

Is the Stella™ 5L system an effective cold sterilization technique for needle-based confocal miniprobes?

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ABSTRACT

Background and Objective: Needle-based confocal laser endomicroscopy (nCLE) under endoscopic ultrasound guidance is a newly developed imaging technique for pancreatic lesions and lymph nodes, enabling a subcellular level of resolution. The confocal miniprobe is an invasive instrument designed to be reused up to 10 times. Therefore, a method that ensures the complete elimination of microbial contaminants on the device is necessary. We studied the bactericidal efficacy of the Stella™ system, which purports to achieve this objective. **Materials and Methods:** The surfaces of three nCLE miniprobes were contaminated with suspensions of *Bacillus atrophaeus* (ATCC9372). One probe was randomly selected to count the bacterial load on the surface. The other two probes were manually cleaned and rinsed. One probe was randomly selected to count bacteria on the surface, and the other probe was sterilized using the Stella™ 5L endoscopic sterilization system before obtaining the bacterial count. The process was repeated for 20 cycles to evaluate the microbicidal efficacy of the Stella™ 5L endoscopic sterilization system. These miniprobes were immersed in the Stella Fuse disinfectant for 72 h. After the 72 h of immersion, the weight loss of probes was determined using a high precision electronic scale to examine corrosion following disinfection. The change in image quality was evaluated by an endoscopist. **Results:** From an initial contamination level of $4.48 \times 10^6 \pm 1.57 \times 10^6$ cfu/mL on the surface of the probes, the bacterial count was reduced to $4.25 \times 10^2 \pm 1.95 \times 10^2$ cfu/mL after manual cleaning (including enzyme washing), and no microorganisms were recovered after 20 cycles with the Stella™ 5L system. The probe weights before and after 72 h of immersion were 45.769 (45.768–45.771) g and 45.762 (45.752–45.768) g, respectively. No change in image quality was observed. **Conclusion:** This study shows that the Stella™ 5L system is capable of the complete elimination of microorganism contamination in a short period and avoids the toxicity of typical disinfectants. It is a safe, cheap, and efficient sterilization approach that provides a new option for nCLE miniprobe sterilization.

Key words: *Bacillus atrophaeus*, needle-based confocal miniprobe, sterilization

INTRODUCTION

Needle-based confocal laser endomicroscopy (nCLE) under endoscopic ultrasound (EUS) guidance is

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a promising new technique that enables real-time laser-assisted microscopic imaging of tissues. The system provides tissue sequences with a high resolution, facilitating *in vivo* histopathology.¹¹⁻⁴¹ During the nCLE procedure, the miniprobe punctures the tissue with a 19G needle. According to the regulatory requirements for disinfection, critical items that enter or touch sterile tissues, the vascular system, or bodily fluids (e.g., blood) must be sterilized because they pose a high infection risk. Therefore, it is necessary to establish a process for reprocessing that ensures the complete elimination of microorganisms that contaminate the miniprobe. Soaking sterilization with most cold sterilants requires 10 h. This can be detrimental to fine instruments. Even the cutting edge, low-temperature plasma sterilizer takes 40–60 min to sterilize instruments. Stella™ 5L System (Tristel, London, UK) is an automated system designed specifically for the decontamination of small- and medium-sized, rigid and flexible, single-lumened, and nonlumened semi-critical medical devices. It is a cold sterilization technique and the entire sterilization cycle only takes 5 min. As the system uses the dedicated Fuse™ disinfectant with chlorine dioxide and sterilization occurs under closed conditions, there are no issues with disinfectant residue, environmental pollution, or occupational injury. The aim of this study was to evaluate the sterilization effect of this system on needle-based confocal miniprobes.

MATERIALS AND METHODS

The Stella™ 5L system uses a 5000 ± 500 mg/L chlorine dioxide Fuse endoscopic disinfectant as a single-use sterilant. It is equipped with sterilization chambers and connection tubes for diverse types and brands of flexible endoscopes. A Stella IQ microcomputer controller and Stella pulse pump work are connected by bluetooth. When the device is applied to single-lumened endoscopes, self-tests before disinfection can identify whether the pulse pump is blocked, the sterilization box is filled with Fuse endoscopic disinfectant, the endoscope is obstructed, or the connection is loosened. Accordingly, when applying the Stella System to the nCLE probe, which is a nonlumened instrument, the supplied surrogate lumen was attached to a pulse tube set. After the sterilization cycle, the disinfectant is automatically discharged and discarded. The entire sterilization cycle only takes 5 min.

In this study, three AQ-Flex needle-based confocal miniprobes (Cellvizio, Mauna Kea Technologies,

Paris, France) were the objects of sterilization. These miniprobes were weighed using a G&G electronic scale (JJ323BC, G&G Measurement Plant, Changshu, China) and sterilized using the Stella™ 5L endoscopic sterilization system for one cycle before testing.

Bacillus atrophaeus (formerly *Bacillus subtilis* var. *niger*, ATCC9372) is a typical spore-forming bacterium, widely applied in the production of biological indicators for sterilization and the studies of disinfection agents. In this study, a suspension of *B. atrophaeus* was prepared with 0.03 mol/L phosphate buffer containing 1% peptone and 5×10^6 – 5×10^7 cfu/mL bacteria for contamination of the thrThe miniprobe was cleaned using the Mall Endoscopic Cleaning Workstation (Mall Science and Technology Limited, Hangzhou, China) with CIDEZYME® XTRA Multi-enzymatic Detergent (Johnson and Johnson, Irvine, CA, USA) at 10 L in a 1:125 solution.

In total, 3 mL of bacterial suspension of *B. atrophaeus* was stained with 3 sterile cotton swabs and uniformly coated on every surface of the three probes. After 30 min of air-drying, one of the three probes was randomly selected and washed with 50 mL of neutralizing agent lavage. Then, 0.5 mL of the irrigation solution was inoculated in the nutrient agar plate and incubated at 37°C for 48 h. The bacterial load was counted.

The probes were placed in the cleaning chamber of the endoscopic cleaning workstation. The surfaces of the probes were washed under the flow of water for 1 min and washed with the diluted CIDEZYME® XTRA Multi-enzymatic Detergent solution for 2 min. Then, the surfaces of the probes were rinsed thoroughly. After the completion of cleaning, one probe was randomly selected and washed with 50 mL of a neutralizing agent. Then, 0.5 mL of the irrigation solution was inoculated in the nutrient agar plate, followed by incubation at 37°C for 48 h. Finally, the bacterial load was counted.

The remaining precleaned miniprobe was placed in the Stella™ 5L system compartment. The Stella IQ computer and pulse pump were turned on. The surrogate tube was connected to the pulse [Figure 1]. One sachet of Tristel Fuse was added to 5L of water and this was added to the inner compartment of the Stella base. The lid was closed and the working procedure was initiated. The cycle time was 5 min,

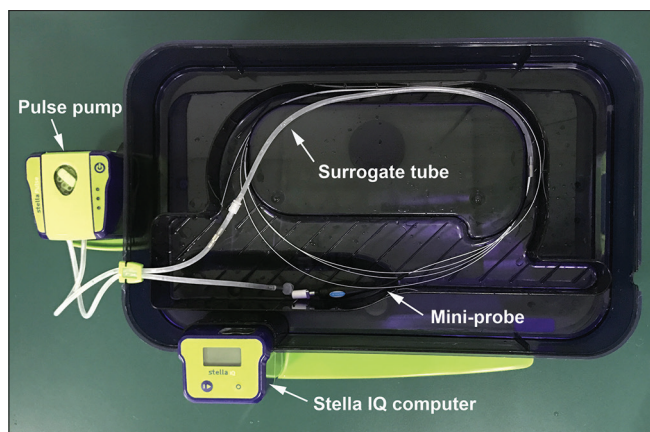


Figure 1. The remaining precleaned miniprobe was placed in the Stella™ 5L system compartment. The Stella IQ computer and pulse pump were turned on. The surrogate tube was connected to the pulse

after which the Stella drains automatically. The probe was washed with 50 mL of neutralizing agent. Then, 0.5 mL of the irrigation solution was inoculated in the nutrient agar plate, followed by incubation at 37°C for 48 h. Finally, the bacterial load was counted.

The above processes were repeated for 20 cycles. These miniprobes were immersed in the Stella Fuse disinfectant for 72 h. The weight loss of probes was examined using the G&G electronic scale to detect corrosion of the probe after disinfection. The change in image quality was evaluated subjectively by an endoscopist after 72 h of immersion.

RESULTS

From an initial contamination level of $4.48 \times 10^6 \pm 1.57 \times 10^6$ cfu/mL on the surface of the probes, the bacterial count was reduced to $4.25 \times 10^2 \pm 1.95 \times 10^2$ cfu/mL after manual cleaning (including enzyme washing). The number of bacteria after manual cleaning was significantly reduced ($P < 0.001$). However, after sterilization with the Stella™ 5L system, there was no bacterial growth in 20 cycles and the bactericidal rate was 100% ($P < 0.001$).

The probe weights before and after the 72-h immersion were 45.769 (45.768–45.771) g and 45.762 (45.752–45.768) g, respectively. No change in appearance was observed, including size, shape, color, smoothness, gloss, flexibility, uniformity, and physical defect. In addition, a change in image quality of the nCLE was not observed based on a subjective analysis.

DISCUSSION

CLE is used for real-time microscopic imaging of tissues *in vivo* at a high resolution (1–3.5 μm). The nCLE AQ-Flex miniprobe can be applied during EUS procedures. It is compatible with a 19-gauge needle for fine-needle aspiration.^[1–4] However, the miniprobes cost approximately \$4000–\$8000, depending on the country, and therefore, the nCLE miniprobe is not designed to be a single-use device but is reusable up to 10 times. Typically, the miniprobe is preloaded and contained by a locking device in the single-use needle and can be pushed under EUS guidance into target tissues. In the era of high prevalence of HIV and hepatitis B virus,^[5,6] as the miniprobe enters sterile tissues, it must be sterilized according to the regulatory requirements for disinfection.^[7–10] However, the nCLE miniprobe is sensitive to hot temperatures, acidity, alkalinity, and oxidates, limiting the options for sterilization. The immersion of instruments in microbicidal fluids, such as glutaraldehyde, takes 10 h and can be detrimental to fine instruments.^[11] Owing to the long disinfection time, one nCLE probe can be applied to a single patient each day. To meet a daily requirement of more than 10 procedures, at least 10 miniprobes are needed, greatly increasing the application cost. At the same time, the volatile glutaraldehyde causes environmental pollution,^[12,13] the final rinse process is cumbersome, and contamination postdisinfection and disinfectant residues are likely.^[14] Various peracetic acid sterilizers are currently used for instrument sterilization, and these sterilization cycles take 30–50 min.^[15] The STERIS system is a typical peracetic acid sterilizer and the cost of one cycle is \$15 in China. However, due to explosive nature of peracetic acid, storage of the disinfectant in clinical facilities carries a security risk. A low-temperature plasma sterilizer is recommended by Cellvizio. This is an effective approach,^[16] requiring 40–60 min for one cycle. The Johnson & Johnson™ low-temperature plasma sterilizer is expensive and the cost of one cycle is more than \$30 in China. Thus, a new sterilization approach is necessary for needle-based confocal miniprobes.

Stella is a new sterilizer; it gained certifications for the cold sterilization of instruments from the China Food and Drug Administration and National Health and Family Planning Commission. It is suitable for the decontamination of small- and medium-sized, rigid and flexible, single-lumened, and nonlumened semicritical medical devices, and the entire sterilization cycle

requires only 5 min. The Tristel Fuse for Stella utilizes Tristel's proprietary chlorine dioxide chemistry (ClO₂), a well-documented and highly effective biocide. Scientific and clinically derived data have demonstrated that Tristel's chlorine dioxide solution does not require instruments to be rinsed postdisinfection.^[17-19] The most likely source of contamination postdisinfection, infection, or injury postendoscopic procedure is typically contaminated rinsing water, rather than ineffective disinfection or residual disinfectant.^[20,21] In addition, there are no issues with disinfectant residue, environmental pollution, and occupational injury.

In this study, the effectiveness of the Stella™ 5L system was confirmed by 20 cycles of contamination, sterilization, and bacterial counting. The sterilization process was simple, convenient, and quick. The entire sterilization cycle (i.e., the killing of bacterial spores) took only 5 min. This system makes it possible to meet clinical needs by requiring fewer miniprobes and reducing cost. Weight loss was not obvious, even after 72 h, and there was no change in appearance. However, the miniprobe was only designed for 10 uses. Since no change in image quality for the nCLE was observed in a subjective analysis, the corrosion level for the Stella Fuse was acceptable. The compartment for sterilization is detachable, removable, and has short-term endoscopic storage and transport functions, minimizing the recontamination of instruments after sterilization. Because instruments are sterilized in a closed compartment and the Stella drains automatically, environmental pollution and occupational injury are not issues. Most importantly, the cost of one cycle is only \$5.

CONCLUSION

In summary, the results of this study show that the Stella™ 5L system is capable of completely eliminating microbial contaminants in a short period and eliminates the toxicity risk associated with disinfectants. It is a safe, cheap, and efficient sterilization approach that provides a new option for nCLE miniprobe sterilization.

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Conflicts of interest

There are no conflicts of interest.

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