Monitoring Steam Sterilization of Surgical Instruments: a Dilemma

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The study of two biological indicators in monitoring "flash" sterilization demonstrated that indicator construction often leads to a false interpretation of spore survival.

High-speed re-sterilization of surgical instruments is an absolute requirement in today's busy hospital operating suites. The most effective and quickest method of re-sterilization of undegradable operating equipment has been shown to be steam sterilization (2). Steam under pressure is inexpensive and sterilizes penetrable materials and exposed surfaces rapidly. Steam sterilization is effective only if used properly. Moisture penetration and air removal are essential for effective sterilization. The effective use of steam sterilization requires knowledge of its use and some of its thermodynamic properties, correct preparation of materials, and proper loading in the sterilizer.

The monitoring of steam sterilizers is an important procedure (and requirement) to demonstrate that the proper conditions of temperature, time, loading, and preparation of materials have been met. This has created a dilemma. The studies of Mayerik (4) and Lee et al. (3) have shown that some commercially available biological indicators performed poorly or only with fair results. When compared with the time-temperature sterilization plot for Bacillus stearothermophilus spores, only 2 of 21 commercially available indicators ran parallel to the time-temperature curve of B. stearothermophilus spores at temperatures between 115.6 and 132.2°C (240 and 270°F) for 2.5 to 20 min (3). The other 19 biological indicators either intersected or fell below the time-temperature curve of the B. stearothermophilus spores.

The monitoring of high-speed steam sterilizers in the operating suite at the Brigham and Women's Hospital with biological indicators as required by the Joint Commission on Accreditation of Hospitals demonstrated that spore growth due to faulty container construction often led to the interruption of operating services because of alarm that instruments were not sterile.

Investigation of sterilization procedures, using two commonly used, commercially available types of biological indicators, neither of which was tested by Lee et al. (3), was conducted during August and September 1979 to resolve this disruptive problem. The first type of biological indicator tested was Attest (Minnesota Mining and Manufacturing Co.), the biological indicator routinely used in the Brigham and Women's Hospital to monitor autoclaves until September 1979. The Attest indicator consists of a B. stearothermophilus spore strip enclosed in a polypropylene vial. After the autoclave cycle at 132.2°C for the proper test time was completed, the Attest indicator was removed. When the vial had cooled for 10 min, the indicator was crushed to mix the indicator medium with the spore strip. Attest was then incubated at 56°C for 48 h and read for spore survival.

The second type of biological indicator tested was Unispores (Castle Sybron Corp.), stored at −28.9°C (5, 6). Unispores strips have been used to monitor the laboratory's autoclaves for the past 16 years. The test strips containing Bacillus subtilis subsp. niger spores and B. stearothermophilus spores in glassine envelopes were employed. A similar strip, used as a growth control, was not autoclaved. After sterilization at 132.2°C, the spore strips were aseptically placed in individual tubes of 10 ml of Trypticase (BBL Microbiology Systems) soy broth and incubated at 55°C for 7 days before being observed for spore survival.

Preliminary studies showed that "flash" sterilization cycles did not destroy the spores in Attest. Inspection of its design suggested that the penetration of moisture was impeded. This hypothesis was studied by comparing intact Attest, Attest with the lid removed, Attest with 0.05 ml of distilled water added and the lid replaced, and Attest with 0.10 ml of distilled water added and the lid replaced. Six sets were prepared to be tested at each time interval of the experiment. Each set was autoclaved in iden-
tical surgical packs at 1, 2, 3, 4, 5, and 6 min at 132.2°C. After sterilization, the indicators were taken to the laboratory for incubation and viable spore determination.

Results showed that during a 1-min flash sterilizing cycle, viable spores were present in 100% of Attest indicators compared with a 50% spore survival rate in the Unispore spore strips (Table 1). After 3 min at 132.2°C, 13 (45%) of the 24 Attest indicators demonstrated spore growth, and all Unispore indicators showed a 100% spore kill by 2 min at 132.2°C. During a flash period of 5 min or longer, all Attest and Unispore indicators demonstrated a 100% spore kill. Table 1 shows that moisture added to Attest vials influenced the spore survival rate. With 0.1 ml of water in each closed Attest container, sterility was achieved in 2 min. With the lid off and no water, sterility was achieved in 3 min; with the lid on and no water, sterility was achieved in 4 min. Clearly, the moisture penetration of the container influenced sterility.

A study of the structure of the Attest polypropylene vial in which the spores were contained showed that although the Attest indicator may be a good monitor for normal sterilization cycles at 122.2°C, it has limitations in monitoring flash sterilization. The polypropylene vial is constructed so that there is a "dead space" between the vial wall and the spore strip. The delay in the penetration of steam through the vial and the failure in the attainment of a temperature sufficiently high to heat the dead space and destroy the viable spores within the 3-min time span for which the sterilizer was designed were demonstrated by test results. When the lid was taken off, the Attest monitor test results indicated a decrease in viable spore survival within 4 min, and the addition of 0.1 ml of distilled water to the dead space of the Attest container reduced the time-temperature curve of 100% spore destruction from 5 to 3 min.

The study demonstrated that control of sterilization by maintaining a critical temperature in the exhaust line for a designated time is the best assurance of routine sterilization. It also indicates that the biological indicator regulations of the Joint Commission on Accreditation of Hospitals merit review. The use of properly designed biological indicators in monitoring specific sterilization cycles must be validated (1). The current regulation of the Joint Commission on Accreditation of Hospitals requires the testing of steam sterilizers with live spores. Biological indicators that have been validated for flash sterilization cycles should, therefore, be listed so that false interpretations of sterilizer cycles will not confuse operating room personnel.

**LITERATURE CITED**


| Table 1. Comparison of the effect of time on the rate of Attest spore survival and Unispore spore survival at 132.2°C |
|-----------------|-----------------|-------|-------|-------|-------|-------|
| Indicator       | 1*               | 2     | 3     | 4     | 5     | 6     |
| Attest—lid, no water added | 100 | 100 | 100 | 33 | 0 | 0 |
| Attest—lid off, no water added | 100 | 17 | 100 | 0 | 0 | 0 |
| Attest—lid on, 0.05 ml of water added | 100 | 100 | 17 | 0 | 0 | 0 |
| Attest—lid on, 0.10 ml of water added | 100 | 83 | 0 | 0 | 0 | 0 |
| Unispore strip | 50               | 0     | 0     | 0     | 0     | 0     |

*Time in minutes.