■Original article

Suture Biological Indicator for the Narrow Channels of Medical Instruments

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Recently using an endoscope with a narrow channel has become very popular in surgery or invasive examination in clinical settings. In healthcare service, it is essential to supply those reusable critical items with high sterility assurance quality. However, most of the flexible endoscopes are not sterilisable with steam. Thus, the need of low temperature sterilisation has been increased for equipments that are easily affected by heat . For sterilising narrow channels, low temperature hydrogen peroxide vapor sterilization is one of the most useful and reasonable ways. In ISO 14937 2009, it is mentioned that any change in product, its package, or the presentation of product for sterilization shall be assessed for the effect on the appropriateness of the sterilization process[1]. However, the validating method for the narrow channel has not been well-established yet.

1. Objective

In this study, thin polyester sutures loaded with indicator microbes (suture biological indicator, hereafter SBI) is tested as biological indicator inside the narrow channels.

2. Methods

As a SBI, polyester suture (0.15mm ϕ × 50mmL) loaded with 10 to the 6th power (10^6) colony-forming unites (CFUs) of *Geobacillus stearothermophilus* ATCC7953 (provided by Mesa Laboratories Inc. 1.3×10^6 CFUs per suture) was employed for this study.

At first, *G. stearothermophilus* of each SBI (n=10) were recovered as control into 0.1% peptone water and 0.05 polysorbate 80 solution by homogeniser with 7000rpm for 3 minutes, attenuated into ten times series, pour cultured in tryptic soy ager at 55℃ for 48 hours, and counted.

Secondly the CFUs of each SBI (n=10) passed through the narrow channels of inner diameter of 1mm and 400mm long guided by monofilament polyamide 66 suture of 180 decitex (dtex)(No.60 Ca 0.135㎜ϕ、FUJIX) were also counted in the same methods in order to prove that the spores on the carrier suture do not decrease significantly by the friction in narrow channel. The SBI was tied at the center of the polyamide guide suture in surgical knot. The SBI formed V-shape with the procedure. The statistic evaluations on CFU number of the above groups were performed by Student's t-test and Mann-Whitney U test (rank sum test) .

Then the SBI set in the middle part of each stainless steel tube was sterilised in half cycle with low temperature hydrogen peroxide vapor (LTHPV) sterilizer (V-PRO1®, Streris). After the sterilisation, they were cultured in the tubes with soybean casein digest broth (SCDB) containing a colour indicator (TSB-BP 13®, MesaLabs) at 55℃ for seven to fourteen days. The inner diameter of the stainless steel tubes tested were 1mm, 2mm and 5mm each, and the length were 125mm, 250mm, 400mm, 500mm and 600mm each. All tubes were steam sterilized before setting the SBI.

The spores on the polyester biological indicator suture before use was observed by environmental scanning electron microscope (JSM-6380LA®, Japan Electron Optics Laboratory Ltd.).

3. Results

Tables 1 and 2 show the number of CFUs recovered from the SBIs before and after passing through the tube of

1mmϕ and 400mm long. There was no significant difference between those two groups (P= 0.72 in Students t-test and P=0.85 in Mann-Whitney U test).

Table 1. CFUs on each SBI as control before use cultured at 55℃ for 48hours

BI	CFUs/BI
C1	0.93×10^6
C2	0.54×10^6
C3	0.91×10^6
C4	1.24×10^6
C5	1.24×10^6
C6	1.55×10^6
C7	1.43×10^6
C8	0.74×10^6
C9	0.81×10^6
C10	0.65×10^6
Mean	1.00×10^6

C1-10: SBIs before passing through the tube of 1mmϕ and 400mm

Table 2. CFUs on each SBI after passing through narrow channel (1mmϕ ×400mmL) and then cultured at 55℃ for 48hours

BI	CFUs／BI
P1	0.85×10^6
P2	0.39×10^6
P3	0.91×10^6
P4	0.76×10^6
P5	1.05×10^6
P6	1.06×10^6
P7	1.14×10^6
P8	1.04×10^6
P9	1.06×10^6
P10	1.11×10^6
Mean	0.93×10^6

P1-10: SBIs after passing through the tube of 1mmϕ and 400mm long.

All the SBIs set in the narrow lumen tube of 1mm, 2mm and 3mmϕ and 125mm, 250mm, 400mm, 500mm and 600mm in length were sterilised by the half cycle of LTHPV sterilisation process except the tube of 1mmϕ and 400mm long shown in Tables 3 and 4.

Table3. Culture results of SBI kept in the middle of tube after half cycle LTHP sterilisation (No.positive/Total number sterilised)

φ	Length	No of positive/ Total No.
1mm	125mm	0/20
	250mm	0/40
	400mm	4/40
2mm	250mm	0/20
	400mm	0/40
3mm	400mm	0/40
	500mm	0/40
	600mm	0/20

Figure 1 illustrates the findings of environmental scanning electron microscope (ESEM). No clump of spores on the polyester suture was observed.

4. Discussion

The results showed that SBI maintained the number of microbes after the extraction into the middle of 1mmϕ narrow channel without statistical decrease of the CFUs.

Therefore, the sterility assurance of SBI was verified, and the sterilisation process is considered to be appropriate for any product and package.

Table 4. Culture results of SBI kept in the middle of tube after half cycle LTHP sterilisation (No. positive/Total number sterilised)

Number of Sterilisation	Inner Diameter(mmϕ) and Length (mmL) of the Test Tubes							
	1mmϕ			2mmϕ		3mmϕ		
	125mmL	250mmL	400mmL	250mmL	400mmL	400mmL	500mmL	600mmL
1	—	—	0/4	—	0/4	0/4	—	—
2	—	—	1/4	—	0/4	0/4	—	—
3	—	—	1/4	—	0/4	0/4	—	—
4	—	—	0/4	—	0/4	0/4	—	—
5	—	—	1/4	—	0/4	0/4	—	—
6	—	0/4	0/4	—	0/4	0/4	0/4	—
7	—	0/4	0/4	—	0/4	0/4	0/4	—
8	—	0/4	1/4	—	0/4	0/4	0/4	—
9	—	0/4	0/4	—	0/4	0/4	0/4	—
10	—	0/4	0/4	—	0/4	0/4	0/4	—
11	0/4	0/4	—	0/4	—	—	0/4	0/4
12	0/4	0/4	—	0/4	—	—	0/4	0/4
13	0/4	0/4	—	0/4	—	—	0/4	0/4
14	0/4	0/4	—	0/4	—	—	0/4	0/4
15	0/4	0/4	—	0/4	—	—	0/4	0/4

Four tubes were set in the chamber up-right and left, and lower- right and left for each sterilisation process. No apparent tendency of those setting position is observed for each positive result.

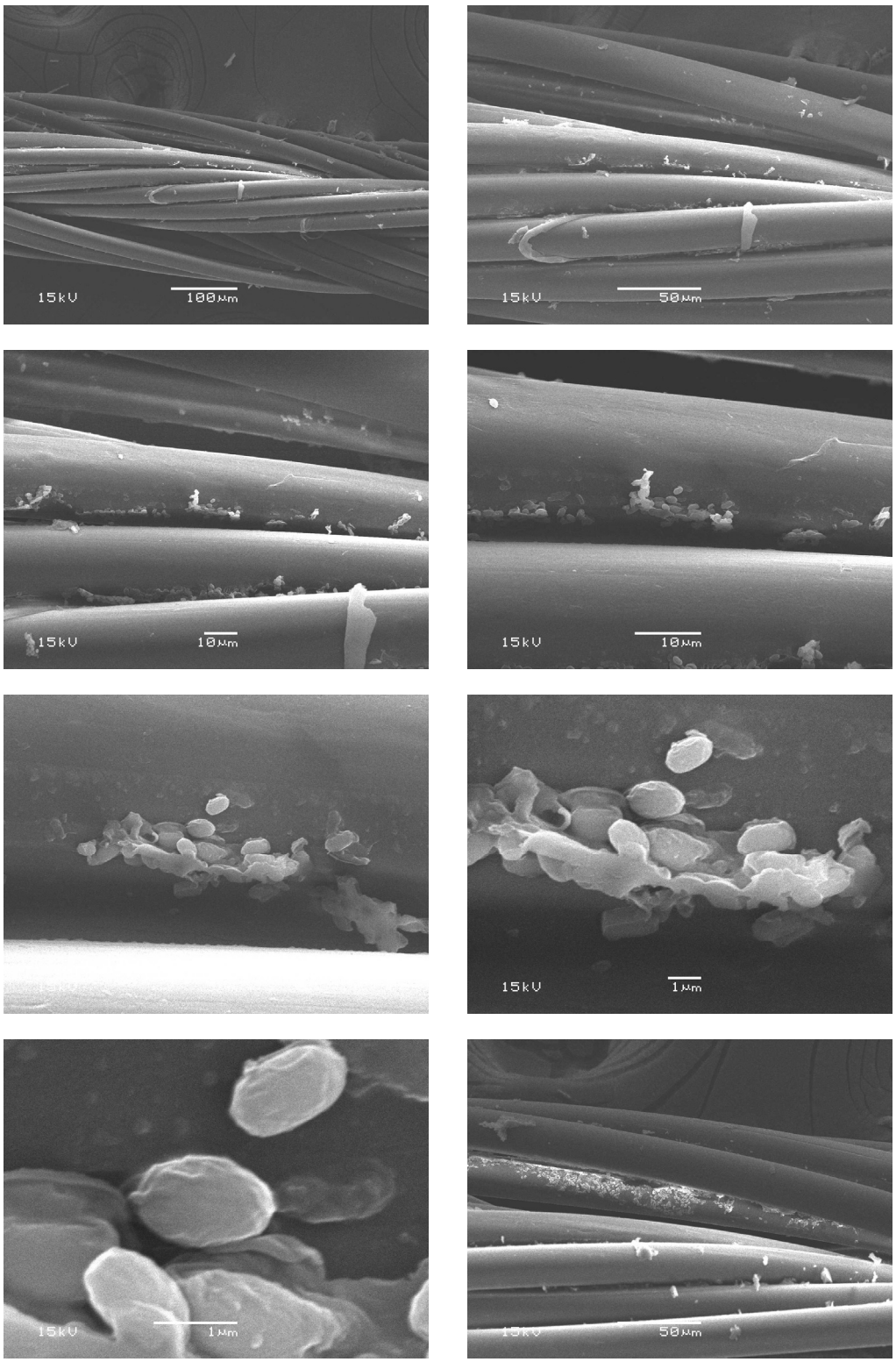

Figure 1. The findings of environmental scanning electron microscope (ESEM)
No clump of spores on the polyester biological indicator suture before use was observed.

The carriers made of flat stainless steel[2] and stainless steel wires[3] are reported to be employed for the sterility assurance of low temperature gas plasma sterilisation in narrow lumen. They are also appropriate for the sterilisation. The results of the environmental scanning electron microscope on the polyester biological indicator suture exhibited no clump of spores, which implies that the interference with the sterilising process was not occurred even a SBI has 10 to the sixth order of spores on thin suture material.

Thus, the SBI can be utilized to determine D-value in the narrow channels of different structures and packings. The method should be extended to test low temperature steam and formaldehyde sterilization of thin and narrow structures. The utilization of the SBI is a practical and useful way to strengthen the sterility assurance of narrow channels.

5. Conclusion

The results of this study show that SBI is a feasible method to validate the effect of low temperature hydrogen peroxide vapor sterilization on narrow channels. The findings of this study suggest that SBI is a practical and effective way to assure the security of sterilisation for products in any type with narrow channel.

Conflicts of interest: None to report.

Reference

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