

## 2021 Coagulation - oxygenator changeout

Permission to print:	Yes
Category	Coagulation
Incident type	Good Catch No Harm Incident
Duration of incident:	minutes
Description:	<p>Patient 39 YO male Ht 175cm and weight 58.5 KG with a history of RHD, S/P balloon MV valvuloplasty. Procedure AVR and MVR with CPB. The circuit consisted of a Sorin S-3 roller pump, Sechrist gas blender, Terumo FX15 oxygenator and Terumo custom tubing pack with X coated tubing set with 3/8 - 3/8" ID AV loop and a 1/2" ID boot. Monitoring consisted of a Specturm M-4 Viper monitor. The patient was heparinized with 300u/KG of unfractionated heparin. The post heparin ACT was 435sec. Since there was 10,000u of heparin in the prime we proceeded to CPB. After initiating CPB the flow was increased to 4.2l/min. The PaO2 was 136mmHg with 100% FiO2. ? This was lower than expected, Our center is located 6300ft above sea level and our hospital oxygen system consists of an oxygen concentrator system. Often our wall oxygen is between 82-95%. I had set my Flo2 at 100% but at that time the Oxygen Concentrator was put out 80-85%. The PO2 increased with cooling to 32C. As cooling proceeded the PaO2 increased to 180mmHg. The initial post membrane line pressure was 195 mmHg. Fifteen minutes after the heart was arrested with 1,000 ml of Del Nido Cardioplegia, it was noted that the post membrane pressure dropped to about 150mmHg and there was a blood leak at a connector before the oxygenator. The pre membrane pressure was measured and found to be approximately 600mmHg. (Trans membrane pressure ~450, should be 100-140). Additional 10,000 units of heparin was administered (subsequent ACT492). A change out in this case was decided primarily due to high pressure excursion. I thought the circuit would explode if we continued. Oxygenation was a marginal secondary problem The membrane was changed without coming off bypass using the PRONTO Technique. Our circuit has a 3/8 bridge around the oxygenator. The pre and post membrane pressure can be measured from LL connection by simply moving a clamp. An inspire 6 oxygenator was added to the circuit. The post membrane pressure increased to 220mmHg and the PaO2 increased to 400mmHg. After CPB the first oxygenator was rinsed and inspected. There was high resistance across the oxygenator and visible clot seen in the fiber bundle.</p>
GOOD CATCH - what went well	<p>The surgeon and anesthesia team was informed about the problem. The PRONTO bridge in our circuit allowed us to check both pre and post membrane pressure. The second oxygenator could be added to the circuit without coming off bypass. There was no interruption of blood flow to the patient or signs of lactic acidosis. We have used a PRONTO bridge in our circuit for every procedure.</p>
What could we do better	<p>Administered more heparin when the initial ACT was less than 480sec. This patient had double valve disease and a presumably higher blood volume. Checked the pre membrane pressure and lower PO2 pre X clamp.</p>
Preventive actions	<p>We might have considered loading with 400u/KG of heparin. A formal check that perfusion is all ok including the pre membrane pressure before aortic cross clamps applied.</p>
Hospital incident filed:	No
Ext Authority Advised	No
Rule issue	Yes
Skill issue	No
Discussed with team:	Yes
Patient outcome variance	Nil
Commentary	<p>This incident exemplifies a good catch with preventive action planning - using the PRONTO bridge for seamless expeditious oxygenator changeout. This procedure was published in 2002 and is attached. A youtube video shows the ease of use of this technique. <a href="https://www.youtube.com/watch?v=kehXUDGjZj8">https://www.youtube.com/watch?v=kehXUDGjZj8</a> . A very recent report to</p>

PIRS on an oxygenator change out fortunately able to be made before cross clamp application elicited a correspondent to PIRS to question why the PRONTO procedure was not in routine use. This report clearly demonstrates the safety advantage of the PRONTO technique and centres should give serious consideration to its adoption. PIRS Ed



Washed out oxygenator showing clot

# Parallel replacement of the oxygenator that is not transferring oxygen: the PRONTO procedure

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We present here a technique to replace a failed oxygenator by inserting a second oxygenator in parallel (PRONTO) within the cardiopulmonary bypass (CPB) circuit. Oxygenator failure is a potential hazard that may result in patient injury or death. Although failures are rare, safety surveys conducted over the last 25 years suggest that the incidence of oxygenator failures is on the rise. This emergency

procedure may be easily applied to any standard CPB circuit with a few minor alterations. The technique is simple; it can be carried out rapidly. An important advantage of this technique is that it may be executed without interrupting blood flow to the patient, which may reduce the incidence of patient injury or death. *Perfusion* (2002) 17, 447–450.

## Introduction

Failure of the oxygenator during cardiopulmonary bypass (CPB) presents the surgical team with a serious and potentially fatal problem requiring a swift and well-coordinated response. Unfortunately, the incidence of oxygenator failure is on the rise.<sup>1–4</sup> We describe here a CPB circuit modification that allows rapid parallel replacement of an oxygenator not transferring oxygen (PRONTO).

If poor oxygenation occurs during CPB, the surgical team should be informed. The use of a checklist or oxygenator failure algorithm can be a useful tool to check for correctable malfunctions such as a leak in the oxygenator gas supply, a malfunction of the oxygen blender, or an incorrect blood flow path. These components should be examined rapidly and thoroughly. If the heart is beating and it is possible to ventilate the patient and separate from CPB, this should be carried out immediately.

If, however, the surgical procedure is at a point where it is not possible to separate from CPB, the decision must be made expeditiously to replace the oxygenator while on bypass. The PRONTO procedure described herein allows rapid transition to a functioning oxygenator, without interrupting blood flow.

## Circuit modification and change-out procedure

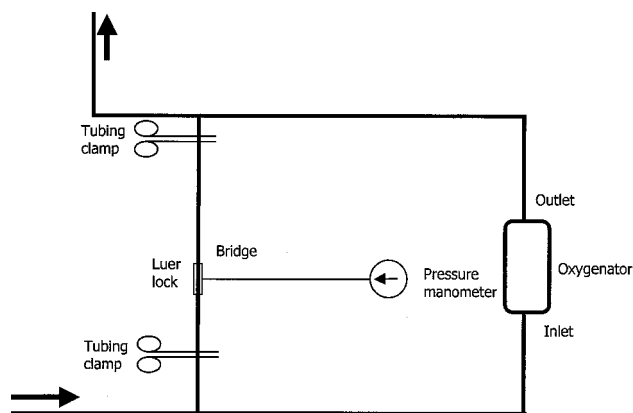
The CPB circuit is routinely set up with a shunt inserted between the inlet and outlet of the oxygenator using a 10-in. length of 3/8-in. tubing and two 3/8 'y' connectors. A luer-lock connector is placed in the center of the shunt. This luer-lock site may be used to monitor the arterial line pressure, and by clamping the shunt distal or proximal to the luer-lock, pre- and postmembrane pressures may be measured as well.

The equipment required for executing the change-out includes one additional tubing clamp, a pair of sterile scissors, an alcohol swab, and a replacement oxygenator.

In the event of an oxygenator failure, additional volume, equivalent to the priming volume of the membrane bundle and the heat exchanger, must be added to the venous reservoir. A clamp is placed on the oxygenator bypass line as close to the distal 'y' as possible (Figure 1). The tubing is swabbed and then divided with sterile scissors equidistant between the luer-lock connector and the distal 'y' (Figure 2). The new oxygenator is connected to the two exposed ends of the tubing (Figure 3). The recirculation lines

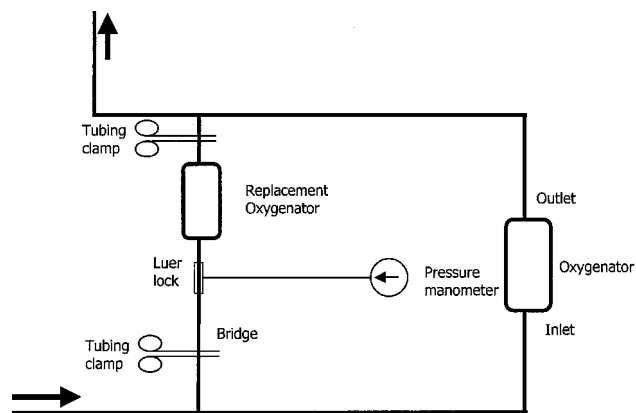
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**Figure 1** Isolating the bridge in preparation for parallel replacement of the oxygenator.

from the new oxygenator are then connected to the cardiotomy reservoir and are left open. The clamp at the inlet of the oxygenator is removed, allowing the unit to fill and causing air to be expelled through the recirculation lines (Figure 4). The oxygenator is tipped and tapped gently to allow all of the air from the connections to be dispelled. After visual inspection to confirm that all of the air has been purged from the device, the gas line is moved to the replacement oxygenator, the recirculation lines are closed, and the clamp distal to the replacement oxygenator is removed and placed proximal to the inlet of the failed oxygenator (Figure 5). The patient is then monitored to confirm adequate oxygenation. After adequate oxygenation has been established, the heat exchanger may be connected to the water supply as necessary. During this procedure, safety devices such as the air bubble detector and low-level alarm remain functional. The arterial line pressure will be reading premembrane pressure and, if desired, a purge line from the arterial filter can be connected to the pressure monitor to determine transmembrane pressure. There are a minimal number of steps involved



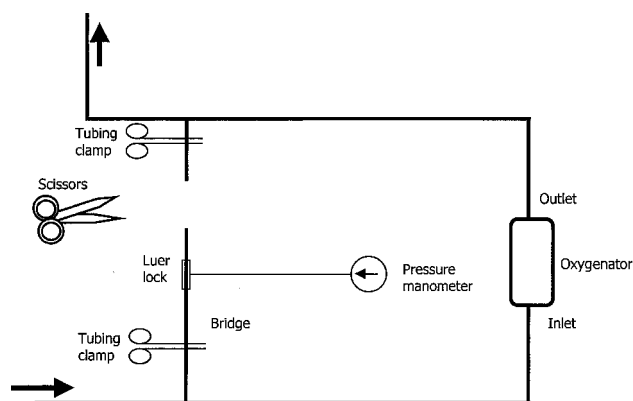
**Figure 3** Replacement oxygenator placed in parallel with failed oxygenator.

with this procedure, which should require less than 90 seconds to complete.

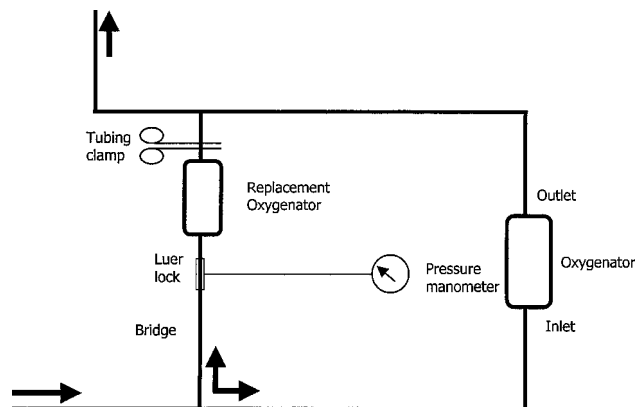
## Discussion

A 1980 survey of open heart centers in the USA determined the incidence of oxygenator failure to be 1:56 000.<sup>1</sup> Similar USA surveys conducted in 1986 and 1999 showed oxygenator failure rates of 1:13 600 and 1:2700, respectively.<sup>2,3</sup> Surveys of the UK and Ireland in 1993 and 1997 showed oxygenator failure rates requiring change-out of 1:4034 and 1:4631, respectively.<sup>4</sup> This increasing rate of oxygenator failures is alarming. However, the incidence remains so infrequent that it has been difficult to definitively determine the causes of these oxygenator failures. A number of proposed mechanisms have been suggested as potential causes.

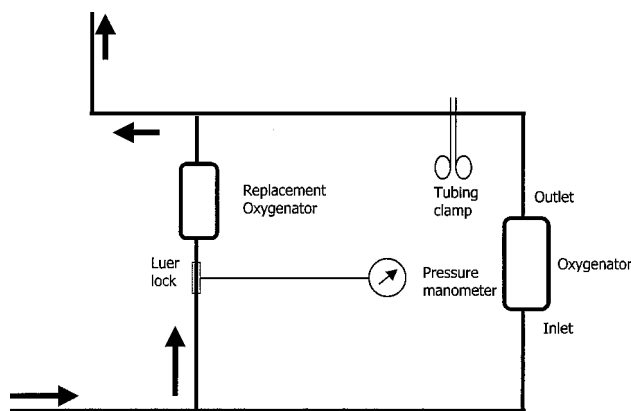
Palanzo *et al.* reported a rapid rise in oxygenator transmembrane pressure shortly after the initiation of CPB.<sup>5</sup> It was believed that this pressure excursion may have been triggered by cooling the patient and



**Figure 2** Bridge divided equidistant between Luer lock and distal 'y'.



**Figure 4** Removal of proximal clamp, allowing replacement oxygenator to prime.



**Figure 5** Clamp moved from outlet of the replacement oxygenator to the inlet of the failed oxygenator.

was alleviated upon warming. This same phenomenon was reported by other centers in the USA, Canada, and Europe, occurring with various hollow fiber oxygenators.<sup>6</sup> Although the exact mechanism remains unknown, there have been numerous hypotheses offered. Bearss *et al.* attribute these increases in transmembrane pressures to the deposition of cold reactive proteins upon the surface of the heat exchanger, causing a narrowing of the blood path.<sup>7</sup> Schaadt believes that the increased incidence of these high transmembrane pressure gradients is due to oxygenator designs that focus on increasing efficiency while decreasing prime volume, and describes that, in an effort to design high-efficiency, low-prime oxygenators, manufacturers must decrease the blood channel dimensions. Thus, any further reduction in these channels' dimensions, caused by depositions, would cause a marked increase in resistance to blood flow and an increase in transmembrane pressure.<sup>6</sup> It has also been noted that these pressure gradients are not limited to low-prime oxygenators, but that this phenomenon is more pronounced and occurs sooner in these than in higher-prime oxygenators.<sup>5,6</sup>

Others have suggested that these increases in transmembrane pressures are caused by the activation of platelets and their subsequent deposition with fibrinogen on the membrane surface. Aniuik *et al.* have noted that many of these occurrences have been associated with the use of hydroxyethyl

starches in the CPB priming solution.<sup>8</sup> Palanzo *et al.* have shown that the addition of albumin in the prime solution prior to CPB can be protective for platelets. Furthermore, this protective effect occurs with as little as 2 g of albumin in the prime solution.<sup>9</sup>

It has also been suggested that sodium nitropruside or nitric oxide may ameliorate this phenomenon by decreasing platelet activation.<sup>10,11</sup> In a study by Rauch *et al.*, nitric oxide was introduced into the sweep gas of an *in vitro* circuit. The scanning electron microscopy study of the oxygenator membranes showed a decrease in fibrin and cellular deposits in the membranes that had nitric oxide added to the sweep gas compared to membranes that were ventilated without nitric oxide.<sup>11</sup>

Wendel *et al.* examined the incidence of high transmembrane pressure gradients and the use of coated circuits. They found a higher rate of abnormally high transmembrane pressures in the noncoated circuits when compared to coated circuits. The group hypothesized that the coated circuits caused less blood activation, which may play a role in the build-up of fibrin and platelets in membrane oxygenators.<sup>12</sup>

Parallel replacement of a hollow-fiber oxygenator was reported as early as 1988 by Hart *et al.*<sup>13</sup> The authors' technique required the placement of sections of tubing and connectors at the oxygenator inlet and outlet. They also recommended the flushing of the device with carbon dioxide. The technique required dividing the tubing in two places. They also reported that the advantage of parallel replacement is that it eliminates the period of circulatory arrest. They further stated that it minimizes the amount of hemodilution that occurs when a failed oxygenator is removed from the circuit and replaced.

An oxygenator failure is a potentially catastrophic event that necessitates an immediate and precise response. Whenever possible, ventilation of the lungs and controlled separation from CPB are the best option, provided the heart has not been arrested, and the heart and aorta are intact. The PRONTO technique allows rapid replacement of a failed oxygenator, there are a minimal number of steps required to perform, and, more importantly, it is safe as there is no interruption in blood flow and all major safety devices remain active and functional.

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