

parameters of plasma (P) and comparison to collected fresh whole blood (WB) are displayed at Table

Table 1: Quality parameters of leucodepleted RBCs (ERD)

Parameter	FRD D0	FRD D42	FRD D0/D42	p*
Hb (g/unit)	57,89±3,8	56,84±3,61	1,02±0,01	< 0.0001
WBC (x10 <sup>6</sup> /unit)	< 1	x	x	x
Hematocrit	0,56±0,03	0,61±0,03	0,92±0,02	< 0.0001
Hemolysis	0,08±0,08	0,61±0,25	0,13±0,1	< 0.0001
GMT anti-B	5,10±2,55	x	x	x
K (mmol/l)	1,66±0,23	47,35±5,39	0,04±0,01	< 0.0001
P (mmol/l)	1,6±0,28	4,44±0,55	0,36±0,07	< 0.0001
2,3-DPG (mmol/l)	3,67±0,96	0,08±0,14	1024,59±1333,28	< 0.0001
ATP (µkat/l)	1,00±0,06	0,77±0,44	0,19±0,02	0.0002
LDH (µkat/l)	0,85±0,24	4,54±1,85	0,22±0,1	< 0.0001
pH	7,32±0,07	6,63±0,05	1,1±0,01	< 0.0001

Table 2: Quality parameters of plasma (P) and comparison to collected fresh whole blood (WB)

Parameter	WB D0	P D0	P D36	WB/P D0	p*	P D0/D36	p*
RBC (x10 <sup>12</sup> /l)	x	< 1	x	x	x	x	x
WBC (x10 <sup>9</sup> /l)	x	< 1	x	x	x	x	x
PLT (x10 <sup>9</sup> /l)	x	< 1	x	x	x	x	x
AT III (%)	91,69±5,15	72,73±4,46	73,89±4,4	1,26±0,06	< 0.0001	0,98±0,03	0,0204
Fbg (g/l)	2,91±0,51	1,93±0,37	1,96±0,46	1,53±0,26	< 0.0001	1±0,09	0,1042
F VII (%)	116,17±26,01	69,81±7,72	68,92±16,68	1,73±0,53	< 0.0001	1,02±0,13	0,4091
vWF (%)	108,25±30,9	86,75±21,49	90,4±24,09	1,24±0,1	< 0.0001	0,97±0,06	0,0131
TP (g/l)	x	49,05±2,57	49,77±2,56	x	x	0,99±0,01	< 0.0001
JaB (g/l)	x	1,49±0,51	1,46±0,5	x	x	1,07±0,03	0,0230
JaM (g/l)	x	1,19±0,36	1,15±0,38	x	x	1,05±0,08	0,0510
JaG (g/l)	x	0,35±1,95	0,64±1,88	x	x	0,97±0,05	0,0049

**Conclusion:** Blood components manufactured in hollow-fiber system ErySep<sup>®</sup> would pass as acceptable with regards to in vitro hematology and biochemistry parameters. Quality parameters are conforming to standards. ErySep<sup>®</sup> disposable set is suitable for manufacturing of high-quality blood products without additional need for any expensive machines, such as centrifuges, blood separators etc.

#### 4C-S30-03

### PRBC MEMBRANE FRAGILITY AS A POTENTIAL STORAGE-TIME-INDEPENDENT QUALITY METRIC

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**Background:** The effect red blood cell (RBC) storage and 'storage lesion' ('new' vs 'old' blood) has on transfusion efficacy and outcomes remains the subject of a considerable debate. However, focusing on storage time as the sole metric for RBC viability loss ignores the variability in properties of RBC even of the same age. Units in storage can potentially differ due to donor-specific differences as well as due to differences in pRBC manufacturing and storage protocols. While the clinical relevance of any in-vitro metrics remains to be shown, it is important to assess age-independence and inter-unit variability of candidate metrics. RBC membrane mechanical fragility has been proposed as a metric of storage lesion potentially relevant to cells' performance in-vivo. **Aims:** To evaluate variability and storage-time dependence of RBC membrane mechanical fragility, and its dependence on several donor-specific and manufacturing variables.

**Methods:** Fifty-nine pRBC samples, all leukoreduced and irradiated, were collected (sample combined from four test segments identical in content to the units) and characterized by storage time (AGE), total hemoglobin (HBT), auto hemolysis (AH), blood type, and donor demographics. To obtain variable-parameter fragility profiles, mechanical stress was applied using a bead mill with the oscillation frequency held at 50 Hz while durations were varied between 0.5 and 45 min. Fragility profiles were described in terms of hemolysis levels at particular durations (H), the inverse thereof (S), and the slope of the fragility profile curve (K).

**Results:** pRBC units exhibited complex and varied mechanical fragility (MF) profiles with many profiles indicative of the existence of intra-unit sub-populations with significantly different MF properties. Samples from different units varied significantly in their MF properties, varying by up to 100-fold for some fragility parameters. Overall, AGE was not a significant predictor of pRBC fragility parameters, accounting for a maximum of 13% of their observed variability. No statistically significant correlation was observed between the MF parameters and donor-specific variables including donor age, hemoglobin at donation, gender and race. Auto-hemolysis was weakly correlated

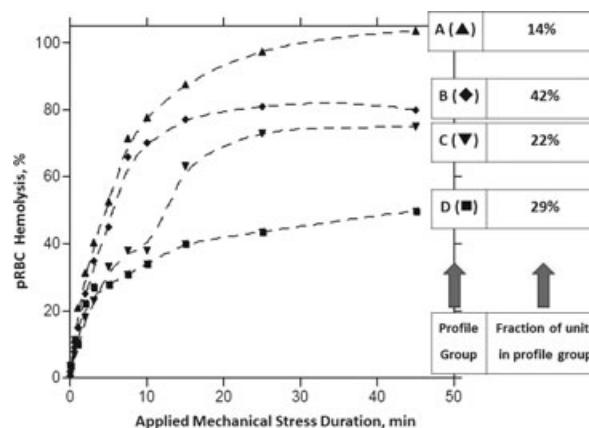
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with both MF parameters and with AGE, indicating that its variability is due predominantly to other, age-independent factors. Method of pRBC manufacturing (whole blood vs apheresis) was an independent predictor of pRBC MF and was responsible for up to 20% variability for some fragility parameters.

Figure 1: Examples of pRBC mechanical fragility profiles



**Conclusions:** High variability and complexity of pRBC mechanical fragility profiles and parameters, including their suggestion of distinct sub-populations, demonstrates the potential of MF to characterize RBC quality. MF properties, though highly variable, were only weakly correlated to storage time. Certain manufacturing methods were found to be a potentially stronger predictor of pRBC membranes' ability to withstand mechanical stress. Remaining variability in MF fragility was likely due to the impact of other manufacturing variables and donor-to-donor differences.

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#### 4C-S30-04

### EFFECT OF LIPEMIC PLASMA ON THE IN VITRO QUALITY OF CELLULAR BLOOD COMPONENTS DURING STORAGE

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**Background:** Dutch guidelines for blood transfusion require that plasma should be not turbid or lipemic (not milky). In case of lipemic plasma, the accompanying cellular components will not be used for transfusion. However, no data on the effect of lipemic plasma on the quality of cellular blood components during storage are available.

**Aim:** The aim of our study was to investigate the effect of lipemic plasma on the quality of cellular blood components during storage.

**Methods:** Whole blood (500 ± 50 ml) was collected in CPD, centrifuged and separated automatically with the Compomat<sup>TM</sup> G5 into a plasma, buffy coat (BC) and red cell concentrate (RCC). Units that were discarded from regular component production because of lipemic plasma were used for further processing. Plasma was sampled for triglyceride analysis. After addition of SAGM, the RCCs were leukodepleted by filtration. RCCs were stored at 2–6°C for 42 days and sampled at regular intervals for in vitro analysis. BCs were used to make a single donor platelet concentrate (SD-PC) in plasma. SD-BCs were stored on a flatbed shaker at 20–24°C and sampled at days 1, 6 and 8 for in vitro analysis. Cellular components made from lipemic blood (n = 8) were compared with those made from regular, non-lipemic blood (n = 11). Values are expressed as mean ± SD. Differences between groups were determined using Student's t-test. Values below 0.05 were considered significant.

**Results:** The triglyceride concentration of lipemic plasma and normal plasma were 6.9 ± 3.0 and 1.5 ± 0.6 mM respectively. The results of SD-PC during storage are shown in the table. Platelets stored in lipemic plasma showed stronger decline in pH and swirling as compared to storage in regular plasma. Metabolic activity, as measured by lactate production, and activation (number of CD62 positive cells) were more pronounced during storage in lipemic plasma. The high numbers of PS-positive cells combined with the high oxygen tension and the decline in platelet count, suggest that a vast majority of platelets is apoptotic after 8 days storage in lipemic plasma. Red cells prepared from lipemic WB showed significantly higher levels of hemolysis during storage. The level of hemolysis correlated with the triglyceride concentration in the plasma: especially RCC made from WB with a triglyceride concentration above 10 mM showed high levels of hemolysis. For the other in vitro parameters, including glucose