Sterilization of Tyvek covered medical packages with UV-C radiation

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INTRODUCTION

Microbiological quality control validates the performance of drug production's sterilization processes through sterility tests. These tests are done for each production batch and its mission is to ensure that there is no microbiological growth inside the primary medical packages.
The aim of this work was to investigate whether UV-C radiation (265 nm) can be applied in sterilization of the surfaces of medical packages. The radiation must not penetrate the packages since it would decontaminate possible microbes that are studied in sterility tests. UV-C sterilization would reduce the laboratory personnel's workload and reduce the use of chemical disinfectants before the sterility tests.

METHODS

Micrococcus luteus, *Aspergillus brasiliensis* and *Bacillus subtilis* were used as model organisms. The UV-C tests were done as illustrated in Fig. 1 for two different medical packages (A & B). The aim of the tests was to study the effects of UV-C radiation to the microbes inside and on the medical packages.

1. Revival of the cells into a buffer or sterile water
2. Inoculation into agar plates (*M. lut & A. bras*)
3. Incubation (*M. lut* 2-3 days, *A. bras* 7 days)
4. Preparing the final suspension from the agar plates (*M. lut & A. bras*) or from a commercial stock (*B. Subt.)*
5. Inoculation of the final suspension inside the medical package (using membranes) or on the package
6. Drying (1-2 hours)
7. UV-sterilization of the packages in three minute sterilization cycles in a UV-sterilization device
8. Taking samples with the contact plates from the surface or picking the membranes from the inside of the package
9. Incubation (1-2 days) and counting CFUs

Figure 1. *UV-testing protocol for medical packages.*

RESULTS

The results did not alter between the two different packages. *A. bras.* and *B. subt.* were treated with three UV-cycles and *M. lut.* was treated with one UV-cycle (Fig. 2-3). The penetration of UV-radiation through the A package is illustrated in Fig. 4.

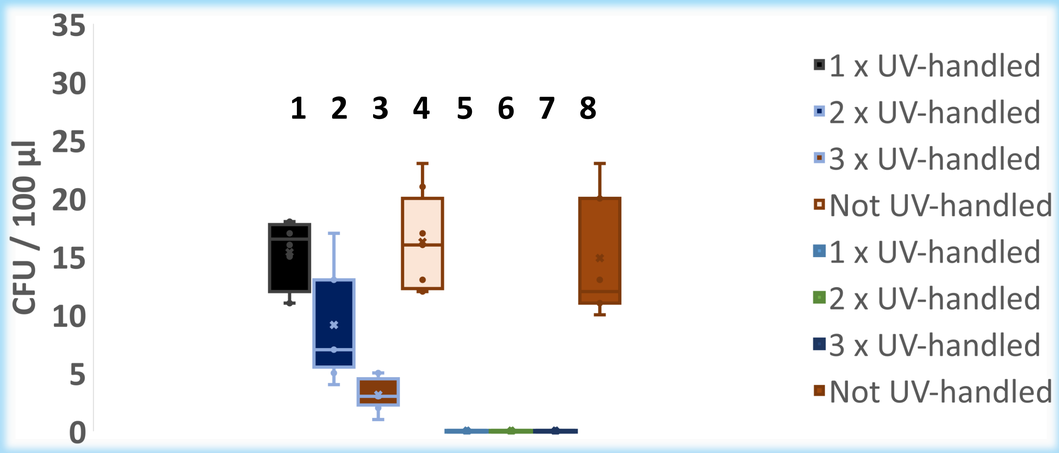

Figure 2. *The effect of three UV cycles on A. bras (1-4) and B. subt. (5-8) inoculated on the surface of the A package.*

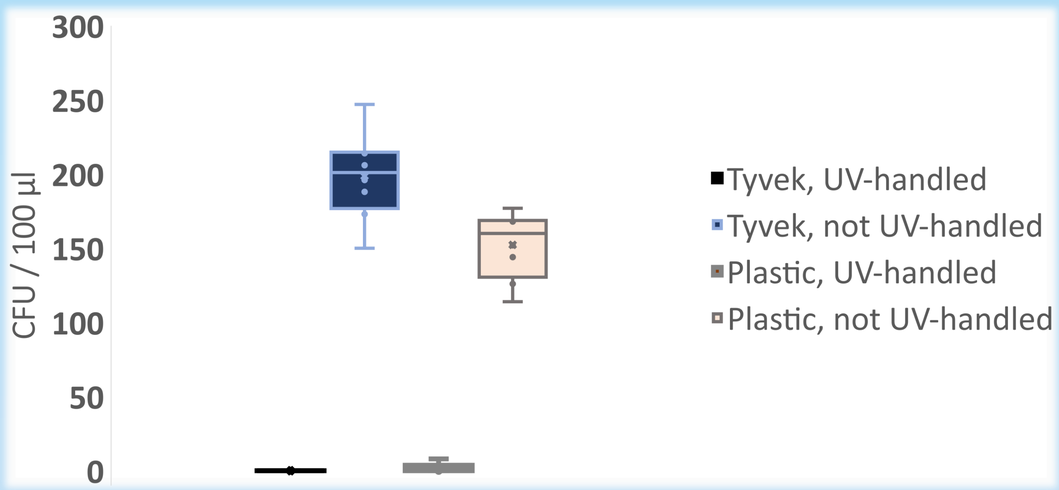

Figure 3. *The effect of one UV cycle on M. lut. inoculated on the surface of the B package.*

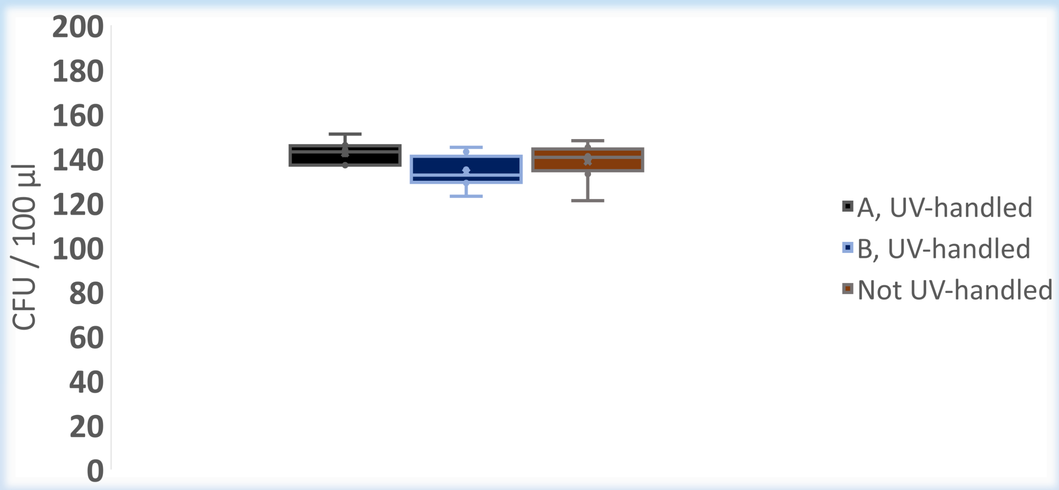

Figure 4. *The effect of three UV cycles on M. lut. inoculated inside the A and B packages.*

CONCLUSIONS

The UV-radiation was not able to penetrate through the medical package. *A. bras.* was the most resistant against the radiation while *B. subt.* and *M. lut.* were disinfected with one UV-cycle. According the results, the UV-C radiation can be considered as a disinfection method for the sterility tests.