A Better Bladder for ECMO Controls
Pump Flow as a Function of Inlet Pressure

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The most popular pump used for ECMO is the roller pump. The RP is a positive displacement pump that is insensitive to inlet or outlet pressure.

The pump can generate:

- Pin –600 mmHg
- Pout > 2,000 mmHg
What does the Bladder do?

The Bladder protects the patient from the excess negative pressure the pump can generate and that can damage the blood as well as the cannulated blood vessel.
How does the Bladder/Bladder Box Work?

When inlet pressure to the pump falls below ambient pressure, the silicone bladder empties. A microswitch senses an empty bladder and switches off the power to the pump.

When the bladder refills the pump restarts.
Silicone Bladder/Bladder Box Limitations

Flow Control

- Gravity Drainage Dependent = Bladder on Floor
- On - Off Flow Control
Limitations

Long Tubing (Patient to Floor)

• Greater prime volume
• Larger foreign surface
• Blood resides in tubing for a longer time (greater heat loss and greater blood/surface interaction)
Silicone Bladder + Bladder Box Limitations

Poor Flow Dynamics

Blood Cells Settle
Limitations of the Silicone Bladder,
Summary

1. Maximum flow is limited to the height of the patient above the floor
2. On/Off control does not take advantage of computer controlled roller pumps
3. Poor flow dynamics - more prone to clotting.
4. Placement on the floor can be hazardous
5. Difficult to use when transporting a patient
What to do?
Develop a Better-Bladder System that provides:

• VAVD for roller pumps that increases flow
• On/Off or Continuous flow control
• Flow pattern less conducive to cell settling
• Shorter tubing
• Need not be placed on the floor
Control pump speed as a function of inlet pressure.

Pressure Monitor and Controller

Negative pressure = Gravity Drainage

Patient
The Inlet Pressure of a Roller Pump is Pulsatile

Pulsatile pressure at pump inlet prevents smooth pump control

![Diagram of a roller pump showing pull and push actions with pulsatile pressure graph]
How the Better-Bladder™ is Made

Tube + Balloon + Housing = BB
The Better-Bladder

- Senses Pressure
- Provides Compliance
Functional Tests: Experimental Setup

INLET PRESSURE INDIRECT

-200 mmHg

INLET PRESSURE DIRECT

-200 mmHg

Reservoir

DIGITAL COMPUTER

DATA ACQUISITION
DATA ANALYSIS
PUMP SPEED CONTROL
BB Provides a High Fidelity Pressure Signal

Avg. Pin = -100 mmHg
The Inlet Pressure of a Roller Pump is Pulsatile

Pulsatile pressure at pump inlet prevents smooth pump control

![Diagram showing roller pump with pull and push arrows]

![Graph showing pulsatile pressure over time]

W/O - Bladder (120 RPM)
Roller Pump + BB
Inlet Pulse Pressure is Dampened

W/O -Bladder (120RPM)

With Better-Bladder (120RPM)
Pump Control with the Better-Bladder:

Inlet pressure signal controls pump speed:

- On/Off
  
or

- Continuos (e.g. CAPS)
Better Flow Dynamics
Silicone Bladder

Blood cells settle

Better-Bladder™

Blood cells wash through
The BB Allows Increased Flow

Flow = \Delta P/\text{Resistance}

The older bladder collapsed at ambient pressure. The BB collapses at the negative pressure set by the user. Blood can be actively pulled from the patient. No need to raise the bed or drop the bladder to the floor.
High Pressure Tests of Balloon

- Housing side is open to atmosphere
- 1500 mmHg applied to blood side
- Balloon expands to housing
- Housing supports thin section
The BB Withstands Large Internal Pressures
The BB Requires Shorter Tubing

- Gravity Drainage
- Silicone Bladder
- Additional tubing length

Pressure Monitor and/or Pump Controller

Negative pressure = Gravity Drainage

Better Bladder

PATIENT
The Better-Bladder Provides:

- “Adjustable” gravity drainage - VAVD
- Flow less conducive to cell settling
- On/off or continuous flow control (e.g. CAPS system)
- Shorter circuit tubing
The Better-Bladder Provides

Shorter Tubing

- Lower prime volume
- Reduced foreign surface
- Blood resides in tubing for a shorter time (lowers heat loss and blood/surface interaction)
Indications for Use – The Better-Bladder™ is a device that isolates pressure transducers from blood contact when measurements of blood pressure in extracorporeal circuits are made during short and long term procedures. The pressure signal can be used to control pump speed. It is also used as an inline reservoir to provide compliance in the circuit during short and long term procedures.
To Bladder or not to Bladder?

Yehuda Tamari

Circulatory Technology Inc. Oyster Bay, NY
Why use a Bladder for ECMO?
Computerized Roller Pumps

Blood flow is controlled as a function of pump inlet pressure.

When inlet pressure drops below a settable pressure, the pump slows down or stops.

When inlet pressure increases above the set point, pump flow returns to its set value.
Recent comments/questions from the ECLS-Net

• “Is anyone removing or considering removing the bladder out of their ECMO circuit that uses roller pumps?”

• “We have PVC tubing in place of the bladder and it has worked very well.”

• “We have a collapsible Silastic bridge.”

No reasons were given for eliminating the bladder.

Cost? Complexity? reliability?

There were no mentions of using a bladder with centrifugal pumps.
When making changes to a circuit

Practice Caution

• What follows are results of some tests that we conducted with and without a bladder under ECMO settings.

• Serve as an outline for the type of tests that should be conducted prior to removing or replacing the bladder.
Pump flow is controlled as a function of inlet pressure

Should we pump
with a bladder or without a bladder

Pressure Monitor and/or Pump Controller

Patient

Better Bladder

Pressure Monitor and Controller

Patient
Pump flow is controlled as a function of inlet pressure.

Compliance can be provided by:

The Silicone Bladder

The Better Bladder

- Pressure Monitor and Controller
- Pump
- Bladder
- Bladder Box
- Negative pressure = Gravity Drainage

Better Bladder
Experimental Setup
Pump Controlled by Venous Line Pressure

Controller set to stop flow at Pin = -30mmHg
Reduce venous flow below pump flow and record the pressures

Sample rate-1000/sec

Data Acquisition
Measure pressure at:
Cannula tip
Pump inlet
Control Pump flow

ECMO Roller Pump

Cannula
Clamp
Bladder

"Patient" venous side
"Patient" arterial side
"LV"
Pump Controlled by the Instantaneous Inlet Pressure:

w/o a Bladder Results in Erratic Pump Flow
Pump Controlled by the Instantaneous Inlet Pressure:

Electronic Pressure Averaging

Time (s)

Pavg@0.05sec

Pavg@1.5sec

Avg 1.5sec, W/O Bladder
Pump Controlled by Electronically Averaged Inlet Pressure

Q\text{pump}=500\text{ml/min}, \quad Q\text{pt.}=400\text{ml/min}

W/O Bladder
Pump Controlled by Electronically Averaged Inlet Pressure

Pavg@1.5sec
Pavg@0.05sec
PLo=-30mmHg

Qpump = 500 ml/min,
Qpt. = 400 ml/min
Avg 1.5sec, W/O Bladder
Pump Controlled by Electronically Averaged Inlet Pressure

w/o a Bladder
The BB at the Pump Inlet Provides compliance and reduces pressure pulsation.

Pressure Monitor and/or Pump Controller

Negative pressure = Gravity Drainage

Better Bladder
Bladders Absorb the Pressure Fluctuations of the Roller Pump
Pump Controlled by Electronically Averaged Inlet Pressure
With a Bladder

W/O Bladder
With Bladder

\[ P_{\text{Lo}} = -30\text{mmHg} \]

\[ Q_{\text{pump}} = 500 \text{ ml/min} \]
\[ Q_{\text{pt.}} = 400 \text{ ml/min} \]

Avg 1.5 sec
High Negative Pump Inlet Pressure is also Seen at the Tip of the Venous Cannula

Qpump = 750 ml/min
Abrupt Venous Flow Cessation
Avg 0.05sec
Pump Controlled by the Instantaneous Inlet Pressure:

Results in Erratic Pump Flow

Pump Set = 600ml/min
Patient = 410ml/min
P instantaneous

P w/o BB
Flow w/o BB
Pump Controlled by the Instantaneous Inlet Pressure

Pump Set = 600 ml/min
Patient = 410 ml/min
P instantaneous
Maximum Suction due to Abrupt Stoppage of Venous Flow. Using the Jostra roller pump with and w/o a bladder.

![Graph showing minimum pressure (mmHg) with different pump flows (ml/min) and with or without a bladder (BB).](cirtec.com)
Are Bladders Required When Centrifugal Pump are Used for ECMO?

Effects of a bladder placed at the pump inlet on:

- the maximum negative pressure at pump inlet due to abrupt stoppage of venous flow.
- the pump outlet pressure due to abrupt stoppage of venous flow.
- the air handling of a CP.
Experimental Setup: CP

Data Acquisition
Measure pressure at:

Control Pressure

Oxygenator Pressure

MicroPorous Memb. Oxy.
Inlet Pressure to a CP - Abrupt blockage of Venous Flow
Pressure drops faster and lower w/o a bladder

-500
-400
-300
-200
-100
0
100

P (mmHg)

Pvenous w/o BB
Pvenous + BB

Flow = 2.5 LPM
Pump = 3700RPM

Time (sec)
Inlet Pressure to a CP - Abrupt Blockage of Venous Flow

Pressure drops faster and lower w/o a bladder

Flow = 5.5 LPM
Pump = 3000 RPM
Pressure at Oxygenator can Become NEGATIVE

Flow = 2.5 LPM
Pump = 3700 RPM
Abrupt stoppage of Venous Flow can Cause the Pressure at Oxygenator to go NEGATIVE

Flow = 5.5 LPM
Pump = 3000 RPM

Time (sec)
Abrupt stoppage of Venous Flow can Cause the Pressure at Oxygenator can Become NEGATIVE

When pressure on blood side of a MPMO falls below the gas pressure then there is a significant possibility that gas will flow across the porous membrane into the blood side of the oxygenator and into the arterial line.
Air handling of roller pumps

A

RP

Heat Exchanger

Bubble Counter

B
Air handling of roller pumps

- A: Heat Exchanger
- B: Bubble Counter
- RP: Roller Pump
Air handling of roller pumps

A

Heat Exchanger

B

Bubble Counter

RP
Air handling of roller pumps

- Heat Exchanger
- Bubble Counter
- RP
Air handling of roller pumps

Heat Exchanger

Bubble Counter

RP

A

B
Air handling of roller pumps
Air handling of roller pumps

Heat Exchanger

Bubble Counter
Air handling of roller pumps
Air handling of roller pumps

- Heat Exchanger
- Bubble Counter
- CP
- A
- B
Air handling of centrifugal pumps

Heat Exchanger

Bubble Counter

CP

A

B
Air handling of centrifugal pumps
Air handling of centrifugal pumps

Heat Exchanger

Bubble Counter
Air handling of centrifugal pumps

Heat Exchanger

Bubble Counter

CP

A

B
Air handling of centrifugal pumps

- A
- CP
- Bubble Counter
- Heat Exchanger
- B
Air handling of centrifugal pumps

Heat Exchanger

Bubble Counter

CP
Air handling of centrifugal pumps
Air handling of centrifugal pumps

Heat Exchanger

Bubble Counter

CP

A

B
Air handling of centrifugal pumps

Heat Exchanger

Bubble Counter

CP

A

B
Air handling of centrifugal pumps
Bladders Trap Air

Bladders trap large bubbles

CP

Large Bubbles

Micro Bubbles

CP
Air handling of centrifugal pumps – Experimental setup

- **Centrifugal Pump**
- **Air in (1, 5, 8cc)**
- **Outlet Pressure**
- **Flow meter**
- **Vacuum -400mmHg**
- **Micorporous memb oxyg**
- **Gas port Closed**
- **Large Bubbles**
- **Small Bubbles**
- **Clamp**
- **Bladder**
- **Heat Exchanger**
- **MP Oxy**
- **Bubble Counter (15u to 95u)**
- **Bubble counted here**
- **500 ml/min**
- **PRV**
- **“Patient”**
- **Air removal**

**Note:** The diagram shows the experimental setup for air handling in centrifugal pumps, focusing on the process of air removal, pressure regulation, and bubble counting.
Centrifugal Pump for ECMO – The Air Study

CP Flow = 500ml/min
Air in = 3cc
Water

- W/O a bladder
- With a bladder

15 u Bubble count

Pump Speed (RPM)
Centrifugal Pump for ECMO – The Air Study
(Blood Flow = 500 ml/min, 1 cc Air)

Flow = 500 ml/min
Poutlet = 300 mmHg
Air in inlet = 1 cc
*Bubbles >100u were not counted

Heat Exchanger Inlet
Heat Exchanger Outlet

With BB | w/o BB | With BB | w/o BB
Roller Pump | 268 | 159 | Centrifugal Pump

cirtec.com
Bladders Add a Safety to Centrifugal Pumps Used for ECMO

• Provide compliance that reduces rate of change in pressure and allow better pump control as a function of venous line pressure.

• Reduce the maximum negative pressure due to abrupt stoppage of venous flow.

• Eliminate negative pressure at the outlet of the pump due to abrupt stoppage of venous flow.

• Reduce microbubbles generation by the pump.
To Bladder or not to Bladder? - Costs Considerations

Avg. cost for a neonatal ECMO ~ $100,000/wk. Peds, post-op cardiac cases, adults, etc. are much higher.

Avg. Cost of ECMO pt. - entire hospital stay .......... $300,000

West Coast hospital
Average hospital cost during ECMO ................. $195,860
Avg. Cost of ECMO pt. - entire hospital stay ........ $427,027

The bladder cost is about 0.1% of the total cost.
To Bladder or not to Bladder? - Costs Considerations

Costs of post hospital care are also significant.

52% ECMO infant survivors have abnormal neuro-imaging (Bulas & Glass Semin Perinat 29:58-65 2005)

12 % have severe mental handicap (FSIQ < 70) and 37% are at risk for school failure. (Rais-Bahrami et. al. Clin Pediatr: 39(3):145-52, 2000)

The bladder cost is less than 0.1% of the total cost.
To Bladder or not to Bladder?

Costs Considerations

Since the bladder’s cost less then 1/1000 of the total cost of ECMO,

If the bladder prevents a single patient from being exposed to microbubbles or vessel damage due to excess negative pressure at the cannula

Then its cost has been justified for hundreds of patients.
Bladders placed at the pump inlet

- Dramatically reduce the maximum negative pressure at the pump inlet and at the tip of the venous cannula. Reduced vessel damage?
- Reduce pressure pulsations at the pump inlet and at the tip of the venous cannula. More Physiological?
- Provide smoother pump operation. Less clotting?
- Cleared by the FDA for that purpose.
- Standard of care - reduce liability.
To change a circuit/procedure the user must answer to the affirmative the following:

- Is it as safe or safer than current practice?
- Is it standard of care?
- Is it supported by publications in a peer reviewed journal?
- Could it introduce other problems?
- Do we have the team with the educational background to properly evaluate the effects of the change?
Blood damage: The Centrifugal Pump

Depends on shear stress (i.e. RPM) and exposure time.

The greater the shear and the longer the exposure time the greater the damage.
CP’s Flow Characteristics*

*Courtesy of Cobe Lab.
Blood damage: The Centrifugal Pump

Since the line pressure in the adult and neonate circuits are similar. And, since the pump speed varies little with flow but is mostly dependent on line pressure. Then, we can conclude that the shear stress within the pump for neonates approximates that for adults. Any difference in blood damage between adults and neonates flow conditions is due to differences in exposure times to that shear.
Blood damage by CPs

For a CP with a prime volume of 50 ml, the residence time at 5.0 LPM is 0.6 sec. At 0.5 LPM it is 10 times longer or 6.0 sec.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Pout mmHg</th>
<th>Flow LPM</th>
<th>Time sec</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult</td>
<td>250</td>
<td>5.0</td>
<td>0.6</td>
</tr>
<tr>
<td>Neonate</td>
<td>250</td>
<td>0.5</td>
<td>6.0</td>
</tr>
</tbody>
</table>
The finger damage test

Exposure to 0.6 sec

= Little or no damage.
The finger damage test

Exposure to 6.0 sec

Major damage
Serotonin released from sheared platelets relates to exposure time*

*Brown et al. Trans. ASAIO 21:35, ‘75
Blood damage: Comparing RP to CP

Hemolysis:
Shear stress (*i.e.* RPM)
Exposure time.

\[ \text{RPM} = f(\text{pressure}) \]
\[ \text{Exposure time} = f(1/\text{Flow}) \]

\[ \text{Shear} \times \text{Time} \approx \text{Pressure} \times (1/\text{Flow}) \]
The effects of pressure and flow on hemolysis caused by Bio-Medicus centrifugal pumps and roller pumps. Guidelines for choosing a blood pump.

Guidelines for choosing a blood pump: RP v. CP

Data taken from: Oku, Jakob, Palder, Englehar, Igo, Kress, and
Guidelines for choosing a blood pump: RP v. CP

Hemolysis for the Biopump is higher than that of the roller pump when the ratio of the pressure divided by the flow is less than 0.35

When:

\[
\frac{\text{Pressure (mmHg)}}{\text{Flow (ml/min)}} > 0.35
\]

use the roller pump.
Hemolysis – Choosing between RP and CP

- Use CP when the flow is less than a certain pressure.
- Use RP when the flow is greater than a certain pressure.
Hemolysis – Choosing between RP and CP

It is important to note that in later studies, when the RP was set nonocclusively, the RP was always less hemolytic than the CP*.

*A dynamic method for setting roller pumps nonocclusively reduces hemolysis and predicts retrograde flow.

Questions?

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