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STERILIZATION OF OPERATING MICROSCOPE AND FLEXIBLE FIBER-OPTIC ILLUMINATOR BY FORMALDEHYDE GAS

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ABSTRACT

We have been sterilizing the operating microscope and flexible fiber-optic illuminator on a mobile stand by formaldehyde gas at ambient temperature for the past four years. The instruments were wrapped in two polyvinyl bags and 60 g of formaldehyde-adsorbed plaster were placed in the bottom of the bags. The efficiency of this sterilizing procedure has been periodically tested by examination with spores of Bacillus subtilis and Bacillus stearothermophilus. Of the 245 tests 17 (6.9%) showed positive growth of bacterial spores, the exposure time of the positive growth ranging from 10 hrs and 30 min to 68 hrs and 15 min. The positive growth rate was markedly higher in the operating microscope than in the flexible fiber-optic illuminator. However, after January of 1980 the exchange interval of the formaldehyde-adsorbed plaster was shortened from 4 to 2 weeks, and as a result, all tests longer than a 25-hr exposure time showed negative growth. Therefore, we concluded that a 24-hr exposure time is satisfactory to obtain sterility of the instruments with this method.

Key words: Sterilization, Operating Microscope, Fiber-optic illuminatr, Formaldehyde Gas

INTRODUCTION

The operating microscope and flexible fiber-optic illuminator on mobile stand are widely used in many fields of surgery. These instruments are used very close to surgical fields and usually handled by surgeons. Therefore, the instruments should be used in the most sterile condition.

However, both the operating micorscope and the flexible fiber-optic illuminator on mobile stand are large and their optical system is sensitive to heat. Suitable sterilization procedures require low temperature heat or ethylene-oxide gas sterilization, but disassembling of the instruments is necessary to perform these procedures.

We have been using formaldehyde gas sterilization under ambient temperature without disassembling the instruments for the past four years and have periodically tested the effectiveness of this mehtod by examining the growth of bacterial spores. This report describes our sterilization method and four years of experience with it.

MATERIALS AND METHODS

We have been sterilizing seven operating microscopes, three of the stand type and four of the ceiling type, and four flexible fiber-optic illuminators on mobile stands. These instruments were wrapped in two large transparent polyvinyl bags without being

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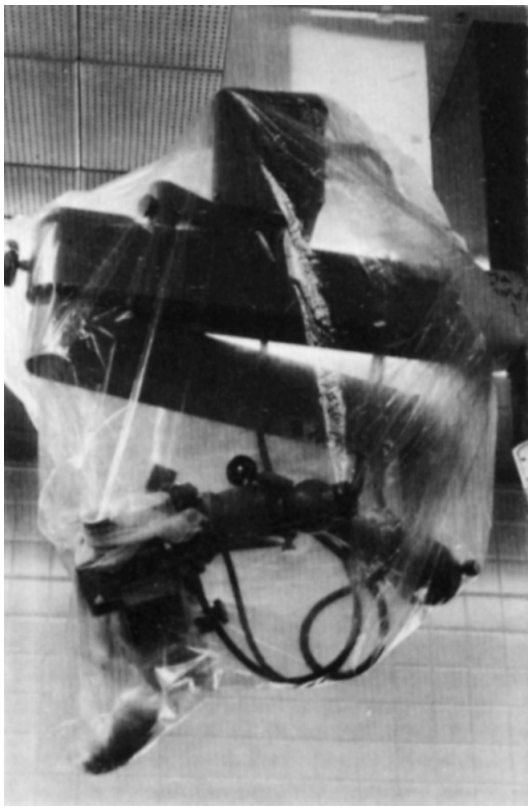

Fig. 1 Showing sterilization of ceiling type operating microscope.
Formaldehyde-adsorbed plaster wrapped in gauze is placed in the bottom.

disassembled. In the bottom of the inner polyvinyl bag, formaldehyde-adsorbed plaster* enclosed in gauze was deposited and then each of the two polyvinyl bags were separately sealed with tape to prevent leakage of the formaldehyde gas. The viewing lense and the tip of the illuminator were covered with gauze to protect them from coming into direct contact with the formaldehyde-adsorbed plaster. Figure 1 illustrates the sterilization procedure for the ceiling type operating microscope. The dose of formaldehyde-adsorbed plaster was one full container cap equivalent to 60 g.

The efficiency of this sterilization procedure has been examined by the growth of bacterial spores. Commercial biological indicator Attest for gas sterilization (populations of Bacillus subtilis spores 10^6) and Attest for steam sterilization (populations of Bacillus stearothermophilus spores 10^5) were both wrapped in a single gauze and fixed close to the viewing lenses of the operating microscope. For the flexible fiber-optic illuminator, these spores were fixed far from the tip of the instrument. The formaldehyde-adsorbed plaster was changed every 4 weeks until December, 1979, but this interval was shortened to 2 weeks in January. 1980.

These biologial indicatores are removed from the instruments during surgery, and Attest for gas sterilization is incubated at 40° C, Attest for steam sterilization at 56° C in an incubator exclusively made for Attest. The results were examined by the color change of the cultured

medium of the Attest biological indicator. A positive biological indicator is yellow in colors indicating bacterial growth. Usually the results were examined after 48 hrs. However, in formaldehyde gas sterilization, positive growth was occasionally observed longer than the 48-hr incubation period. Therefore, routine incubation was continued for seven days. In questionable instances, spores were cultured on a heart infusion agar plate and the bacterial growth was examined.

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RESULTS

During the past four years, sterilization tests by bacterial spores were carried out 245 times. Table 1 summarizes our results. The shortest exposure time for formaldehyde gas was 8 hrs, and the longest exposure time was 1106 hrs (46 days and 1 hr), the average exposure time being 153 hrs (6 days and 9 hrs).

Positive growth of either spores of Bacillus subtilis or Bacillus stearothermophilus was found in 17 tests (6.9%). With exposure times of shorter than 32 hrs, positive growth was

Table 1. Effect of formaldehyde gas on bacterial spores (B. subtilis 10^6 and B. stearothermophilus 10^5) at ambient temperature

Exposure time (hr)	No. of tests	Positive growth	%
Under 8	1	0	0
9 — 16	8	4	50.0
17 — 24	22	8	36.4
25 — 32	7	3	42.9
33 — 40	0	0	0
41 — 48	14	1	7.1
49 — 72	56	1	1.8
73 — 96	17	0	0
97 — 120	22	0	0
121 — 144	3	0	0
145 — 168	19	0	0
169 — 192	5	0	0
193 — 216	3	0	0
217 — 240	3	0	0
Over 240	65	0	0
Total	245	17	6.9

Table 2. Comparison of the effect on bacterial spores in the operating microscope and in the flexible fiber-optic illuminator following exposure to formaldehyde gas

Instrument	No. of tests	Positive growth	%
Operating microscope	174	16	9.2
Flexible fiber-optic illuminator	71	1	1.4
Total	245	17	6.9

frequent. Of 38 such tests, 15 (39.5%) were positive. In 70 tests with exposure times between 41 hrs and 72 hrs, only 2 tests (2.9%) showed positive growth. Of the 137 tests with exposure times of over 72 hrs, no positive growth was observed. There were 65 tests with an exposure time of over 10 days. This illustrates that some of the operating microscopes or fiber-optic illuminators were exposed to formaldehyde gas for such long periods of time; neverhteless, none of these instruments were damaged by the gas nor was metal corrosion of the surface observed in any of the instruments.

The positive growth rate was different for the two instruments as shown in Table 2. The rate was markedly higher for the operating microscope than for the flexible fiber-optic illuminator. The sterilization procedure was identical in both instruments, but the complex structure of the microscope resulted in a larger air space to be sterilized with the same dose of formaldehyde-adsorbed plaster; thus the effectiveness was reduced. The simple structure of the flexible fiber-optic illuminator and the relatively small air space inside of the covered polyvinyl bag made it possible to obtain excellent results.

Table 3 summarizes a detailed description of the 17 positive growth tests. In 9 tests, both the spores of Bacillus subtilis and Bacillus stearothermophilus were positive, and in the remaining 8 tests spores of the Bacillus subtilis were positive in 3 and the spores of the Bacillus stearothermophilus were positive in 5 tests.

The shortest exposure time of positive growth was 10 hrs and 30 min, the longest exposure time was 68 hrs and 15 min. However, 15 tests were within an exposure time of 27 hrs and only 2 tests exceeded 27 hrs. As previously described, the exchange interval of formaldehyde-adsorbed plaster was shrotened from four to two weeks in 1980. Two positive tests with an

Table 3. Number of tests showing growth of bacterial spores following exposure to formaldehyde gas

No.	Exposure time	Growth of bacterial spores				Instrument
		B. subtilis		B. stearothermophilus		
1	10 hrs 30 min	+			−	Operating microscope
2	14 ″	+		+		″
3	14 ″	+		+		″
4	15 ″		−	+		Fiber-optic illuminator
5	19 ″	+		+		Operating microscope
6	19 ″	+		+		″
7	19 ″ 40 min	+		+		″
8	19 ″ 50 ″		−	+		″
9	20 ″		−	+		″
10	20 ″ 15 ″	+		+		″
11	21 ″		−	+		″
12	23 ″	+			−	″
13	25 ″		−	+		″
14	26 ″ 30 ″	+		+		″
15	27 ″	+		+		″
16	42 ″	+		+		″
17	68 ″ 15 ″	+			−	″
	Total	12	5	14	3	

exposure time of longer than 27 hrs were observed before 1980, and after January 1980, all tests with an exposure time of longer than 25 hrs showed negative growth. Therefore, currently, a 24-hr-exposure time is satisfactory to obtain sterility of the instruments.

However, a 24 hr-sterilization time naturally prohibits everyday use of one instrument. To facilitate everyday use of one instrument, we keep a sterile polyvinyl bag containing formaldehyde-adsorbed plaster, and at the completion of surgery, the surgeon with sterile gloves on wipes off the surface of the instrument using ethyl alcohol and recovers it with the same polyvinyl bag. With this technique, the sterility of the instrument is not interrupted.

DISCUSSION

There are three commonly used sterilizing methods of the operating microscope and the flexible fiber-optic illuminator: the draping method, the ethylene-oxide gas method, and the formaldehyde gas method.

1. Draping mtehod[1)]

Probably this is the most widely used method. The body of the operating microscope or the tip of the flexible fiber-optic illuminator are covered with a sterilized drape made either of cloth or a transparent polyvinyl drape. The instruments are covered on their mobile stand, and disassembling of the instruments is unnecessary. The draping method is very simple, is applicable to any hospital, and is advantageous in emergency surgery. The disadvantage of this method is the difficulty in handling the instruments and the inability to change parts during surgery, such as in case of an operating microscope. However, this method is recommended for the flexible fiber-optic illuminator.

Sterilized covers only for covering the handling knobs and viewing lenses are available for the opertaing microscope, but the risk of contamination is extremely high; therefore they should not be used.

2. Ethylene-oxide gas method

Ethylene-oxide gas is sporicidal and is used in many hospitals to sterilized operative instruments. The body of the operating microscope and the tip of the flexible fiber-optic illuminator should be removed from their stand and wrapped in a polyethylene bag and placed in an ethylene-oxide gas sterilizer. Kurze[2)] exposed the operating microscope to an ethylene-oxide CO^2 mixture at 54.4°C with a humidity of 50% for four and a half hrs. The instrument is aerated for 8 hrs afterwards. Kurze reported no visible signs of operating microscope deterioration after more than 3 years of use. However, Pia[3)] has abnadoned ethylene-oxide gas sterilization since 1973 due to damage to the coating layer of the operating microscope and its optical system. Ethylene-oxide gas sterilization of the flexible fiber-optic illuminator has not been reported. The current ethylene-oxide gas sterilizer is equipped with a prevacuum cycle and this probably damages the optical system of the instruments. An additional disadvantage of this method is the cumbersome instrument assembling and disassembling process.

3. Formaldehyde gas method

Pia[3)] reported on the sterilization of the operating microscope and its additional equipment with formaldehyde gas in a specially developed container. He tested the effectiveness of formaldehyde gas by the vegetative form of various bacteria and reported that 10 g of formaldehyde for an exposure of 10 hrs killed all of the bacteria tested, but the effect of the bacterial spores was not tested. Disassembling of the operating microscope is also required for this method.

Our formaldehyde gas method is different from Pia's method since we enclosed the

The effectiveness of this method was tested by two kinds of bacterial spores 245 times over a four-year period.

Presently, we have concluded that a 24-hr exposure time is able to kill both spores of Bacillus subtilis 10^6 and Bacillus stearothermophilus 10^5 and that this method is highly effective for the flexible fiber-optic illuminator. Formaldehyde-adsorbed plaster should be changed biweekly and air-tightness should be maintained during the whole procedure. The advantage of this method is its simplicity and ease in application, but the major disadvantage is its long sterilization time.

operating microscope or the flexible fiber-optic illuminator on mobiel stand with transparent polyvinyl bags and placed 60 g of formaldehyde-adsorbed plaster in the bottom of the bag.

CONCLUSION

Sterilization of the operating microscope and the flexible fiber-optic illuminator on mobile stand using formaldehyde gas at ambient temperature has been performed for the past four years. The instruments were wrapped in polyvinyl bags in which 60 g of formaldehyde-adsorbed plaster was placed. The sterilization time varied from 8 hrs to 1105 hrs and the average time was 153 hrs. The effectiveness of the method was periodically examined using spores of Bacillus subtilis and Bacillus stearothermophilus. Of a total of 245 tests, only 17 (6.9%) were found to have positive growth. In 1980, the exchange interval of formaldehyde-adsorbed plaster was shortened from 4 to 2 weeks, and as a result, all tests having a sterilization time of longer than 24 hrs showed no positive growth of either the spores of Bacillus subtilis or Bacillus stearothermophilus. Deterioration or surface damage of the instruments was not observed.

REFERENCES

1) Harii, K: Current status and problems of the operating microscope. *Jap. J. Medical Instrumentation,* **50**, 105-110, 1980. (in Japanese)
2) Kurze, T, Apuzzo, M, Weiss, M, *et at.*: Experiences with sterilization of the operating microscope. *J. Neurosurg,* **47**, 861-863, 1977.
3) Pia, H. W: Sterilization of the operating microscope. *Acta. Neurochir,* **35**, 243-245, 1976.