Effect of Vessel Compliance on the In-Vitro Performance of a Pulsating Respiratory Support Catheter

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Intravena caval respiratory support (or membrane oxygenation) is a potential therapy for patients with acute respiratory insufficiency. A respiratory support catheter is being developed that consists of a bundle of hollow fiber membranes with a centrally positioned pulsating balloon to enhance gas exchange. This study examined the influence of vessel compliance on the gas exchange performance of the pulsating respiratory support catheter. Polyurethane elastic tubes were fabricated with compliance comparable to that measured in bovine vena cava specimens. The gas exchange performance of the respiratory catheter was studied in an in-vitro flow loop using either the model compliant tube or a rigid tube as a "mock" vena cava. Balloon pulsation enhanced gas exchange comparably in both rigid and model compliant vessels up to 120 bpm pulsation frequency. Above 120 bpm gas exchange increased with further pulsation in the rigid tube, but no additional increase in gas exchange was seen in the compliant tube. The differences above 120 bpm may reflect differences in the compliance of the elastic tube versus the natural vena cava.
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Introduction

Intravenous respiratory support is a potential alternative to mechanical ventilation under development for patients with acute respiratory insufficiency [1–3]. The process involves placing a bundle of hollow fiber membranes, as used in standard extracorporeal blood oxygenators, into the vena cava through insertion at the common femoral vein. The fiber membranes are manifolded and connected to an external oxygen source that provides for continual oxygen "sweep" gas flow through the fiber lumens. Oxygen diffuses out of the fibers into the venous blood, while CO_2 diffuses out of venous blood into the fibers, thus providing supplemental respiratory support independent of the lungs. The extrapulmonary gas exchange reduces the need for mechanical ventilation, and thus can also reduce the associated progressive lung damage that can further exacerbate respiratory insufficiency in the patient [4]. The respiratory support catheter being developed in our laboratory uses a centrally positioned balloon within the fiber bundle [5,6]. Rapid balloon pulsation promotes blood flow past the fiber surfaces, reduces diffusional boundary layer thickness, and increases the gas exchange rate of the respiratory catheter. In recent ex-vivo tests of the catheter [7], balloon pulsation increased gas exchange for both O_2 and CO_2 by 50-500 percent depending on balloon pulsation rate and blood flowrate past the catheter.

Rational design development of a respiratory support catheter requires ongoing device characterization and testing on the bench, usually within a "mock" vena cava flow loop, in which the device is placed within a cylindrical vessel (tube) and perfused at physiological flowrates [6]. As design changes are made in fibers and fiber bundle configuration, pneumatic pathways, and balloon geometry for our catheter, the mock vena cava test allows assessment of these changes under physiologically relevant conditions of controllable known flowrates and defined fixed vessel geometry. Most often rigid tubing has been used as the "mock" vena

cava in a variety of in-vitro bench studies of other intravascular oxygenators [8–10]. Similar to these other studies the "mock" vena cava within which the catheter lies in our bench test is Tygon tubing, which is chosen to reflect the average size of the adult human vena cava, but unlike the vena cava is essentially noncompliant (rigid) in the pressure range involved. Clearly, compliance of the host vessel per se may affect the gas exchange characteristics of a respiratory support catheter with a pulsating balloon. Balloon pulsation and the associated pressures swings can produce wall motion and diameter oscillations in a compliant vessel. These oscillations may impact on the flow patterns surrounding the respiratory catheter and as a result may affect gas exchange achieved by the catheter.

The purpose of this study was to assess in an in-vitro test whether physiologically relevant compliance of the host vessel markedly influences the gas exchange performance of a pulsating respiratory support catheter. Custom fabricated polyurethane tubing was used as the mock vena cava in the bench test system to tailor the compliance of the host vessel to that of the vena cava. Because the literature appears scant for direct measurements of normal vena cava compliance, or compliance of other large veins, we began this study with measurements of vessel compliance in bovine vena cava specimens.

Materials and Methods

The overall methods involved measuring the compliance of bovine vena cava specimens, fabricating an elastic tube with comparable compliance, and measuring the gas exchange performance of the respiratory support catheter in the model compliant tube along with the standard rigid tube as mock vena cava.

Compliance Measurement. Unbranched venous segments of approximately 6 cm were obtained from five calves at necropsy by dissection of the inferior vena cava immediately below the right atrium. The external diameter of the vessel segment was measured with a caliper before removal from the animal. Prior to dissection a fixed clamp was attached to the vessel and the vessel was
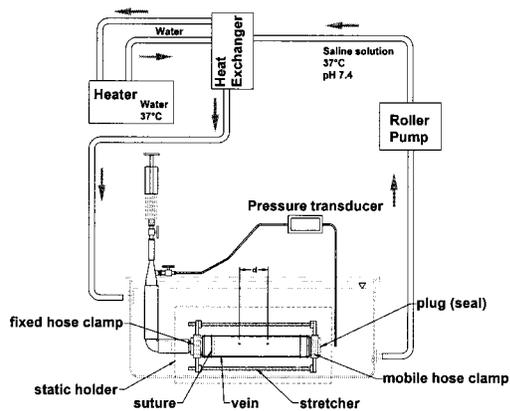
Fig. 1 Experimental setup used to measure specific compliance of bovine vena cava segments and custom fabricated elastic tubes

(i.e., the resting volume). The pressure-volume relationship was then determined by infusing buffer in $\Delta V = 0.5$ ml increments until the transmural pressure reached 40 mmHg (5.33 KPa), at which time the vessel was returned to V_0 and buffer was removed in 0.5 ml increments until the transmural pressure reached -5 mmHg (-0.67 KPa). Transmural pressure was measured using a Validyne differential pressure sensor (CD 379, Northridge, CA) with one port in the vessel lumen and the other in the bath at the same elevation. The pressure volume relationship was averaged over three cycles after two preconditioning cycles to eliminate hysteresis [11]. Specific compliance of the vessel was determined at each transmural pressure as $C = V^{-1} \Delta V / \Delta P$, where V is the volume at the transmural pressure and $\Delta V / \Delta P$ correspond to increasing increments.

The same procedure was also used to measure the specific compliance of the custom fabricated elastic tubes (described below). As a check of our methodology, the specific compliance of commercially available latex tubes (Dynatek Delta Scientific Instruments, Galena, MO) was also measured ($C = 0.0086 \pm 0.00128$ [1/mmHg]) and found to be within approximately 5 percent of the compliance reported by the manufacturer.

Fabrication of Model Compliant Tubing. Custom elastic tubes were fabricated by dipping an aluminum rod 1 in (2.54 cm) diameter and 20 in (50.8 cm) length in a cylinder containing liquid polyurethane solution (Tecoflex Resin SG-85A, Thermedics Inc., Woburn, MA, dissolved in tetrahydrofuran) with viscosity between 760-840 cps. A range of compliance values was achieved by varying the number of dips while allowing 30 min. between dips. Tubes with two dips were found to have comparable compliance as the bovine vena cava and a total of five these tubes were made and tested.

Measurement of Gas Exchange in Compliant and Rigid Tubing. The setup used to measure the gas exchange performance of the respiratory support catheter is shown in Fig. 2. A section of either rigid (Tygon tubing, Cole Palmer, Vernon Hills, IL) or model compliant tubing was mounted in a Plexiglas chamber attached to a flow circuit. Distilled water was pumped at $Q_{\text{water}} = 3$ l/min using a Biomedicus centrifugal pump (Medtronics Inc., Minneapolis, MN) through the vessel test section. An extra-corporeal hollow fiber oxygenator (Plexus, Shiley Inc., Irvine,

marked with two reference ink dots a measured distant apart so that vessels could later be tested at their in-vivo length.

Vessel compliance was measured by placing the dissected vessel segment within the static holder of the setup shown in Fig. 1. Each end of the vessel was tied onto a threaded connector and the connectors were attached to two hosepipe clamps of the static holder, attached to one another by two long screws. The screws were adjusted until the vessel was at its in-vivo length as measured by the reference ink dots. A plug was placed at one connector and the other connector was attached to a piece of tubing. The static holder was then submerged in a solution of isotonic saline, heparin (10 ml/1000 ml), and sodium bicarbonate (8 ml/1000 ml saline) at 37°C, and pH 7.4. The tubing was then attached to a fitting in the chamber that enables the vessel to be filled and emptied.

Before determining the pressure-volume relationship of the vena cava specimen, the vessel was filled with a volume of fluid comparable to its in-vivo volume (V_0) as estimated by the measured in-vivo diameter and length; this is also approximately the volume at which the transmural pressure just rises above zero
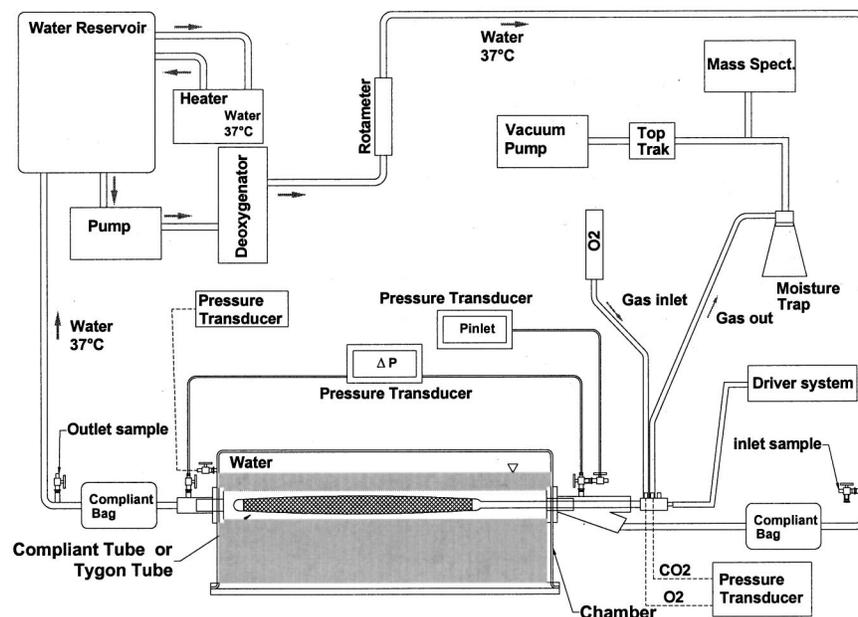

Fig. 2 In-vitro bench circuit for evaluation of gas exchange performance of respiratory support catheter using either rigid tube or custom compliant tube

CA) was placed before the test section to adjust the pO_2 and pCO_2 of the water to 25-40 mmHg (3.34-5.34 KPa) and 45-50 mmHg (6-6.67 KPa), respectively. A circulating temperature bath maintained fluid temperature at 37°C. Compliance bags positioned on both ends of the test section (Neoprene breathing bag, Qosina, Edgewood, NY) were used to absorb volume pulsations of the balloon.

Pure oxygen was pulled at $Q_{gas} = 3$ l/min through the respiratory support catheter fibers under a vacuum pressure of approximately 150 mmHg. Oxygen exchange was determined by measuring the O_2 partial pressure (pO_2) using an ABL-330 blood-gas analyzer (Radiometer, Copenhagen, Denmark) in samples taken before and after the test section. The O_2 exchange was computed according to:

$$VO_2 = (pO_{2in} - pO_{2out})(\alpha * Q_{water}) \qquad (1)$$

where α is the O_2 solubility in water at 37°C (0.0232 ml/ml/760 Torr). The CO_2 exchange rate was determined by measuring the percentage of CO_2 in the exhaust gas from the fiber using a mass spectrometer (Medical gas analyzer, Marquette Electronics, Milwaukee, WI). The CO_2 exchange was computed using:

$$VCO_2 = \%CO_2 * Q_{gas} \qquad (2)$$

Three sets of measurements were taken at each balloon pulsation rate (0, 30, 60, 120, 180, 240 and 300 bpm). VO_2 and VCO_2 exchange rates were normalized to fiber surface area, and in addition the VCO_2 exchange was also normalized to an inlet pCO_2 of 50 mmHg [7]. This minimized the variation in CO_2 exchange associated with changes in the inlet pCO_2 during and between experiments.

Gas exchange performance was first measured for the rigid tube then the model compliant tube. For the model compliant tube, the transmural pressure was adjusted by changing the chamber pressure until the vessel size yielded comparable CO_2 and O_2 exchange rates as in the rigid tube *without pulsations*. This transmural pressure value was maintained at all balloon pulsations. Performance in the model compliant tube and rigid tube was compared by using a Student's t test, with a value of p<0.05 considered a statistically significant difference (*).

All gas exchange tests used our standard respiratory support catheter (10 series) with a 25 cc balloon, a fiber fabric bundle containing 750 polypropylene hollow fibers (X30-240, Celgard, Charlotte, NC) of 30 cm length, and a total membrane surface area of 0.21 m^2.

Results and Discussion

Excised Vena Cava and Model Vessel Compliance. Typical pressure-volume curves for excised bovine vena cava and the fabricated polyurethane tube are shown in Figs. 3(a) and 3(b), respectively. The pressure-volume curve for the vena cava specimen (Fig. 3(a) shows a marked decrease in compliance (increase in slope) with transmural pressures above about 6-9 mmHg (0.8-1.2 KPa). Above this transmural pressure, the decreased compliance reflects the increasing stiffness of stretching wall constituents at greater distension or strain, i.e., nonlinear elasticity of wall tissue [11]. Conversely, the fabricated polyurethane tube (Fig. 3(b) generates a negligible transmural pressure until the tube is completely filled (i.e., an essentially infinite compliance until filled), but once filled (31 ml for the segment shown) offers a finite and approximately constant compliance (slope).

The specific compliance, $C = V^{-1} dV/dP$, associated with all the bovine vena cava specimens ($N=5$) and fabricated polyurethane tubes ($N=5$) tested is shown in Figs. 4(a) and 4(b), respectively. The vena cava specific compliance decreases with increasing transmural pressure, consistent with the increased stiffness that the vessel wall exhibits at increasing levels of strain. In our acute animal implants studies [12,13], central venous (i.e., right atrium) and inferior vena cava pressure typically varies from about 5 to 15 mmHg. In this range of transmural pressure the
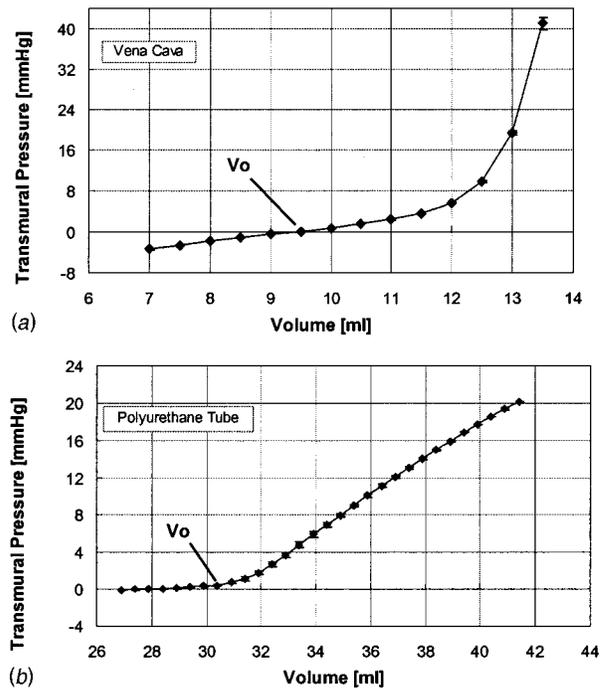

Fig. 3 Typical pressure-volume curves of excised bovine vena cava (a) and fabricated polyurethane tube (b). The data represent the mean ±SD obtained from 3 cycles.
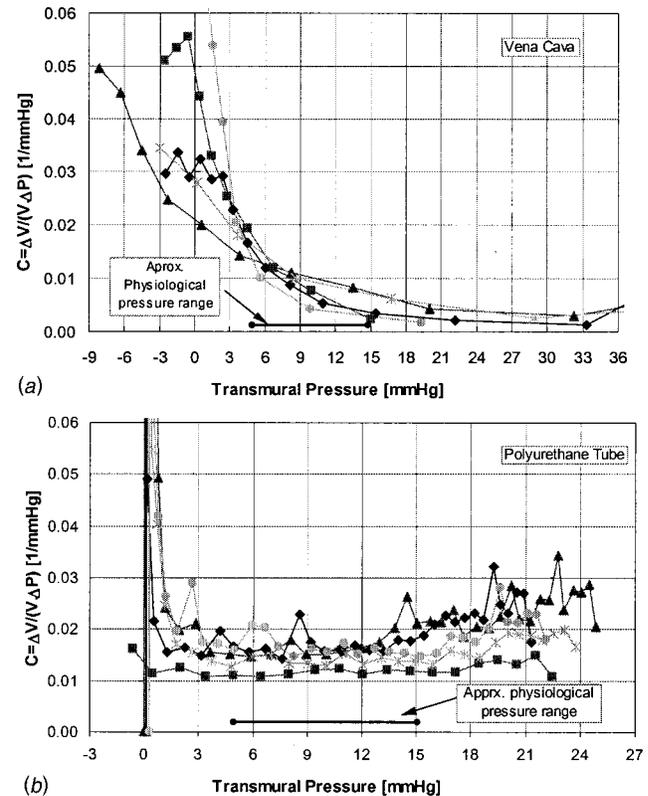

Fig. 4 Compliance curves obtained from experimentation with five bovine vena cava segments (a) and five polyurethane tubes (b). At physiological venous pressure (5–15 mmHg) the compliance of the custom tube is comparable than the vena cava compliance.

Table 1 Compliance of human and canine vessels

Ref.	Vessels	Compliance*	Observation
14	Canine femoral vein	0.19 ± 0.04	Compliance measured between 0 - 3.7 mmHg
15	Human saphenous vein	$0.0220 \pm 0.004 \times 10^{-2}$	
	Human femoral artery	$0.0295 \pm 0.003 \times 10^{-2}$	
19	Human saphenous vein	$0.0225 \pm 0.003 \times 10^{-2}$	Compliance measured between 80 - 120
	Canine femoral vein	$0.0275 \pm 0.003 \times 10^{-2}$	
16	Human saphenous vein	$0.0210 \pm 0.005 \times 10^{-2}$	
	Canine vein	$0.0285 \pm 0.005 \times 10^{-2}$	
17	Human saphenous vein	$0.0170 \pm 0.002 \times 10^{-2}$	
This study	Bovine vena cava	0.0115 ± 0.006	Compliance measured between 5 - 15 mmHg

* All data had been estimated as $C = V^{-1} \Delta V / \Delta P$ [1/mmHg]

average specific compliance for all the specimens shown in Fig. 4 is $C = 0.0115 \pm 0.00606$ [1/mmHg].

To our knowledge the specific compliance of bovine vena cava has not been previously reported and hence the values measured here cannot be directly compared to other studies. Ohhashi et al. [14] measured the specific compliance of the canine vena cava in the transmural pressure range from 0 to 4 mmHg and reported an average value of 0.19 ± 0.04 [1/mmHg] (see Table 1), which is approximately six times the compliance of the bovine vena cava we measured in that same pressure range (0.0310 ± 0.014 [1/mmHg] from Fig. 4). Although species differences are likely, whether this difference can be entirely attributed to species remains unclear. Most studies of vein compliance have addressed veins as arterial vessel autografts [15–18]. Accordingly, these studies have been carried out using femoral arteries [15] or saphenous veins [15–17,19,20], with compliance determination in pressure ranges exceeding 80 mmHg (10.7 KPa), significantly beyond the transmural pressures considered here. Walden et al. [15] and Abbott et al. [16] have shown that at elevated nonvenous pressures (from 50 to 170 mmHg) (6.7-22.7 KPa) veins have less compliance than arteries, with typical values of 0.0220×10^{-2} and 0.0295×10^{-2} [1/mmHg] respectively (Table 1). In this study, at the maximum transmural pressures load placed on the bovine specimens (about 30 mmHg) (4 KPa) the vena cava compliance was less than 0.005 1/mmHg.

Table 2 Compliant measurements in calves' vena cava and polyurethane tubes over physiological pressure range (5-15 mmHg)

	Calves' vena cava mean ± SD [1/mmHg]	Polyurethane tube mean ± SD [1/mmHg]
	0.0112 ± 0.00291	0.0177 ± 0.00342
	0.0115 ± 0.00727	0.0170 ± 0.00210
	0.0091 ± 0.00830	0.0166 ± 0.00182
	0.0104 ± 0.00721	0.0115 ± 0.00058
	0.0115 ± 0.00607	0.0138 ± 0.00080
Average	0.0115 ± 0.00606	0.0155 ± 0.00290

The specific compliance of the fabricated polyurethane tubes once filled (above about 1-2 mmHg) (0.14-0.27 KPa) is essentially constant in our pressure range of interest ($\sim$ 5-15 mmHg). In this range the average compliance for all five fabricated polyurethane tubes is 0.0155 ± 0.0029 [1/mmHg] (Table 2). The differences in compliance among the fabricated tubes results from slight variations in wall thickness based on dip casting procedures. For the gas exchange studies described below, we used the longest fabricated tube (symbol* in Fig. 4(b)), which had an average specific compliance of $C = 0.0138$ [1/mmHg] over the physiological pressure range. Thus the effective compliance of the model vessel is comparable or greater than vena cava compliance in our pressure range of interest.

Gas Exchange in Rigid Versus Model Compliant Vessel. The O_2 and CO_2 exchange rates for the respiratory support catheter in the rigid (i.e., Tygon tube) versus model compliant vessel (i.e., fabricated polyurethane tube) are compared over a range of balloon pulsation rates from 0 to 300 bpm in Figs. 5(a) and 5(b), respectively. In the absence of balloon pulsation (0 bpm), the O_2 (Fig. 5(a)) and CO_2 (Fig. 5(b)) exchange rates in the rigid vessel and compliant vessel are comparable, at approximately 12 ml/min/m² for O_2 and 21 ml/min/m² for CO_2. Vessel size is one of the key determinants of the gas exchange performance of a passive (nonpulsating) intravascular oxygenator [9], since for a given flowrate vessel size dictates the average flow velocity past the oxygenator. Accordingly, that the gas exchange rates in the rigid versus compliant vessel are comparable without balloon pulsation indicates that the average cross-sectional size (i.e., mean diameter or area) of the compliant vessel under the test conditions is effectively equivalent to that of the rigid vessel. Indeed, in our methods we adjusted the transmural pressure in the compliant tube to accomplish this.

Balloon pulsation has a significant and similar effect on the O_2 and CO_2 exchange rates for both the rigid and model compliant vessels. For O_2 (Fig. 5(a), balloon pulsation up to 120 bpm enhanced gas exchange in the model compliant vessel in the same proportion as in the rigid tube, both achieving exchange rates of 67 ml/min/m² at 120 bpm, which represents an approximately 5-fold enhancement relative to no pulsation in both cases. Above
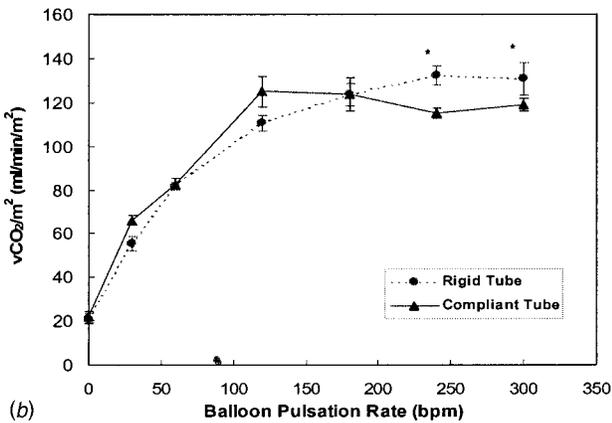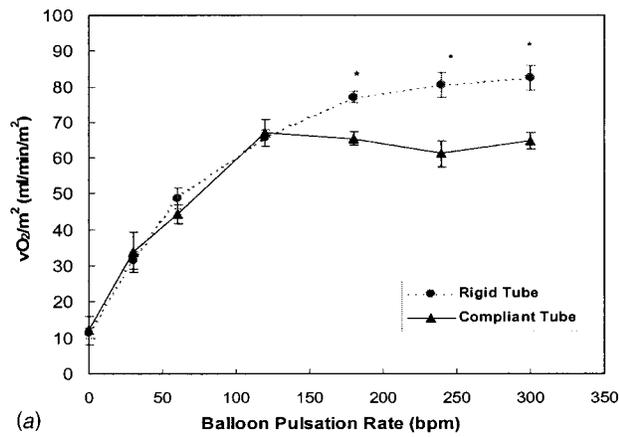
Fig. 6 Mean pressure drop and transmural pressure across the vessels test section measured over the range of pulsation rate

Fig. 5 Oxygen (*a*) and carbon dioxide (*b*) exchange rates in nine experiment of a respiratory support catheter placed in rigid tube and custom compliant tube. The mean flowrate through the test section was maintained at 3.0 liters/minute over the range of pulsation rates. The gas exchange rates had been normalized to the surface area of the respiratory support catheter ($A=0.21$ m^2); VCO_2 also normalized to an inlet PCO_2 of 50 mmHg. The difference in gas exchange in the model compliant vessel versus rigid tube was compared by Student's t test (statistically difference at $P<0.05$*).

120 bpm, the O_2 exchange rate continually increased with balloon pulsation in the rigid vessel, up to 83 ml/min/m^2 at 300 bpm, whereas no additional gain in O_2 exchange above 120 bpm was seen for the model compliant vessel. Indeed, above 120 bpm the O_2 exchange rate appears to decrease slightly in the model compliant vessel. The differences in O_2 exchange in the rigid versus model compliant vessel were statistical significant at and above 180 bpm at the p levels indicated.

Similar qualitative behavior is seen for the variation in CO_2 exchange with balloon pulsation in the rigid versus compliant vessel (Fig. 5(*b*). For CO_2, balloon pulsation up to 180 bpm yielded similar gas exchange enhancement in the model compliant vessel as in the rigid tube, both achieving exchange rates of 125 ml/min/m^2 at 180 bpm, or an approximately 6-fold enhancement relative to no pulsation. Above 180 bpm, the CO_2 exchange rate in the rigid tube continued to increase as balloon pulsation rate increased, up to 131 ml/min/m^2 at 300 bpm, whereas no additional increase in CO_2 exchange above 120 bpm was seen in the model compliant vessel. As for O_2, the CO_2 exchange rate appears to decrease with balloon pulsation rate above 120 bpm, but only the differences in exchange rate for the rigid versus model compliant vessel at and above 240 bpm were statistically significant at the p levels indicated.

For both O_2 and CO_2 the gas exchange behavior in the model compliant vessel above 120 bpm deviates from the continual in-
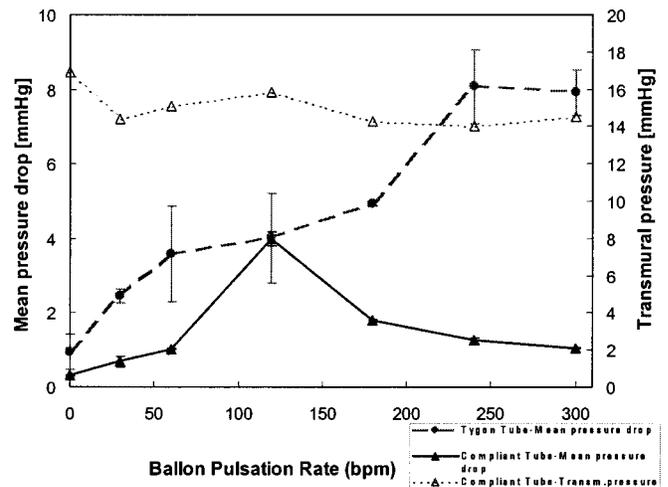
crease in gas exchange characteristic of and seen in the rigid vessel. This departure in behavior from the rigid vessel is also seen in the mean pressure drop across the vessel test section, as shown in Fig. 6. Whereas at lower beat rates the mean pressure drop across the compliant vessel test section increases with balloon pulsation, as it does for the rigid vessel over all pulsation rates, above 120 bpm the mean pressure drop across the compliant vessel test section begins to decrease with increasing balloon pulsation. The decreased flow resistance for the compliant vessel above 120 bpm in general terms reflects less interaction of fluid elements traversing the test section with the respiratory support catheter and its fiber surfaces, which imparts drag on these elements. By similar mechanisms, if fluid drag is reduced (i.e., fiber-fluid momentum transfer) mass transfer is reduced, and thus the apparent decrease in gas exchange for both O_2 and CO_2 in the model compliant vessel is at least consistent with the flow dynamics as described by the mean pressure drop across the test section. These linked effects cannot be attributed to a general *overall* increase in the size of the model compliant vessel above 120 bpm. No marked increase in vessel size was observed, and the mean transmural pressure difference across the model compliant vessel (dashed line in Fig. 6, right ordinate) remains nearly constant or decreases slightly with increasing balloon pulsation rate.

The genesis of the decreased gas exchange and mean pressure drop above 120 bpm can be related to substantial local motion of the vessel wall immediately below (inferior to) the pulsating balloon, a motion that intensified at the higher beat rates. Much of the *observable* effect of balloon pulsation on the model compliant vessel was seen as movement of the immediately inferior wall to and from the fiber bundle and pulsating balloon. While this motion was seen at all pulsation rates and increased with increasing pulsation rate, the inferior wall motion was noticeably stronger above 120 bpm. Figure 7 shows images of the compliant vessel at balloon deflation during no pulsation (0 bpm, Fig. 7(*a*)) and pulsation at 60 bpm (Fig. 7(*b*)) and 240 bpm (Fig. 7(*c*)). The model compliant vessel is approximately cylindrical with no pulsation (*a*) and shows only slight wall movement with pulsation at 60 bpm (*b*). Conversely, the displacement of the inferior wall at a balloon pulsation rate of 240 bpm (c) is appreciable. Furthermore, above 120 bpm the inferior wall noticeably flattens during balloon pulsation (not shown), appearing almost "floppy" during part of the pulsation cycle. This indicates that during balloon deflation at the higher pulsation rates the local transmural pressure difference at the vessel wall below the balloon is near zero, i.e., is sufficiently small that the wall is no longer in tension. Unlike the
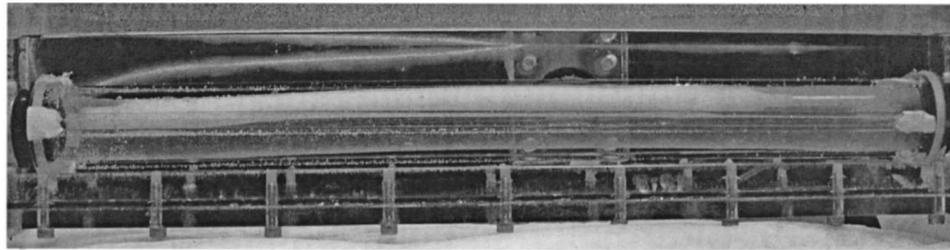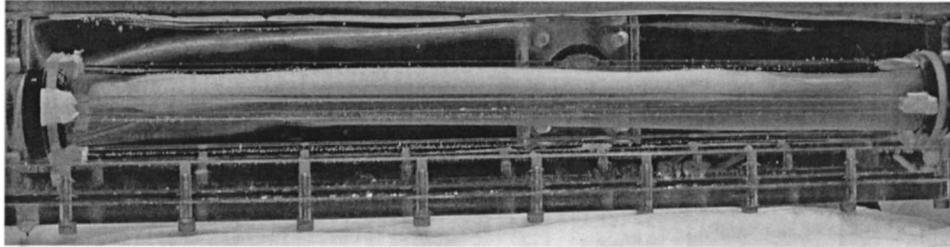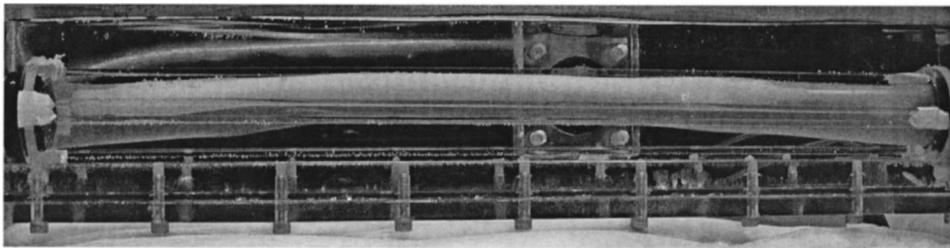
Fig. 7 Respiratory support catheter into the custom compliant vessel during balloon pulsation at 0 bpm (*a*), 60bpm (*b*) and 240 bpm (*c*)

natural vena cava, the compliance of the model compliant vessel rapidly increases near zero transmural pressure (see Fig. 4(*b*)) and motion of the vessel wall would be intensified by this large compliance.

Thus our conclusion is that the unnaturally large compliance of our fabricated compliant vessel at small transmural pressures leads to local changes in vessel geometry at the higher pulsation rates that reduces the interaction of traversing fluid with the fiber bundle, thus reducing gas exchange and the mean pressure drop as a result. If our custom fabricated tubing had shown finite compliance at small transmural pressure, as does the normal vena cava, we would have expected that the vessel wall motion underneath the pulsating balloon would not have been accentuated at the higher beat rates, as seen in these studies. In the absence of that accentuated wall motion the O_2 and CO_2 exchange rates in the compliant model vessel should be similar to that for the rigid vessel at all balloon pulsation rates. In support of this conclusion, our acute in-vivo studies of the respiratory support catheter [12,13] have not indicated that a decrease in gas exchange or blood pressure drop across the catheter occurs as balloon pulsation rate increases above a particular value. We also have not seen accentuated wall motion of the vena cava at higher pulsation rates when we have observed the respiratory catheter pulsing in-situ during open-chested animal preparations.

In this study we chose not to investigate the performance of the respiratory catheter at various levels of vessel compliance. The compliance of our model compliant vessel was close to the high end of compliance measured for the bovine vena cava specimens. Had we found, using this model compliant vessel, that vessel compliance per se does influence the gas exchange performance of the respiratory support catheter we would have needed to assess

the effects of compliance over a broader range, including compliance values intermediate to those investigated here.

Our bench studies of respiratory catheter performance are not intended to mimic in-vivo conditions or predict how a given catheter prototype will specifically perform in-vivo. The in-vivo environment of the respiratory catheter is complicated by features that are difficult to model in-vitro, including irregular shape and size of the vena cava, distributed veins draining into the vena cava and the compliance that these veins provide for flow and pressure pulsations, bidirectional flow past the catheter because of placement partly in the superior vena cava and partly in the inferior vena cava, and potential physiological variations in vessel geometry and flow with time. The bench test of the respiratory catheter is designed primarily as a tool to characterize and compare the performance of different prototype designs along the development pathway. In these bench characterization tests we perfuse with distilled water rather than blood for simplicity and to accommodate the need for multiple and repeatable tests on the same device. Our experience is that catheter performance in water is a good relative predictor of in-vitro performance in blood (i.e., a catheter design yielding greater gas exchange performance in water will also show superior performance in blood). Vaslef et al. have shown a similar correspondence of the gas exchange levels in blood versus water using commercially available membrane oxygenators [21]. Our desire to address the effects of vessel compliance in the bench test is driven less by wanting a more realistic test setup of venous conditions than by recognition that comparative evaluation of balloon enhanced gas exchange among different catheter prototypes might be affected if vessel wall motion resulting from vessel compliance is important. Our conclusion based on these studies is that vessel compliance per se is most likely not

important and that bench tests in rigid model vessels should offer a suitable platform for comparative evaluation of pulsating respiratory catheter prototypes.

Summary and Conclusions

The specific compliance of the bovine vena cava decreased with increasing pressure. In a physiological relevant pressure range (5-15 mmHg), the average specific compliance of all five specimens tested was 0.0115 ± 0.00606 [1/mmHg]. The specific compliance of the fabricated polyurethane tube was approximately constant in the same pressure range with average value of 0.0155 ± 0.0029 [1/mmHg].

Gas exchange levels in the rigid and model compliant tubes increased with 0 balloon pulsation at the same rate up to a pulsation frequency of 120 bpm. Above this frequency no increase in gas exchange occurred in the model compliant vessel, whereas gas exchange in the rigid vessel continued to increase. We attribute this behavior to the local movement above 120 bpm of the vessel wall immediately below the pulsating balloon. This behavior is most likely not seen in physiological application of the respiratory support catheter because unlike the natural vena cava, the model compliant tube has a large (effectively infinite) compliance near zero transmural pressure.

Acknowledgments

References

[1] Tao, W., Zwischenberger, J. B., Cox, C. S., Graves, D., and Bidani, A., 1998, "Intracorporeal Gas Exchange Taking Further Steps," ASAIO J., **44**(3), pp. 224–226.

[2] Zwischenberger, J. B., and Bartlett, R. H., 1995, *ECMO Extracorporeal Support in Critical Care*, Extracorporeal Life Support Organization.

[3] Hattler, B. G., and Federspiel, W. J., 1999, "Progress with the Development of the Intravenous Membrane Oxygenator (MO)," Perfusion, **14**, pp. 311–315.

[4] Rossi, N., Kolobow, T., Aprigliano, M., Tsuno, K., and Giacomini, M., 1998, "Intratracheal Pulmonary Ventilation at Low Airway Pressures in a Ventilator-Induced Model of Acute Respiratory Failure Improves Lung Function and Survival," Chest, **114**, pp. 1147–1157.

[5] Hattler, B. G., Gary, D. R., Sawzik, P. J., Lund, L. W., Walters, F. R., Shah, A. S., Rawleigh, J., Goode, J. S., Klain, M., and Borovetz, H. S., 1994, "Development of an Intravenous Membrane Oxygenator: Enhanced Intravenous Gas Exchange Through Convective Mixing of Blood Around Hollow Fiber Membranes," Artif. Organs, **18**, pp. 806–812.

[6] Federspiel, W. J., Hewitt, T., Hout, M. S., Walters, F. R., Lund, L. W., Sawzik, P. J., Reeder, G., Borovetz, H. S., and Hattler, B. G., 1996, "Recent Progress in Engineering the Pittsburgh Intravenous Membrane Oxygenator," ASAIO J., **42**(5), pp. M435–M442.

[7] Federspiel, W. J., Golob, J. F., Merrill, T. L., Lund, L. W., Bultman, J. A., Frankowski, B. J., Watach, M., Litwak, K., and Hattler, B. G., 2000, "Ex-vivo Testing of the Membrane Oxygenator," ASAIO J., **46**, pp. 261–267.

[8] Tao, W., Zwischenberger, J. B., Nguyen, T. T., Tzouanakis, A. E., Matheis, E. J., Traber, D. L., and Bidani, A., 1994, "Performance of an Intravenous Gas Exchanger (IVOX) in a Venovenous Bypass Circuit," Annals of Thoracic Surgery, **57**, pp. 1484–1491.

[9] Von Segesser, L. K., Tonz, M., Mihaljevic, T., Marty, B., Leskosek, B., and Turina, M., 1996, "Intravascular Oxygenation. Influence of the Host Vessel Diameter on Oxygen Transfer," ASAIO J., **42**(4), pp. 246–249.

[10] Sueda, T., Fukunaga, S., Morita, S., Sueshiro, M., Hirai, S., Okada, K., Orihashi, K., and Matsuura, Y., 1997, "Development of an Intravascular Pumping Oxygenator Using a New Silicone Membrane," Artif. Organs, **21**, pp. 78–78.

[11] Attinger, E. O., 1969, "Wall Properties of Veins," IEEE Trans. Biomed. Eng., **16**, pp. 253–261.

[12] Macha, M., Federspiel, W. J., Lund, L. W., Sawzik, P. J., Litwak, P., Walters, F. R., Reeder, G. D., Borovetz, H. S., and Hattler, B. G., 1996, "Acute In-Vivo Studies of the Pittsburgh Intravenous Membrane Oxygenator," ASAIO J., **42**, pp. M609–M615.

[13] Golob, J. F., Federspiel, W. J., Merrill, T. L., Frankowski, B. J., Litwak, K., Russian, H., and Hattler, B. G., 2000, "Acute In-Vivo Testing of an Intravascular Respiratory Support Catheter," ASAIO J., (In press).

[14] Ohhashi, T., Morimoto-Murase, K., and Kitoh, T., 1992, "Physiology and Functional Anatomy of the Venous System," *Veins: Their Functional Role in the Circulation*, Springer-Verlag, New York, pp. 33–47.

[15] Walden, R., L'Italien, G. J., Megerman, J., and Abbott, W. M., 1980, "Matched Elastic Properties and Successful Arterial Grafting," Archives Surgery, **115**, pp. 1166–1169.

[16] Abbott, W. M., and Bouchier-Hayes, D. J., 1978, "The Role of Mechanical Properties in Graft Design," *Graft Materials in Vascular Surgery*, Herbert Dardik, Chicago, pp. 59–78.

[17] Lye, C. R., Summer, D. S., and Strandness, D. E., 1975, "The Transcutaneous Measurement or the Elastic Properties of the Human Saphenous Vein Femoropopliteal Bypass Graft," Surg. Gynecol. Obstet., **141**, pp. 891–895.

[18] Duncan, D. D., Bargeron, V. B., Borchardt, S. E., Deters, O. J., Gearhart, S. A., Mark, F. F., and Friedman, M. H., 1990, "The Effect of Compliance on Wall Shear in Casts of a Human Aortic Bifurcation," ASME J. Biomech. Eng., **112**, pp. 183–188.

[19] Benbrahim, A., L'Italien, G. J., Milinazzo, B. B., Warnock, D. F., Dhara, S., Gertler, J. P., Orkin, R. W., and Abbott, W. M., 1994, "A Compliant Tubular Device to Study the Influence of Wall Strain and Fluid Shear Stress on Cells of the Vascular Wall," J. Vasc. Surg., **20**, pp. 184–194.

[20] Walker, R. D., Smith, R. E., Sheriff, S. B., and Wood, R. F. M., 1999, "Latex Vessel with Customized Compliance for Use in Arterial Flow Model," Physiological Measurement, **20**, pp. 277–286.

[21] Vaslef, S. N., Mockros, L. F., Anderson, R. W., and Leonard, R. J., 1994, "Use of a Mathematical Model to Predict Oxygen Transfer Rates in Hollow Fiber Membrane Oxygenators," ASAIO J., **40**, pp. 990–996.