Evaluating Bacterial Contamination of Clean Room Clothing

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CLEANROOMS AND OPERATORS

Cleanroom function

- minimise particle introduction/production/retention\(^1\)

Sterile medicinal products

- manufacture requires aseptic dispensing facilities\(^2\)
- all individual components must be sterile\(^2\)
- sources of contamination must be tightly controlled and continuously monitored to minimise particulate and microbial contamination of these products\(^1\)

CONTAMINATION SOURCES

Sources of cleanroom contamination

- operators, room surfaces, air and water

Cleanroom operator

- primary source of contamination
- humans shed approx $1 \times 10^9$ skin cells daily
- 5-10% of shed skin scales carry microorganisms
- >95% microorganisms are bacteria

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## CLEANROOM SUITS

<table>
<thead>
<tr>
<th>Fabric</th>
<th>Chemstat 909 extruded polyester</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air permeability</td>
<td>0.5 ml cm(^{-2}) sec(^{-1})</td>
</tr>
<tr>
<td>Pore size</td>
<td>40µm</td>
</tr>
<tr>
<td>Physical features</td>
<td>Stud fastening at neck, cuffs &amp; ankles</td>
</tr>
<tr>
<td>Clothing type</td>
<td>Bacterial dispersion per minute(^6)</td>
</tr>
<tr>
<td>Underwear only</td>
<td>6</td>
</tr>
<tr>
<td>Tunic, trousers and underwear</td>
<td>487</td>
</tr>
<tr>
<td>Cleanroom suit ceramic polyester</td>
<td>1108</td>
</tr>
</tbody>
</table>

Men and Women

- differ in levels of sweat and sebum excreted\(^7\)
- contrasting skin pH and microflora\(^7\)

Consequently

- operator gender affects room contamination levels
- greater bacterial diversity on female skin\(^8\)
- males disperse more microbe carrying particles\(^4\)
- inter-gender differences exist\(^1\)

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HUMAN BACTERIAL FLORA

Outermost layer of human skin

- carries ~ $1 \times 10^6$ microorganisms per cm$^2$
- aerobic/anaerobic species inhabit hair follicles
- more than 150 distinct bacterial phylotypes inhabit skin surface on palm of the hand
- both hands exhibit similar bacterial diversity

Gram-positive bacteria most commonly detected

- *Micrococcus, Staphylococcus, Corynebacterium*

RESEARCH OBJECTIVES

- Assessment of bacterial contamination of cleanroom clothing at various time intervals
- Determination of most highly contaminated areas of cleanroom clothing
- Examination whether wearing gloves prior to donning garments impacts on the subsequent bacterial load of cleanroom clothing
Bacterial detection assessment methods
- standardised swabbing procedure
- use of contact plates
- use of CleanTrace\textsuperscript{©} ATP monitoring system

Assessment of limiting suit contamination through glove use
- no gloves
- non-sterile disposable gloves
- sterile disposable gloves
Assessment of suit contamination
- 30 minute sampling
  - 8 males and 27 females
- 60 minute sampling
  - 18 males and 24 females

Limiting suit contamination through glove use
- 3 females
TEST SITES

- Mouth (over hood)
- Chest 5 cm from zip
- Left wrist
- Nape of neck
- Lower back
- Right wrist
- Umbilical region
## SUIT CONTAMINATION AT 30 MINUTES

<table>
<thead>
<tr>
<th>Sample site</th>
<th>Mean colony forming units recovered ((p) value &lt; 0.001)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Male ((n = 8))</td>
</tr>
<tr>
<td>Nape of neck</td>
<td>1-9 x 7; 10-20 x 1</td>
</tr>
<tr>
<td>Lower back</td>
<td>Zero x 3; 1-9 x 5</td>
</tr>
<tr>
<td>Mouth (over hood)</td>
<td>Zero x 3; 1-9 x 2</td>
</tr>
<tr>
<td></td>
<td>&gt; 20 x 3</td>
</tr>
<tr>
<td>Chest</td>
<td>Zero x 1; 1-9 x 7</td>
</tr>
<tr>
<td>Umbilical region</td>
<td>Zero x 1; 1-9 x 7</td>
</tr>
<tr>
<td>Inner right wrist</td>
<td>Zero x 1; 1-9 x 7</td>
</tr>
<tr>
<td>Inner left wrist</td>
<td>Zero x 3; 1-9 x 5</td>
</tr>
</tbody>
</table>
## Suit Contamination at 60 Minutes

<table>
<thead>
<tr>
<th>Sample site</th>
<th>Mean colony forming units recovered ($p$ value &lt; 0.001)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Male (n = 18)</td>
<td>Female (n = 24)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nape of neck</td>
<td>0 x 2; 1 - 9 x 12; 10 - 20 x 1; &gt;20 x 3</td>
<td>0 x 15; 1 - 9 x 7; &gt;20 x 2</td>
</tr>
<tr>
<td>Lower back</td>
<td>0 x 3; 1 - 9 x 10; &gt;20 x 5</td>
<td>0 x 20; 1 - 9 x 4</td>
</tr>
<tr>
<td>Chest</td>
<td>0 x 3; 1 - 9 x 7; 10 - 20 x 6; &gt;20 x 2</td>
<td>0 x 16; 1 - 9 x 5; &gt;20 x 3</td>
</tr>
<tr>
<td>Umbilical region</td>
<td>0 x 3; 1 - 9 x 9; 10 - 20 x 4; &gt;20 x 2</td>
<td>0 x 18; 1 - 9 x 5; 10 - 20 x 1</td>
</tr>
<tr>
<td>Inner right wrist</td>
<td>0 x 4; 1 - 9 x 13; &gt;20 x 1</td>
<td>0 x 21; 1 - 9 x 2; &gt;20 x 1</td>
</tr>
<tr>
<td>Inner left wrist</td>
<td>0 x 5; 1 - 9 x 9; 10 - 20 x 1; &gt;20 x 3</td>
<td>0 x 16; 1 - 9 x 6; &gt;20 x 2</td>
</tr>
</tbody>
</table>
GENDER AND SUIT CONTAMINATION

Highest female bacterial contamination sites
- nape of neck
- chest area

Highest male bacterial contamination sites
- chest
- nape of neck
- lower back
- umbilical region
## GLOVES AND SUIT CONTAMINATION

<table>
<thead>
<tr>
<th>Sample Site</th>
<th>Bacterial suit contamination (colony forming units) ($p$ value &gt; 0.05)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No gloves</td>
<td>Non sterile gloves</td>
</tr>
<tr>
<td>Nape of neck</td>
<td>0 x 4; 1-9 x 3; 10-20 x 2</td>
<td>0 x 6; 1-9 x 3</td>
</tr>
<tr>
<td>Lower back</td>
<td>0 x 7; 1-9 x 1; 10 -20 x 1</td>
<td>0 x 7; 1-9 x 2</td>
</tr>
<tr>
<td>Mouth (over hood)</td>
<td>0 x 1; 1-9 x 6; &gt;20 x 2</td>
<td>0 x 1; 1-9 x 5; &gt;20 x 3</td>
</tr>
<tr>
<td>Chest</td>
<td>0 x 4; 1-9 x 5</td>
<td>0 x 4; 1-9 x 5</td>
</tr>
<tr>
<td>Umbilical region</td>
<td>0 x 5; 1-9 x 4</td>
<td>0 x 6; 1-9 x 2; 10-20 x 1</td>
</tr>
<tr>
<td>Inner right wrist</td>
<td>0 x 6; 1-9 x 2; &gt;20 x 1</td>
<td>0 x 7; 1-9 x 2</td>
</tr>
<tr>
<td>Inner left wrist</td>
<td>0 x 8; &gt;20 x 1</td>
<td>0 x 5; 1-9 x 4</td>
</tr>
</tbody>
</table>
CONCLUSIONS

- Reduction in bacterial suit contamination
  - no significant difference in suit contamination detected when operators wore no gloves, non-sterile gloves or sterile gloves when donning suits

- Suits worn by male operators
  - high levels of microbial contamination

- Highest level of bacterial contamination
  - nape of neck and chest common to males and females
  - plus lower back and umbilical regions in males
ACKNOWLEDGEMENTS

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