

Clinical and *In vitro* Evaluations of Contemporary Oxygenators

Advances in cardiopulmonary bypass equipment have played a critical role in improving outcomes for cardiac surgery patients. Recent advancements include reduced priming volumes, biocompatible coatings and gaseous microemboli (GME) handling, as well as the incorporation of an arterial filter into the oxygenator.

In recent years, all oxygenator manufacturers in Canada have brought new products to the marketplace leading to opportunities for perfusion departments to potentially provide better patient care.

With our current oxygenator nearing the end of its production cycle, we took this opportunity to evaluate all products on the market through both a small clinical evaluation, as well as an *in vitro* GEM evaluation.

Oxygenators assessed in the clinical evaluation included the Sorin Synthesis[®] (n = 30), the Sorin Inspire 6F[®] (n = 10) and Inspire 8F[®] (n = 30), the Terumo FX15[®] (n = 13) and FX25[®] (n = 30), the Maquet Quadrox-i[®] (n = 30) and the Medtronic Fusion[®] (n = 30). Parameters assessed included functional prime volumes, gas exchange, pressure gradients and the effects on patient hematology. The Inspire 6F, 8F and Fusion had the greatest O₂ transfer. The Sorin oxygenators required the lowest sweep gas flows to obtain a PaCO₂ of 40 mmHg. The Sorin oxygenators had the largest pressure gradients. While no differences were observed for hemoglobin and platelet levels post cross-clamp removal, the Sorin Synthesis and Inspire 8F had the largest increases in white blood cell (WBC) counts (122% and 141% of baseline, respectively) and neutrophils (162% and 185% of baseline, respectively). The data demonstrate that no single product is superior in all aspects.

As GME generated during cardiopulmonary bypass (CPB) can present a significant risk to patient outcomes, we chose to conduct an *in vitro* evaluation using the EDAC[®] system. The goal was to evaluate the GME-handling capacity of venous reservoirs *and* oxygenators. The oxygenators evaluated included those of the clinical evaluation with the absence of the Medtronic Fusion[®]. The venous reservoir of the Quadrox-i was the most effective in removing all sizes of GME and total GME load, while the Synthesis was the least effective. The FX15 and FX25 were least effective removing small GME, while the FX15 and Quadrox-i were the least effective at removing medium GME. The Quadrox-i was least effective at removing large GME. In terms of complete venous reservoir/oxygenator systems, the Synthesis permitted the greatest amount of GME to pass, while the other systems appeared largely equivalent.

Ultimately, the choice of ideal oxygenator depends on the aspect(s) of oxygenator performance the perfusion team believes most clinically acceptable based on available data. However, with the increasing influence of purchasing departments on consumables used in these times of fiscal restraint, we propose that perfusion departments become active participants in the process by conducting similar evaluations to demonstrate product quality.