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CRYOPRESERVATION OF APHERESIS PLATELETS COLLECTED USING THE AMICUS SEPARATOR AND STORED IN THE COLLECTION CHAMBER.

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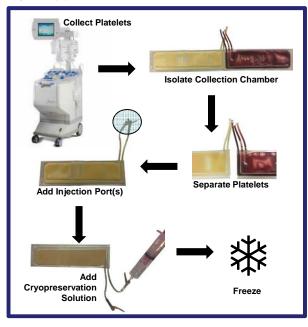
Introduction

Typical preparation of cryopreserved platelets involves introduction of a DMSO containing solution to the platelet product with subsequent volume reduction via centrifugation. The excess plasma/DMSO solution is then expressed off resulting in a concentrated product ready for frozen storage.

As an alternative, the Amicus Separator is capable of providing a convenient source of hyper-concentrated platelets to which a cryopreservation solution can be directly added without subsequent manipulation.

This feasibility study sought to evaluate the quality of cryopreserved platelets prepared by this method.

Figure 1. Cryopresevation Procedure.



Materials & Methods

Hyper-concentrated platelets in residual plasma obtained from the Amicus Separator were resuspended in the collection chamber. Cold cryopreservation solution was added (CryoStor®CS10, BioLife Solutions®; Final [DMSO] was approx. 6%) and the product stored at -80°C for a minimum of 1 month.

Thawed platelets were reconstituted in PAS-5 platelet additive solution (approx. 300 mL) and transferred to a 1L PL2410 container. Time 0 sampling was performed, then platelets were allowed to rest for 2 hrs. Post rest, platelets were sampled again, then stored at room temperature with agitation. Sampling was performed at 6 and 24 hour time points.

Results

Pre-freeze platelet yields ranged from $(2.38-3.17) \times 10^{11}$ PLT/unit. Post-thaw platelet content was not significantly different by paired t-test (ave. PLT/unit: $2.85\pm0.02 \times 10^{11}$; p > 0.05).

Table 1. Pre-Freeze/Post-Thaw Platelet Parameters.

Parameter, Mean ± SD (N=10)	Pre-Freezing	Post-Thaw	
Plt Conc (x10 ⁹ /L)	4475 ± 431	4718 ± 266	
Morphology Score (0 - 400)	338 ± 9	284 ± 21	
Morphology Disc (%)	67 ± 3	47 ± 9	
CD62p (%)	3.3 ± 5.0	45.8 ± 9.9	

Figure 2. Platelet Morphology: Pre-Freeze vs Post-Thaw.



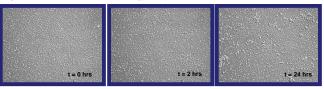
Results

Post PAS addition, platelets maintained HSR response through 24 hrs of storage, peaking at the 6 hr time point. No significant changes were observed in platelet activation during this time period.

Table 2. Post PAS Addition Platelet Parameters

Parameter,	Post PAS Addition (hr)				
Mean ± SD (N=10)	0	2	6	24	
Plt Conc (x10 ⁹ /L)	789 ± 65	721 ± 51	656 ± 54	687 ± 50	
Morphology Score (0 - 400)	299 ± 13	297 ± 13	284 ± 5	241 ± 19	
Morphology Disc (%)	54 ± 4	53 ± 4	49 ± 4	35 ± 6	
HSR (%)	30.9 ± 9.0	37.5 ± 4.9	38.1 ± 4.2	21.1 ± 4.3	
CD62p (%)	54.1 ± 14.0	53.2 ± 13.7	54.5 ± 15.3	51.4 ± 14.9	

Figure 3. Post PAS Platelet Morphology Comparison.



Representative images of platelet morphology at Post PAS time points are presented in Figure 3. Platelets products were free of visible aggregates. Microaggregates tended to form between 2–6 hr time points, and were present throughout products by 24 hrs.

Conclusion

Hyper-concentrated platelets obtained directly from the Amicus Separator can be used for the preparation of cryopreserved platelet products without the need for additional centrifugation.