New Closed System Using a Sterile Connection Device and Preconnected PRP Pack for Extended Storage of Apheresis Platelet Products

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Recently, a unique sterile connection device (SCD, SCD™ model 312, DuPont, Wilmington, DE, USA) was developed to make a sterile, welded connection between two pieces of tubing through an application of the thermal welding process. Here we wish to introduce a new functionally closed system using such a device for collection of single donor platelet-rich plasma (PRP). Fig. 1 shows a disposable apheresis set of a plasma collecting system (PCS, Haemonetics Corp., Braintree, MA, USA), in which the apheresis bowl set was preconnected with a 16G needle and a double 0.6- and 1-liter polyvinyl chloride (PVC) plastic (plasticizer: di (2-ethylhexyl) phthalate, DEHP) bag system (Kawasumi Co., Ltd., Tokyo) for plasma and platelet preservation. A 0.5-liter of acid-citrate-dextrose formula A (ACD-A) solution was sterilized in PVC bags with preattached 20 cm tubing (Kawasumi Co.

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At the beginning of plateletapheresis, the tubing from the ACD-A solution and the anticoagulant line from the apheresis set were sterilely welded by using the SCD device. The preconnected Haemonetics PRP pack (List No. 685), including a double 1-liter PVC (plasticizer: tri (2-ethylhexyl) trimellitate, TOTM) and 0.6-liter PVC/DEHP bags (Cutter Biol., Berkeley, CA, USA), was also used. Twelve volunteers underwent PRP collection in the new closed Haemonetics PCS system with a 1:12 ratio of ACD-A solution. A 450 ml of PRP in 1-liter PVC bags was centrifuged at 2055 × g for 6 min to prepare platelet concentrates (PCs) followed by flat-bed agitation at 22°C for 5 days. Using the SCD with a preconnected harness simplified the overall procedure. The volume of PRP collected was 465 ± 10 ml (mean ± s.d.; n = 12). No bacterial growth appeared in PCs after two week culture. The pH at 37°C of 5-day-stored 6 PCs was 7.1 ± 0.1 in PVC/DEHP bags containing 0.8–1.2 × 10^{11} platelets and 7.0 ± 0.1 in PVC/TOTM bags containing 0.8–1.4 × 10^{11} platelets. The shelf life of platelet products is determined by two major factors, the sterility and viability of stored platelets (Strauss et al. 1987). Bacteria were only occasionally detected even in the open system (Szymanski 1985). Although the present study is not on a large scale, it suggests that the connection using SCD between the preconnected PRP set and ACD-A solution may reduce the chance of bacterial introduction into the system at the injection site of the ACD-A bag. Platelet deterioration has been noted in vitro when PC pH is decreased below 6.2 (Murphy 1985). The oxidative metabolism of platelets may play a key role in maintaining PC pH at a neutral level during storage (Kilkson et al. 1984). The present 1-liter PVC/DEHP and PVC/TOTM bags can contain platelets of the maximum number of 1.7 × 10^{11} and 2.2 × 10^{11}, respectively, with the oxidative metabolism (Kouketsu and Shimizu 1988). Therefore, if the number of platelets per bag is limited to below the above mentioned values, the rapid fall of pH of PCs could be prevented.

**References**