Original Article

The Proposed Use of Performance Indices to Evaluate and Compare the "Gish Vision" Membrane Oxygenator

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Keywords: oxygenator evaluation, membrane oxygen transfer, oxygenator performance indices

ABSTRACT

The objective of this investigation was to evaluate and compare the recently released Gish Vision® oxygenator with previously studied oxygenators. We utilized our previously described membrane oxygenator evaluation techniques as well as proposed the use of four new performance indices: 1) oxygen transfer index; 2) shunt fraction index; 3) pressure drop index; and 4) consistency index.

We concluded that the new Gish Vision® membrane oxygenator offers the clinician the highest level of oxygen transfer "reserve" of any oxygenator we have tested. The use of our proposed performance indices enables the perfusionist to quickly and objectively compare various oxygenator performance characteristics and make a meaningful clinical comparison.

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INTRODUCTION

Gish Biomedical Incorporated has recently introduced the Vision® adult hollow fiber membrane oxygenator. This device represents their first oxygenator entry into the perfusion marketplace. The physical characteristics of this new membrane oxygenator (priming volume, membrane surface area, etc.) can be easily compared with other devices currently on the market by simply referring to the manufacturers' product brochures. However, clinically relevant performance data, i.e., oxygen transfer, are not readily available. Although the manufacturers provide *in vitro* performance data for their devices, this information has limited clinical application (1,2). In this current study, we will apply our previously described membrane oxygenator evaluation techniques (3-6) to assess the Vision® oxygenator. In addition, we will propose the use of four new performance indices which will enable the clinician to quickly and objectively compare various oxygenator performance characteristics and make meaningful clinical comparisons between devices.

MATERIALS AND METHODS

GISH VISION® MEMBRANE OXYGENATOR[a]

Venous blood enters at the bottom of the oxygenator, into a stainless steel, bellows type heat exchanger. From the heat exchanger, the blood is then directed to the 2.45 m^2 fiber bundle. Oxygenated blood then exits the unit through the arterial blood outlet port located at the bottom of the fiber bundle.

OTHER EQUIPMENT/DISPOSABLES

The Stockert heart lung machine[b], custom PVC tubing packs[c], an arterial line filter[c], a Delphin centrifugal pump/console[d], and an air-oxygen blender[e] were used on all cases. Arterial oxygen saturation (SaO_2), venous oxygen saturation (SvO_2), and hemoglobin (Hb) were monitored on-line[f]. The priming volume consisted of: 1400 ml of Normosol R[g], 100 ml of 25% albumin (25g),and 50 ml of mannitol (12.5g).

PERFUSION TECHNIQUE

The components of the cardiopulmonary bypass (CPB) circuit were inspected and set up in accordance with the manufacturers' instructions. The circuit was flushed with carbon dioxide for several minutes prior to gravity priming. Adequate debubbling and recirculation were performed in all cases. The alpha-stat scheme (7) for acid/base management was utilized for pH and PCO_2 (analyzed and reported at 37°C). Generally, for the sake of expedience, PO_2 values are also analyzed and reported at 37°C when alpha-stat is used. In a quantitative study such as this one, failure to correct PO_2 values to the circulating blood temperature would result in a high degree of inaccuracy (elevated oxygen transfer and reduced shunt fraction calculations) and potentially spurious conclusions. All samples were analyzed using the CIBA Corning 288 and 178[h]. These devices are self-calibrating ,and controls are performed every eight hours as required by CLIA standards. Activated clotting times (ACT) were monitored with the HemoTec Automated Coagulation Timer[i] and maintained above 400 seconds.

DATA COLLECTION

Thirty-two blood samples (16 arterial and 16 venous) from 16 Vision membrane oxygenators were used in this study. Arterial samples were drawn from a manifold fed by a continuous purge line off the arterial filter and venous samples were taken directly from the venous line via 3-way stopcock. Each test device provided one hypothermic and one normothermic set of samples (both arterial and venous). In this way, each oxygenator would contribute an equal amount of data and would not be under-or over-represented. To gain entry into this study, each set of samples was required to meet the following criteria: 1) Hb greater than or equal to 7g/dL; 2) SvO_2 within the range of 65% - 75%; 3) corrected PaO_2 140 mmHg (± 30 mmHg); and 4) patient perfused with non-pulsatile blood flow. If these specific entry criteria were not met, the data from that device were excluded from the study.

OXYGEN TRANSFER LINE (OTL)

Using the Fick equation (8), the patient's oxygen consumption/ membrane oxygen transfer (VO_2/min) was calculated for each of the 16 sets of samples for the Vision oxygenator. The VO_2/min, and the actual FiO_2 that was required to achieve a PaO_2 value within the specified range (140 mmHg +/- 30 mmHg), were then entered into a computer statistics software program[j]. A scatterplot was generated and then a best fit line was drawn, using the regression equation provided in this software program. The slope of this line reflects the change in FiO_2 for a given change in VO_2/min.

OXYGEN TRANSFER INDEX – 300 ml O_2/min ($O_2T_{1\text{-}300}$)

Using the slope and intercept (value of y, when x = 0), from the oxygen transfer line, the FiO_2 setting necessary to achieve any clinical oxygen transfer challenge while maintaining a PaO_2 of 140 (+/-30 mmHg) can be calculated according to:

$$FiO_2 = (O_2 \text{ transfer X slope}) + \text{intercept}$$

We have chosen to index oxygen transfer at 300 ml O_2/min because we believe that while it poses a significant transfer challenge to the oxygenator, it is still clinically relevant.

a Gish Biomedical Inc., Santa Ana, CA
b Sorin Biomedical, Irvine, CA
c Medtronic Corp., Irvine CA
d Sarns/3M Health Care, Ann Arbor, MI
e Sechrist Industries, Inc., Anaheim, CA
f Medtronic BioTrend, Medtronic Corp., Irvine, CA
g Abbott Laboratories, Chicago, IL
h CIBA Corning, Medfield, MA)
i Medtronic HemoTec, Inc., Englewood, CO
j Microstat, Ecosoft, Inc.

EXTRAPOLATED MAXIMUM OXYGEN TRANSFER

From the slope and the intercept of the OTL, the maximum VO_2/min that would be predicted, while maintaining PaO_2 within the range of 140 mmHg+/-30 mmHg, was extrapolated according to:

$$\text{Maximum oxygen transfer} = \frac{(1.0 - \text{Intercept})}{\text{Slope}}$$

To determine the maximum transfer per square meter of membrane surface area:

$$\text{Maximum oxygen transfer/m}^2 = \frac{\text{maximum oxygen transfer}}{\text{membrane surface area}}$$

BLOOD SHUNTING

The degree to which venous inlet blood flows through an oxygenator, without participating in effective oxygen transfer, was calculated using the physiologic shunt equation (9) where:

$$\text{Shunt Fraction} = \frac{CiO_2 - CaO_2}{CiO_2 - CvO_2} \times 100$$

Ci = ideal oxygen content (maximum theoretical content)
Ca = arterial oxygen content
Cv = venous oxygen content

The shunt fraction was calculated from each set of samples for each oxygenator. Using the MicroStat software program, each calculated shunt fraction was plotted against the blood flow rate (at the time the samples were drawn). A scatterplot of these data was created and a best fit line was drawn through the data points. From the slope and intercept of this line, the shunt fraction at any blood flow rate can be predicted and compared for each oxygenator.

SHUNT FRACTION INDEX - 6 l/min ($SF_{1\text{-}6.0}$)

Using the slope and intercept values from the shunt fraction line, the shunt fraction at any specific clinical blood flow is calculated according to:

Shunt Fraction(%) = (Blood Flow X slope) + intercept X 100

The use of our proposed Shunt Fraction Index offers direct comparison between different oxygenators. We have chosen to index shunt fraction at a blood flow rate of 6 l/min because we believe it to be both clinically relevant and appropriately challenging.

PRESSURE DROP

The pressure drop (PD) across the Vision oxygenator was found by subtracting the blood outlet pressure (P2) from the blood inlet pressure (P1) (10). Thirty one PD determinations from six Vision oxygenators were performed. To minimize the impact that temperature would have on pressure drop (viscosity), all PD determinations were carried out at 37°C (+/- 1°C). Using the Microstat software program, each PD measurement was plotted against the blood flow rate (at the time the pressure measurements were made). A scatterplot of these data was created and a best fit pressure drop line was drawn.

PRESSURE DROP INDEX - 6 l/min ($PD_{1\text{-}6.0}$)

Using the slope and intercept values from the pressure drop line, the average PD at a specific clinical blood flow rate is calculated according to:

Pressure Drop (mmHg) = (Blood Flow X slope) + intercept

The use of our proposed PD Index offers the clinician a direct comparison between different oxygenators. Once again, we have chosen to index PD at a blood flow rate of 6 l/min because we believe it to be both clinically relevant and appropriately challenging.

Table 1: Raw data for Gish Vision

#	Hb (g/dl)	SaO_2 (%)	SvO_2 (%)	PaO_2(corr) (mmHg)	PvO_2(corr) (mmHg)	Flow (l/min)	FiO_2
1	8.7	99.3	66.7	139	18	2.1	.30
2	8.3	99.2	74.0	155	36	4.0	.42
3	8.5	99.1	68.9	123	19	2.8	.30
4	8.7	98.9	71.7	141	37	4.8	.44
5	8.6	99.0	72.1	142	29	4.9	.40
6	8.3	99.1	69.8	167	39	5.6	.50
7	9.3	99.2	65.1	170	28	2.3	.32
8	8.7	99.0	71.1	155	37	4.5	.45
9	9.1	99.1	67.5	132	22	2.1	.30
10	9.1	99.0	70.1	147	35	3.4	.42
11	8.4	99.1	66.0	142	24	3.1	.35
12	7.9	98.9	70.0	155	39	4.7	.48
13	8.4	99.1	65.4	141	27	4.5	.40
14	7.6	99.2	69.9	162	35	6.6	.51
15	7.1	99.0	68.2	131	25	3.9	.38
16	7.6	98.9	68.7	143	36	4.8	.45
17	9.9	99.1	70.8	154	31	4.5	.45
18	10.6	98.7	68.7	135	37	5.5	.50
19	11.7	98.9	66.0	130	28	3.7	.45
20	11.8	99.0	68.6	148	34	5.1	.60
21	9.2	99.1	66.8	158	28	4.1	.45
22	8.5	98.9	65.3	146	33	5.7	.55
23	7.4	98.8	69.1	114	25	2.9	.30
24	9.4	98.5	67.1	120	34	4.0	.40
25	7.5	99.0	67.4	138	25	4.0	.41
26	7.1	99.0	67.3	155	36	5.7	.55
27	7.7	98.8	71.6	127	29	3.2	.33
28	7.4.	98.9	71.6	150	38	5.0	.48
29	8.4	99.1	69.6	143	24	3.0	.33
30	8.5	99.1	67.8	168	38	5.0	.48
31	9.0	99.0	71.4	136	28	3.2	.36
32	8.0	99.1	72.6	158	39	4.7	.50
MEAN	**8.6**	**99.0**	**69.0**	**145**	**31**	**4.2**	**.42**

Figure 1: Scatterplot and OTL for the Gish Vision

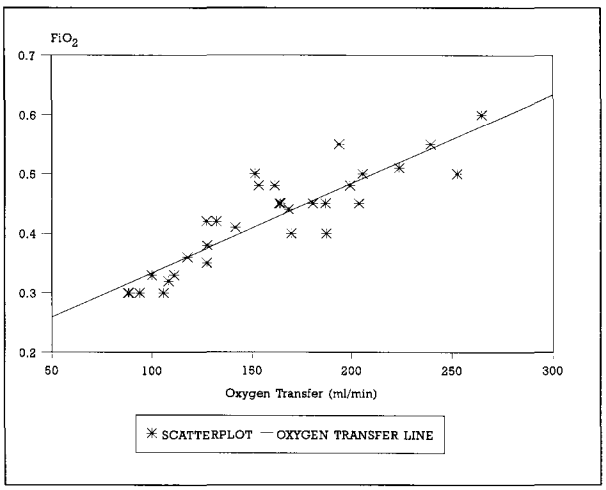


Figure 2: Absolute and relative extrapolated maximum oxygen transfer

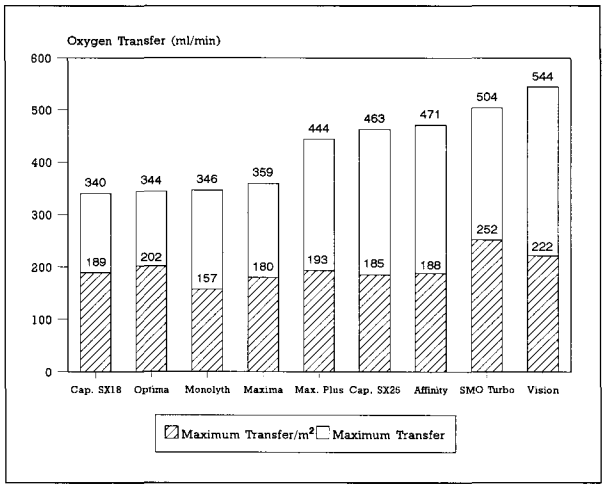


Figure 3: Scatterplot and shunt fraction line for the Gish Vision

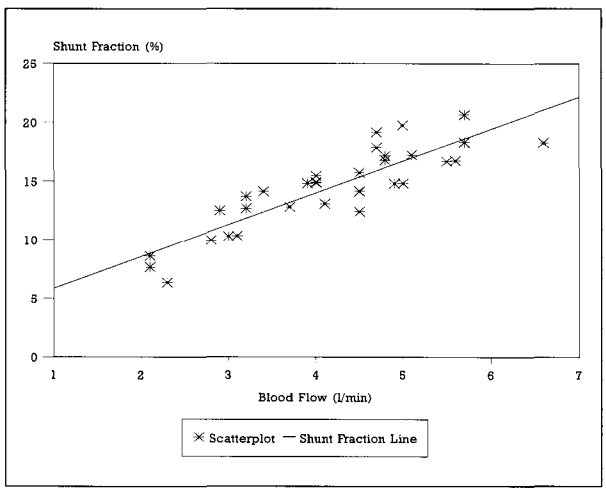
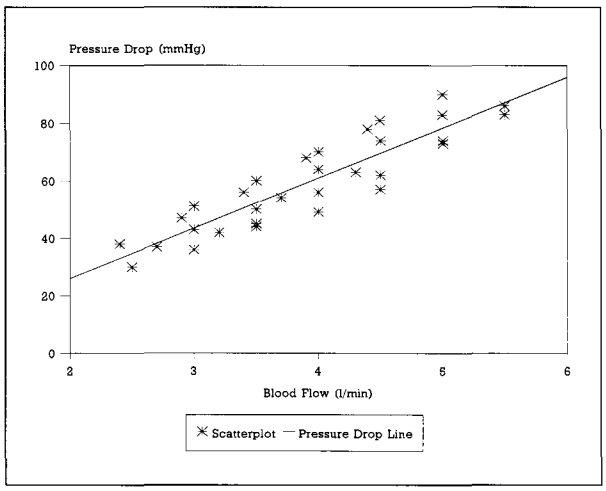


Figure 4: Scatterplot and pressure drop line for the Gish Vision



CONSISTENCY AND CONSISTENCY INDEX (C_I)

The oxygen transfer, shunt fraction, and pressure drop lines for the Vision were derived from the data collected from many devices.

These aggregate measurements reflect the average performance of a large number of test oxygenators and do not offer direct information regarding device-to-device consistency. To assess the degree of consistency from Vision-to-Vision, the r-value (11) (Pearson correlation coefficient) generated from the scatterplot and oxygen transfer line, was compared with previously studied membrane oxygenators utilizing the same methodology.

RESULTS

The raw data for the Gish Vision is listed on Table 1. The mean temperature for the 16 sets of hypothermic samples was 32.1°C with a range of 28.7°C to 34.3°C. Oxygen transfer ranged from 88.03 to 264.42 ml O_2/min with a mean of 159.54 ml O_2/min. The range and mean FiO_2 was 0.30 to 0.60 and 0.42, respectively. The scatterplot and oxygen transfer line for the Vision is graphically presented on Figure 1. Maximum extrapolated oxygen transfer and transfer/m^2 was 544.0 ml O_2/min and 222.0 ml O_2/min/m^2, respectively. Absolute and relative maximum oxygen transfers for the Vision and several previously evaluated membrane oxygenators (3-6; Avecor Affinity and Cobe Optima, unpublished data) are presented in Figure 2.

The scatterplot and shunt fraction line for the Vision is presented in Figure 3. The shunt fractions ranged from 6.37 to 20.67% with a mean of 14.48%. The range and mean blood flow was 2.1 to 6.6 l/min and 4.17 l/min, respectively.

The scatterplot and pressure drop line for the Vision is presented in Figure 4. The slope and intercept of the Oxygen Transfer Line, Shunt Fraction Line, and Pressure Drop Line for the Vision, and previously evaluated membrane oxygenators (3-6; Avecor Affinity and Cobe Optima, unpublished data), is presented in Table 2. The $O_2T_{I\text{-}300}$, $SF_{I\text{-}6.0}$, $PD_{I\text{-}6.0}$, and C_I for the Vision and previously evaluated devices are illustrated in Figures 5–8, respectively, and listed in Table 3 (3-6; Avecor Affinity and Cobe Optima, unpublished data).

Table 2: Slope and intercept values for: oxygen transfer, shunt fraction, and pressure drop lines

OXYGENATOR	OXYGEN TRANSFER (SLOPE/INTERCEPT)	SHUNT FRACTION (SLOPE/INTERCEPT)	PRESSURE DROP (SLOPE/INTERCEPT)
GISH	0.150×10^{-2}	2.717	17.454
VISION	0.184	3.155	-8.869
SARNS	0.170×10^{-2}	3.205	24.239
TURBO	0.142	1.096	6.799
AVECOR	0.179×10^{-2}	3.630	10.821
AFFINITY	0.157	0.332	-11.899
TERUMO	0.171×10^{-2}	3.110	22.443
CAPIOX SX25	0.209	4.595	-22.650
MEDTRONIC	0.179×10^{-2}	3.580	7.717
MAXIMA PLUS	0.206	3.050	19.468
MEDTRONIC	0.214×10^{-2}	3.520	7.817
MAXIMA	0.233	6.360	22.627
SORIN	0.219×10^{-2}	3.274	7.828
MONOLYTH	0.243	7.809	-4.932
COBE	0.220×10^{-2}	3.602	--------
OPTIMA ($1.7m^2$)	0.243	6.300	--------
TERUMO	0.225×10^{-2}	3.744	23.934
CAPIOX SX18	0.236	6.223	-28.388

DISCUSSION

From this study we have concluded that the new Gish Vision membrane oxygenator offers the clinician the highest level of oxygen transfer "reserve" of any oxygenator we have tested.

We believe that the four new performance in-

Figure 5: Oxygen transfer indices

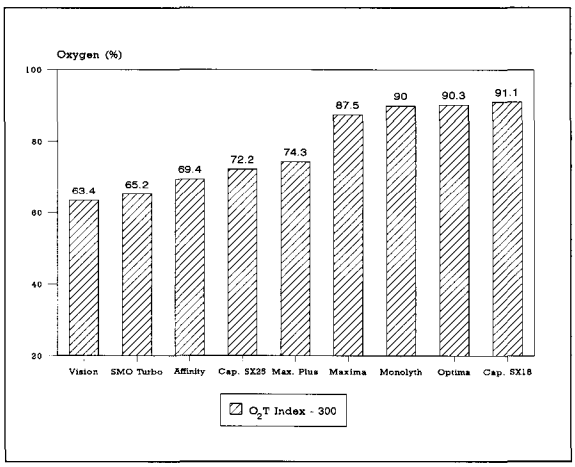


Figure 6: Shunt fraction indices

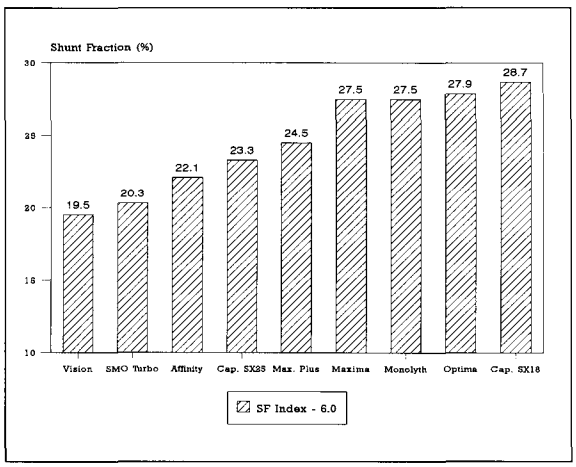


Figure 7: Pressure drop indices

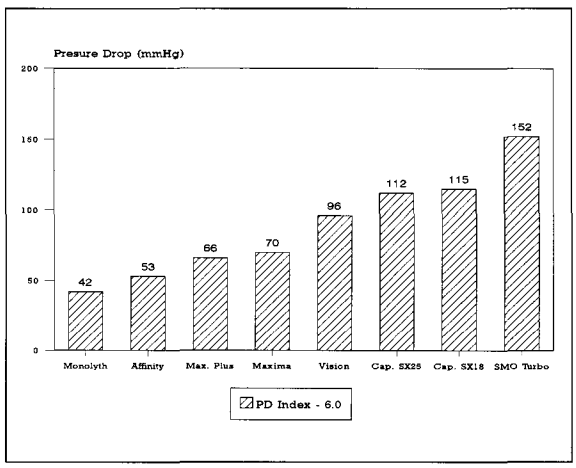
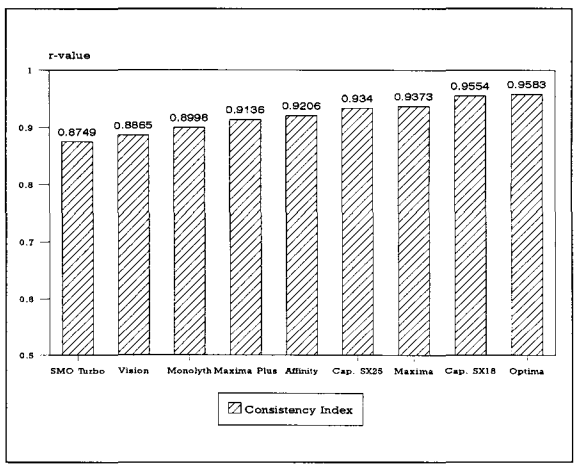


Figure 8: Consistency indices



dices we have proposed will enable the perfusionist to easily compare: 1) the oxygen transfer capability; 2) the degree of blood shunting; 3) the blood side pressure drop; and 4) device-to-device oxygen transfer consistency.

These four indices, coupled with the manufacturer's product information and other clinical oxygenator evaluations, provides perfusionists with objective criteria upon which to base their choice of oxygenator.

Table 3: Oxygen transfer, shunt fraction, pressure drop, and consistency indices for the Gish Vision

OXYGENATOR	O_2T_{I-300} (%)	$SF_{I-6.0}$ (%)	$PD_{I-6.0}$ (mmHg)	C_I
GISH VISION	63.4	19.5	95.9	0.8865
SARNS TURBO	65.2	20.3	152.2	0.8749
AVECOR AFFINITY	69.4	22.1	53.0	0.9206
TERUMO CAPIOX SX25	72.2	23.3	112.0	0.9340
MEDTRONIC MAXIMA PLUS	74.3	24.5	65.8	0.9136
MEDTRONIC MAXIMA	87.5	27.5	69.5	0.9373
SORIN MONOLYTH	90.0	27.5	42.0	0.8998
COBE OPTIMA ($1.7m^2$)	90.3	27.9	--------	0.9583
TERUMO CAPIOX SX18	91.1	28.7	115.2	0.9554

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