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Novel highly biocompatible hollow fiber membrane for plasma filtration

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The blood of a donor or patient can be separated by plasma separation or apheresis medical technologies. The separation of whole blood into plasma and cellular components can be achieved either by centrifugation or by passing the blood through a plasma separation membrane. While centrifugation techniques have the advantage of being fast and cost effective, they often fail by leaving impurities of cells or cell debries in the separated plasma. In order to overcome the disadvantages of centrifugation systems, membrane systems have been introduced for plasmapheresis.[1,2]

The requirements of a plasma separation membrane for plasmapheresis can be classified into those related with its separation properties (high sieving coefficient for the whole spectrum of plasma proteins and lipoproteins; high filtration performance; hydrophilic, spontaneously wettable membrane structure and low fouling properties) and those required for a medical device (low protein adsorption; smooth surfaces in contact with blood; low or no tendency to haemolysis during blood processing; good biocompatibility, no complement activation, low thrombogenicity; sterilizability by steam, gamma radiation and/or ETO; low amount of extractables).[3,4] Here we introduce a novel highly biocompatible hollow fiber membrane for plasma filtration with outstanding separation performance.

The Plasmylane 6 membrane is manufactured by solution spinning through a nozzle followed by phase inversion in a coagulation bath. The polymer solution consists of a blend of poly(aryl ether sulfone) (PAES) and poly(vinyl pyrrolidone) (PVP). Each hollow fiber has an inner diameter of approximately 320 □m (hollow fiber internal diameter) and a wall thickness of 50 □m. The membrane is packed into filters with a total membrane surface area of either 0.15 or 0.6 square meters.

The membrane structure has been tailored for optimized biocompatibility and enhanced separation performance. As can be seen in Fig. 1(a), the inner surface is very smooth, a characteristic that promotes a positive blood contact and is expected to be the cause for the low thrombogenicity and absence of complement activation observed during in vitro and in vivo studies. Additionally, the separation layer is not located at the inner surface of the hollow fiber but rather close to the outer surface, as can be observed from the cross-sectional image in Fig. 1(b). This shift of the selective layer towards the interior of the membrane allows for high filtration rates without performance detriment due to protein fouling on the membrane inner surface. This is reflected on very stable filtration and sieving properties during treatment.

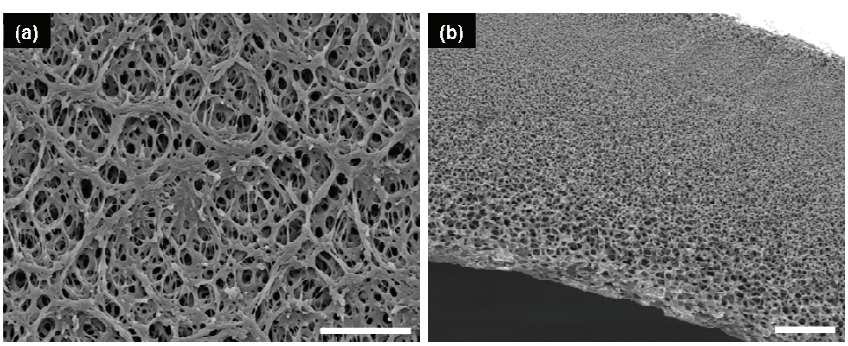

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Figure 1: Scanning electron micrographs of the (a) inner surface and (b) cross-sectional cryogenic fracture of the plasma filtration hollow fiber membrane in Plasmylane 6. Scale bar represents 10 □m.

The membrane development presented is a first-class example of how tailoring the membrane structure leads to a performance optimization that has not been achieved in the plasma separation membranes to the date. The Plasmylane 6 membrane present separation and biocompatibility characteristics that are unmatched by commercially available filters and will therefore set a new benchmark for plasma separation membranes.

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