Horizontal Plasma Freezing: A New and Efficient Technique?

Picker SM, Ebner B, Stürner S, Oustianskaja L, Jedrzejewska M, Gathof BS
Email: birgit.gathof@medizin.uni-koeln.de
Transfusion Medicine, University of Cologne, Joseph-Stelzmann-Str. 9, 50924 Cologne, Germany

Introduction and background:

Transfusion of plasma is used in order to correct bleeding and coagulation disorders. Therefore plasma preparation has to ensure availability of all coagulation factors, even when labile. Since quality of plasma constituents is best maintained in the frozen state, freezing and thawing are critical steps in conservation.

During freezing pure ice is formed and the plasma solutes are concentrated in the remaining water. Here solute displacement occurring with an increasing freezing time exposes labile factor molecules to a high concentration of salts which leads to inactivation. At high freezing rates ice formation overtakes the solute displacement without prolonged contact between highly concentrated, displaced salts and labile coagulation factors. Decrease of factor VIII occurs when the solidification of plasma takes more than 1 hour to bring down the temperature to - 30 °C or below. To ensure high quality of FFP, 3 points are mainly important:

1. The **rate of cooling must be as rapid as possible** and should **reach a core temperature of – 30 °C or below within 60 minutes**.
2. Plasma bags should be **regularly configured** to maximize exposure to the freezing process (bags laid flat if horizontal or in metal formers if vertical). Standardized frozen products are required for optimal use of new deep freeze storage systems (like KLS 2400/40 MABAG). These new systems use prefabricated cassettes to store uniformly frozen plasmas at temperatures maintained by liquid nitrogen.
3. Processing steps have to **prevent all conditions with may destroy bag integrity,** since frozen bags are brittle.

Our study was to evaluate a new horizontal freezing technique compared to a commonly used vertical technique analyzing these three processing conditions.

Results and discussion:

1. Desired temperature of - 30 °C was reached essentially faster by horizontal freezing technique (12-18 min vs. 38 min).

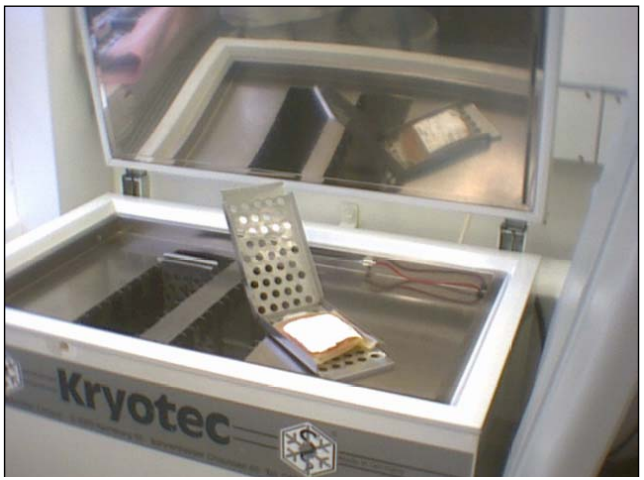
2. To prevent air filled cavities leading to inconstant freezing conditions quality of horizontal freezing depends on homogenous weight distribution. FFP weights are less important in case of vertical technique because of prefabricated metallic formers. On the other hand horizontal freezing leads to more equally formed products which facilitates handling like package and labeling.

3. Bag integrity could be destroyed by sharp edges of the metallic formers particularly when being removed. Since horizontal technique does not depend on metallic holders product integrity may be more preserved by this technique.

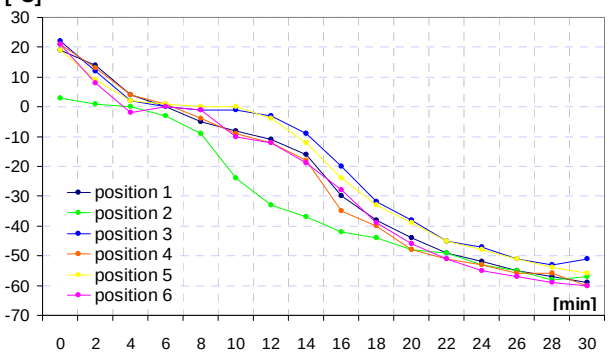
Materials and methods:

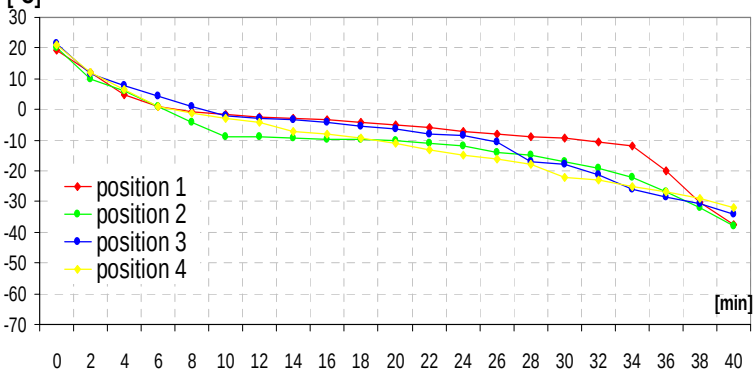
We compared freezing times up to - 30 °C between KLF 12-18/40 (Fa. MABAG, Hamburg, Germany), horizontal technique versus KRYOTEC KPE 12/70 (Fa. Schröder, Hamburg, Germany), vertical technique. We took the temperatures between two dummy bags filled with FFP representing together average weights (289 g, range: 243.7 g – 297.1 g). Temperatures were measured in fully loaded freezers by internal equipment monitoring and documented in defined steps at different positions. During measurements same FFP units were used in both freezers.

Freezer KLF 12 - 18/40 (horizontal technique)



Kryotec KPE 12/70 (vertical technique)





Conclusion:

In both instruments, KLF 12-18/40 and KRYTEC KPE 12/70, plasma core temperatures reach – 30 °C within 60 minutes. Therefore plasma freezing can be performed by both techniques. Horizontal freezing is faster and leads to more homogeneously formed units which enables us to use the whole storage capacity of the new deep freeze storage system KLS 2400/40. To guarantee same core temperatures at same times vertical freezing, in contrary to horizontal freezing, is dependent on FFP weights because of preformed holders. On the other hand these formers may affect product integrity.

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