

# PHYSIOLOGICAL BLOOD OXYGENATION AND PUMPING DURING EXTRACORPOREAL CIRCULATION WITH A SINGLE, INTEGRATED DEVICE

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## INTRODUCTION

In clinical practice, extracorporeal circulation (ECC) is normally performed with non-pulsatile flow by means of centrifugal or roller pumps, which makes it rather non-physiological for patients [1-3]. Currently used circuits are quite voluminous, characterized by large priming volumes and by extended blood contact with foreign surfaces. We have previously proposed an innovative ECC device, the *Pumping Oxygenator* (PO) [4], a single, compact device where pulsatile blood pumping and membrane oxygenation are functionally integrated. Its design has been carried out in the perspective of gathering the advantages of physiologic hemodynamics with the benefits of integration and compactness, *i.e.* reduced blood trauma and low intrinsic and extrinsic priming volumes. Prototypes of the new device have been subjected to experimental evaluation both in terms of oxygenation and of pulsatile pumping.

## MATERIALS AND METHODS

Fig. 1 schematically depicts the PO's working principle. A set of non-porous, distensible semipermeable membranes, placed within a rigid housing, delimit a number of parallel blood channels.

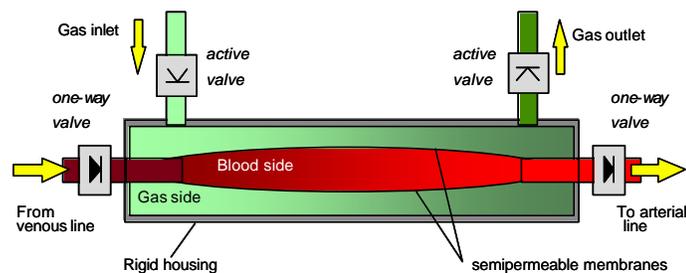


Figure 1. The working principle of the *Pumping Oxygenator*.

Blood enters and leaves the device through one-way valves. The gas side is alternately pressurized/depressurized with oxygen through two active valves, which, thanks to membrane distensibility, causes

pulsatile pumping to be originated as in an ordinary pneumatic pump. Moreover, during both pumping phases blood is supplied with oxygen and stripped of carbon dioxide through the semipermeable membranes.

Pediatric (~ 1 m<sup>2</sup> exchange surface area; 0.7-1.3 l/min blood flow rate) PO prototypes were manufactured by superimposing a number of equal, parallel, flat-membrane blood and gas channels, obtaining a compact device. Fig. 2 is a photograph of one prototype. The detailed design features of such prototypes are summarized in the following:

- Rated blood flow  $Q_b = 700 \div 1300$  ml/min
- Membrane surface width  $W = 100$  mm
- Membrane surface length  $L = 180$  mm
- Exchange surface area  $A_e = 0.97$  m<sup>2</sup>
- Blood film thickness  $t_b = 0.2 \div 0.3$  mm
- Maximum static priming volume  $V_p = 97 \div 146$  ml

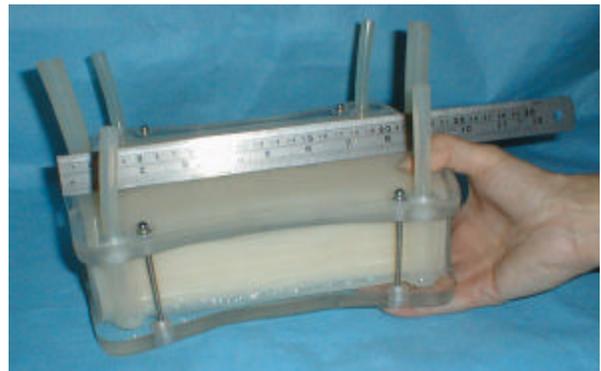


Figure 2. Pediatric prototype.

The realized prototypes were subjected to *in vitro* tests with blood to attest the efficiency of combining pumping and oxygenation. To this purpose, the employed *in vitro* circuit was a standard, closed-loop, deoxygenated circuit where preload and afterload were applied to the tested device by means of recirculated, constant-head weir reservoirs.

Prototypes with  $t_b = 0.2$  mm were tested with vacuum-supplied diastole; prototypes with  $t_b = 0.3$  mm were tested with atmospheric diastole. Oxygenation and carbon dioxide removal were evaluated at different pumping conditions by veno-arterial blood sampling and gas analysis (ABL 500 and OSM 3, Radiometer). Hemodynamic performance was evaluated with separate tests, conducted with a blood analogue. The circuit for such tests is sketched in Fig. 3. The patient's hydraulic impedance was reproduced using a resistant/compliant lumped-parameter paediatric mock bench. The circuit was equipped with transit-time flowmeters (HT 110, Transonic) and pressure probes (140PC series, Honeywell Microswitch). The flow-specific patient-delivered pulsatile power ( $\langle W_{p,s} \rangle$ ) was determined from the tracings measured downstream of the arterial cannula as:

$$\langle W_{p,s} \rangle = \frac{1}{nT \langle Q \rangle} \int_0^{nT} Q(t) \cdot p(t) dt - \langle p \rangle \quad (1)$$

where  $T$  is the cycle period,  $n$  is an integer number of cycles for the numerical evaluation of the integral ( $n = 3$  in our calculations),  $Q(t)$  and  $p(t)$  are the instantaneous measured flow rate and pressure, and  $\langle Q \rangle$  and  $\langle p \rangle$  are their mean values calculated upon  $n$  cycles.  $\langle W_{p,s} \rangle$  was calculated at different operating conditions (pulse rate, mean flow rate, and arterial pipe length) and compared with the  $\langle W_{p,s} \rangle$  delivered by a state-of-the-art pulsatile ECC system, made with an intermittent roller pump and a commercial membrane oxygenator (see Fig. 3).

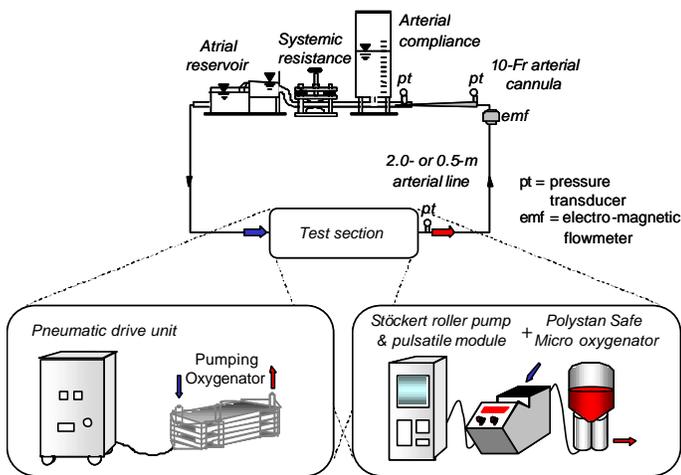


Figure 3. Functional layout of *in vitro* pulsatile power tests.

## RESULTS

Gas transfer results are shown in Fig. 4, both for prototypes with  $t_b = 0.2$  mm and 0.3 mm. Physiological oxygen transfer (5 ml/dl) was obtained at mean flow rate up to 900 ml/min; about 4 ml/dl at 1250 ml/min. Carbon dioxide transfer ranged from 4.8 ml/dl at 400 ml/min to 2.1 ml/dl at 1250 ml/min. Gas transfer is barely influenced by pulse rate, which means that pumping and oxygenation functions may be effectively regulated independently. Prototypes with  $t_b = 0.2$  mm could pump blood at higher flow rate thanks to vacuum suction adopted to facilitate diastolic filling.

Fig. 5 shows the results of the hemodynamic analysis in terms of patient-delivered  $\langle W_{p,s} \rangle$ . In all experimental conditions, the PO's  $\langle W_{p,s} \rangle$  exceeded the roller pump's  $\langle W_{p,s} \rangle$  by an amount of 30% to 80%. Physiologic-like flow waveforms were attainable with the new device, which is unfeasible with the roller pump.

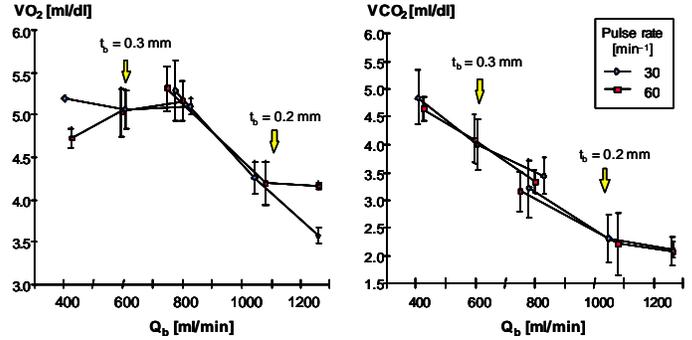


Figure 4. Oxygen and carbon dioxide transfer (veno-arterial increase) vs. delivered flow rate.

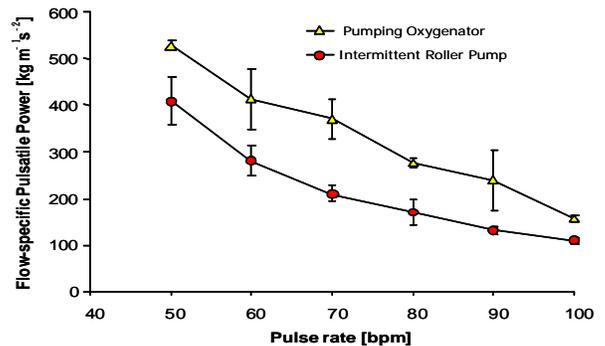


Figure 5. Comparison of the patient-delivered flow-specific pulsatile power.

## CONCLUSIONS

Combining energy transfer (blood pumping) and mass transfer (oxygenation) in a single device has led to satisfactory results. The developed prototypes are capable of transferring physiological  $O_2$  quantities while pumping blood at flowrates within their pediatric range.  $CO_2$  transfer is somewhat impaired by the use of solid silicone membranes, however reaches physiologic levels.

As for the device haemodynamic evaluation,  $\langle W_{p,s} \rangle$  is an index of the benefits of pulsatile flow, related to the amount of additional mechanical energy delivered with respect to steady flow. We therefore infer that the PO allows a more physiological circuit-to-patient fluid dynamic coupling than current circuits. This is accompanied by a greater compactness than state-of-the-art layouts, with minimized priming volume, pipeline length, blood-contacting artificial surfaces.

## REFERENCES

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