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Experimental quantification of the fluid dynamics in blood-processing devices through 4D-flow imaging: A pilot study on a real oxygenator/heat-exchanger module

Filippo Piatti [a,1,*], Maria Chiara Palumbo [a,1], Filippo Consolo [a,b], Francesca Pluchinotta [c], Andreas Greiser [d], Francesco Sturla [a], Emiliano Votta [a], Sergii V. Siryk [e], Riccardo Vismara [a], Gianfranco Beniamino Fiore [a], Massimo Lombardi [c], Alberto Redaelli [a]

[a] Department of Electronics, Information and Bioengineering, Politecnico di Milano, Milan, Italy
[b] Anesthesia and Cardiothoracic Intensive Care, Università Vita Salute San Raffaele, Milano, Italy
[c] Multimodality Cardiac Imaging Section, IRCCS Policlinico San Donato, San Donato Milanese, Milan, Italy
[d] Siemens Healthcare GmbH, Erlangen, Germany
[e] National Technical University of Ukraine "Kiev Polytechnic Institute", Kiev, Ukraine

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ABSTRACT

The performance of blood-processing devices largely depends on the associated fluid dynamics, which hence represents a key aspect in their design and optimization. To this aim, two approaches are currently adopted: computational fluid-dynamics, which yields highly resolved three-dimensional data but relies on simplifying assumptions, and *in vitro* experiments, which typically involve the direct video-acquisition of the flow field and provide 2D data only. We propose a novel method that exploits space- and time-resolved magnetic resonance imaging (4D-flow) to quantify the complex 3D flow field in blood-processing devices and to overcome these limitations.

We tested our method on a real device that integrates an oxygenator and a heat exchanger. A dedicated mock loop was implemented, and novel 4D-flow sequences with sub-millimetric spatial resolution and region-dependent velocity encodings were defined. Automated *in house* software was developed to quantify the complex 3D flow field within the different regions of the device: region-dependent flow rates, pressure drops, paths of the working fluid and wall shear stresses were computed.

Our analysis highlighted the effects of fine geometrical features of the device on the local fluid-dynamics, which would be unlikely observed by current *in vitro* approaches. Also, the effects of non-idealities on the flow field distribution were captured, thanks to the absence of the simplifying assumptions that typically characterize numerical models.

To the best of our knowledge, our approach is the first of its kind and could be extended to the analysis of a broad range of clinically relevant devices.

1. Introduction

Blood-processing devices are widely used in different clinical applications. These include, e.g., total artificial hearts and ventricular assist devices for heart failure patients, mass/heat exchangers to be used in cardio-pulmonary bypass, in extracorporeal membrane oxygenation or in hemodialysis, as well as prosthetic heart valves.

The detailed and comprehensive analysis of the fluid dynamics within blood-processing devices represents a key aspect during their design optimization process. On the one hand, fluid-dynamic optimization addresses important blood-handling-related issues, such as shear stress overstimulation of red blood cells and platelets (Bluestein et al., 2010; Consolo et al., 2016), respectively. On the other hand, for many of such devices it is the device function itself that relies on inner fluid dynamics: this particularly applies, e.g., for fiber-based blood treatment devices such as oxygenators (Bhavsar et al., 2011; Gage et al., 2002; Haworth, 2003), polymeric heat exchangers (Consolo et al., 2015; Segers et al., 2001), dialyzers (Eloot et al., 2002), blood purification cartridges (Fiore et al., 2006b; Ronco et al., 2001).

So far, fluid-dynamic analyses are carried out through numerical, e.g., computational fluid dynamics (CFD), or experimental

* Corresponding author.
E-mail address: filippo.piatti@polimi.it (F. Piatti).
[1] These authors equally contributed to the work.

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methods. In the former case, a highly space- and time-resolved 3D quantification of the fluid dynamics is obtained, but several assumptions are needed to implement the model. These typically include the idealization of the device geometry (Malinauskas et al., 2017), the description of the fiber bundles through the use of porous media models (Zhang et al., 2007), the simplified description of blood rheological properties (Zhang et al., 2007), and, in case of fluid–structure interaction models accounting for the motion of deformable solid components, the modeling of inertial and mechanical properties of solid materials (Long et al., 2014). On the other hand, experimental quantifications mostly rely on techniques requiring the direct vision of the velocity field, as in the case of particle image velocimetry (PIV) (Kaesler et al., 2017; Schlanstein et al., 2015) and laser doppler velocimetry (LDV) (Taylor et al., 2016). Hence, this class of techniques is inherently limited to the analysis of transparent devices or prototypes, hampering their application to tests with whole blood. Also, with few exceptions, these analyses yield only 2D quantifications that can be inadequate when dealing with complex three-dimensional systems (Cooper et al., 2008). To avoid the need for direct vision, echo Doppler- (Sato et al., 2003) or scintigraphy-based (Fiore et al., 2006a; Ronco et al., 1992) techniques were proposed in the past, but these were so roughly resolved in space, to be liable to 1D approximations only. These techniques were suitable for the description of the flow field along the length of the fiber bundles of blood hemofilters, and were not versatile enough to be suitable for a wide variety of blood-treatment devices.

In this work, we hypothesized that, in case of devices, or device prototypes, made of non-ferromagnetic materials, it is possible to measure the associated complex 3D fluid dynamics without the need for direct vision, or transparent surfaces, by means of space- and time-resolved phase contrast magnetic resonance imaging (4D-flow), thus overcoming the limitations of the current experimental approaches and the simplifying assumptions that characterize numerical models. 4D-flow imaging has been successfully exploited to quantify the complex three-dimensional blood velocity field in native anatomical districts, including heart chambers (Elbaz et al., 2014), thoracic aorta (Hope et al., 2011; Morbiducci et al., 2009; Piatti et al., 2017b), carotid arteries (Harloff et al., 2009), and cerebral veins (Schuchardt et al., 2015). Currently, the time- and space-resolution of the measured velocity data represent a drawback of the technique (Markl et al., 2014). These are typically in the order of 20–30 frame/cardiac cycle and 1–3 mm, respectively, since they are constrained by the need for minimizing the time required by acquisitions on humans, according to current guidelines (Dyverfeldt et al., 2015). However, time- or space-resolution could be improved if longer acquisitions were possible.

On this basis, we tested our hypothesis on a real device that integrates an oxygenator (OXY) and a heat exchanger (HE): the INSPIRE 6 LPM module by Sorin (LivaNova PLC, London, United Kingdom). This specific device was chosen as benchmark because of three reasons: first, it is entirely fabricated with polymeric materials; second, it is characterized by an extremely complex inner structure that includes bundles of fibers and tortuous paths with sub-millimetric characteristic dimensions; third, our research group contributed to the optimization of the device design (Consolo et al., 2015) and hence has the a priori knowledge of the device structure and functioning needed to implement the study and to judge the reliability of the information yielded by the 4D-flow acquisitions.

2. Materials and methods

2.1. Description of the device

The INSPIRE 6 LPM module (LivaNova PLC, 2016) is characterized by a pseudo-cylindrical external housing, which includes the inlet and the outlet ports (inner diameter of 9.52 mm); the housing incorporates two coaxial modules, each one containing a polymeric hollow-fiber bundle (Fig. 1a). The CAD model of the device was used to extract the resulting fluid domain (Fig. 1b). The inner module of the domain is the HE, which receives blood from the inlet through six windows (Fig. 1c). The HE fibers are packed on a core element (polyurethane fibers, 0.550 mm diameter, 0.88 mm inter-fiber gaps). The geometry of the surfaces facing the bundle is designed to optimize blood pre-heating (Consolo et al., 2015): longitudinal ribs drive blood along radial cross-flow paths that run radially inwards through the bundle into six internal vanes and then outwards into ten external vanes (Fig. 1c). The HE module is connected to the OXY module through an interface composed by eight quadrilateral windows (Fig. 1d). By crossing the OXY bundle fibers (polypropylene fibers, 0.480 mm diameter, 0.67 mm inter-fiber gaps), blood is oxygenated and guided towards the collector region and to the outlet port (Fig. 1a, b).

2.2. Experimental set-up and protocol

One INSPIRE 6 LPM module was tested using the ad-hoc hydraulic mock loop sketched in Fig. 2, filled with de-ionized water ($\mu = 1$cP, $\rho = 1000\ kg * m^{-3}$) at room temperature. A centrifugal pump (BM04APP, Savino-Barbera, Brandizzo, TO, Italy) pumped water towards the inlet port of the device with stationary 5 L/min flow rate to replicate clinically pertinent flow conditions; the circuit was then closed into the reservoir, which is connected to the device's outlet port. The flow rate was monitored through a transit-time flow meter (HT110R, Transonic Systems, Ithaca, NY, USA) with a 3/8″ flow probe downstream of the centrifugal pump. The metal components of the circuit were positioned outside of the MR scanner room, while the connections between the hydraulic line and the device were assembled with non-ferromagnetic materials. The estimated priming volume of the hydraulic circuit was about 5 L.

Prior to connecting the device to the mock loop, the ports of the heating fluid/gas lines of the HE/OXY were connected through an auxiliary line. The latter was used to pre-fill the lumen of the fibers with deionized water to avoid fiber collapse and to degas the modules, so to avoid air-induced salt-and-pepper noise effects in the subsequent of 4D-flow acquisitions (Nayak et al., 2015). Degassing of the whole device was repeated after connecting it to the mock loop.

4D-flow acquisitions were performed on a 1.5 T scanner (Magnetom Aera, Siemens Healthcare, Erlangen, Germany). The device was positioned inside the MR scanner with its longitudinal axis parallel to the head-foot direction (Fig. 1b), with a cylindrical phantom alongside to increase the signal received by the scanner. Standard MR scout sequences were performed on short-/long-axis views of the device to confirm the absence of major artifacts related to residual bubbles. Three prototype 4D-flow sequences were performed on the same field of view (FOV) entirely encompassing the device (FOV size $104 \times 149 \times 190$ mm, spatial resolution $0.52 \times 0.52 \times 2$ mm, echo-time 4.36–4.94 ms, repetition time 83.4–176.0 ms, flip angle 8°), and with the same triggering and temporal sampling (100 ms time resolution), using a simulated ECG signal with a 600 ms period. Each acquisition had a different velocity encoding (VENC) set to improve the velocity signal-to-noise ratio in a specific region of the device: (i) 40 cm/s for the HE and OXY bundles ($V_{4D,40}$); (ii) 80 cm/s for the internal and external vanes, and the HE-OXY interface ($V_{4D,80}$); (iii) 200 cm/s for the inlet, the collector and the outlet ($V_{4D,200}$). The average scan time for each acquisition was 45 min. Further details regarding the implementation of the 4D-flow sequences can be found in (Hanneman et al., 2014).