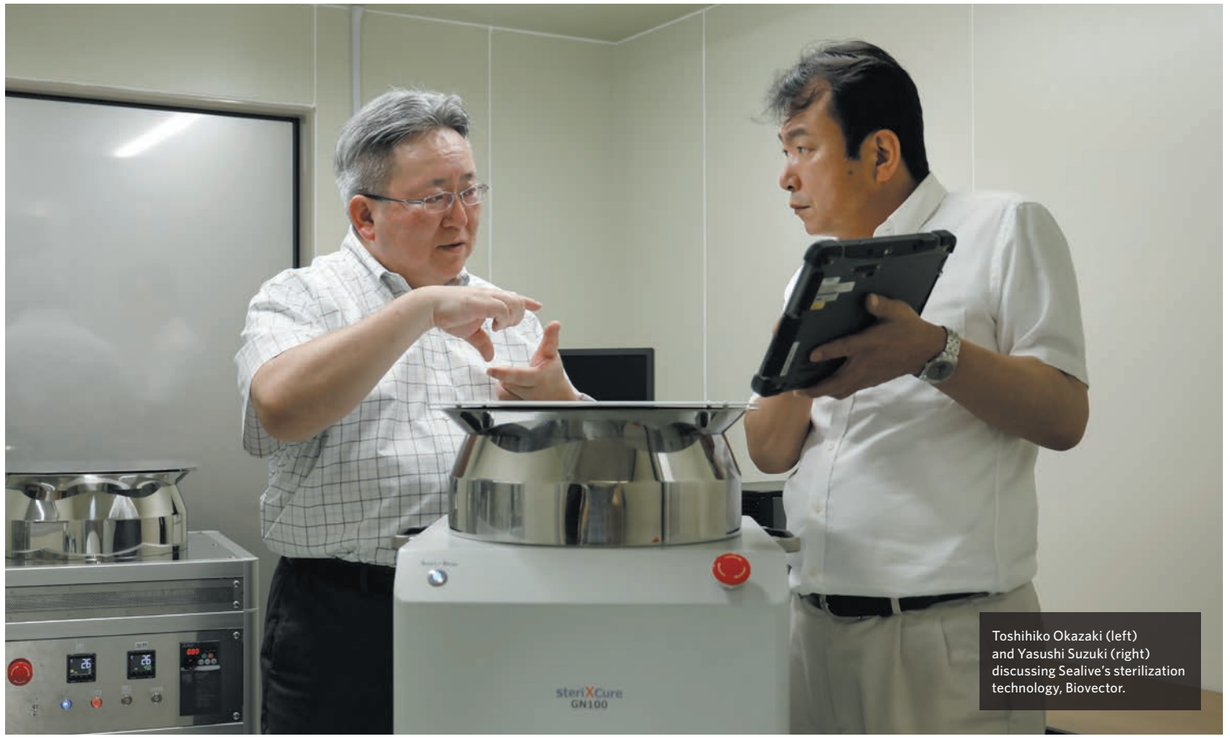
ADVERTISEMENT FEATURE

The next milestone in sterilization

The ability to break microorganisms, viruses, and endotoxins down into smaller fragments enhances THE UTILITY OF STERILIZATION SYSTEMS in hospitals and laboratories.



Toshihiko Okazaki (left) and Yasushi Suzuki (right) discussing Sealive's sterilization technology, Biovector.

Commonly used in healthcare, autoclaves are not always effective against endotoxins.

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The sterilization of endoscopes between patients takes a considerable amount of time.

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For decades, developments in sterilization procedures have been driven by improvements of mainstream techniques. "Steam, ethylene oxide gas, formaldehyde, and hydrogen peroxide, etc. are each defined as general sterilization methods in the Centers for Disease Control and Prevention (CDC) guidelines. But they can't be applied 'as is' to contaminated rooms and areas," explains Yasushi Suzuki, CEO of Sealive. While methods for killing microorganisms are established, the inactivation of certain viruses continues to be a burden from a clinical point of view. "To improve usability in hospitals, as well as to prevent DNA and RNA contamination in laboratory settings, we need to think not only about inactivating microorganisms and viruses, but about breaking them down to the level of nucleobases."

VIRUS INACTIVATION IS NOT A ONE-SIZE-FITS-ALL

TO THE LEVEL OF SINGLE BASES

"Virus inactivation is not one-size-fits-all; the effectiveness depends greatly on the virus and the sterilization method," says Toshihiko Okazaki, a professor at Osaka University Hospital's Center for Clinical and Translational Research. Viruses are incapable of self-replication and require host cells to replicate, and evaluation of viral inactivation is not easy. While some disinfectants are known to have an inactivating effect on viruses, sensitivity to disinfectants varies greatly depending on the type and amount of virus, contact time, and presence of organic substances.

The problem of viruses embedded in biofilms in endoscopy is a glaring example. "While the RNA for viruses that do not have an envelope are relatively easy to damage, others like HIV and the hepatitis C virus (HCV) are also difficult to inactivate even in a clinical setting. In order to reprocess the endoscope between patients, it needs to be sterilized with a proper disinfectant for a sufficient length of time. "Emerging methods enable us to dissolve a biofilm, but nothing is directly aimed at inactivating a virus itself. Even when viruses are broken down and inactivated, residual peptide fragments can elicit strong immune responses, much like the way in which the mRNA in some COVID-19 vaccines do. Breaking the viral RNA down into the level of bases would make for a more solid solution," explains Okazaki.

The amount of time a sterilization agent comes into contact with a pathogen is a key determinant of how likely a pathogen is to become inactivated. "A technology that frees us from the problem of contact time would be radically helpful for the repeated use of essential medical equipment," says Okazaki.

Faster sterilization would also advance work in P3 labs, which require the second-highest level of biocontainment precautions. "Researchers in regenerative medicine that work in P3 labs are keen to sterilize the lab rooms much more quickly," says Suzuki. When switching from the processing of one patient's cells to another, a changeover protocol – including sterilization – needs to be followed in order to avoid contamination by aerosols as well as by different cell lines. The process involves at least five to eight hours of sterilization, followed by a sanitary cleaning procedure. This generally takes a couple of days. "Cells are living and delicate, so in many cases they can't afford to wait that long," says Suzuki.

INACTIVATING ENDOTOXINS

Okazaki sees the inactivation of endotoxins as an area that warrants further study. Endotoxins, the lipopolysaccharides in the cell wall of small bacteria, are released when the bacteria have disintegrated; their hydrophobic nature draws them to common plastic labware, creating contamination. Autoclaves are steam sterilizers commonly used in healthcare, but they are not always effective against endotoxins.

"The mainstream method for inactivating endotoxins is dry heat sterilization, where instruments are treated with hot air, free of water vapour," says Okazaki. "But dry heat sterilization has the drawback that it cannot be used for plastics, drugs, or any other materials affected by high heat. A low-temperature technology with the same level of inactivation ability as dry heat sterilization, would be revolutionary."

The need for such a technology has been amplified by the COVID-19 pandemic. "Currently, we have a severe shortage of endotoxin-free plastics products that are used in COVID-19 vaccine manufacturing, bags and tubes for example," adds Okazaki. "At the moment, we are looking at a one- to two-year wait list for these products. It's a situation that was unthinkable before."

Gamma-ray radiation is an effective method for low-temperature sterilization, and is also effective against endotoxins, enabling sterilization without residuals. However, areas not exposed to the radiation are not sterilized, and discolouration is caused by radicals.

"A new method that employs gases would be expected to be used in a wide range of applications, and a sterilization system that can simultaneously decompose nucleic acids in a large space at room temperature and normal pressure is envisioned by taking advantage of the characteristics of the gas," says Suzuki. "An important factor worth careful consideration is the conditions under which the gases work, like the size of the chamber or rooms the gases are released in. The effect would vary substantially by the levels of exposure, and conditions like the exposure level need to be optimized to get the proper effect."

Suzuki and Okazaki are working to validate the effectiveness of Sealive's core sterilization technology, Biovector, against microorganisms, viruses, and endotoxins. The technology targets microorganisms and viruses by releasing activated gas consisting of much lower concentrations of methanol and formaldehyde (less than one-tenth). "In an era where contact with unknown pathogens is more likely than ever," Suzuki says, "we expect triple-buster technologies that inactivate microorganisms, viruses, and small fragments like endotoxins to play an increasingly important role in infectious disease prevention. In partnering with manufacturers that possess specialized know-how, we hope to develop sterilization solutions for a wider range of contexts." ■

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