

# STERILIZATION OF OPERATING INSTRUMENTS BY FORMALDEHYDE CABINET AT AMBIENT TEMPERATURE

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## ABSTRACT

Formaldehyde cabinets at ambient temperature have been used to sterilize heat-sensitive operating instruments in our operating rooms. The instruments were placed in formaldehyde cabinets with a capacity of 0.4 m<sup>3</sup> either wrapped in linen cloth or not wrapped. To generate the formaldehyde gas, 240g of formaldehyde-adsorbed plaster was deposited in the bottom of the cabinet. The efficiency of the sterilizing process was periodically examined using the spores of *B. subtilis* and *B. stearothermophilus*. During the past four years and two months, a total of 224 tests were performed, and 58 tests (25.9%) showed positive bacterial growth. Of 63 tests performed in the year of 1978 and 1979, no positive bacterial growth was observed at the exposure time of over 97 hrs. However, in January of 1980, the exchange interval of formaldehyde-adsorbed plaster was shortened from 4 to 2 weeks; thereafter, among 161 tests no bacterial growth was observed at the exposure time of over 73 hrs.

Keywords: Sterilization of operating instruments, Formaldehyde cabinet, Bacterial spores

## INTRODUCTION

Low-temperature steam with formaldehyde gas has been used to sterilize operating instruments in the United Kingdom and in the Scandinavian countries.<sup>1)2)</sup> The bactericidal and sporicidal properties of steam with formaldehyde have been demonstrated by Line<sup>3)</sup> and Alder.<sup>1)</sup> However, the sporicidal property of formaldehyde gas at ambient temperature has not been confirmed. Newsom<sup>4)</sup> demonstrated that the vapor from liquid formalin at ambient temperature did not sterilize bacterial spores after overnight exposure. Lowbury,<sup>5)</sup> also, stressed that the formaldehyde cabinet at ambient temperature was an unreliable sterilization method and should not be used in hospitals.

It is considered that these reports dealt with relatively short exposure time to formaldehyde gas. Therefore, we investigated the sterilization effect of formaldehyde gas using formaldehyde cabinets in which the exposure time was much longer than those of previous reports. The efficiency of the sterilizing process was examined by the bacterial spores.

## MATERIALS AND METHODS

Formaldehyde cabinets at ambient temperature have been used to sterilize heat-sensitive operating instruments in our operating rooms. Some of the instruments sterilized by this method were electric drills, air-driven bone saws, cystoscopes, and laparoscopes. These instruments were placed in a porous tray and wrapped in linen cloth, but endoscopes were

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placed in the tray without any wrapping. These were then placed in a formaldehyde cabinet having a capacity of 0.4 m<sup>3</sup>. To generate formaldehyde gas, formaldehyde-adsorbed plaster\* was deposited in the bottom of the cabinet. The dose of formaldehyde-adsorbed plaster was four full container caps, equivalent to 240g.

Each formaldehyde cabinet was used to sterilize certain types of operating instruments. All endoscopes were sterilized in one formaldehyde cabinet. Electric drills and bone saws wrapped in linen cloth were sterilized in three of the other formaldehyde cabinets. The instruments were transferred from the first-day cabinet to the second-day cabinet on the second day. On the third day they were again transferred to the third-day cabinet and stored in this cabinet until surgical use.

With this procedure, the opening of the first-day cabinet was rather frequent, but the second-day and third-day cabinets were opened only once a day, hence the loss of formaldehyde gas was kept to a minimum.

The efficiency of the sterilizing process was determined by the bacterial spores. Commercial biological indicator Attest for gas sterilization (by *B. subtilis* at spore population of 10<sup>6</sup>) and Attest for steam sterilization (by *B. stearothermophilus* at spore population of 10<sup>5</sup>) were both wrapped in a single piece of gauze and left in the center of the tray.

During surgery these spores were collected and incubated at 40°C for *B. subtilis*, at 56°C for *B. stearothermophilus* in an incubator exclusively made for Attest. Normally, the results were determined at 48 hrs; however, positive growth was frequently observed longer than a 48-hr incubation period in formaldehyde gas sterilization. Therefore, a final decision was made after seven day's incubation. The formaldehyde-adsorbed plaster was exchanged every 4 weeks until December, 1979. However, this interval was shortened to 2 weeks in January, 1980, since Yamamoto<sup>6)</sup> reported that the generation of formaldehyde gas from formaldehyde-adsorbed plaster markedly reduced after 2 weeks.

## RESULTS

Sterilization tests of formaldehyde cabinets by bacterial spores have been carried out 224 times since May, 1978. The results are summarized in Table 1. These tests were performed on a monthly basis for a period of four years and two months. The average exposure time to formaldehyde gas was 112 hrs and 50 min.

In an overall test period, positive bacterial growth of *B. subtilis* or *B. stearothermophilus* spores or both was observed in 58 tests (25.9%). In the test period from 1978 to 1979, out of 63 tests, positive growth was observed in 32 tests (50.8%), and the exposure time for positive growth was under 96 hrs. No positive growth was observed at an exposure time of over 97 hrs.

However, in the test period from 1980 through 1982, 26 (16.1%) out of 161 tests showed positive growth, and the exposure time for positive growth was under 72 hrs. There was no positive growth at the exposure time of over 73 hrs.

Therefore, biweekly exchange of formaldehyde-adsorbed plaster resulted in marked reduction in the percentage of bacterial growth and reduced the exposure time for positive bacterial growth from 96 hrs to 72 hrs.

In the test period from 1978 to 1979, there were 5 positive growth tests with exposure times between 73 hrs and 96 hrs. The tests were performed in the fourth week using the same formaldehyde-adsorbed plaster; therefore, the formaldehyde gas concentration was probably

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Table 1. Effect of formaldehyde cabinets on bacterial spores (*B. subtilis* 10<sup>6</sup> and *B. stearothermophilus* 10<sup>5</sup>) at ambient temperature with a comparison between two test periods.

Exposure time (hr)	Test period					
	1978—1979*		1980—1982**		Total	
	No. of tests	Positive growth (%)	No. of tests	Positive growth (%)	No. of tests	Positive growth (%)
Under 24	14	12 ( 85.7)	6	3 (50.0)	20	15 (75.0)
25 — 48	12	10 ( 83.3)	24	5 (20.8)	36	15 (41.7)
49 — 72	9	5 ( 62.2)	110	18 (16.4)	119	23 (19.3)
73 — 96	5	5 (110.0)	7	0	12	5 (41.7)
97 — 120	1	0	4	0	5	0
121 — 144	5	0	0	0	5	0
145 — 168	0	0	2	0	2	0
169 — 192	3	0	0	0	3	0
193 — 216	0	0	1	0	1	0
217 — 240	0	0	1	0	1	0
Over 240	14	0	6	0	20	0
Total	63	32 ( 50.8)	161	26 (16.1)	224	58 (25.9)

\* Formaldehyde-adsorbed plaster was exchanged every 4 weeks.

\*\* Formaldehyde-adsorbed plaster was exchanged every 2 weeks.

Table 2. Incubation period of positive bacterial growth

Incubation period (day)	Spores of <i>B. subtilis</i> (%)		Spores of <i>B. stearothermophilus</i> (%)		Total (%)	
2	19	(46.3)	36	(69.2)	55	(59.1)
3	9		9		18	
4	3		5		8	
5	2	22 (53.7)	2	16 (30.8)	4	38 (40.9)
6	3		0		3	
7 and over	5		0		5	
Total	41	(100.0)	52	(100.0)	93	(100.0)

insufficient to kill the bacterial spores in spite of such long exposure time.

Of the 58 positive growth tests, both of the bacterial spores were positive in 35 tests. The spores of *B. stearothermophilus* alone were positive in 17 tests, and that of *B. subtilis* alone in 6. Thus, the spores of *B. stearothermophilus* were more resistant to formaldehyde gas than that of *B. subtilis*.

The actual number of positive bacterial spore strips are listed in Table 2. As shown in this table, after a 2-day incubation period 55 out of 93 spore strips (59.1%) were positive. The rest

of the 38 spore strips (40.9%) were found to be positive after an incubation period of 3 to 7 days. These results were similar for both *B. subtilis* and *B. stearothermophilus*.

## DISCUSSION

Low-temperature steam (80°C) with formaldehyde gas is a sporicidal gaseous mixture and has been used for the sterilization of heat-sensitive materials.<sup>1)2)</sup> In regard to the effect of formaldehyde gas at ambient temperature, Newsom<sup>4)</sup> demonstrated that an 18-hr exposure to vapor from heated formalin was sporicidal, but overnight exposure to vapor from liquid formalin at ambient temperature failed to sterilize the  $10^4$  spores of *B. subtilis*. Perkins,<sup>7)</sup> also, stated that the bactericidal effect of the formaldehyde cabinet was disappointing unless much moisture was present. Lowbury<sup>5)</sup> agreed with Perkins' view and stated that formaldehyde cabinets were unreliable and should not be used as a method for disinfection.

The major disadvantage of formaldehyde gas is its poor penetration into the materials compared with ethylene oxide gas; however, the time required for dissipation of the residual gas is markedly short for formaldehyde gas. Therefore, an airing-off period after sterilization is not necessary for materials, sterilized with formaldehyde gas.

To compensate for the poor penetration characteristic of formaldehyde gas, there are two alternatives, namely, to raise the sterilizing temperature or to extend the exposure time. A study was made to elucidate the adequate exposure time for formaldehyde gas at ambient temperature so as to kill all the bacterial spores.

Our investigation clearly demonstrated that formaldehyde gas at ambient temperature killed both the  $10^6$  spores of *B. subtilis* and  $10^5$  spores of *B. stearothermophilus*. However, the time required to sterilize these spores was remarkably long, 97 hrs. In January, 1980, the exchange interval of the formaldehyde-adsorbed plaster was shortened from 4 to 2 weeks. This resulted in marked reduction both in the sterilization time and in the percentage of positive bacterial growth. Thereafter, the longest exposure time for positive growth of the spores was 72 hrs. Therefore, at present, we keep the heat-sensitive operating instruments in a formaldehyde cabinet at ambient temperature for a period of 73 hrs or more before surgical use.

Because of the long sterilization time, this sterilization procedure is only applicable for instruments which are used infrequently or are abundant in number.

When applying bacterial spores to determine the efficiency of formaldehyde gas sterilization, the final decision should not be made after a 48-hr incubation period, but should be made after a 7-day incubation period.

## CONCLUSION

The sterilization effect of formaldehyde cabinets having a capacity of  $0.4 \text{ m}^3$  at ambient temperature was investigated using both  $10^6$  spores of *B. subtilis* and  $10^5$  of *B. stearothermophilus* as the indicators in the sterilizing process. Formaldehyde gas was generated from 240g of formaldehyde-adsorbed plaster deposited in the bottom of the cabinets. No positive bacterial growth was observed in the tests having exposure times of over 97 hrs.

A further improvement was obtained by shortening the exchange interval of the formaldehyde-adsorbed plaster from 4 to 2 weeks. As a result, no positive bacterial growth was observed after a 73-hr exposure period.

## REFERENCES

- 1) Alder, V. G., Brown, A. M., Gillespie, W. A.: Disinfection of heat-sensitive material by low-temperature steam and formaldehyde. *J. Clin. Path.*, **19**, 83—89, 1966.
- 2) Alder, V. G., Gingell, J. C., Mitchell, J. P.: Disinfection of cystoscopes by subatmospheric steam and steam and formaldehyde at 80°C. *Brit. Med. J.*, **3**, 677—680, 1091.
- 3) Line, S. J. and Pickerill, J. K.: Testing a steam-formaldehyde sterilizer for gas penetration efficiency. *J. Clin. Path.*, **26**, 716—720, 1973.
- 4) Newson, S. W. B. and Walsingham, B. M.: Sterilization of the biological safety cabinet. *J. Clin. Path.*, **27**, 921—924, 1974.
- 5) Lowbury, E. J. L., Ayliffe, G. A. J., Geddes, A. M. *et al.*: Control of hospital infection. Chapman and Hall, London, p.146 1977.
- 6) Yamamoto, Y. and Kawamura, M.: Reduction of formaldehyde gas concentration with time and sterilization effect of formaldehyde-adsorbed plaster (F-gen). *Byoin Yakugaku*, **1**, 81—84, 1975. (in Japanese)
- 7) Perkins, J. J.: Principles and methods of sterilization in health sciences. Charles C Thomas, U.S.A., p.339 1973.