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Technical note

A numerical performance assessment of a commercial cardiopulmonary by-pass blood heat exchanger

Filippo Consolo[a,*], Gianfranco B. Fiore[a], Alessandra Pelosi[a], Stefano Reggiani[b], Alberto Redaelli[a]

[a] Dipartimento di Elettronica, Informazione e Bioingegneria, Politecnico di Milano, Piazza Leonardo da Vinci 32, 20133 Milano (MI), Italy
[b] Sorin Group Italia, Via Statale 12 Nord 86, 41037 Mirandola (MO), Italy

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ABSTRACT

We developed a numerical model, based on multi-physics computational fluid dynamics (CFD) simulations, to assist the design process of a plastic hollow-fiber bundle blood heat exchanger (BHE) integrated within the INSPIRE^{TM}, a blood oxygenator (OXY) for cardiopulmonary by-pass procedures, recently released by Sorin Group Italia. In a comparative study, we analyzed five different geometrical design solutions of the BHE module. Quantitative geometrical-dependent parameters providing a comprehensive evaluation of both the hemo- and thermo-dynamics performance of the device were extracted to identify the best-performing prototypical solution. A convenient design configuration was identified, characterized by (i) a uniform blood flow pattern within the fiber bundle, preventing blood flow shunting and the onset of stagnation/recirculation areas and/or high velocity pathways, (ii) an enhanced blood heating efficiency, and (iii) a reduced blood pressure drop. The selected design configuration was then prototyped and tested to experimentally characterize the device performance. Experimental results confirmed numerical predictions, proving the effectiveness of CFD modeling as a reliable tool for *in silico* identification of suitable working conditions of blood handling medical devices. Notably, the numerical approach limited the need for extensive prototyping, thus reducing the corresponding machinery costs and time-to-market.

1. Introduction

For open-heart surgery that requires cardiopulmonary by-pass (CPB), a blood heat exchanger (BHE) is used to control the patient's blood temperature during the surgery. An integral component of a BHE is a hollow-fiber membrane oxygenator (OXY). In the last few years, the design of cross-flow BHEs based on polymeric hollow-fibers was developed [1]. In those devices, the heating fluid (usually water) is delivered to the inner lumen of the hollow fibers while venous blood is gently channeled through the extracapillary space of the fiber bundle to absorb the necessary heat while passing through the fibers.

Plastic fiber BHEs provide many advantages over the limitations associated with traditional BHEs made with metal (e.g., stainless steel) heating coils [2]. Essentially, the introduction of plastic heating elements dramatically improved the device biocompatibility. In fact, even though they require higher surface contact area to counterbalance the limited heat capacity rate of plastic materials and ensure effective warming of the blood, platelets' contact activation is reduced significantly in plastic fibers. Coating of the fiber surface with proteins/molecules offer enhanced antithrombotic behavior, which is adopted often to further decrease thrombus susceptibility, without compromising the heat exchange efficiency [3]. In addition, in plastic fibers, most of the temperature gradient occurs across the fiber wall thickness rather than at the blood–fiber surface interface, which intrinsically limits the local thermal shock to blood constituents at the fiber wall-adjacent blood layers. Also, plastic hollow-fiber bundles provide a gentle transfer of heat through a stable (as opposed to tortuous, or even turbulent) blood stream, so that, stagnation/recirculation areas eliciting thrombus formation, and high velocity pathways, responsible of non-physiologic shear stress inducing hemolysis and platelet activation, are minimized. Moreover, multiple layers of fibers are packed to form compact size bundles leading to reliable design solutions with reduced priming volumes. Lastly, the use of polymeric fibers results in a faster manufacturing process and comparable manufacturing costs with respect to metal BHE; although metallic heating coils are potentially cheaper than plastic fibers, indeed, the plastic fibers allow assembly of both the OXY and BHE modules through a one-step manufacturing procedure, namely a single potting of the two fiber bundles.

* Corresponding author. Tel.: +39 02 2399 4144; fax: +39 02 2399 3360.
E-mail address: filippo.consolo@polimi.it (F. Consolo).

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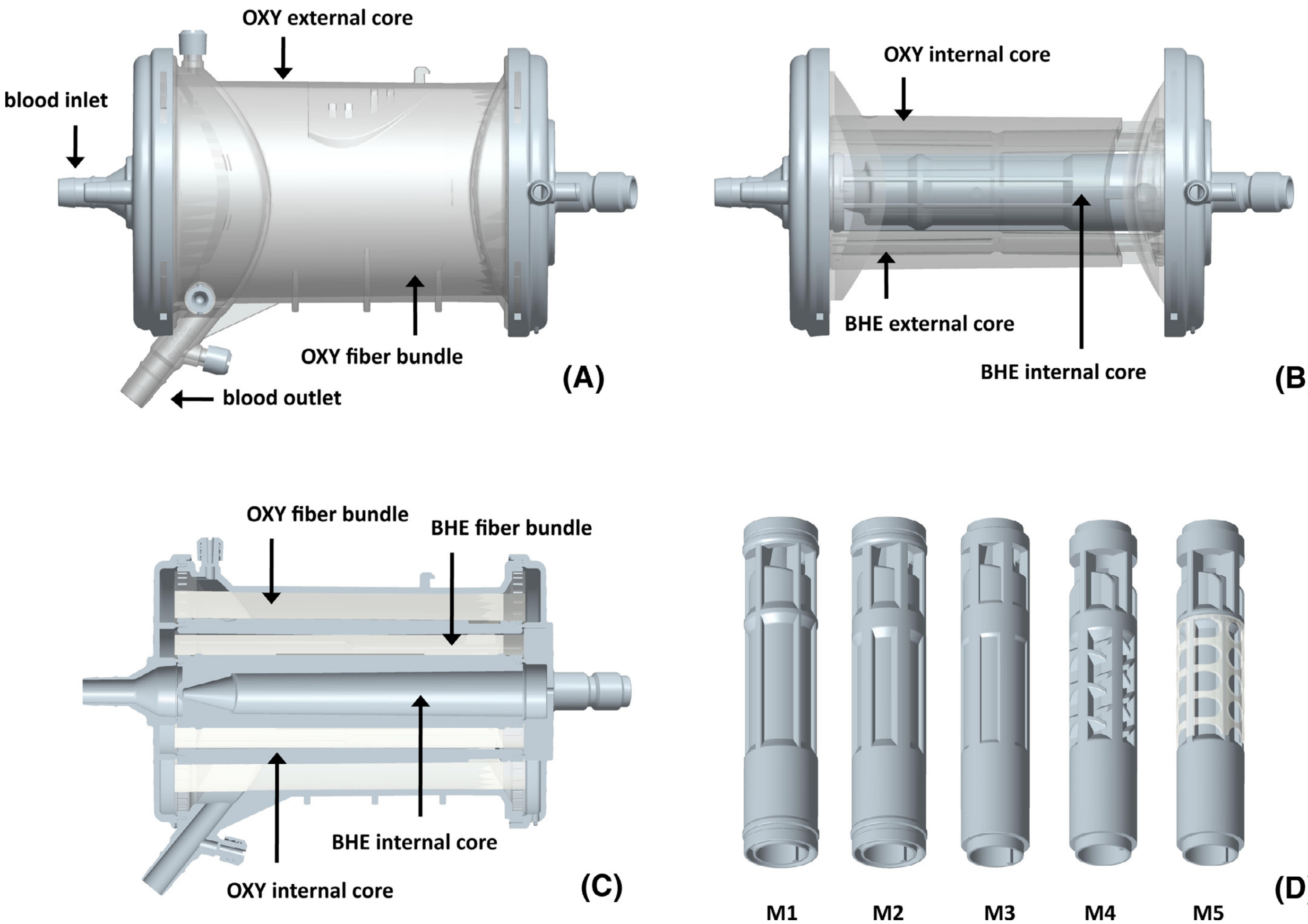

Fig. 1. Internal view CAD 3D drawings of the INSPIRE^{TM} blood OXY-HE module showing (A) the OXY fiber bundle, (B) the OXY internal core and the outer and inner solid cores surrounding the BHE fiber bundle; (C) cross-sectional view showing a cut-away portion of the device in the longitudinal plane; (D) CAD 3D drawings of the five different prototypes of the BHE internal core.

Nevertheless, the use of plastic fiber bundles introduces the need to preserve a proper spatial arrangement of the fibers to ensure the blood flows uniformly, with minimal resistance/disturbance to flow. Indeed, flow shunting can result from preferential pathways for blood flow caused by inadequate fit of the fiber bundle to the supporting case or from regions of non-uniform fiber packing within the bundle [4]. In those situations, the blood could partially (or entirely) bypass the fiber mat without being adequately heated before re-infusion into the patient, eventually degrading or totally compromising the device efficacy. To prevent the onset of such undesired conditions, convenient geometrical design solutions must be considered.

The present work is a performance assessment study aimed at identifying a convenient design solution of a new commercial plastic fiber BHE integrated into a hollow-fiber OXY, called INSPIRE^{TM}, recently released by Sorin Group Italia (SGI) and intended for use in adult patients during open-heart surgery. Within the device, transverse blood flow was established, enabling multiple passages of the blood through the fibers to enhance heat exchange efficiency, without any relevant increase in device priming volume or in blood-surface contact area with respect to currently available BHEs. In a comparative analysis, the hemo- and thermo-dynamics performance of five different prototypical BHE geometries were evaluated. The five different configurations were conceived by SGI as possible design solutions addressing the multiple technical requirements of BHEs, and, in particular, in order to effectively support the polymeric fiber bundle. Through a numerical approach based on multi-physics computational fluid dynamics (CFD) simulations, we identified the design solution complying with the most convenient trade-off in terms of (i) uniformity of blood flow patterns within the fiber bundle to prevent blood flow shunting and the formation of stagnation/recirculation areas and/or turbulent blood flow; (ii) enhancement of heat transfer efficiency; (iii) minimization of pressure drops and (iv) minimization of priming volume, as general design requirements for any CPB device. The selected design was then prototyped and tested and *in vitro* data were compared with respect to CFD predictions.

2. Materials and methods

2.1. Device description

The device (Fig. 1A–C) consists of two pseudo-cylindrical polymeric hollow-fiber bundles (OXY: polypropylene, BHE: polyurethane fibers) coaxially arranged within the external housing where the blood inlet and outlet ports are located. In particular, the bundle of the BHE unit is housed within a cylindrical external shell and an inner core connected to the inlet port facilitating the blood to be pre-heated in the BHE fiber bundle. The inner and outer surfaces of the BHE are provided with six longitudinal ribs each, which provide vanes between the hollow fiber bundle and the inner cylindrical core and the outer shell, respectively. Such vanes are spatially arranged to impart a radial component to the blood flow, a characteristic design