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Evaluation of Mimesys® Phosphorylcholine (PC)-Coated Oxygenators during Cardiopulmonary Bypass in Adults

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Abstract: A new generation of coating extracorporeal circuitry with biocompatible polymers has entered the North American perfusion market. This new biomimetic coating process uses synthetic phosphorylcholine (PC) containing polymers to bond covalently to the surface of the Sorin Monolyth® oxygenator, under the brand name of Mimesys®. In part one of a three-part investigation, 160 Mimesys®-coated oxygenators were randomly evaluated against 36 uncoated oxygenators for blood flow, hemodynamic resistance, and pressure differentials. In part two, retrospective analysis of platelet data collected in this study was compared with platelet data collected from a previous investigation using uncoated Monolyth oxygenators with albumin and crystalloid perfusates. Part three examined the risk-adjusted clinical outcomes of 71 patients treated with Mimesys®-coated oxygenators, compared with 71 case-matched patients treated with uncoated oxygenators. There was no difference found in the Mimesys-coated group, when compared to the control group, with regard to pressure differentials or hemodynamic resistance. However, we conclude that platelet protection with PC-coated Monolyth's using crystalloid perfusates, was similar to platelet protection with albumin perfusates, and significantly better than uncoated Monolyths® using crystalloid perfusates. **Keywords:** phosphorylcholine, phospholipid, coated, oxygenators, biocompatible, platelets, zwitterionic, stroke, pressure excursion, adult, cardiopulmonary. *JECT. 2003;35:6–12*

The possibilities of disease transmission and public concern have dictated the removal of any blood or blood-derived products from routine bypass procedures (1–3), while the marketing side of cardiac care has attempted to answer the needs of their consumers by providing smaller and more highly efficient membranes to achieve prime reduction goals (4,5). It seems that these two well-intended objectives have met head on, with less platelet protection and more efficient oxygenators. The results may have led to growing reports of a phenomenon called High Pressure Excursions (HPE), which are sudden and often transient blockages of the fluid pathway through modern membrane oxygenators by platelets adhering to their surfaces (6–9). It is most likely that HPE has been around for many years (9), but with its very infrequent nature, the larger membrane surfaces that were used, and the previous common use of human serum albumin (HSA) in perfusates, transmembrane pressure events never seemed to surface as a major problem (10,11).

Over the past several years, clinicians have attempted to use various perfusate combinations to preserve platelet protection (11–14), and manufacturers have been developing polymers to solve the problem of bio-incompatibility by coating the surfaces of oxygenators and extracorporeal tubing with biopassive materials that prevent fibrinogen and platelets from reacting to their surfaces (15–17). These surface-modifying additives have taken many forms, such as Carmeda® and Trillium® coatings (Medtronic, Inc., Parker, CO), Duraflo II® (Baxter Healthcare Corp., Deerfield, IL), Surface Modifying Ad-

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ditive® (Cobe-Sorin, Arvada, CO), X Coating® (Terumo Corporation, Tokyo, Japan), and Bioline® and Safeline® coatings (Jostra Medizintechnik, Hirrlinger, Germany) (18).

After years of experience with biocompatibility on contact lenses, guidewires, chest tubes, and coronary artery stents, Biocompatibles, UK™ (England) has joined with Sorin Biomedica to introduce what they believe to be the first true Biomimetic coating (15,19,20). This coating, called phosphorylcholine (PC), is a nonheparin, synthetic phospholipid-based polymer that mimics the outer surface of biological cell membranes, making it biologically inert to native circulation (19). Instead of inhibiting the coagulation cascade, as heparin-coated circuits do, PC essentially imitates the surface of the vascular wall by mimicking the electrically neutral (zwitterionic) hydrophilic head groups (phosphorylcholine) of blood cells and platelets. The main mechanism of action in PC coatings is to minimize the surface adsorption of protein (and its subsequent coagulation consequences) by allowing free water molecules to assume a hydration state with these PC head groups. Therefore, PC coatings do not influence or alter the coagulation process, but mimic a biological membrane surface with a stable, inert, nontoxic, and nonleaching surface coating (19).

In 1998, under the trade name of PHISIO®, phosphorylcholine coatings were released in Europe for pediatric CPB surfaces by Dideco™ (Sorin Biomedica, Mirandola, Italy). Initial in vitro results by DeSomer et al. (21), using the PC-coated Dideco D901® oxygenators, showed promising results on platelet and complement activation in neonates. These were followed by clinical evaluations in both the pediatric and adult populations using the D901® and the Avant® (Dideco, Italy) oxygenators (22,23). We present here, our findings with the use of PC-coated Monolyth oxygenators in the adult population.

MATERIALS AND METHODS

After receiving hospital and divisional approval, a series of Mimesys®-coated oxygenators were evaluated for use in our cardiac surgical programs. In the first part of this trial, a total of 160 Mimesys-coated Monolyth® (Sorin Biomedica, Italy) oxygenators with hard-shell venous reservoirs and 36 control (uncoated) Monolyth oxygenators with hard-shell venous reservoirs were evaluated for blood flow rate (BFR) transmembrane pressures (TMP) and hemodynamic resistance (HR). There were no changes to institutional perfusion practices during this trial period, and all cases were done using the Sorin CAPS, Sorin SIII (Sorin Biomedica, Italy) and Sarns 9000 (Terumo Corporation, Japan) heart–lung machines. Temperature control was maintained using the Cincinnati Sub Zero (Sorin Biomedica, Arvada, CO) and Sarns heater/cooler units (Terumo Corporation, Tokyo, Japan). The Sorin BCD blood cardioplegia (Sorin Biomedica, Mirandola, Italy) was used at a ratio of 4:1 in all cases. There were a total of 61 (41.3%) D734® (Dideco Corp., Italy) and 99 (58.7%) Affinity® (Medtronic, Inc., Parker, CO) arterial filters used in the Mimesys group, and 36 Affinity® filters in the control group.

In the Mimesys®-coated group, there were three different primes used in the two different centers. Eighty patients (50.0%) received either Normosol R® (Abbott Laboratories, Montreal, PQ, Canada) or Plasmalyte A® (Baxter, USA) as a crystalloid only prime (mean 1783 ± 154 mL). Fifty-six patients (35.0%) received a combination of 50 mL autologous blood as described by Myers et al. (13) and Normosol R (mean 1885 ± 91 mL). Twenty-four patients (15.0%) received a combination of 500 mL Pentaspan® (Braun Medical, Melsunger, Germany) and Plasmalyte A (mean 1693 ± 226 mL). The 36 control patients consisted of uncoated Monolyth® oxygenators, using a crystalloid only prime of 1809 ± 191 mL Normosol R.

The median dosage of porcine heparin (Hepalean®, Organon Teknika, Canada) added to all perfusates involved in this article was 5000 ± 2386 units. All patients received the usual anesthesia-loading dose of heparin between 300–350 U/kg. With the exception of one patient who was actively cooled to 28°C, there was no active cooling in all other cases performed.

As part of the anesthetic prebypass medication regimen, 23 patients (14.5%) received Trasylol® (Aprotinin–Bayer, Inc., West Haven, CT), 57 patients (35.8%) received Cyklokapron® (Tranexamic Acid, Pharmacia & Upjohn, Inc., Toronto, ON, Canada), 84 patients (52.8%) received Amicar® (Epsilon Aminocaproic Acid, Wyeth-Ayerst, Markham, ON, Canada), and 96 patients (60%) received Diprivan® (Propofol, Zeneca Pharma, Oakville, ON, Canada).

Before cardiopulmonary bypass (CPB), all perfusates were kept at normothermic temperatures and circulated through the arteriovenous loop at 4.0 liters per min (LPM). From this flow, premembrane and postmembrane pressures were used to determine the transmembrane pressure drop (ΔP) in both the Mimesys® (Table 1) and the control group (Table 2). One of the potential benefits from coated membranes is in the dramatic reduction of the HPE phenomena (8,17,24,25). To determine if a HPE was recorded during the course of this study, ΔP was used to establish the membranes hemodynamic resistance before going on bypass and every 5 min (to a maximum of 40 min) after bypass started. HR was measured by using the following simple formula.

$$HR = \frac{\text{Premembrane Pressure} - \text{Postmembrane Pressure}}{\text{Blood Flow Rate}}$$

In keeping with our previous evaluation of HPE in the uncoated Monolyth® oxygenator (9), HPE was considered

Table 1. Uncoated Monolyth's (control).

$N = 36$	Press in (mmHg)	Press out (mmHg)	ΔP	Blood flow LPM	HR (mmHg/L)
Perfusate	52.1 ± 9.8	11.4 ± 6.9	40.1 ± 9.2	4 ± .02	10.0 ± 2.3
5 min	252 ± 32	153 ± 20	98.2 ± 21.6	4.9 ± 0.5	20.0 ± 3.1
10 min	255 ± 33.5	156 ± 21.8	99.8 ± 24.0	4.8 ± 0.6	20.6 ± 4.1
15 min	255 ± 37.4	157 ± 23.8	99.0 ± 25.4	4.8 ± 0.6	20.8 ± 4.1
20 min	252 ± 45.1	159 ± 23.3	98.8 ± 26.1	4.7 ± 0.7	20.7 ± 4.1
25 min	258 ± 43.5	158 ± 27.0	99.4 ± 26.0	4.8 ± 0.7	20.6 ± 3.6
30 min	255 ± 39.0	157 ± 22.3	98.1 ± 25.1	4.7 ± 0.7	20.9 ± 4.0
35 min	254 ± 39.7	158 ± 27.6	96.1 ± 24.1	4.6 ± 0.7	21.0 ± 3.8
40 min	247 ± 54.6	156 ± 21.9	97.5 ± 23.8	4.6 ± 0.7	21.0 ± 3.7

Values are expressed as ± standard error of the mean.
Press in: premembrane pressure.
Press out: postmembrane pressure.
ΔP: difference between press in and press out (press in–press out).
Blood flow: pump flow rate.
HR: hemodynamic resistance (press in–press out)/blood flow.

Table 2. Mortality and stroke.

	Uncoated ($N = 71$)	Mimesys ($N = 71$)
Age >70 (%)	19.7	19.7
Female (%)	21.1	21.1
Preoperative stroke (%)	7.0	7.0
Redo (%)	7.0	5.6
Urgent (%)	7.0	7.0
EF < 40% (%)	8.7	10.0
Renal failure (%)	2.8	2.8
PVD/VD (%)	23.9	21.1

Values are expressed as ± standard error of the mean.
All cases were done using case matching and risk adjusted analysis.
Press in: premembrane pressure.
Press out: postmembrane pressure.
ΔP: difference between press in and press out (press in–press out).
Blood flow: pump flow rate.
HR: hemodynamic resistance (press in–press out)/blood flow.

to have taken place in this study if the prebypass HR was exceeded by a value of 125% at any time during the 40-min study period. After 10 min on CPB with PC-coated oxygenators, blood samples from all three perfusate groups were drawn and measured for platelet count and corrected for hemodilution (net platelet drop), using the formula as described by Palanzo et al. (26). Platelet results were then evaluated for statistical significance in all perfusate groups.

In the second part, we did a retrospective analysis of platelet data from a previously completed investigation using uncoated Monolyth® oxygenators at this center (13). Platelet count decreases in the latter group of 63 patients using a prime of 250 mL 5% HSA with 1650 ml Normosol R®, and 53 patients using a prime of 1800 mL of Normosol R® only, were compared with platelet data from the Mimesys ®-coated oxygenators used in this study. Patient demographics for all groups are found in Table 3. Both groups had the use of identical equipment, techniques, sampling, and measurements performed. The results of platelet count drops during the first 10 min of CPB were examined from the uncoated albumin and crystalloid groups, then compared to all three Mimesys-coated groups (Tables 4,5). The findings were statistically analyzed for relevance.

Table 3. Patient demographics.

	Control ($N = 36$)	Mimesys ($N = 160$)	*Albumin ($N = 63$)	*Crystalloid ($N = 53$)
Age (yrs)	67 ± 8.5	64.3 ± 10.5	63 ± 12.1	64 ± 9.9
Weight (kg)	83.5 ± 19.9	84.9 ± 16.9	83.6 ± 21.6	81.8 ± 13.7
Gender				
Male	83%	70%	66%	70%
Female	17%	30%	34%	30%

*Myers, GJ, Legare, JF, Sullivan, JA, et al: The use of autologous blood as part of the perfusate for cardiopulmonary bypass: A priming technique. Perfusion. 2002;17:211–16.
Values are expressed as ± standard error of the mean.

The final part of this investigation looked into the question of whether Mimesys ®-coating affected clinical outcomes. Clinical outcomes, as well as preoperative demographic and morbidity data were obtained from the Maritime Heart Center cardiac surgery database. This database tracks all cardiac surgery patients from admission to discharge. Consecutive patients who underwent coronary artery bypass surgery with the Mimesys-coated oxygenators were matched one-to-one with patients drawn from a contemporaneous group of patients operated upon with uncoated oxygenators. Patients were matched for all risk factors relevant to outcome. Outcomes of interest included mortality, stroke, and hospital stay transfusion (Tables 6, 7).

Statistics

All continuous variables were expressed as a ± standard deviation of the mean. Hemodynamic resistance was evaluated using analysis of variance (ANOVA) for repeated measures, with Huynh–Feldt epsilon correction. Differences in the decrease in platelets among the different perfusates used, and the coated versus uncoated devices were evaluated using ANOVA, and post hoc means comparisons were made using Tukey–Kramer studentized range test. For all tests, p values of $\leq .05$ were considered significant.

RESULTS

After priming the arteriovenous loop and de-airing the arterial filters in part one, both control and PC-coated oxygenators were evaluated for TMP and HR by running the pump at a mean of 4.0 ± 0.15 LPM (Figure 1) and recording ΔP at a mean perfusate temperature of 36.0 ± 3.3°C. The mean pre-bypass TMP in the control group was measured at 40.1 ± 9.2 mmHg, and in the Mimesys® group

Table 4. Platelet decrease (albumin vs Mimesys).

	N	Preplatelets × 1000/mm^3	Pump-platelets × 1000/mm^3	Plt/dec (%)	Net Plt/Dec (%)	*p*
*Uncoated albumin/crystalloid	63	207.0 ± 56.9	124.0 ± 39.6	39.4 ± 14.7	**	NS
PC-coated crystalloid only	80	221.0 ± 88.4	135.0 ± 58.0	37.5 ± 13.8	6.2 ± 0.05	NS
PC-coated autologous blood/crystalloid	56	233.0 ± 72.6	144.0 ± 51.2	38.5 ± 11.3	11.1 ± 0.04	NS
PC-coated pentaspan/crystalloid	24	184.5 ± 86.5	118.5 ± 28.9	33.0 ± 8.3	6.2 ± 0.05	NS

*Myers, GJ, Legare, JF, Sullivan, JA et al. The use of autologous blood as part of the perfusate for cardiopulmonary bypass: A priming technique. Perfusion. 2002;17:211–16.
There was no significant difference (P = NS) between uncoated monolyth with albumin/crystalloid perfusate and the PC-coated monolyth with three perfusates.
**Not available.
Preplatelets: platelet count before CPB.
Pump platelets: platelet count 10 min after CPB started.
Plt/Dec: percentage decrease in platelets.
Net Plt Dec: percentage decrease in platelets corrected for volume.
Uncoated: uncoated Monolyth oxygenators.
PC-coated: Mimesys-coated monolyth oxygenators.

Table 5. Platelet decrease (uncoated vs. Mimesys)

	N	Preplatelets × 1000/mm^3	Pump-platelets × 1000/mm^3	Plt/dec (%)	Net plt/dec (%)	*p*
*Uncoated crystalloid only	53	237.5 ± 64.6	127.0 ± 43.5	46.8 ± 10.6	**	.002
Mimesys coated crystalloid only	80	221.0 ± 88.4	135.0 ± 58.0	37.5 ± 13.8	6.2 ± 0.05	.02
Mimesys coated autologous blood/crystalloid	56	233.0 ± 72.6	144.0 ± 51.2	38.5 ± 11.3	11.1 ± 0.04	.05
Mimesys-coated pentaspan/crystalloid	24	184.5 ± 86.5	118.5 ± 28.9	33.0 ± 8.3	6.2 ± 0.05	.01

*Myers, GJ, Legare, JF, Sullivan, JA et al. The use of autologous blood as part of the perfusate for cardiopulmonary bypass: A priming technique. Perfusion. 2002;17:211–16.
There were significant differences (p = .002) between uncoated Monolyth with crystalloid only perfusate and the albumin/crystalloid coated Monolyth, as well as the Mimesys-coated oxygenator with three perfusates.
**Not available.
Preplatelets: platelet count before CPB.
Pump platelets: platelet count 10 min after CPB started.
Plt/Dec: percentage decrease in platelets.
Net Plt Dec: percentage decrease in platelets corrected for volume.
Uncoated: uncoated Monolyth oxygenators.
PC-coated: Mimesys-coated monolyth oxygenators.

Table 6. Mimesys-coated Monolyth's.

N = 160	Press in (mmHg)	Press out (mmHg)	ΔP	Blood flow LPM	HR (mmHg/L)
Perfusate	59.7 ± 17	17.7 ± 16.3	41.9 ± 11.3	4.0 ± .28	10.5 ± 2.8
5 min	238 ± 48	142 ± 33	90.4 ± 24	4.6 ± 0.7	19.4 ± 3.8
10 min	240 ± 48.1	147 ± 31.8	93.5 ± 26.6	4.6 ± 0.6	20 ± 4.1
15 min	241 ± 48.4	148 ± 32.4	93 ± 26	4.6 ± 0.6	20.2 ± 4.0
20 min	243 ± 45.6	148 ± 30.1	94.8 ± 25.7	4.6 ± 0.6	20.5 ± 3.9
25 min	239 ± 45.9	146 ± 29.7	93 ± 25.8	4.5 ± 0.6	20.4 ± 3.9
30 in	239 ± 44.3	147 ± 29.9	91.8 ± 26.5	4.7 ± 2.3	20.3 ± 3.9
35 min	241 ± 46.2	149 ± 31.5	93.6 ± 25.8	4.5 ± 0.7	20 ± 4.0
40 min	240 ± 44.9	147 ± 31.0	92.4 ± 24.9	4.5 ± 0.6	20.4 ± 3.8

Age: percentage of patients greater than 70 years old.
Female: percentage of female patients.
Redo: patients who had previous bypass surgery.
Urgent: those patients done in 24 hours notice.
EF: percentage of patients with ejection fractions less than 40 percent.
PVD/CVF: those patients with either peripheral vascular or cerebrovascular disease.
BSA: percentage of patients with body surface area less than 1.8.
Hemoglobin: percentage less than 120 g/L.
Renal failure: percentage of patients with renal failure.
Preoperative stroke: percentage of patients with preoperative strokes.

Table 7. Hospital stay blood transfusion.

	Uncoated *N* = 71	Mimesys *N* = 71
Age >70 (%)	19.72	19.72
Female (%)	21.13	21.13
BSA <1.8 (%)	21.13	21.13
Redo (%)	7.04	5.63
Urgent (%)	5.63	7.04
EF <40% (%)	8.7	10
Renal failure (%)	1.41	2.82
Hemoglobin <120 (%)	9.9	9.9

All cases were done using case matching and risk adjusted analysis.
Age: percentage of patients greater than 70 years old.
Female: percentage of female patients.
Redo: patients who had previous bypass surgery.
Urgent: those patients done in 24 hours notice.
EF: percentage of patients with ejection fractions less than 40 percent.
PVD/CVF: those patients with either peripheral vascular or cerebrovascular disease.
BSA: percentage of patients with body surface area less than 1.8.
Hemoglobin: percentage less than 120 g/L.
Renal failure: percentage of patients with renal failure.
Preoperative stroke: percentage of patients with preoperative strokes.

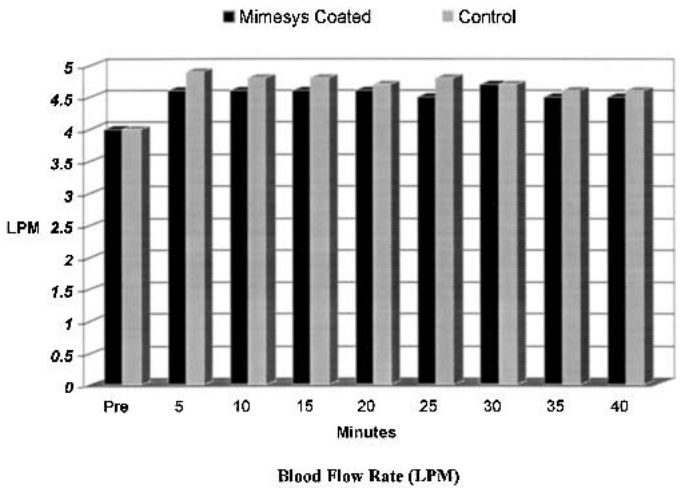

Figure 1. Blood flow rate. (MmHg: millimeters of mercury; LPM: liters per minute; TMP: transmembrane pressure).

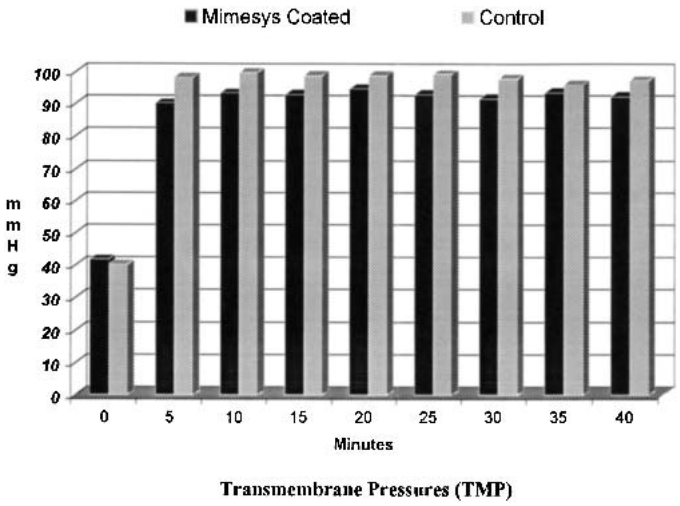

Figure 2. Transmembrane pressures (TMP). (MmHg: millimeters of mercury; LPM: liters per minute).

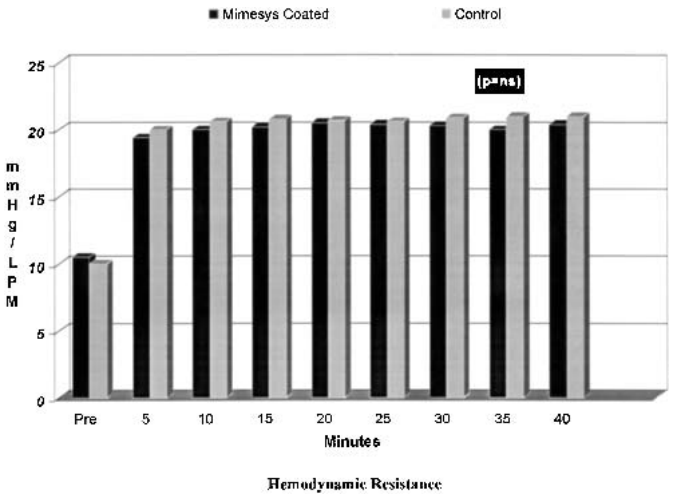

Figure 3. Hemodynamic resistance. (MmHg: millimeters of mercury; liters per minute; TMP: transmembrane pressures).

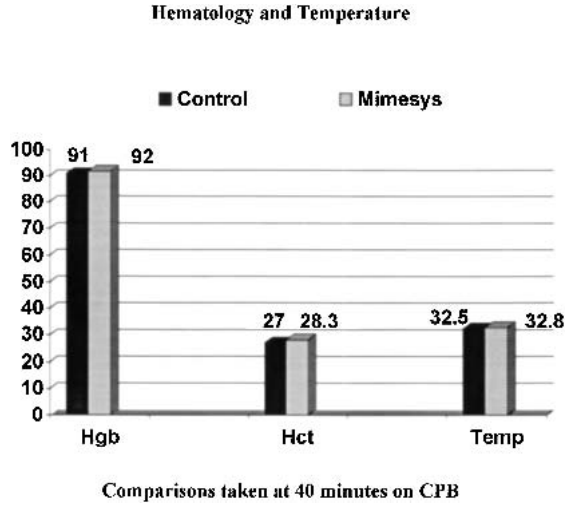

Figure 4. Comparisons taken at 40 min on CPB. Hgb: hemoglobin in g/L; Hct: hemotocrit in percentage; Temp: nasopharangeal in degrees C).

at 41.9 ± 11.3 mmHg (Figure 2). The mean calculated values for pre-bypass HR were 10.0 ± 2.3 mmHg/LPM in the control group and 10.5 ± 2.8 mmHg/LPM in the Mimesys group (Figure 3). Hemodynamic resistance measured at 15 and 40 min on CPB were compared in both the control and the Mimesys groups. It was determined that there was no significant difference between either of the groups ($p = .97$), and there was no significant time group interaction ($p = .77$).

When we compared the pre-bypass HR to the on-bypass HR, we found no increases greater than 125% in either group (Figure 3). In the control group, the mean intraoperative hemoglobin (Hgb) at 40 min on CPB was 91.0 ± 15.6 g/L, and the mean intraoperative Hematocrit (Hct) was 27 ± 0.05%. In the coated group, the mean intraoperative Hgb at 40 min on CPB was 92.0 ± 15.1 g/L, and the mean intraoperative Hct was 28.3 ± 0.05%. The mean arterial blood temperature at 40 min on bypass was 32.5 ± 2.5°C in the control group and 32.8 ± 4.2°C in the Mimesys®-coated group (Figure 4).

Looking at part two, after 10 min on CPB, platelet counts were measured, and platelet count decreases (Plt/Dec) were calculated (corrected and uncorrected) with all three perfusates in the PC coated group. As shown in Table 4, there were no differences (p = NS) in Plt/Dec among the three PC perfusate groups themselves, and no significance (by ANOVA) when the latter were compared to data collected from uncoated Monolyth® oxygenators with albumin/crystalloid perfusates. However, when the group using albumin/crystalloid perfusates were compared with uncoated Monolyth oxygenators using crystalloid

only perfusates (13), the Plt/Dec was significantly lower in the albumin/crystalloid group ($p = .002$). Compared to the uncoated crystalloid only group, Pct/Dec was also significantly lower in each of the Mimesys®-coated groups (Table 5). Overall, significantly better platelet protection was found with those perfusion methods using coated oxygenators (e.g., albumin and phosphorylcholine), as compared to those using uncoated oxygenators.

Part three examined clinical outcomes for mortality, stroke, and transfusion. These were examined in 71 CABG patients using Mimesys®-coated oxygenators, and compared with 71 uncoated Monolyth® oxygenators in a case matched, risk adjusted analysis (Tables 6,7)

There were two deaths (2.3%) in the Mimesys®-coated group and two deaths (2.3%) in the matched controls. There was one stroke (1.4%) in the Mimesys-coated group and three strokes (4.2%) in the uncoated control group (p = NS). Nine patients (12.9%) in the coated group received a transfusion during their hospital stay, while 12 patients (16.7%) in the control group were transfused (p = NS).

DISCUSSION

Results found in this study indicate that coating Monolyth® oxygenators with synthetic phosphorylcholine (PC) material does not interfere with blood flow characteristics, as demonstrated by the comparisons of ΔP and HR between the control and PC-coated groups. The "gold standard" of perfusates has always been considered to be a combination of HSA and crystalloid for priming extracorporeal circuitry (28–30). This perfusate seems to have not only provided the best protection for platelets and colloid osmotic pressure in uncoated oxygenators, but the best protection against HPE, as well. When comparing platelet decreases after going on CPB in part two, we see that there is no significant difference between uncoated oxygenators with albumin/crystalloid perfusates and any of the three-perfusate groups used with the Mimesys®-coated oxygenators (Table 4). These results seem to be consistent with other published literature (26,27) on heparin-coated oxygenators presently available.

When reviewing the literature, the overall reported incidence of postoperative stroke associated with coronary artery bypass surgery is found to be approximately 5.0% (30). Our group of 71 Mimesys® patients in part three of this investigation, had a preoperative stroke rate of 7.04%, which was identical to the case matched uncoated group. There was no statistically significant difference in death, stroke, or transfusion between the coated and uncoated oxygenator groups. These results must be interpreted with caution because we are statistically underpowered because of small sample sizes to assert the null hypothesis. When using heparin-coated systems in our clinical practice, there is always a subgroup of patients whose use may be contraindicated. For example, the incidence of heparin-induced thrombocytopenia (HIT) is approximately 3.8% in the general population (31). Avoidance of heparin-coated devices with HIT patients may prevent serious intraoperative and postoperative complications. Another autoimmune disorder, antiphospholipid antibody syndrome (APAS), may indicate that caution is required with the use of phosphorylcholine-coated systems. The incidence of APAS in the general population is approximately 2–4% (32,33). Despite the fact that PC coating relies on the use of electrically neutral phospholipid head groups (zwitterionic phospholipids), and evidence suggests that APAS antibodies are directed at negatively charged biological phospholipids (34), the use of PC coating in the presence of APAS should be avoided without further study into this complex autoimmune disorder.

Table 8. Clinical outcomes.

	Uncoated (N = 71)	Mimesys (N = 71)
Postoperative stroke (%)	3 (4.2%)	1 (1.4%) p = NS
Blood transfusion (%)	12 (16.9%)	9 (12.7) p = NS
Mortality (%)	2 (2.3%)	2 (2.3%) p = NS

In conclusion, we find that PC-coated Monolyth® oxygenators (with all perfusates tested), provide platelet protection that is statistically better than uncoated Monolyth® oxygenators using crystalloid only as a perfusate. However, there is no statistical difference in platelet protection between PC-coated Mimesys® oxygenators (with all perfusates tested) and those uncoated Monolyth oxygenators using albumin in their perfusates. Because of the consistent findings with hemodynamic resistance and platelet protection that is similar to those reports with heparin-coated devices, PC-coated oxygenators may be able to provide similar protection against high-pressure excursions. Clinical outcomes with coated oxygenators were similar to a case matched set of uncoated cases. However, a larger outcomes study in totally PC-coated circuits and oxygenators with adult CPB cases is recommended.

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