apply to particle sizes > 3, > 5 and > 10 µm. Due to the large scaling required in the chosen representation form, this cannot be recognised at first glance. Surprisingly, wearing the cleanroom garments several times during these experiments had no negative effect on the particle counts at neck and workplace height.

Discussion

Since there have been no publications on the subject of germ contamination on cleanroom garments depending on the garments worn underneath, it is unfortunately not possible at this point to compare the results obtained in this study with others. However, the proven significant reduction in germs suggests that defined cleanroom compatible undergarments (such as made of the Light-Tech fabric) in microbiologically controlled areas are definitely recommended.
Also the direct correlation between microbiological and particulate contamination has become obvious in this test series. Based on the results, however, it is not advisable to wear sterile cleanroom garments several times (even when using cleanroom compatible undergarments).

The reductions in airborne particulate matter detected in these tests show the same clear trends as the results of the ITV studies at the beginning of the 1990s [1–3]. In contrast to the current studies, however, the older studies mainly examined the degree of contamination of the garments and not the number of particles accumulating at workplace level in the cleanroom. However, reductions of more than 50% could be demonstrated in both studies. Another difference between the studies is the type/material of the undergarments.

With the recent studies a 100% polyester fabric was chosen instead of a 100% polyester knitted fabric. The main advantage of this «switchover» is the greater employee acceptance (due to the more pleasant product properties) for this new material of the cleanroom compatible undergarments.
Both versions (100% polyester fabric and 100% polyester knitted fabric) produce, due to their higher abrasion resistance, considerably fewer particles and fibres under the cleanroom garments than cotton, thus minimising the risk of this «abrasion» leaving the cleanroom garment system unintentionally and minimising the risk of product contamination.
The fact that considerably more particles have been detected at workplace height than at neck height can certainly be explained by the air flow in the cleanroom. After the particles have left the garment system (especially at head/neck height), they are caught by the air flow and carried forwards / downwards in a kind of elliptical curve. Since this type of airflow is found in many controlled areas, all the more importance should be attached to the suitability of all garment components, including the undergarments too.
The rising costs for the current supply (cleaning, provision etc.), which would increase with the introduction of cleanroom suitable undergarments, are certainly in relation to the expected positive effect of the significant reduction of particles and germs in a controlled area. The unambiguous results of these, in part very complex studies (especially with regard to the microbiological part), support the above statement.

Acknowledgements

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