STeady Performance and Multiple Procedures: Two Soft-Housed Platelet Concentrates Leukodepletion Filters Provide Evidence

IT IS FEASIBLE

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BACKGROUND  Quality and reliability are pivotal features in the processing of blood components and mainly of platelet concentrates (PCs). Manifold, different platelet (PLT) handling procedures and storage conditions are available which affect platelets quality and reactivity. To this purpose, Fresenius HemoCare designed two new soft-housed filters intended for the laboratory leukodepletion of PCs by gravity, through manual procedure (BioP flex), or by pressure, through the use of an automatic separator (Bioflex CS), in order to increasingly fulfil quality market requirements, improving standardization and easy-of-use.

METHODS  A different number of PCs was leukoreduced over the BioP flex (gravity procedure) or the Bioflex CS (automatic procedure under pressure) filters in different blood banks, following their own internal procedures. Test conditions were selected as to handle blood components of different age (fresh or old), suspension medium (Composol® or plasma), volume and cellular concentration.

RESULTS  Table I and II show collected data for BioP flex and Bioflex CS filters, respectively (C = Composol®, P = plasma). Both filters show a steady level of leukocyte depletion in all working conditions. The soft-housing allows the effortless emptying of filters at the end of filtration without the need of further manipulation, thus promoting the production of PCs with a high PLT yield.

Gravity procedure: the BioP flex filters (picture 1) were connected to the PC bags and filtrations were performed by gravity; volume, PLT and leukocyte (WBC) concentrations were assessed on both pre- and post-filtration samples; filtration times were also recorded. The priming phase was performed with filter in upside down position.

Automatic procedure: the Bioflex CS filters (picture 2) were connected to pools of 5 BCs in Composol® or in plasma, then centrifuged according to individual blood banks settings. Separation and leukoreduction of PLT-rich supernatant was performed on Compat G4 automatic device, according to a dedicated program. Volume and cell concentrations were assessed on BC-pool, BC-residue and leukoreduced PC (LR-PC).

RESULTS  Table I and II show collected data for BioP flex and Bioflex CS filters, respectively (C = Composol®, P = plasma). Both filters show a steady level of leukocyte depletion in all working conditions. The soft-housing allows the effortless emptying of filters at the end of filtration without the need of further manipulation, thus promoting the production of PCs with a high PLT yield.

Gravity procedure: flow rate through BioP flex filter keeps steady from 1 to 5 days storage and from additive solution to plasma use. The flexible housing allows the emptying of the filter at the end of filtration, thus setting the average volume loss on 15 ml without further manipulation. The mean PLT recovery of BioP flex filter is usually above 90%. A slight decrease was recorded when PLT at the expiry date were used, as it is well known from literature that, during storage, variable degrees of PLT lesions may occur, resulting in decreased levels of in vitro quality markers and an unavoidable cell loss.

BioP flex filter well keeps residual WBC below $1 \times 10^6$/unit, even when the cellular pre-filtration load in day-1 group was increased on purpose (WBC pre-filtration load $> 1 \times 10^9$/unit). A capability analysis of long term leukodepletion performance was carried out on the most consistent group of fresh PLT in Composol® (n = 127) using the software Minitab 15®. Residual WBC data, recorded on different filter batches, were neither normally distributed, nor a transformation or a distribution able to fit them was identified; therefore, the empirical percentile method was applied (A). BioP flex 05 filter could claim for a 99% conformity to $1 \times 10^6$ WBC/unit regulatory limit with 95% confidence.
Automatic procedure: The assessment of filtration PLT recovery in automatic procedures was instead very difficult, as the end result is deeply affected by BC pool processing and the amount of PLT retained in the BC-residue.

Nevertheless, we could establish that the PLT yield was in line with local requirements and a steady level of WBC depletion was reached in all working conditions. The addition of plasma, for instance, promoted the extraction of PLT from red cells and ensured a higher PLT yield. Anyway, the small volume loss of Bioflex CS filter maximized PLT recovery.

PLT production was also monitored in routine (Centre D) to assess the short term process capability (Cpk). 54 procedures were monitored (5 BCs pooled in plasma). The PLT yield requirement was fixed at \( 250 \times 10^9/\text{unit} \): the process was under control and the expected % defectiveness \(< 0.250 \) was 0.8%, with a Cpk=0.84. 13/54 WBC counts were below the detection limit of FACs and all were below 160.000 /unit. The WBC not normal data distribution allowed only a non-parametric approach to process capability (Poisson distribution\(^{(B)}\)): \( > 90\% \) conformity to \( 0.2 \times 10^6 /\text{unit} \) limit with 95% confidence was assessed.

CONCLUSIONS  The soft-housing of the 2 new designed PC leukodepletion filters promotes both handling (better and safer centrifuge placement, effortless emptying of filters at the end of filtration) and quality (steady WBC depletion and optimised PLT recovery). The performance data relevant to different procedures suggest the reliability of the two filters into the wide-ranging manual and automatic production methods for leukoreduction of PCs.

REFERENCES  (A) Capability indices for non normal data, Quality engineering 12 (4), 489-495 (2000)

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