Benefits of Gas Plasma Sterilization

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Editorial

Gas plasma sterilization technique is a relatively new technology found in 1970. Since then mostly engineering researchers studied by self-made equipment. Therefore, data is not reproducible and has many mistakes due to lack of microbiology and chemistry. From 2000, microbiologists and chemists have word together, somewhat mistaken have been disappeared, but still remain in sterilization filed.

Gas plasma sterilization method has a benefit to attain both SAL (sterility assurance level) of 10-6 and material/functional compatibility in success. On the contrary current sterilization procedures such as gamma-ray, electron beam, autoclaving, dry heating, ethylene oxide gas, and hydrogen peroxide gas can attain SAL of 10-6, but failed to attain material/functional compatibility, so the real marketing of the gas plasma sterilizer is keenly desired.

The papers carried out by only engineering researches have many mistakes on microbiology and sterilization. As above mentioned microbiologist and chemist joined the gas plasma sterilization research, so mistakes by chemist and microbiologists are somewhat disappeared, but engineering researchers have still mistakes as follows;

The tailing phenomenon (Figure 1) is due to clumping (multilayer of microorganisms) as biological indicators they used are self made and 10^6 CFU (colony forming unit)/carrier is inoculated too narrow of microorganisms) as biological indicators they used are self made so mistakes by chemist and microbiologists are somewhat disappeared, microbiologist and chemist joined the gas plasma sterilization research, mistakes on microbiology and sterilization. As above mentioned gas plasma sterilizer is keenly desired.

On the contrary current sterilization procedures such as gamma-ray, electron beam, autoclaving, dry heating, ethylene oxide gas, and hydrogen peroxide gas can attain SAL of 10^-6, but failed to attain material/functional compatibility, so the real marketing of the gas plasma sterilizer is keenly desired.

The mechanisms of gas plasma sterilization have been studied from 1970 to now, but defined mechanisms are still unclear. We studied that ion and electrons are out of discussion because outer layer of spore, gram negative and gram positive microorganisms are ionic (Figure 3), so interfere at the outer layer, so ionic and electronic ones are out of discussion. UV and VUV are also discussed their possibility to gas plasma sterilization, but finally defined their contribution were also minor, even though not at all. The rest are radicals and metastables (Figure 4). Radicals such as OH, NH, O, OOH, OONO and so on are quite short-lived at around μ second and the flight distance during life period is 0.003 cm/μ second,

Even though gas penetration depth of gas plasma sterilization is quite shallow ~10-20 nm, but this penetration is sufficient to kill bioburden as bioburden scattered in the product surface, so no clumping formed. According to authority, they require 6 log reduction. This does not indicate from initial population of 10^6 CFU/carrier to SAL of 10^-6, but initial population of bio-burden level of 10^6 CFU to SAL of 10^-6 (Figure 2). Anyhow in all sterilization procedures SAL of 10^-6 is required, this requirement is reasonable. SAL of 10^-6 considers the closest zero in ISO 11137-1. If the 6 log reduction from 10^6 CFU/carrier to SAL of 10^-6 can be conducted, it is no clumping, therefore no tailing and this sterilization is quite realistic. The authors studied fallen microorganisms at dialysis room of the healthcare facility in Nagoya, Japan and found 40-50 CFU/500L of airborne microorganisms and 2-3 CFU/plate as fallen microorganisms. Fallen microorganisms have a resemble concept as the bioburden, so I consider that the bioburden is a few CFU/carrier in real and dirty circumstances.

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so their contribution is not major, but minor. On the contrary, metastable has a so and so life period of 2-7 seconds and the flight distance is 144 cm/2 seconds, indicating metastable is thought to be major. They attack dipicolinic acid (DPA) in the core to hydrate DPA and result in inactivation of DPA. This is quantitatively determined [1]. The phenomenon of death of DPA can be observed and determined, but the cause of DPA death is only speculation, but no final decision.

In anyway, it is quite reasonable that flight distance of active factors of gas plasma sterilization is not always long enough, so in real gas plasma sterilizer, the capacity of the chamber is not large enough compared with the current sterilizers. However, it has a benefit that it can attain both SAL of $10^{-6}$ and material/functional compatibility in success. Current sterilizers without exception must fail material/functional compatibility due to too much large penetration including Sterad®, which is commercialized hydrogen gas plasma sterilizer. Chamber volume of Sterad® is 100-150 L, which is out of discussion as gas plasma sterilizer. Shallow penetration depth of gas plasma sterilization is the benefit as well as a weak point not to destroy clumping and biofilms. Attainment of both of SAL of $10^{-6}$ and material/functional compatibility is quite difficult problems in several meanings.

References