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Note

Effect of repeated formaldehyde low-temperature steam sterilization on physicomechanical properties of PVC tubing

Jean Chopineau [1], Jacques Barthélemy [2] and Pierre Bastide [3]

[1] *Pharmacie Centrale, Hôpital Saint-Jacques, 63003 Clermont-Ferrand (France),* [2] *Pharmacie Centrale, Centre Hospitalier Général, 03000 Moulins (France) and* [3] *Clinical Pharmacy Department, Faculty of Pharmacy, Centre Hospitalier Universitaire, 63003 Clermont-Ferrand (France)*

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Summary

Resterilization of non-reusable medical devices has been proposed for economical reasons in hospitals although one cannot assume that reprocessing such materials does not alter the physicomechanical properties and consequently safety in medical practice. The purpose of this study was to determine whether, and in which way, multiple sterilization cycles could be prejudicious to a material commonly used in medical routine in a number of articles. After 5–50 cycles of sterilization by the low-temperature steam formaldehyde technique at 56 °C, the resistance of plasticized vinyl polychloride (PVC) tubing has been tested using a simple stretching test. The breaking strength decreases with increasing number of cycles, being statistically significant between 10 to 20 cycles with a mean loss of 0.282% per cycle ($p < 0.01$). The breaking length increases when the number of cycles diminishes being statistically significant between 5 to 10 cycles ($p < 0.01$), with a mean change of 1.306% per cycle. Since the mechanical properties undergo significant deterioration after five cycles, leading us to suspect that reutilization in medical practice may not be safe for the patients, we cannot recommend multiple resterilization of PVC materials by this method. Nevertheless, if necessary, the hospital pharmacist bears the entire responsibility of reprocessing disposables. In this case, an absolute limit of three cycles should not be exceeded.

The sterilization of heat-labile equipment still remains a problem in the health services (Alder, 1987) and the use of formaldehyde gas is an alternative for the sterilization of the catheters and tubings used in urology, for example (Fleck et al., 1984). Gaseous formaldehyde is a very good sterilizing agent indeed and its addition to the steam greatly increases its sterilizing power with deep penetration into fabrics and destruction of spores (Alder et al., 1966). It has been employed in Great Britain since 1964 for disinfection of endoscopic instruments (Alder et al., 1971). Since it is as efficient a sterilizing agent as ethylene oxide, and because of its lower toxicity, it is more commonly used in hospitals than the latter (Le Bottlan, 1985).

Since 1986 in France, the resterilization of non-reusable medical devices, 'single-use' or 'dis-

Correspondence: J. Chopineau, Pharmacie Centrale, Hôpital Saint-Jacques, 63003 Clermont-Ferrand, France.

posables', has been forbidden. Economics is still at the heart of the controversy today, thus it seems clear that resterilizing medical devices several times would allow substantial savings in hospitals (Chopineau et al., 1967). Nevertheless, we cannot say whether multiple resterilizations do not modify significantly the properties of materials and ensure that the safety of patients can be preserved. In addition, it is obvious that hospitals do not have adequate quality assurance programmes to reprocess their single-use disposables (Greene, 1986). Therefore, many questions arise regarding the infection risk, toxicity, pyrogenicity, functional reliability, biocompatibility, and physical state. Namely, what are the maximum number of resterilizations permitted? Is the resterilized device as safe from a toxicological point of view as the original device? Does the reprocessed device function as well as the original device? And what tests and standards were used in the hospital to evaluate functional effectiveness?

This study was undertaken in order to determine to which degree the reprocessing by low-temperature steam formaldehyde at 56 °C could spoil medical devices by testing the physicomechanical properties of plasticized PVC tubings by a simple test.

Plasticized PVC tubings were used in this study (CAIR laboratory, France). Five groups of ten samples of 12–15 cm long PVC tubings were subjected to 0 (control), 5, 10, 20 and 50 sterilization cycles by the low-temperature steam-formaldehyde method previously described (De Riberolles et al., 1983). The stretching test, as perfected previously in our laboratory (unpublished), was performed for each group of tubings by measuring breaking length and strength. The tubings were then loaded in tension until breaking occurred. Breaking length (mm) and breaking strength (daN) were then noted whatever the level of the rupture (lower part, middle, higher part).

The crosshead velocity was constant at 500 mm/min using a universal testing machine (Adhamel Lhomargy Dynamometer) and both ends of the tubings were strongly fixed by the two jaws spaced exactly 50 mm apart. In this technique, no knot of the tubing resulted but the breaking point is expected to be approximately in the middle. Breaking points situated at the level of the jaws have not been taken into account: they arise from cutting off at the level of one jaw. In order to avoid this phenomenon, each end of the tubing was secured in a larger tube.

All the tests were carried out by the same experimenter, specially accustomed to this technique, and in a constant temperature room (22 °C).

Results are expressed as means ± standard error of the mean (SE) and statistical evaluation was carried out using Student's t-test, the differences observed being significant for $p < 0.05$.

Breaking strength as a function of the number of sterilizations: Breaking strength decreases with increasing number of sterilization cycles. Up to 10 cycles this effect is small (−0.2%, NS) but becomes more marked at the 20th cycle (−3.02%, NS) and significant at the 50th cycle (−4.09%, $p < 0.05$).

The mean relative loss of breaking strength is 0.0818% by cycle. Between 10 and 20 cycles, the mean loss by cycle is 0.282% ($p < 0.01$) whilst only 0.0206, 0.0194 and 0.0357% are found for 0–5 cycles (NS), 5–10 cycles (NS) and 20–50 cycles (NS), respectively.

Breaking length as a function of the number of sterilizations: Breaking length increases with fall in the number of sterilization cycles. Up to 5 cycles this effect is small (+2.14%, NS) but then increases regularly from 10 cycles (+8.67%, $p <$ 0.01) to 20 (+12.14%, $p < 0.001$) and 50 cycles (+16.4%, $p < 0.01$).

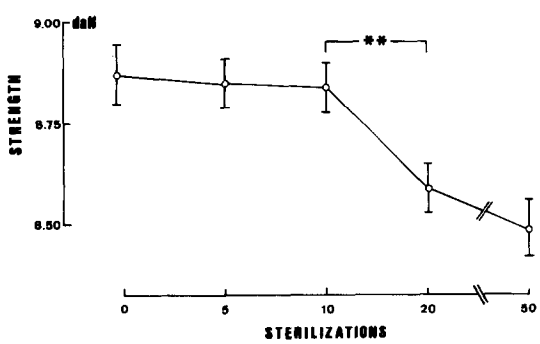

Fig. 1. Breaking strength of plasticized PVC tubing (daN) as a function of the number of sterilizations.

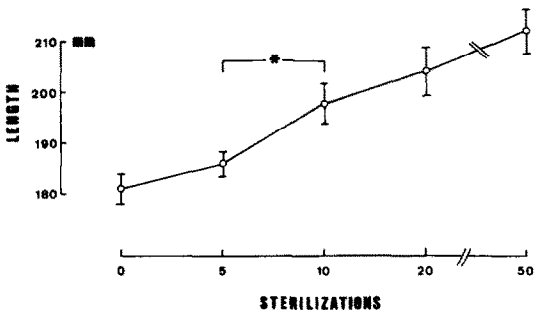

Fig. 2. Breaking length (mm) of plasticized PVC tubing as a function of the number of sterilizations.

After 50 cycles, the mean increase per cycle is 0.328%. As observed earlier, maximum change was noted for 10 sterilization cycles with 1.306% increase per cycle ($p < 0.01$). Below this limit, from 1 to 5 cycles, the mean change per cycle is non-significant (+0.428%, NS) and above 10 the intensity of changes decreases: 0.357% for 10–20 cycles and 0.139% for 20–50 cycles (NS).

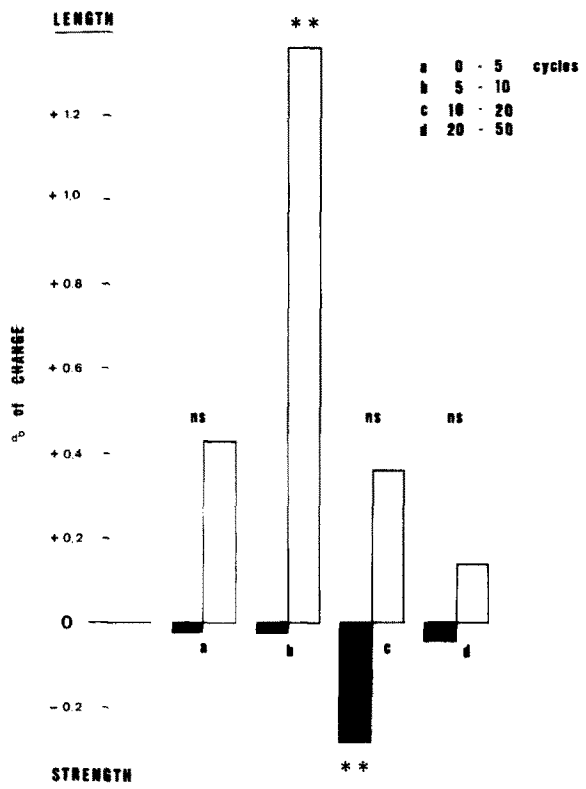

Fig. 3. Variation of breaking strength and breaking length of plasticized PVC tubing expressed as mean percentage of change (%) per cycle.

To a certain degree the more important the number of cycles of sterilization is, the more obvious are the changes. Among the two parameters studied in this work, the first to be affected the more precociously and significantly is the breaking length (from 5 cycles) prior to the breaking strength (from 10 cycles). Although both parameters did not react similarly in time and intensity of change, we can consider that both are representative of the physicochemical properties of the material and consequently must both be taken into account. They can predict a possible deterioration of materials even if changes would not be clearly visible in clinical practice.

The sterilization was carried out at 56 °C; although the effects at 80 °C were not examined in this work, one can assume that the deterioration would perhaps be emphasized at higher temperature. This hypothesis has to be verified in the future.

Some authors investigated the sterilization of polyfilament suture by autoclaving 10–20 times at 121 °C during a period of 30 min. There was about 0.5% loss in breaking strength per cycle. Since the repeated steam sterilization cycles alter the physical properties in a detrimental way, the conclusion was drawn that consideration should be given to the number of cycles (Dubin and Greenberg, 1981). After multiple resterilizations of polyethylene implants by ethylene oxide, no change occurs in the material itself but after steam treatment at a high temperature (135 °C), it becomes soft (Brinckmann, 1984). The author noted that there are no adverse effects if the material undergoes a maximum of 2–3 resterilizations. Studying the physicomechanical integrity of polyethylene after reprocessing of angiographic catheters by ethylene oxide, the authors noted that breaking strength was not modified, hence the reuse of such catheters appears to be possible without risk of loss of mechanical safety (Zapf et al., 1987a). In addition, 60 sterilization cycles did not give rise to any significant change from the surface of the material (Zapf et al., 1987b).

There are only few reports on reprocessing by formaldehyde. A particularly marked reduction

of strength of resterilized rubber goods was observed in the first sterilization cycles and coefficients of change of physicomechanical properties after 100 sterilizations with formaldehyde were thus close to those after 10 sterilizations (Frosin et al., 1983).

This is in complete agreement with our findings, since extending the number of cycles does not involve proportional deterioration. The material undergoes deterioration after a minimal number of five cycles in this work, a limit which should not be exceeded.

These results suggest that multiple resterilizations of PVC materials by the low-temperature steam-formaldehyde method are not safe, since they alter the quality of the medical devices in a way that could be prejudicious for the patients. Further experiments are needed in order to determine whether or not such findings would have clinical consequences.

We therefore cannot recommend multiple resterilizations by this method; nevertheless, if necessary, the hospital and particularly the pharmacist bears the entire responsibility of reprocessing disposables and in this case it appears to be reasonable not to exceed an absolute limit of three cycles.

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