

Original Article

Oxygenator Evaluation: Maxima 1380 Versus Maxima Plus

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ABSTRACT

Continual improvement of oxygenators has been important in the growing demands of patient safety and support during cardiopulmonary bypass. The purpose of this study was to compare the Maxima 1380 oxygenator to the upgraded Maxima Plus oxygenator.

Thirty-two adult patients were randomized to either the 1380 group or the Plus group. Information was recorded on the patients' weight, age, body surface area, esophageal temperature, arterial temperature, venous oxygen saturation, arterial pO₂, arterial pCO₂, blood flow, hematocrit, gas sweep, and FiO₂.

No significant difference was found between the two groups' mean weight, body surface area, arterial pO₂, arterial pCO₂, age, esophageal temperature, arterial temperature, venous oxygen saturation, and blood flow ($p > 0.05$). The Plus group demonstrated significantly lower mean gas sweep rates and FiO₂ settings than the 1380 group. FiO₂ of the 1380 was dependent on age, body surface area, blood flow, and esophageal temperature ($r = 0.89, p < 0.001$). FiO₂ of the Plus was correlated with weight, esophageal temperature, arterial temperature, and arterial pO₂ ($r = 0.93, p < 0.001$). Gas sweep rate of the 1380 was dependent on age, weight, esophageal temperature, blood flow, arterial temperature, and arterial pCO₂ ($r = 0.84, p < 0.001$). The gas sweep rate of the Plus was dependent on weight and esophageal temperature ($r = 0.55, p < 0.001$). Based on these analyses, the new Maxima Plus oxygenator is more efficient in oxygen and carbon dioxide transport than the Maxima 1380.

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INTRODUCTION

Since the introduction of membrane oxygenators, a challenge has existed to improve gas exchange efficiency while minimizing device priming volume. Adequate oxygenation and carbon dioxide removal in larger patients with high metabolic requirements requires a device with high gas transfer efficiency.

Gas transfer in the hollow fiber membrane oxygenator design is enhanced by decreasing the distance the gas must diffuse or increasing membrane surface area. Practically, a paradox exists, because moving the oxygenator membranes closer together (decreasing diffusion distance) tends to increase the pressure drop across the device, and increasing surface area tends to increase oxygenator priming volume (1).

The Medtronic Maxima 1380^a oxygenator was one of the first microporous hollow fiber membrane oxygenator designs to utilize blood flow on the outside of the hollow fibers. The Maxima Plus^a oxygenator design has altered the fiber weave and fiber radius of the Maxima 1380 in an attempt to increase gas exchange efficiency while maintaining the same priming volume.

The ability to predict FiO₂ settings and gas sweep rates for a particular clinical situation gives the perfusionist an additional quantitative verification that the system is responding as expected (2). The purpose of this study will be to compare the Maxima 1380 to the refined Maxima Plus oxygenator in gas exchange performance.

MATERIALS AND METHODS

Thirty-two elective adult cardiac cardiopulmonary bypass patients were randomized into the Maxima 1380 or the Maxima Plus group. The extracorporeal circuit consisted of the study oxygenator, venous reservoir bag^a, cardiotomy^b, and a custom tubing pack^c. The circuits were primed using 2 liters of Plasma-Lyte A^d, 10,000 units heparin, 22 milliequivalents sodium bicarbonate, 25 grams mannitol, and 50 grams albumin. Data collection consisted of each patient's age, weight, body surface area, esophageal temperature, arterial temperature, venous oxygen saturation, paCO₂, paO₂, FiO₂, blood flow, hematocrit, arterial oxygen saturation, and sweep gas flow.

Blood gases were drawn every 30 minutes during cardiopulmonary bypass to assess the paO₂, paCO₂, hematocrit, arterial oxygen saturation, and venous oxygen saturation. The established criteria was to maintain non-temperature corrected paCO₂ between 35-45 mmHg, non-temperature corrected paO₂ between 150-250 mmHg, hematocrit above 20 percent, and blood flow between 1.8 and 2.4 liters/minute/m². The Student's t-test (two sample assuming equal variances) was used to determine differ-

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 b Bentley Laboratories, Irvine, CA 92714
 c C.R. Bard, Inc., Tewksbury, MA 01876
 d Baxter Healthcare Corp., Chicago, IL 60015

Table 1. Mean, Standard deviations, and significance.

Parameters	Maxima 1380 mean ± SD	Maxima Plus mean ± SD	Sig*
Age (years)	57.2 ± 17.0	62.3 ± 15.8	NS
Weight (kilograms)	86.5 ± 22.8	82.2 ± 25.5	NS
Body Surface Area (m ²)	2.02 ± 0.28	1.99 ± .39	NS
Esophageal Temp (°C)	31.0 ± 3.9	31.2 ± 4.1	NS
Arterial Temp (°C)	31.5 ± 4.9	31.4 ± 4.9	NS
Venous O ₂ Saturation (%)	76.0 ± 9.0	78.0 ± 8.0	NS
Arterial O ₂ Saturation (%)	98.2 ± 0.6	98.2 ± 0.9	NS
paO ₂ (mmHg)	207.9 ± 50.9	223.9 ± 46.6	NS
paCO ₂ (mmHg)	36.2 ± 3.6	37.6 ± 4.1	NS
Hematocrit (%)	25.5 ± 4.9	23.7 ± 3.8	p < 0.05
Blood Flow (L/min)	4.29 ± 0.66	4.12 ± 0.91	NS
Gas Sweep Rate (L/min)	2.82 ± 1.67	2.13 ± 0.81	p < 0.05
FiO ₂	0.58 ± 0.15	0.51 ± 0.15	p < 0.05
O ₂ Consumption (ml/min)	123.1 ± 74.3	101.6 ± 54.8	NS

*NS = not significant.

Table 2. Regression equations.

Maxima 1380

$$FiO_2 = [(BSA)(.158) + (Q)(.048) + (ET)(.024) - (Age)(.002) - 0.619]$$

$$r = 0.89; p < 0.001$$

$$Sweep = [(WT)(.039) + (Q)(.54) + (ET)(.22) - (Age)(.023) - (AT)(.171) - (paCO_2)(.129) + 1.64]$$

$$r = 0.84; p < 0.001$$

Maxima Plus

$$FiO_2 = [(WT)(.002) + (ET)(.012) + (AT)(.014) + paO_2)(.001) - 0.68]$$

$$r = 0.93; p < 0.001$$

$$Sweep = [(WT)(.015) + (ET)(.044) - 0.495]$$

$$r = 0.55; p < 0.001$$

ET = esophageal temperature (°C)
 AT = arterial temperature (°C)
 Q = blood flow (liters/minute)
 BSA = body surface area (m²)
 WT = weight (kg)
 Age (years)
 paCO₂ (mmHg)
 paO₂ (mmHg)

ences between the group means ($p < 0.05$). Regression analysis and correlation was used to determine the parameters that significantly related to FiO_2 and gas sweep rate within the study criteria ($p < 0.05$).

RESULTS

Table 1 displays the mean and standard deviation of both groups. Age, weight, body surface area, esophageal temperature, arterial temperature, venous oxygen saturation, arterial oxygen saturation, paO_2 , $paCO_2$, blood flow, and oxygen consumption were not significantly different between the groups. Hematocrit, FiO_2 , and gas sweep rate were significantly higher in the 1380 group.

Regression equations developed for both oxygenators to predict FiO_2 and gas sweep rates are presented in Table 2. Patient weight significantly correlated with FiO_2 settings in both groups and is illustrated in Figure 1 with best fit lines for each group. Patient weight also significantly correlated with gas sweep rate in both groups. This scatter plot with best fit lines is shown in Figure 2. Blood flow significantly correlated with FiO_2 in both groups and is represented in Figure 3.

DISCUSSION

The Maxima Plus oxygenator has maintained the same priming volume of 480 milliliters as the Maxima 1380 but has increased the surface area from 2.0 m^2 to 2.3 m^2 by decreasing the fiber diameter. The fiber weave of the Maxima Plus was also altered to decrease the gas diffusion distance. Decreasing the gas diffusion distance may potentially increase the pressure drop across the device. Although no line pressure data was collected, the perfusionists observed no obvious increases in line pressure with the Maxima Plus compared to the 1380.

The patients sampled in this study demonstrated no significant difference between the groups with regards to age, weight, body surface area, esophageal temperature, arterial temperature, paO_2 , blood flow, venous oxygen saturation, $paCO_2$, and arterial oxygen saturation ($p > 0.05$). The hematocrit was significantly different between the groups; however, the differences in the means

Figure 1. FiO_2 versus weight.

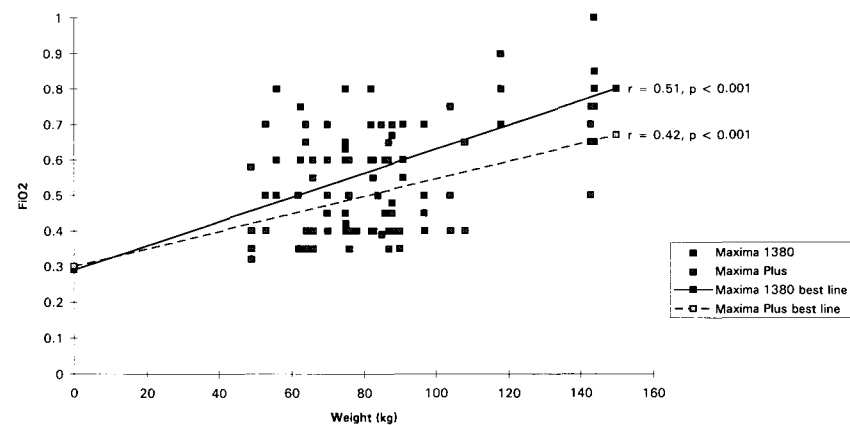


Figure 2. Sweep versus weight.

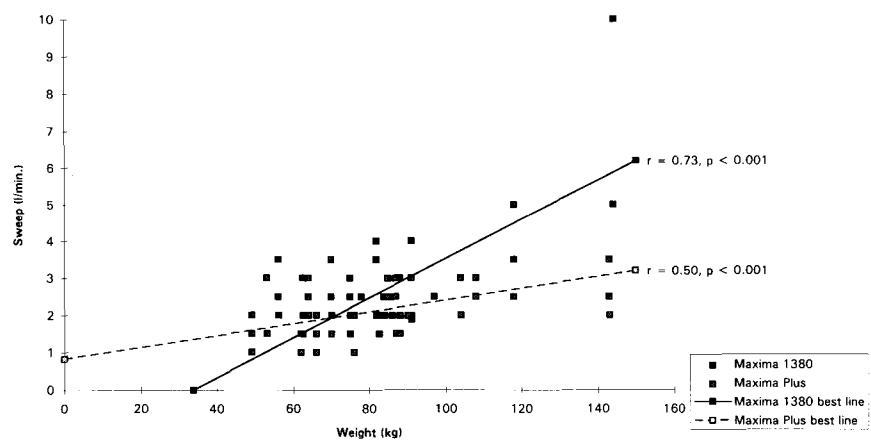
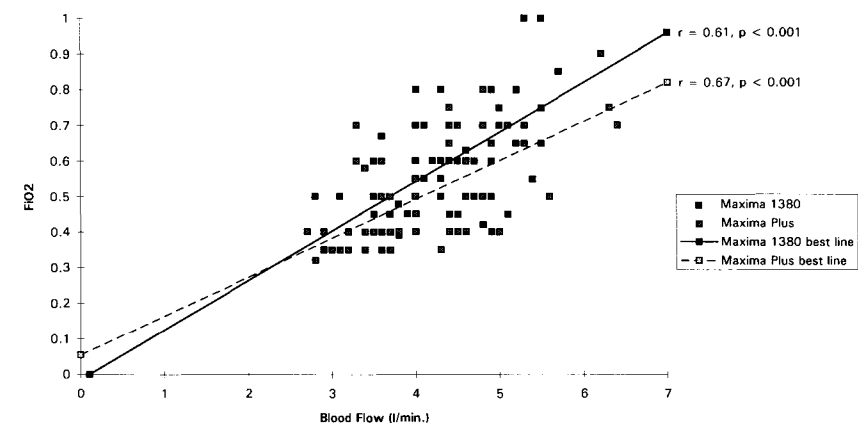


Figure 3. FiO_2 versus blood flow.



were small and not determined to be clinically significant because the oxygen transfer rates were not significantly different.

Decreasing temperatures during cardiopulmonary bypass decrease patients' metabolic demands as well as increase the solubility of carbon dioxide and oxygen (3). This is demonstrated in the regression equations for both the Maxima 1380 and Maxima Plus in that the FiO_2 settings and gas sweep rates for both the Maxima 1380 and the Maxima Plus are dependent on esophageal temperature. Age is inversely related to metabolic rate (4) and the effect of this parameter is demonstrated in the regression equations for the Maxima 1380.

Patient size is directly related to FiO_2 and gas sweep settings due to the correlation between patient mass and oxygen consumption (4). In some form this is a dependent variable in both the FiO_2 and gas sweep equations. Thus, the regression equations relate the reference of metabolic rate and device performance to FiO_2 and gas sweep rate.

The mean gas sweep rates and FiO_2 settings were significantly higher in the 1380 group without significant differences in paO_2 , oxygen transfer, and $paCO_2$. From this study, we concluded that the Maxima Plus required a significantly lower FiO_2 setting and gas sweep rate than the Maxima 1380 with no difference in oxygen transfer, paO_2 , $paCO_2$, and priming volume. The Maxima Plus was more efficient in gas transfer and can be recommended for patients with higher metabolic demands during cardiopulmonary bypass.

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