



Maintaining Platelet Temperature and Quality During Shipping Without Agitation

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Background

Extended delays that can occur during shipment of blood products into areas of operation during times of conflict make it difficult to ship platelet concentrates (PC's) and ensure that the product maintains viability and functionality. Shipping platelets can severely decrease their quality due to a lack of proper temperature control and an inability to maintain continuous agitation. These are two reasons why liquid platelets are not being shipped and utilized in current military operational theaters. New shipping methods that ensure delivery of functional PC's are needed.

The Code of Federal Regulations (CFR) states "If stored at 20° to 24° C, a continuous gentle agitation of the platelet concentrate shall be maintained throughout the storage period,"¹ while American Association of Blood Banks (AABB) Standards only state that the total duration of interruption of agitation should not exceed 24 hours². Most PC studies have been performed with simulated shipping conditions only, storing PC's in a stationary shipping container, yielding results that are not a true representation of the shipping environment of blood products. During normal transportation of liquid blood products, the shipping container likely will undergo a certain degree of movement, providing PC's with adequate agitation in order to maintain active oxidative phosphorylation and a pH \geq 6.7.

This study was performed to test the feasibility of shipping PC's with intermittent agitation by the shipping process itself in a new prototype container designed to maintain temperature between 20°C and 24°C.

1. Code of Federal Regulations Title 21, parts 600-799. (2004). Washington, D.C.: Government Printing Office.
2. Silva M, ed. Standards for Blood Bank and Transfusion Services. 23rd Ed. Bethesda: American Association of Blood Banks, 2004.

Materials and Methods

Twelve units of apheresis PLTs were each split into two 287 ml aliquots (one control and one test) and stored on a rotator at 22°C-24°C with continuous agitation. Pairs of test units were placed in the platelet container (Minnesota Thermal Science; Plymouth, MN) inside a Collins box with bubble wrap and subjected to a round-trip 24 or 48 hour cross-country air shipment. Dual-channel palm-sized temperature data recorders (Escort Data Logging Systems Ltd; Auckland, New Zealand) measured the container, Collins box, and ambient temperatures at 5 minute intervals. After returning, the units were placed back on the rotator with the control aliquots. The following biochemical and pathologic markers were tested on Day 1, immediately after shipment, and Day 5: pH, ATP, glucose, lactate, hypotonic shock response (HSR), extent of shape change (ESC), PLT counts, PLT swirling, P-selectin by flow cytometry, PO2 and PCO2.



TABLE 1. Effects of shipping PC's* without agitation at 20 to 24 °C for 24 hours

Assay	Day 1		End of 24-hour Shipment		End of 5-day storage	
	Continuous agitation	Discontinuous agitation	Continuous agitation	Discontinuous agitation	Continuous agitation	Discontinuous agitation
pH	7.27 ± 0.04	7.27 ± 0.03	7.35 ± 0.04	7.10 ± 0.12†	7.32 ± 0.06	7.27 ± 0.09‡
PLT count (x 10 ¹¹)	2.98 ± 0.64	3.00 ± 0.63	2.82 ± 0.60	2.84 ± 0.61	2.66 ± 0.53	2.66 ± 0.58
ATP (mM/10 ¹¹ PLT)	3.86 ± 1.36	4.15 ± 1.54	3.48 ± 1.40	3.44 ± 1.17	4.18 ± 1.36	3.88 ± 0.83
Lactate (mmol/L)	2.31 ± 0.75	2.48 ± 0.70	3.34 ± 0.64	5.67 ± 2.63‡	6.91 ± 0.98	9.05 ± 2.03†
PCO ₂ (mmHg)	36.8 ± 6.94	36.7 ± 6.48	28.0 ± 4.36	45.9 ± 12.5†	24.1 ± 4.18	23.1 ± 3.51
PO ₂ (mmHg)	83.4 ± 22.5	79.2 ± 21.3	84.3 ± 24.8	63.9 ± 16.6†	93.5 ± 23.6	90.3 ± 22.2‡
ESC (%)	18.2 ± 5.33	20.6 ± 6.30	22.5 ± 4.30	25.2 ± 5.36	19.9 ± 5.71	22.8 ± 4.94‡
HSR (%)	58.5 ± 10.2	60.3 ± 13.0	64.5 ± 11.1	68.7 ± 8.20	56.7 ± 11.0	60.7 ± 9.37
Glucose (mmol/L)	18.1 ± 1.52	18.6 ± 2.06	16.6 ± 2.68	15.4 ± 2.25‡	15.5 ± 1.43	14.5 ± 1.46
CD62P (% gated positive)	19.9 ± 3.56	18.7 ± 3.11	22.0 ± 5.25	20.6 ± 5.51	19.4 ± 10.5	16.9 ± 9.68
PLT swirling (scale 1-3)	NT	NT	NT	NT	2.83 ± 0.41	2.33 ± 0.52

*PCs (n = 6)
†P<0.01.
‡P>0.01, P<0.05.

TABLE 2. Effects of shipping PC's* without agitation at 20 to 24 °C for 48 hours

Assay	Day 1		End of 48-hour Shipment		End of 5-day storage	
	Continuous agitation	Discontinuous agitation	Continuous agitation	Discontinuous agitation	Continuous agitation	Discontinuous agitation
pH	7.26 ± 0.02	7.26 ± 0.02	7.34 ± 0.03	7.14 ± 0.05†	7.31 ± 0.05	7.26 ± 0.07‡
PLT count (x 10 ¹¹)	2.78 ± 0.36	2.84 ± 0.43	2.62 ± 0.36	2.65 ± 0.35	2.47 ± 0.32	2.48 ± 0.39
ATP (mM/10 ¹¹ PLT)	3.44 ± 1.61	3.68 ± 1.43	3.46 ± 1.36	3.61 ± 1.43	3.66 ± 1.50	3.49 ± 1.60
Lactate (mmol/L)	1.82 ± 0.48	1.90 ± 0.32	4.10 ± 1.02	5.59 ± 1.79†	6.61 ± 0.73	8.06 ± 1.42‡
PCO ₂ (mmHg)	36.3 ± 4.85	35.6 ± 3.50	25.0 ± 3.53	36.9 ± 3.64†	21.5 ± 3.49	21.6 ± 3.92
PO ₂ (mmHg)	95.2 ± 20.6	92.2 ± 24.7	101.3 ± 16.8	83.3 ± 20.3‡	111.2 ± 14.8	106.3 ± 17.0‡
ESC (%)	17.7 ± 5.83	18.2 ± 8.66	18.1 ± 5.53	22.1 ± 4.45	17.9 ± 5.99	19.9 ± 5.01‡
HSR (%)	58.7 ± 9.27	58.9 ± 5.30	67.3 ± 11.8	68.3 ± 10.8	59.5 ± 12.0	62.2 ± 8.46
Glucose (mmol/L)	17.7 ± 1.47	18.1 ± 1.26	16.5 ± 1.77	15.7 ± 1.50‡	15.1 ± 1.60	14.4 ± 1.99
CD62P (% gated positive)	20.2 ± 3.86	17.1 ± 1.59	19.6 ± 6.16	17.8 ± 6.33	17.9 ± 12.2	15.9 ± 10.9
PLT swirling (scale 1-3)	NT	NT	NT	NT	2.83 ± 0.41	2.50 ± 0.55

*PCs (n = 6)
†P<0.01.
‡P>0.01, P<0.05.

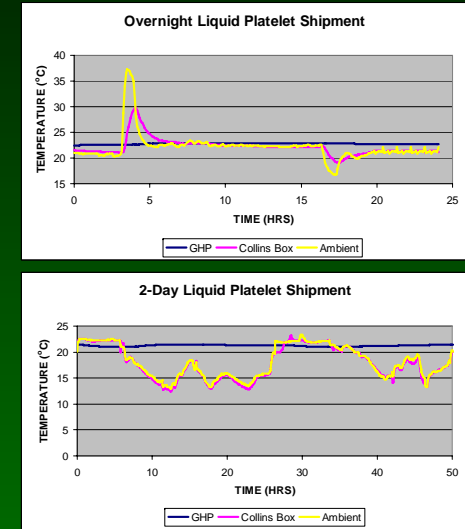


Fig. 1. Typical Performance charts of the Golden Hour Platelet container when subjected to 24 hour shipment (Top) and 48 hour shipment (Bottom) conditions of this study. Each line represents a single evaluation for each temperature measurement inside the Golden Hour Platelet container, inside the Collins box, and external temperature.

Results

Platelet container temperature was maintained at 21°C-23°C for all six shipments despite external variations of 13°C-35°C during transit. pH levels decreased during shipment but not below 7.1, increasing towards normal range of 7.3-7.4 by the end of 5-day storage. PCO₂ levels increased during shipping but returned to control levels by Day 5. PO₂ levels decreased by 18%-24% over controls during shipping, with 36%-70% greater lactate accumulation. ATP concentration was not different between the two groups. PLT morphology markers (PLT swirling and PLT activation), and PLT counts were unaffected by the shipping protocol. HSR and ESC showed no evidence of PLT damage, while expression of P-selectin remained normal.

Conclusions

- The new platelet container can maintain internal temperature within the required range for shipping.
- Interruption of continuous agitation for 24 or 48 hours does not produce PLT damage measurable by these *in vitro* techniques.
- Maintenance of normal ATP levels accompanied by a small decrease in pH, moderate excess lactate accumulation, increased CO₂ and decreased O₂ content indicate that agitation was sufficient for the PC's to maintain balanced metabolic activity during shipping.
- Platelets shipped in this manner appear to retain full 5-day storage viability.