



A study on the reliability of pouch with a side gusset type of sealing quality



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Background

Sealing of sterilization bag is one of the crucial elements to guarantee the quality of sterility maintenance. In our previous study on 1,000 used pouches in clinical settings, 2012 Kami and Kobayashi conducted blue ink test and found leak channels in the sealing among 148 pouches. Among the 148 pouches, 108 were gusset type.

Objectives

To investigate the residual channels in the sealing part of gusset type pouches after heat-sealing.

Method

The following three tests were conducted to examine the leak channel in the sealing.
Blue ink test was conducted to examine the residuals channel before and after steam-sterilization.
Peel test was conducted to examine the gusset sealing by a tensiometer (Strograph®, Toyoseiki).
Powder transfer test was conducted to test the passage of powder (0.2µm in diameter) through the residuals channels from inside of the pouch to the outside.

Blue ink test

Conventional type Sealer



pass

fail

Results

1. In the results of the blue ink test, the pouch sealed by lower heat (180 to 190 °C) revealed frequent failure with residual channels, especially after the sterilization as shown in Figure 1.
2. In the results of the peel test, some leak channels were found in the gusset parts when the gusset was not properly heated. (Figure 2)
3. In the results of the powder transfer tests, the powder migrated from the bag through the channel. The results suggest that bacteria may pass into the sterile inside of pouch after sterilization. (Figure 3)

Figure 1

Comparison of sealing temperature:
No. of failed/Total tested

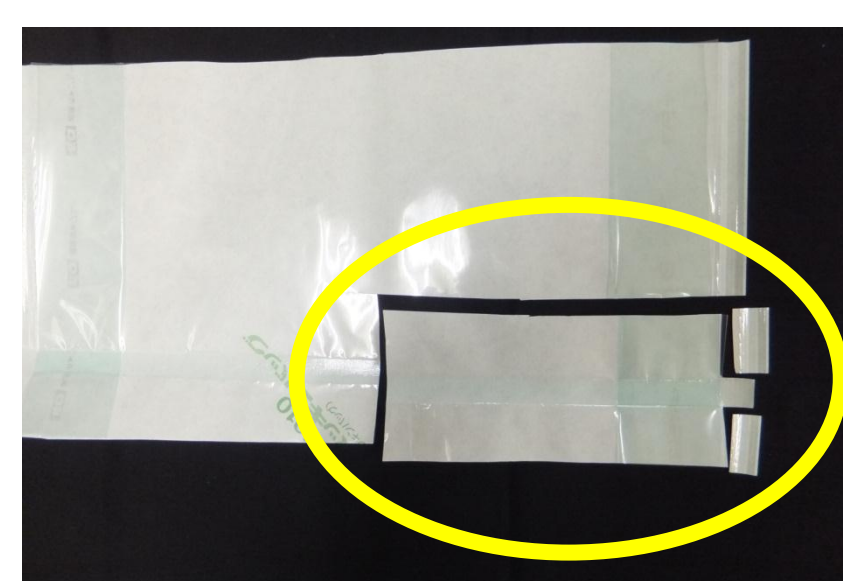
Conventional Type Sealer			
Temperature	Pouch width	Sterilization	
		Before	After
180°C	15cm	10/10	10/10
190°C	15cm	0/10	10/10
200°C	15cm	0/10	0/10
180°C	30cm	10/10	10/10
190°C	30cm	4/10	8/10
200°C	30cm	0/10	5/10

Sealer conditions / Pressure time: 3 Stop time: 3 (1≈1.7sec)

Figure 2

cut the Gazette part.

tensiometer



Gazette on both sides, heat sealer is not transmitted.

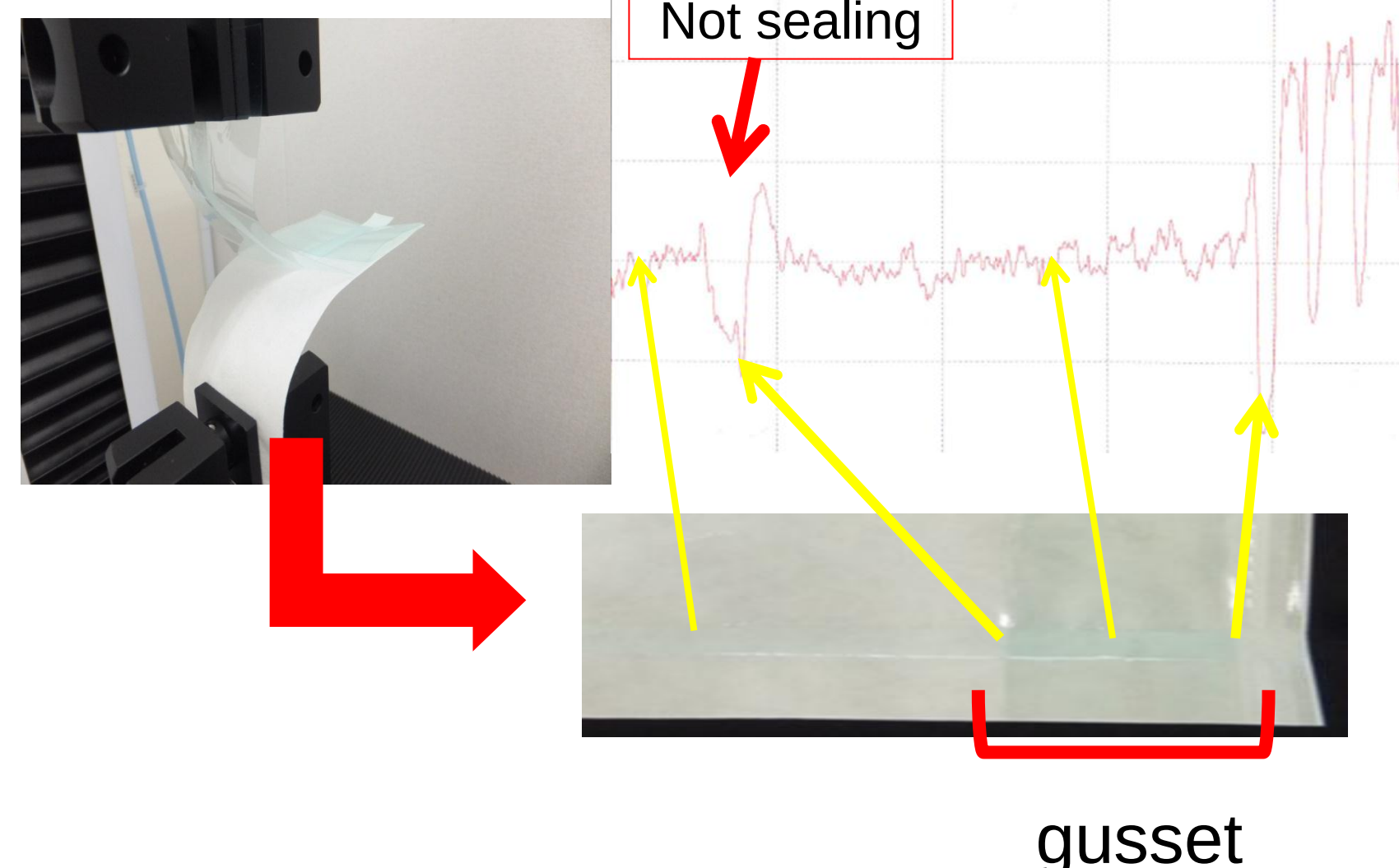
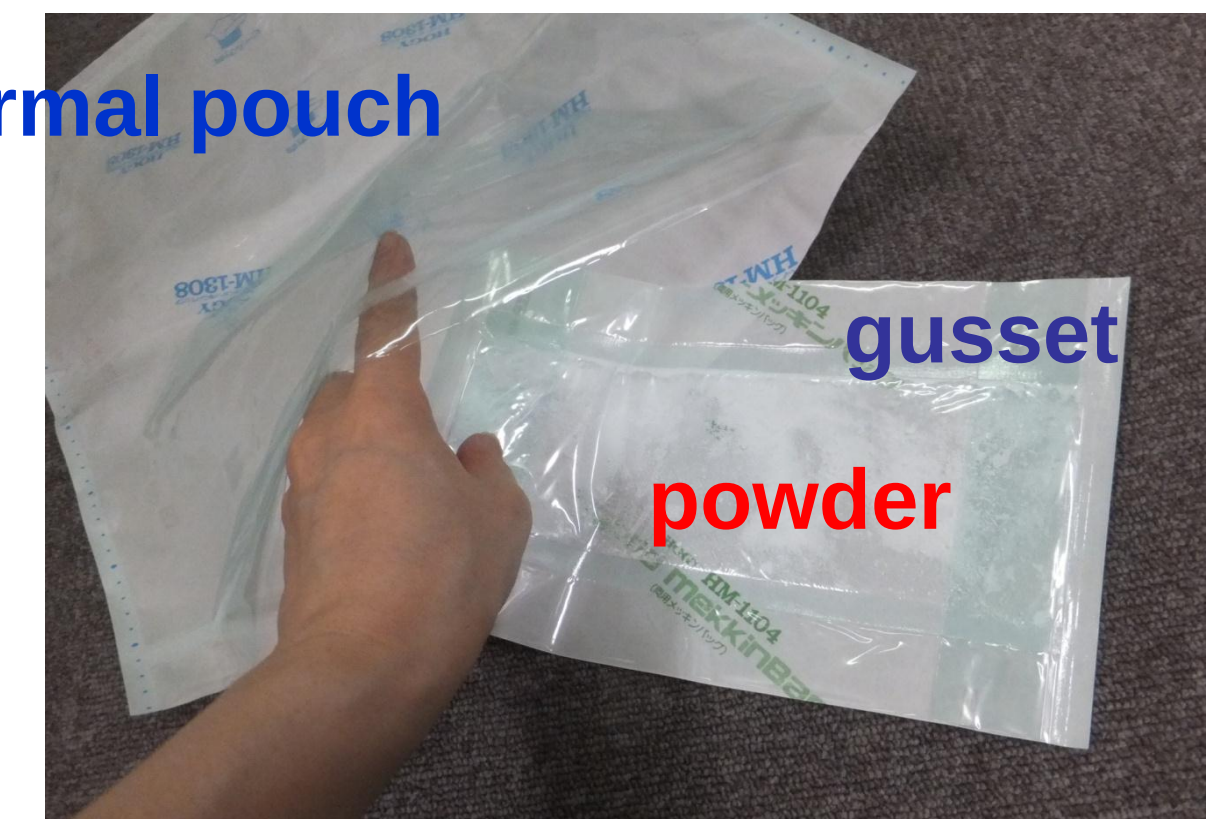


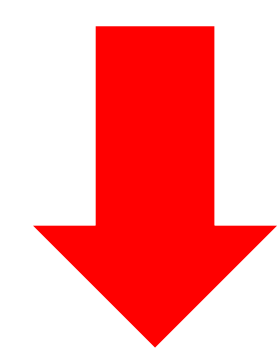
Figure 3

Powder tests
Movement of powder from Fail ?

Normal pouch

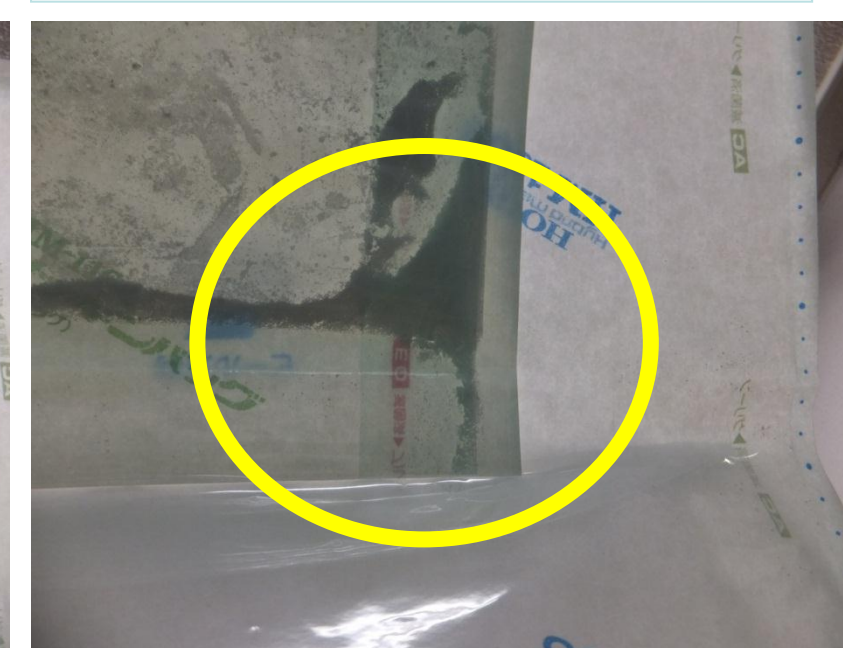


Powder (0.2µm diameter)



Before sterilization

After sterilization



- From the channel of the Gazette, the powder was easy to move.
- considered sterile and fail bacteria invade.

Conclusion

For the pouch sealing, we propose to select higher temperature, to use adequate type of sealer and to avoid the use of gusset type pouch if possible. When the gusset type is used, it is safer to employ double sealing.
★Gusset type pouches
: recommend the 200 degree temperature of sealer.
: selected a sealer is important.
: We recommend changes to the wrap from gusset type pouches.
If these are not possible, is perform 2 times sealing.