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IN VITRO CELL QUALITY OF PLATELETS TREATED WITH MIRASOL∩ PRT AT THE BEGINNING OF STORAGE AND GAMMA-IRRADIATED AT DIFFERENT TIMES DURING STORAGE

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Background: Mirasol pathogen reduction technology (PRT) treatment targets nucleic acids and inactivates leukocytes and a wide range of bacteria, viruses and parasites that may be present in blood products. This process involves the addition of riboflavin in combination with UV light. Data from prior clinical studies showed that patients who received Mirasol treated platelets had comparable hemostasis and transfusion requirements to patients receiving untreated control platelets. In addition, no adverse reactions or safety concerns after transfusion to patients were observed. Leukocytes in blood products have been shown to lead to a number of donor anti-recipient responses such as transfusion-associated graft versus host disease (TA-GVHD). Current approaches to inhibit such responses include leukoreduction and exposure of blood components to gamma-irradiation. Although Mirasol treatment by itself has been shown to effectively prevent TA-GVHD, blood centers or transfusion services may want to have the option to also perform gamma-irradiation on platelet units treated with Mirasol.
Aim: The objective of this study was to evaluate the in vitro cell quality of platelets after Mirasol PRT treatment plus gamma-irradiation.
Methods: Single donor platelets suspended in plasma were collected on the Trima apheresis platform. Units were Mirasol treated after collection followed by gamma-irradiation on day 1, 4 or 5 of storage. A panel of in-vitro cell quality parameters was analyzed at day 5 of storage. Data was obtained from two different study sites: the site in the US compared gamma-irradiation on day 4 to day 5 and the site in Spain compared gamma-irradiation on day1 to day 4. Toxicology assessment of samples after treatment was performed at the US site.
Results: The cell concentration of collected products was between $1400–1600 \times 10^6$/mL in 250–300 mL of plasma. The addition of riboflavin (35 + 5 ml) decreased the cell concentration of Mirasol treated products from 1549 ± 88 to $1229 \pm 77 \times 10^6$/mL. As previously described, the Mirasol PRT process induces an increase in platelet glycolysis as represented by increases in glucose consumption and lactate production. The glucose concentration on day 5 in treated products compared to untreated products was 7.22 + 1.74 vs. 7.98 + 1.23 mmol/10^{12} cells. The same trend was observed for the lactate concentration on day 5 in treated products compared to untreated products, which was 9.36 + 1.38 vs. 5.34 + 0.64 mmol/10^{12} cells. The higher metabolic rate triggered by the Mirasol process was also reflected in increased P-selectin expression on day 5 (52.9 + 9.9 vs. 28.2 + 11.0%). Values for pH (22°C) on day 5 were decreased in treated products (7.07 + 0.15 vs. 7.45 + 0.09). Day 5 in vitro cell quality of Mirasol treated products gamma-irradiated on day1 and day 4 or day 4 and 5 of storage showed no statistically significant difference between the time points of gamma-irradiation. At each site, all in vitro cell quality parameters analyzed were comparable, independent of the day of irradiation ($p > 0.05$). Toxicology assessment of Mirasol treated platelets gamma-irradiated on day 5 of storage showed no geno- or acute toxicity or neoantigenicity in treated platelets. The concentration of riboflavin or its photoproducts (2′-Ketoriboflaivn, 4′-Ketoriboflavin, Formylmethylflavin and Lumichrome) was not significantly affected by gamma-irradiation.
Conclusion: As observed in earlier studies the Mirasol PRT treatment process increases platelet cell metabolism. Nevertheless in vitro cell quality parameters remain within acceptable ranges for clinical use. Mirasol treatment plus gamma-irradiation on day 1, 4 or 5 of storage does not alter the *in vitro* cell quality of platelets, making gamma-irradiation at any time point throughout storage feasible.

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THE MIRASOL EVALUATION PROGRAM: USE OF MIRASOL PATHOGEN REDUCTION TECHNOLOGY FOR PLATELETS IN ROUTINE CLINICAL PRACTICE

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Background: MIRASOL pathogen reduction technology (PRT) treatment inactivates leukocytes and a wide range of bacteria, viruses and parasites in blood products. The system involves the addition of riboflavin in combination with UV light. Platelet products are treated in 100% plasma and can be stored in plasma or additive solution. The system is currently CE-marked for plasma and platelets and has been implemented in several European blood centers.
Aims: Evaluation of the Mirasol system for platelets and disposables in routine use.
Methods: The Mirasol PRT System for Platelets and Plasma has been evaluated under routine use conditions in blood centers throughout Europe. Data on ease of use of the process and in vitro cell quality was collected. Follow-up on patients transfused with Mirasol treated platelets was performed. The Mirasol process was evaluated for ease of use by a rating scale from 1 (excellent) to 4 (poor); *in vitro* evaluation included cell counts, swirl, pO2, pCO2, pH, glucose and lactate con-

Table 1. *Most units were transfused prior to day 5 (for abstract P-395).

	Pre-illumination (approx. n=111)	Post-illumination (approx. n=108)	Day 5 (approx. n=34*)
pO_2 (mmHg)	98 +/- 41	75 +/- 39	67 +/- 27
pCO_2 (mmHg)	55 +/- 20	47 +/- 16	23 +/- 8
pH (22°C)	7.3 +/- 0.2	7.2 +/- 0.2	6.9 +/- 0.3
Glucose concentration (mmol)	18 +/- 3	16 +/- 3	9 +/- 3
Lactate concentration (mmol)	4 +/- 3	4 +/- 2	13 +/- 3
Yield ($x10^{11}$)	3.52 +/- 0.8	3.53 +/- 0.7	3.54 +/- 0.5

