

Concise Communications

Sporicidal Activity of a New Low-Temperature Sterilization Technology: The Sterrad 50 Sterilizer

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ABSTRACT

This study was undertaken to evaluate the efficacy of a new low-temperature sterilization system that recently has been cleared by the Food and Drug Administration, the Sterrad 50. Flat stainless steel carriers were inoculated with approximately 10^6 *Bacillus stearothermophilus* spores. These carriers were placed aseptically in the middle of 40-cm-long stainless steel-lumened test units of varying diameters (1 mm, 2 mm, and 3 mm). After inoculation, the test units were processed in the Sterrad 50. After sterilization, the carriers were assayed for growth of the *B. stearothermophilus* spores. Our data demonstrated that the Sterrad 50 was highly effective in killing the *B. stearothermophilus* spores (no positive carriers with 30 tests of each lumen-diameter test unit). The Sterrad 50 is likely to be clinically useful for the sterilization of heat-sensitive medical equipment (*Infect Control Hosp Epidemiol* 1999;20:514-516).

Critical medical devices and supplies that are sensitive to temperature and moisture require low-temperature sterilization. Ethylene oxide (EtO) has been the most widely used low-temperature sterilization process in the United States. However, healthcare facilities currently are considering alternative processes to EtO for several reasons. First, some states (eg, California, New York) require EtO emissions to be reduced 90% to 99.9%. Second, EtO represents a potential toxic hazard to staff and patients, because EtO is a probable carcinogen and is flammable. Finally, the Environmental Protection Agency, under the authority of the Clean Air Act, has banned production of the chlorofluorocarbons (CFCs) that were used as a stabilizing agent in combination with EtO.¹⁻⁴

Alternative technologies to EtO with CFCs are increasingly being developed. These include 100% EtO, EtO with a different stabilizing gas such as carbon dioxide or hydrochlorofluorocarbons, vaporized hydrogen peroxide, gas plasmas, ozone, peracetic acid, and chlorine dioxide.^{4,5} We recently compared the sporicidal activity of several new low-temperature technologies: EtO with hydrochlorofluorocarbon, liquid peracetic acid, and two plasma sterilization processes that use vaporized hydrogen peroxide, the Sterrad 100 (Advanced Sterilization Products, Irvine, CA) and the Sterrad 100S (Advanced Sterilization Products).¹ The results of our evaluation of a new sterilizer, the Sterrad 50 (Advanced Sterilization Products), which is similar in operational design to the Sterrad 100S, are reported here.

METHODS

The Sterrad 50 sterilizer process consists of two consecutive and equal sterilization phases. In the initial stage of sterilization, a 44-L sterilization chamber (Sterrad 100 has a 73-L volume) is evacuated to a vacuum of approximately 0.5 mm Hg. A volume of 1.8 mL of 58% hydrogen peroxide, contained in a disposal cassette of 10 pre-measured charges, is delivered to the sterilizer (minimum, 14.4 mg/L of hydrogen peroxide) through an automated delivery system and allowed to diffuse as a vapor for a fixed period of time. Then, the vapor is excited by a radiofrequency energy of 13.6 MHz, creating a secondary, low-temperature plasma (~104°F) that forms around the products being sterilized. Free radicals (eg, hydroxyl and hydroperoxyl) that are microbiocidal are generated in the plasma. These products recombine at the end of the cycle, leaving water and oxygen as by-products, thus eliminating the need for aeration. A Sterrad 50 sterilization cycle, which is 45 minutes in duration, consists of two diffusion stage-plasma stage cycles.

Data obtained on the Sterrad 50 was compared to data from evaluation of the Sterrad 100S.¹

Test Pathogens

The sporicidal activity of the sterilization processes was assessed using *Bacillus stearothermophilus* (lot numbers PB49T, PB56T, PB101T), prepared by Dr. Irving J. Pflug (University of Minnesota, MN). This organism was used because bacterial spores were found to be the organism most resistant to the process, and the most resistant bacterial spore was found to be *B. stearothermophilus*.⁶

Carrier Inoculation and Quantitation

Our method of carrier inoculation and quantitation has been described previously.¹ In brief, a use-dilution spore suspension was prepared by making a 1:10 dilution of a stock spore suspension (~ 10^9 colony-forming units [CFU]) in 0.1% Tween 80 in sterile water. Stock and use-dilution spore suspensions were stored at 4°C until use. Once the use-dilution spore suspension was confirmed to have ~ 10^8 CFU/mL, the carriers were inoculated. The carriers were number 10 Bard-Parker (Becton-Dickinson Acute Care, Franklin Lakes, NJ) stainless steel surgical blades or rectangles (1 mm×10 mm) cut from the Bard-Parker blades.

Carriers were quantitated, in triplicate, prior to use and on a weekly basis, by placing the carrier in a test tube containing 10 mL of sterile water and sterile glass beads. These tubes were sonicated for 5 minutes, chilled in an ice-water bath for 2 minutes, vortexed for 2 minutes, and then

chilled in an ice-water bath again for 2 minutes. After repeating these steps twice, the samples were heat shocked for 15 minutes at 100°C and then chilled in an ice-water bath. Serial dilutions (1:10 dilution \times 4) were made for each sample, with the last two dilutions of each set being plated, in triplicate, to trypticase soy agar using the pour plate method. These plates were incubated at 55° to 60°C for 48 hours.

Efficacy Test Methods

The sporicidal activity of the sterilization systems was assessed by aseptically placing inoculated carriers into 40-cm-long stainless steel tubes of varying lumen diameters (1 mm, 2 mm, or 3 mm). Two types of lumened tubes were used, a lumen test unit with a removable 5-cm center piece (1.2-cm diameter) of stainless steel sealed to the narrower steel tubing by hard rubber septums and a straight lumen. Following inoculation, the Bard-Parker carriers were placed in the middle of the lumened tubes or the rectangles were placed in the middle of the straight-lumen tubes.¹ Five of the lumened test units were placed in a standardized tray designed for use with Sterrad. The non-lidded tray was wrapped with Spunguard One-Step (Kimberly Clark, Roswell, GA) sterilization wrap and placed in one of the three low-temperature processes as per manufacturer's recommendations. No other medical devices or supplies were placed in the sterilizer when the Sterrad 50 and Sterrad 100S were tested. Additional medical devices or supplies were placed in the EtO sterilizer during test runs.

Following sterilization, the carriers were removed aseptically and placed in tubes containing 10 mL of trypticase soy broth. These tubes were incubated at 55° to 60°C for 14 days and observed for growth. After 14 days, they were heat shocked and reincubated an additional 7 days to ensure that no latent spores were present.

RESULTS

The Sterrad 50 was equally as effective as EtO and the Sterrad 100S in killing approximately 10⁶ *B. stearothermophilus* spores present in the center of narrow-lumen stainless steel tubes (Table). The Sterrad 50, as well as EtO and the Sterrad 100S, sterilized the carriers in even the smallest-lumened device, which was 1 mm in diameter.

DISCUSSION

Medical devices that have contact with sterile body tissues or fluids are considered critical items. Such items (eg, surgical instruments, biopsy forceps, and implants) should be sterile when used, because any microbial contamination could result in disease transmission.^{1,7} If these items are heat-resistant, the recommended sterilization process is steam sterilization, because it has the largest margin of safety. However, reprocessing heat- and moisture-sensitive items requires use of a low-temperature sterilization technology. Regardless of the sterilization method used, thorough manual cleaning must precede sterilization to remove organic debris and salts. This investigation was undertaken

TABLE

COMPARATIVE EVALUATION OF THE SPORICIDAL ACTIVITY OF NEW LOW-TEMPERATURE STERILIZATION TECHNOLOGIES

Sterilization Method	Units Positive/Units Tested			
	LTU, 3 mm	LTU, 2 mm	LTU, 1 mm	SL, 3 mm
EtO-HCFC*	0/50	0/40	0/40	0/50
Sterrad 100S*	0/50	0/40	0/40	0/40
Sterrad 50†	0/30	0/30	0/30	0/30

Abbreviations: EtO-HCFC, ethylene oxide with hydrochlorofluorocarbon; LTU, lumen test unit; SL, straight lumen.

* Data adapted from Rutala et al.¹

† Mean inoculum per carrier is 1.0 \times 10⁶.

to evaluate the biocidal potency of a new low-temperature sterilization technology.¹

The Sterrad 50 is a smaller version of the Sterrad 100S. It contains a single shelf for placement of instruments to be sterilized within a rectangular chamber, in contrast with the Sterrad 100S, which has two shelves and a cylindrical chamber. Both devices were highly effective in killing high numbers of *B. stearothermophilus* spores and comparable to the efficacy of ethylene oxide. All of these processes were effective even when tested using a test lumen that was only 1 mm in diameter.

Our experimental design did not incorporate either a salt (inorganic) or protein (organic) residue. The inorganic or organic load on used medical devices following cleaning is unknown. Investigators have shown that inorganic and organic residues constitute important barriers to low-temperature sterilization technologies, including EtO.⁸ Recent studies have demonstrated that spores of *Bacillus* occluded in salt crystals are more resistant to inactivation than spores associated with organic matter.⁹ However, it is unlikely that cleaned medical instruments would ordinarily have microorganisms protected in crystals.⁹

In conclusion, our data demonstrated that the Sterrad 50 is able to sterilize contaminated lumened test objects seeded with a high number of very resistant test microorganisms. Because of its size and shorter cycle time, this system is likely to be used in many clinical settings for the sterilization of heat-sensitive medical equipment.

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This study was supported, in part, by Advanced Sterilization Products, Irvine, California.

98-CC-214. Rutala WA, Gergen MF, Weber DJ. Sporicidal activity of a new low-temperature sterilization technology: the Sterrad 50 sterilizer. *Infect Control Hosp Epidemiol* 1999;20:514-516.

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