In Vitro Comparison of ECC Blood Flow Measurement Techniques

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Abstract

Four extracorporeal blood flow measurement devices were compared for accuracy: the digital display (Stockert-Shiley roller pump), the Sarns doppler flow probe, the Transonic ultrasonic flow probe and the Biomedicus electromagnetic flow probe. The effects of changing temperature and hematocrit at various flows were compared.

Eighty-four blood flow measurements were recorded for hematocrits from 17.5% to 35.0%, temperatures from 25 to 37°C and flows from 3.0 to 5.5 LPM. A summary of the results follows:

<table>
<thead>
<tr>
<th>Device</th>
<th>ACTQ(r²)</th>
<th>HCT</th>
<th>TEMP</th>
<th>INTER</th>
<th>MEAN</th>
<th>STD. DEV</th>
<th>%DIFF</th>
<th>%DIFF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biomedicus</td>
<td>.98</td>
<td>.0001</td>
<td>NS</td>
<td>.0053</td>
<td>1.0</td>
<td>2.3</td>
<td></td>
<td></td>
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<tr>
<td>Sarns</td>
<td>.96</td>
<td>.0203</td>
<td>NS</td>
<td>.0053</td>
<td>1.0</td>
<td>3.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sarns RPM</td>
<td>.99</td>
<td>NS</td>
<td>NS</td>
<td>.05</td>
<td>2.2</td>
<td>3.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transonic</td>
<td>.99</td>
<td>.0001</td>
<td>NS</td>
<td>.0053</td>
<td>2.2</td>
<td>3.0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ACTQ(r²) = correlation with actual flow, HCT = hematocrit effect on difference (p value), TEMP = temperature effect on difference (p value), INTER = 2way ANOVA interaction, MEAN/STD DEV %DIFF = average and one standard deviation of the percent difference between actual and reported flow, NS = non-significant.

All flow measurement systems correlated with actual flow(p<.001). The Biomedicus, Sarns and Transonic errors were affected by hematocrit, while none were affected by temperature. (p<.05)

Introduction

Accurate knowledge of the blood flow rate during extracorporeal circulation (ECC) is an important aid in judging the adequacy of perfusion and in performing calculations such as oxygen delivery, oxygen consumption, systemic vascular resistance and cardiac index. The purpose of this study was to compare four flow measuring devices and determine the accuracy of each. The actual output was measured via a graduated container and compared to a roller pump digital display, an ultrasonic flow probe, a doppler flow probe and an electromagnetic flow probe. The effects of changing hematocrits and temperature on the accuracy of the flow measuring devices were also quantitated since fluctuations in these variables may result in reported flow rates that are significantly different from actual flow rates (1, 2, 4, 5).

Concerning the roller pump, an analogy can be made comparing its output and the left heart output (2):

LV Cardiac Output = Stroke Volume x Heart Rate (Eq. 1) or

ECC Pump Flow Output = Pump Stroke Volume x RPM (Eq. 2)

The roller pump stroke volume is determined by (3):

Roller Pump Stroke Vol = Raceway Length x Pi x Radius² (Eq. 3).

For the roller pump, perfusionists find it most convenient to calibrate flow rate in liters per minute to a specific number of roller head RPM's; thereby enabling the flow reading from the digital display (4). The digital display has a calibration factor set and confirmed prior to each case/procedure by the perfusionist.

Pump Blood Flow = Calibration Factor x RPM's (Eq.4)

The calibration factor is assumed to remain constant with normal ECC technique variables. However, the roller pump flow readout may not always be an accurate estimate of flow rate, particularly if the occlusion is not set properly (2, 3). An ECC device which accurately measures blood flow rate independent of the variables which affect the roller pump output is desirable. Three such devices are available: the Transonic ultrasonic flow probe, the Sarns doppler flow probe and the Biomedicus electromagnetic flow probe.

The Transonic flow probe consists of a probe body housing an upstream and a downstream ultrasonic transducer on one side and a fixed acoustic reflector positioned midway between the two transducers on the opposite side. The circuitry within the
flowmeter operates the flow probe through two cycles. First, an electrical excitation causes the downstream transducer to emit a plan wave of ultrasound. This wave passes through the tubing, bounces off the acoustic reflector, passes through the tubing again, and is received at the upstream transducer. The upstream transducer converts the received acoustic vibrations into electrical signals. The flowmeter analyzes the received signal and records an accurate measure of the time it took for the wave of ultrasound to pass from one transducer to the other. Next, the transmit-receive sequence of the upstream cycle is repeated, but with the transmitting and receiving functions of the transducers interchanged. Thus, the liquid flow is now transversed by the ultrasonic wave in the opposite direction. Again, the flowmeter derives and records from this transmit-receive sequence an accurate measure of the transit time. The transit time measured by the flow probe is affected by motion in the ultrasound-conducting medium. On the upstream cycle, the sound wave travels against one vector component of the flow on each half of its reflective pathway, which increases the total transit time by a specific amount. In the downstream cycle, the sound wave travels with a vector component of the flow on each half of its reflective pathway, which decreases the total transit time by the same amount. Flowmeter circuitry then subtracts the downstream transit time from the upstream transit time, resulting in a difference signal proportional to the volume flow of the moving liquid. The transit time shift difference signal is subsequently scaled to correspond with the predetermined calibration factor of the flow probe and displayed as the absolute volume rate of flow through the flow probe in ml/min or l/min (a).

The Sarns (b) doppler flow probe utilizes a transmitting transducer that emits an ultrasonic signal which reflects off red blood cells to a receiving transducer. Blood velocity is detected by way of the frequency shift of the reflected ultrasound. The blood velocity is multiplied by the internal cross-sectional area of the tubing to yield flow rate in l/min (7).

The Biomedicus electromagnetic flow probe contains an externally excited electromagnet which creates a magnetic field across the probe in a direction perpendicular to the blood flow. An ion-bearing blood flows through the lumen of the tubing it generates a voltage directly proportional in magnitude to the velocity of the flowing blood. The voltage creates a current which flows through the detecting electrodes to an amplifier where the voltage is dropped across a large resistor. From the voltage difference velocity of the blood is determined, and flow rate may be calculated by multiplying velocity by the internal cross-sectional area of the probe lumen (5).

Hematocrit and temperature are two ECC parameters that are routinely changing during cardiopulmonary bypass. Variations in either parameter have been known to alter roller pump output by altering blood viscosity and tubing flexibility (2, 6).

Methods and Materials

The in vitro extracorporeal circuit in Diagram 1 was created utilizing a Stockert-Shiley roller pump (c), a Sarns membrane oxygenator (d), a Baxter-Bentley custom periodic tubing pack (e), a CR Bard H4700 filtered cardiotomy (f) an Atrium closed drainage system (g) (ACDS), a Sarns doppler flow probe (b), a Bio-Medicus electromagnetic flow probe (h), a Transonic ultrasonic flow probe (i), and a Hemotherm heater/cooler (j).

Diagram 1:

![Diagram 1: IN VITRO ACCURACY TEST CIRCUIT](image)

c. Shiley, Inc., Irvine, CA 92714
d. Sarns Inc., Ann Arbor, MI 48103
e. American Bentley, Irvine, CA 92714
f. C.R. Bard Inc., Billerica, MA 01821
g. Atrium Medical Corporation

h. Bio-Medicus, Eden Prairie, MN 55344
i. Transonic Systems Inc., Ithaca, NY 14850
j. Cincinnati Sub Zero, Cincinnati, OH 45241
k. BMDP Statistical Software, Inc., Los Angeles, CA 90025
The circuit was designed to facilitate accuracy, safety and ease of blood flow measurement. The primary circuit involved circulation of blood through line "A". A second circuit utilizing line "B" was then created to divert blood flow from the primary circuit into a graduated measurement system (a modified ACDS) to obtain actual flow. A second roller pump was then utilized to return the contents of the ACDS back to the cardiotomy. By judicious placement of tubing clamps, blood flow could be channeled to the cardiotomy for recirculation, or to the ACDS for measurement. Measurement accuracy of the ACDS collection chamber was tested against a laboratory grade graduated cylinder and found to be accurate to within 0.5%.

All flow probes were positioned in line according to manufacturers' specifications, distal to the oxygenator and proximal to the cardiotomy. The roller pump digital flow readout was calibrated by verifying the output read 2.65 LPM at 100 RPM's and the circuit was primed with 0.9% NaCl solution. Occlusion of the roller pump was set at just non-occlusive (1 cm/min fluid drop at a 30 cm height), and was not readjusted for the duration of the experiment.

Following removal of the initial crystalloid prime from the system, the circuit was primed with outdated packed red blood cells, outdated fresh frozen plasma, 5% human albumin, sodium heparin (1000 U/ml), and NaHCO₃ (1 mEq/ml). The prime was adjusted at each stage of the experiment to achieve the desired test hematocrit, temperature and colloid oncotic pressure.

The three flow probes were then zeroed and calibrated per manufacturers' instructions. Calibration of the Sarns doppler flow probe, which is a clamp-on sensor, entailed verification that the correct flow sensor had been selected for the tubing size and that the calibration number from the flow sensor was entered into the message display on the pump console. The Biomedicus electromagnetic flow probe, which utilizes a disposable in-line connector, required entering the appropriate gain factor from the probe into the pump console. The Transonic ultrasonic flow probe, another clamp-on probe, requires factory calibration for a specific temperature and tubing type. The manufacturer states that for accurate measurements at alternate temperatures or tubing types factory calibration is usually necessary. For this reason, a specific section of polyurethane tubing, supplied by the manufacturer, was inserted in-line and used with the Transonic flow probe.

Two subgroups were created from the study parameters. Subgroup one held temperature constant at 25°C and varied blood flow and hematocrit. Subgroup two held blood flow constant at 4.49 LPM and varied temperature and hematocrit. After the stabilization of blood temperature and hematocrit, blood flow through the primary circuit was manipulated until the study flow rate was indicated on the digital display of the roller pump. The flow rate value from each flow measurement was inserted in-line and used with the Transonic flow probe. The manufacturer states that for accurate calibration is usually necessary. For this reason, a specific section of polyurethane tubing, supplied by the manufacturer, was inserted in-line and used with the Transonic flow probe.

Subgroup one held temperature constant at 25°C and varied blood flow and hematocrit. Subgroup two held temperature constant at 4.49 LPM and varied flow and hematocrit. After the stabilization of blood temperature and hematocrit, blood flow through the primary circuit was manipulated until the study flow rate was indicated on the digital display of the roller pump. The flow rate value from each flow measurement was then recorded. The actual blood flow was then collected and measured. This was accomplished by three simultaneous events: the placement of a tubing clamp on the cardiotomy return line (line "A"), the removal of a clamp from the ACDS inlet line (line "B"), and the starting of a quartz crystal stopwatch. Pump flow was diverted into the ACDS for exactly 15 seconds and multiplied by four to obtain the actual flow in LPM. Each measurement was performed in triplicate.

Mean % error from actual blood flow and standard deviation of the % error for each measurement system were calculated and recorded. The effect of temperature and hematocrit on the flow measurement system was evaluated independently. The mean % errors at each hematocrit, at all flows and temperatures, were subjected to an analysis of variance utilizing BMDP Statistical Software (k), and likewise, the mean % errors at each temperature were analyzed.

A significant difference between hematocrit or temperature groups was indicated at p<.05. In addition, a two-way analysis of variance was performed on each device at every combination of hematocrit and temperature to determine if there existed any interaction between hematocrit and temperature and if this interaction contributed to any error in flow reporting.

**Results**

As shown in Table 1, each flow measurement device has a very strong correlation ($r^2$) with the actual flow (p<.0001) over all ranges of flows, temperatures and hematocrits (n=84). In addition, Table 1 lists each device's mean % error and standard deviation of % error.

<table>
<thead>
<tr>
<th>TABLE 1</th>
<th>CORRELATION COEFFICIENT ($r^2$)</th>
<th>MEAN % ERROR</th>
<th>STD. DEV %ERROR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biomedicus</td>
<td>.98</td>
<td>1.0</td>
<td>2.3</td>
</tr>
<tr>
<td>Sarns Doppler</td>
<td>.96</td>
<td>1.6</td>
<td>3.2</td>
</tr>
<tr>
<td>Shiley RPM</td>
<td>.99</td>
<td>-2.3</td>
<td>1.5</td>
</tr>
<tr>
<td>Transonic</td>
<td>.99</td>
<td>4.3</td>
<td>1.4</td>
</tr>
</tbody>
</table>

Each device's measured flow versus actual flow is shown in Graphs 1-4. The regression equation and correlation coefficient are provided with each graph.

**GRAPH 1**

![ACTUAL FLOW VERSUS BIOMEDICUS FLOW](image)

Y = 0.98X + 0.18. r² = .98
Table 2 summarizes the effects of hematocrit and temperature variations on the percent error of each device.

Variations in temperature from 25°C to 37°C had no significant effect on mean % error of any device. The mean % error at each temperature, for all hematocrits and flows, is shown for all devices in Graph 5.

Hematocrit affected all devices except the Shiley roller pump digital readout. Graph 6 shows the mean % error at each
hematocrit for each device over all temperatures and flows. Analysis of variance between the mean % error at each hematocrit for the Bio-Medicus flow probe showed a statistically significant difference (p<.05), as shown in Table 3.

**TABLE 3: HCT Effect on Biomedicus Flow Probe**

<table>
<thead>
<tr>
<th>HCT</th>
<th>17.5</th>
<th>25.0</th>
<th>29.0</th>
<th>35.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>17.5</td>
<td>----</td>
<td>.0059</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>25.0</td>
<td>----</td>
<td>NS</td>
<td>NS</td>
<td>.0001</td>
</tr>
<tr>
<td>29.0</td>
<td>----</td>
<td>NS</td>
<td>NS</td>
<td>----</td>
</tr>
<tr>
<td>35.0</td>
<td>----</td>
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</tr>
</tbody>
</table>

NS = not significant (p>.05)

The mean % error at hematocrit 17.5% is statistically different than each other hematocrit; however, mean % error at hematocrits of 25.0%, 29.0% and 35.0% do not differ from each other.

The mean % error of the Sarns doppler flow probe was significantly influenced by changing hematocrits. As shown in Table 4, the comparison between flow mean % error at hematocrit 17.5% and hematocrit of 35.0% was the only-grouping to show significant statistical difference.

**TABLE 4: HCT Effect on Sarns Flow Probe**

<table>
<thead>
<tr>
<th>HCT</th>
<th>17.5</th>
<th>25.0</th>
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<th>35.0</th>
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<tbody>
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<td>NS</td>
<td>.0052</td>
</tr>
<tr>
<td>25.0</td>
<td>----</td>
<td>NS</td>
<td>NS</td>
<td>----</td>
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<td>----</td>
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<tr>
<td>35.0</td>
<td>----</td>
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</tr>
</tbody>
</table>

NS = not significant (p>.05)

The mean % error of the flow reading of the Transonic flow probe was statistically affected by changes in hematocrits. Table 5 shows matched groups that were different along with their associated p value.

**TABLE 5: HCT Effect on Transonic Flow Probe**

<table>
<thead>
<tr>
<th>HCT</th>
<th>17.5</th>
<th>25.0</th>
<th>29.0</th>
<th>35.0</th>
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<td>17.5</td>
<td>----</td>
<td>NS</td>
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<td>.0001</td>
</tr>
<tr>
<td>25.0</td>
<td>----</td>
<td>NS</td>
<td>.0007</td>
<td>----</td>
</tr>
<tr>
<td>29.0</td>
<td>----</td>
<td>NS</td>
<td>----</td>
<td>----</td>
</tr>
<tr>
<td>35.0</td>
<td>----</td>
<td>----</td>
<td>----</td>
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</tr>
</tbody>
</table>

NS = not significant (p>.05)

A two-way analysis of variance was performed on all the data for each flow measuring device to determine if there existed any interaction between the effects of changing hematocrit and temperature. The Bio-Medicus flow probe was the only device to show such an interaction (p=.0054). (See Table 2)

**Discussion**

Comparing the reported flow rate of the four flow measuring devices, Shiley roller pump digital display, Sarns doppler flow probe, Transonic ultrasonic flow probe and Biomedicus electromagnetic flow probe to actual flow provided the conditions necessary to evaluate the accuracy of each device. For a device to be accurate it must be both unbiased, which refers to the tendency of a set of measurements to be equal to a true value, and precise, which refers to the spread of observations and is measured by the standard deviation. The values of mean % error and standard deviation of % error reported in Table 1 were derived from all measurements taken, over all flows, temperatures and hematocrits (n=84).

Since conditions during bypass are not static but vary with regard to flow, temperature and hematocrit, we felt our method of scrutinization was appropriate. Likewise, since the opportunity to stop flow and zero and calibrate flow measuring devices rarely occurs during bypass, each device was zeroed and calibrated, per manufacturers' specifications, at the onset of the investigation and not readjusted.

As reported in Table 1, no one device was the most unbiased and most precise. The Bio-Medicus electromagnetic flow probe was the most unbiased while the Transonic ultrasonic system was the most precise. Each device exhibits a very high correlation coefficient which is an indication of the strength of the relationship between measured and actual flow. Upon examination of Graphs 1-4, it can be noted that the Bio-Medicus flow probe is more unbiased at higher flows while the Shiley roller pump readout is most unbiased at the lower flow rates. The error in the Sarns and Transonic flow probes does not appear to be flow dependent. Each device is judged to be accurate since a percent error less than five is considered clinically acceptable. These findings agree with previously published studies.

In determining the effects of temperature variation on the flow measuring device the mean % error at each temperature (over all flows and hematocrits) was compared by analysis of variance.

As reported in Table 2 and shown in Graph 5, temperature alone did not affect the mean % error of any of the devices tested (p>.05). The output of the roller pump is believed to be afterload insensitive as long as the occlusion of that pump is properly set. However temperature affects tubing flexibility which may change the occlusion setting or memory and therefore change the pump stroke volume. Contrary to other studies, which found that as temperature increases roller pump output increases, the range of temperatures used in this study did not effect (p=.89) the mean % error of the roller pump.

The Transonic ultrasonic flow measuring system is calibrated at the factory for use at a specific temperature. The probe used in this study was calibrated for a temperature of 37°C. Even with this temperature specification the device displayed no significant change (p=.88) in mean % error over the range of temperatures studied.

The Bio-Medicus electromagnetic flow probe, which has been reported to show a significant increase in error at higher
temperatures (9), did show an increase in % error at higher
temperatures (Graph 5), but was determined to not be of
significance (p=.15). Likewise, the Sarns doppler flow probe
displayed no statistically significant (p=.69) change in mean %
error over the range of temperatures utilized in our study.

As reported in Table 2, change in hematocrit did affect
changes in mean % error in three of the four devices tested. The
effects of changing hematocrit on the Bio-Medicus
electromagnetic flow probe have been previously investigated
(5, 9). Wagoner has reported that as hematocrit increases, a
series of events proceed which lead to an artificial reduction of
flow indication (5). Our results support the conclusion that as
hematocrit increases the electromagnetic flow measurement
decreases; in addition, the results indicate that at lower
hematocrits the measured flow is erroneously elevated
(p=.0059). Moreover, an analysis of variance between mean %
errors at each hematocrit reveals that the error at hematocrit
17.5% is the only mean to be statistically different from all the
others and increasing hematocrit from 25.0% to 35.0% leads to
no significant change in mean % error.

The doppler flow measuring devices have been shown to read
false low at hematocrits below 19.0%. The findings of this
study concur with this trend. (In fact, upon priming our test
circuit with crystalloid solution the Sarns doppler flow probe
was unable to report any flow at all.) Over the range of
hematocrits tested here, the only significant (p=.0052) change in
% error was found by comparing mean % error of the 17.5%
hematocrit with the 35.0% hematocrit group. This indicates that
large variations in hematocrit are necessary to disrupt the Sarns
doppler flow probe’s measuring ability. Also, Graph 6 shows
that as hematocrit decreases the mean % error of the doppler
probe become negative.

The Transonic flowmeter is not dependent upon the
movement of red blood cells or charged molecules for its flows
measurements and is therefore reported to be essentially
hematocrit insensitive. Hematocrit does, however, have a slight
effect on the acoustic velocity of blood, and therefore on the
difference in transit-time. For blood with normal hematocrit
(38%-45%), the Transonic flowmeter sensitivity will vary
slightly. This slight effect on reported or measured flow at
normal hematocrits can, however, become increasingly
important if the blood is diluted with saline, plasma or other
media. The Transonic manufacturers offer the following: for
every 8.3 unit decrease in hematocrit, apparent Transonic flow
will increase by 1%. When saline is used as a diluent, every
7.25 unit decrease in hematocrit yields a 1% increase in
apparent flow. Our findings strongly agree with those
guidelines. As shown in Graph 6, when decreasing hematocrit
from 35.0% to 29.0% the mean % error increases by 0.6 and a
decrease in hematocrit from 29.0% to 25.0% yields an increase
of 0.7 in the mean % error and a further drop in hematocrit from
25.0% to 17.5% results in an increase in mean % error of 0.9.
The results of the analysis of variance of the hematocrit effect
on the Transonic flow probe are shown in Table 5.

In conclusion, we feel that all the flow measurement devices
tested in this study demonstrate an acceptable degree of error.

Variations in temperature had no significant effect on any
device while variations in hematocrit significantly affected the
Biomedicus electromagnetic flow probe by causing falsely
elevated readings at low hematocrits. The Sarns doppler flow
probe required large variations in hematocrit (17.5 to 35.0%) to
be significantly affected, while the Transonic flow probe was
significantly effected by moderate variations in hematocrit (17.5
to 29.0% or 25.0 to 35.0%).

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Questions and Answers

Q. I was wondering if you did all of your calculations against zero
resistance or if you built in some line resistance to simulate a pump
run?
A. We didn't build in any resistance. We initially considered
keeping an afterload constant on the roller pump with a screw clamp,
but decided not to. It did measure afterload at a little bit higher flow
and it was around 100mm mercury for the whole range of flows. But
we didn't increase afterload more than this. That might be a
consideration if we ever wanted to repeat the experimentation, use a
screw clamp to apply 300mm mercury afterload which would be
consistent over the whole range of measurements.

Q. First let me congratulate you on a well thought out paper. I was
wondering if you had incorporated or thought about the influence time
has over flow. Because our finding with the Biomedicus was initially,
the accuracy seems to hold over an extended period of time. Then
accuracy has a tendency to wander i.e., the flow probe, the read out
wander from its own set at 0 so I am wondering if you extrapolated out
a time sequence into your studies?
A. No, sir, we didn't. When we achieved our desired flow
temperatures and hematocrit we allowed it to circulate there for a while
for proper mixing of the hematocrit and so forth to make sure it was
consistent throughout the circuit. Once we observed a fairly stable
reading from all the flow devices—the doppler, Transonic® and
electromagnetic—we let it circulate before we wrote those numbers
down. We didn't keep a record of how long we simply wrote those
numbers down. It's an interesting point though, thank you.