

Background

Ethylene oxide (EO) has negative effects on persons' health, and remains in sterilized medical devices. It is necessary to remove residual EO in the sterilized medical devices. It is questionable that the management of the current devices are safe considering the residual EO value of the legal regulation in Japan. This study examines the aeration time at hospitals that is less than Food and Drug Administration (FDA) regulatory value of the sterilization.

Residual EO value

FDA advocated the regulation value of 250ppm (=250 μ g/g) in the 1970s. According to report of previous studies, inhalation toxicity is 33ppm and hemolysis is 80ppm.

Optimal aeration time

Association for the Advancement of Medical Instrumentation (AAMI) advocated the optimal aeration time of 8 hours at 60°C or 12 hours at 50°C in the 1970s.

Materials & Method

The residual EO in three types of plastics ; polyvinyl chloride (PVC), polyoxymethylene (POM), and thermoplastic polyurethane (TPU) were examined with a gas chromatography after 12-, 24-, 48-, and 72-hour aeration (n=5). A comparison between the analytical value and the specified value of FDA was compared to verify the more appropriate aeration.

gas chromatography (GC) as head space (HS) : ① Seal ② Warming ③ Collecting the gas phase ④ Analysis



test pieces of plastics

Sterilization Standard solution



plastic after sterilization

It was heated 3 hours at 70°C to evaporating the volatile component in the sample, and collecting the gas phase.



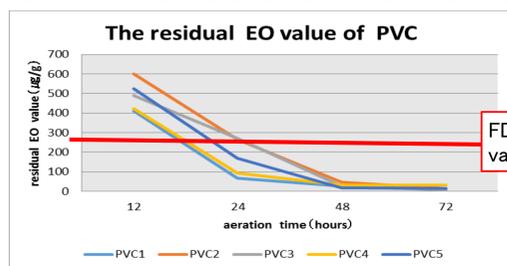
gas chromatography GC-4000 plus® (GL Sciences Inc.)



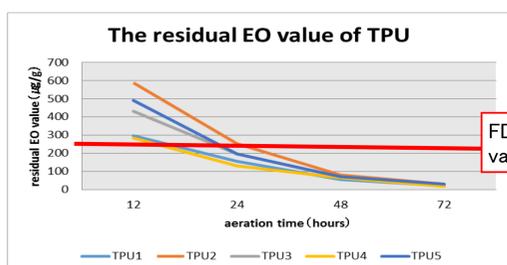
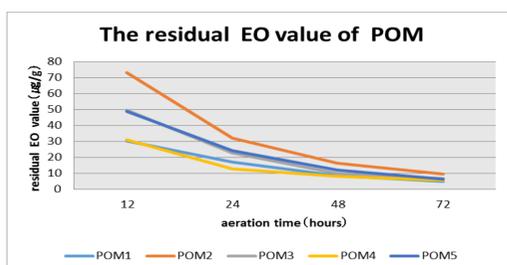
capillary column DB-WAX® (Agilent Technologies Inc.) Length 60m, Inner diameter 0.32mm, Thickening 0.5 μ m

Results & Discussion

Figure 1. The residual EO value in plastics (n=5)



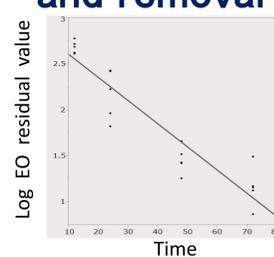
FDA advocated the regulation value of 250 μ g/g



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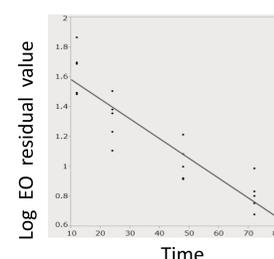
The plastics after 12-24 hour sterilization were high in residual EO concentration. The results suggest longer aeration time is necessary. There was differences in degree the residual EO for the same plastic, the difficulty of management in the medical devices has been speculated. There was a correlation between EO residual values and removal time.

Figure 2. The correlation between EO residual value and removal time of plastics (250 μ g/g=Log 2.40) (n=5)



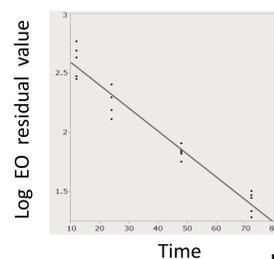
$$\text{PVC : Log 2.40} = -0.025t + 2.859 (R^2 = 0.870)$$

The aeration time of PVC 24 hours



$$\text{POM : Log 2.40} = -0.013t + 1.715 (R^2 = 0.838)$$

The aeration time of POM > 10 hours



$$\text{TPU : Log 2.40} = -0.019t + 2.785 (R^2 = 0.952)$$

The aeration time of TPU 27 hours

There was a correlation between EO residual values and removal time, which shows the correlation of the contribution rate from 0.84 to 0.95. And it enables to calculate the definite aeration time. It was suggested, possibility of medical devices that are insufficient EO removal in clinical settings, which reduce the safety. The device management should be practiced considering the residual EO, because the aeration time heavily depends on the type of plastic.

Need to manage residual EO of medical devices, including the handling way.

Need more aeration time than conventional in order to remove residual EO high concentration.

Conclusions

The EO residual value and removal time showed correlation, which offers an index for the optimal aeration time in clinical settings at hospitals.

Conflict of interest statement

TK is employee of Yoshida Pharmaceutical Co., and HK is consultant for Yoshida Pharmaceutical Co., Saraya Co. and Sakura Seiki.

Funding sources

None.