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Holder System for External Pumps Positioned Remote from the CPB Console: 23 Years' Experience

Umberto Borrelli, Marc Detroux, Remi Nottin, Stephane Nikis and Pierre Nakers

Additional information is available at the end of the chapter

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Abstract

Since 1995, our objective is to set up the extracorporeal circulation (ECC) in a manner that is both safe and versatile with a holder system which makes possible to install the oxygenator and vacuum-assisted venous drainage (VAVD) hard-shell venous reservoir (HSVR) together with the external pumps, at a distance from the cardiopulmonary bypass (CPB) console but at the same height as the patient's shoulder. The aim is to reduce the effects of ECC by reducing surface of air/blood, blood/materials contact, the dead space of the system and priming volume of the circuit. Our ECC systems have a biocompatible surface treatment, the oxygenator and HSVR are adapted to the patient (body surface area, pathologies, etc.) and circuit includes short 3/8 in arterial and venous line (adult patients). We introduced into routine VAVD, retrograde autologous priming (RAP), including arterial line, arterial filter and antegrade autologous priming of the venous line (VAP) before the start of ECC. To confirm this development strategy of the ECC, we conducted a series of studies that have permitted to demonstrate the positive impact on postoperative outcomes of patients. Since September 2007, our objective was attained through the creation of a holder system (System U. Borrelli).

Keywords: extracorporeal circulation, holder system, external pumps, reducing surface, vacuum-assisted venous drainage

1. Introduction

The extracorporeal circulation (ECC) is associated with a systemic inflammatory response (SIRS), with an activation of different biological pathways such as the coagulation and the fibrinolysis [1]. The ECC creates many hemostatic disturbances that may lead to major

bleeding risks, and eventually to thrombotic, myocardial, renal or pulmonary complications and neurological dysfunctions [2–4]. During the last decade, several improvements have been made on the ECC used within cardiac surgery, especially with the arrival of many systems in the market, such as the mini-ECC and the optimised conventional ECC which are closer to the patient's physiology and having surface treatments capable of improving the hemocompatibility of ECC [5]. These new systems have allowed to reduce the aggressiveness of the ECC on the patients, allowing as a consequence a reduction of the SIRS and its negative effects on them; the final result is a decrease of morbidity and mortality of patients postoperatively.

2. Miniaturised conventional extracorporeal circulation system

In 1995, our project was to set up a new concept of a miniaturised conventional extracorporeal circulation (McECC) system that is both safe and versatile, which allows to reduce to the maximum console and the circuit of the ECC. A brand-new console of CPB with a holder system that permits the installation of oxygenator and HSVR at the height of the patient's shoulder, together with the five external pumps (**Figures 1 and 2**).

When I realise the drawing of **Figure 1**, the CPB console of that type did not exist yet, and it was absolutely unthinkable and impossible to place the holder system on the CPB consoles which would have been launched on the market in 1995. For this reason, we put the project regarding the holder system on hold.

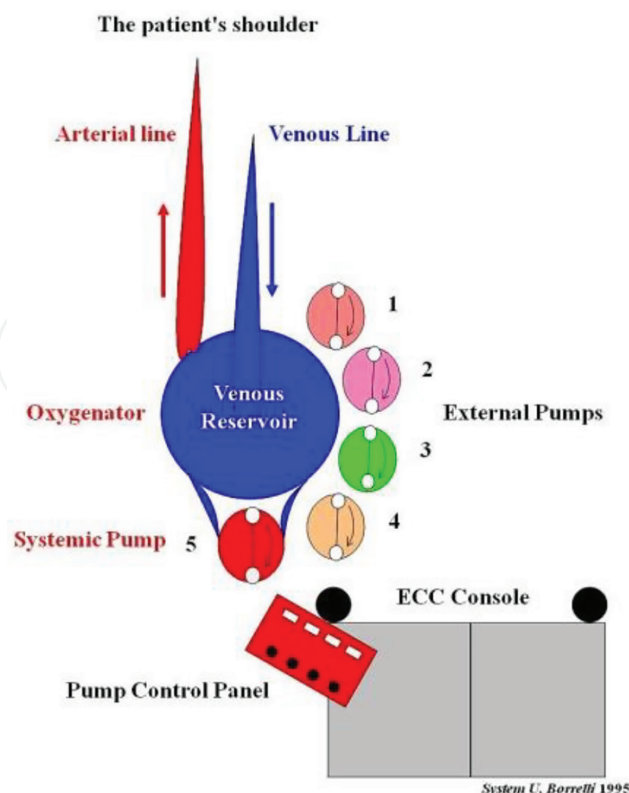


Figure 1. Top view.

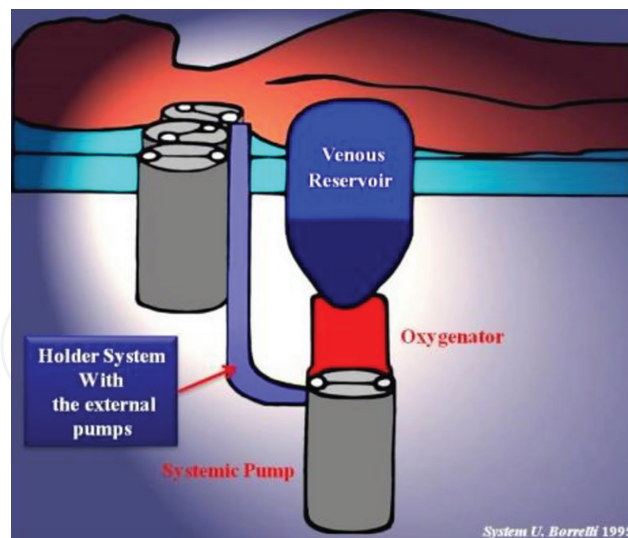


Figure 2. Profile view.

2.1. Study on the ECC surface reduction

In order to be able to confirm the hypothesis stating that the decrease of the ECC system can enhance the postoperative period on patients that have undergone a cardiac surgery, in 1997 we asked the technician of the society (Stöckert®, München, Germany) to carry out some modifications on our CPB console “CAPS “of that time (Figures 3 and 4). This action has allowed the positioning of the systemic pump near the oxygenator, and the introduction of a set consisted of the console, oxygenator and the HSVR as close as possible to the patient.

The outcome has been a drastic reduction of the length of the lines, dead space and the ECC priming volume. We gave it the name of “Compact ECC” (Figures 3 and 4). Regarding the “Compact ECC”, we have conducted many studies and research that we have published [6, 7].



Figure 3. Modified CPB “CAPS” console 1998.

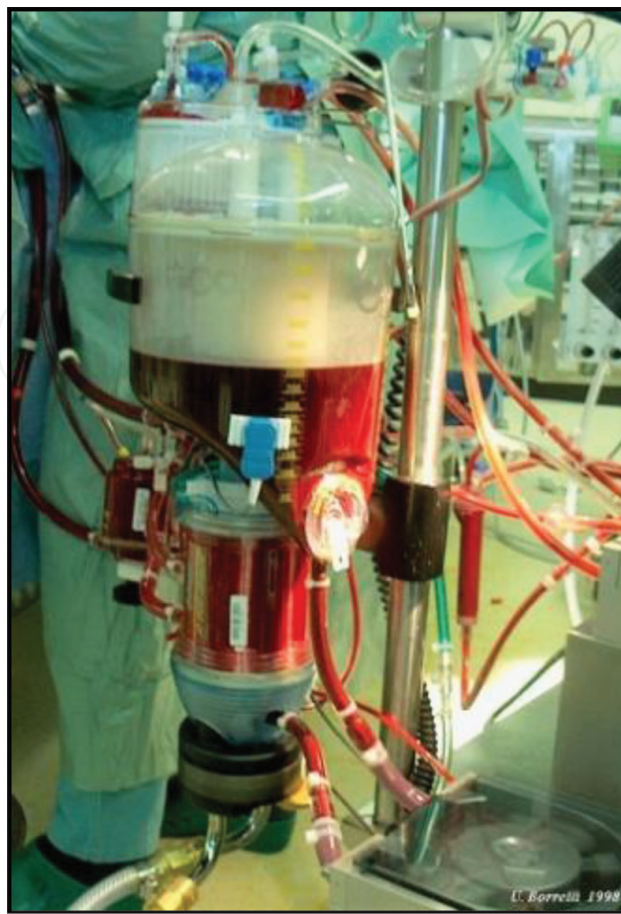


Figure 4. Systemic pump near the oxygenator.

In summary, this study has been conducted on three groups of patients which have undergone a coronary artery bypass grafting (CABG), from 1999 to 2004. A total of 50 patients have been analysed for the first group, from 1999 to 2001, and 25 patients in 2001 for the second group, and 25 patients for the third group from 2003 to 2004.

A significant difference among the groups concerning the patient's age, the Parsonnet score, the number of anastomoses performed, the haemoglobin before ECC, the ECC time and the systemic flow of the ECC have not been found. The systemic flow (L/min) has been measured using a flow index of 2.4 l/min/m² for each group.

All groups were operated with an open circuit McECC. We have reduced from group ¹ up to group ³ the surface of air/blood contact, blood/materials contact, the dead space of the system and the priming.

After the distribution of the new systems (oxygenator and HSVR) and knowing that the surface of contact of oxygenators is the most important of the ECC circuit set, the reduction of the membrane surface area of the oxygenator adapted to the patient (e.g., body surface area, pathologies, etc.) from the group ¹ up to the group ³ has been fundamental (**Figure 5**).

For each group, we have used the oxygenator, HSVR and the ECC circuit of the same company (Dideco®, Mirandola, Italy).



Figure 5. Group ¹ oxygenator Compact Flow D703; group ² oxygenator Avant D903; group ³ oxygenator Eos D905 and compatible HSVR with VAVD (Dideco®, Mirandola, Italy).

We introduced into routine retrograde autologous priming (RAP), including arterial line, arterial filter and antegrade autologous priming of the venous line (VAP) before the start of CPB. This action has allowed a precise control of the hemodilution of patients.

In interventions like CABG, during the aortic cross-clamping (closed-heart surgery), discharge of the left heart by aortic root vent is performed for the group ¹⁻² by gravity and for the group ³ by vacuum-assisted venous drainage (VAVD); the depression exerted in the aortic root is equal to that applied in the venous reservoir by the VAVD system (**Figures 6 and 7**).

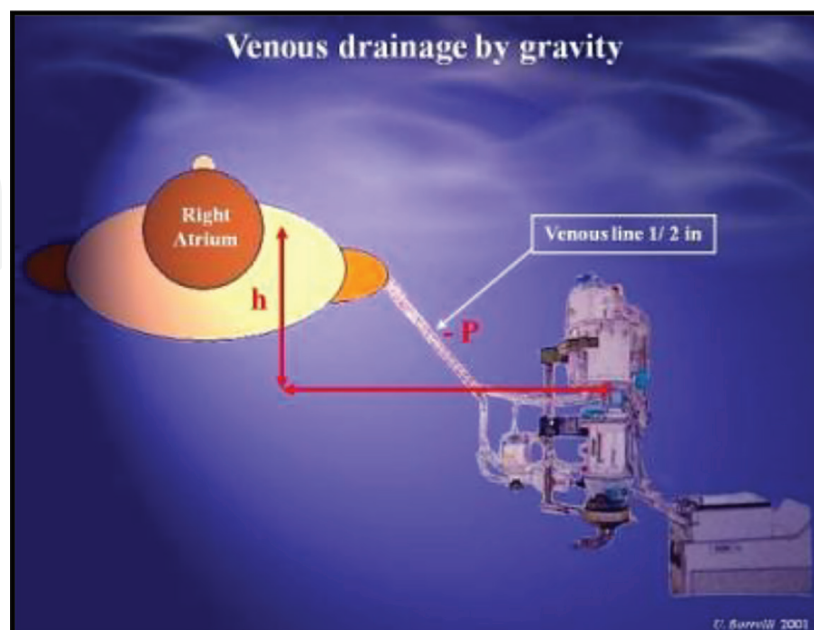


Figure 6. Group ¹ and group ².

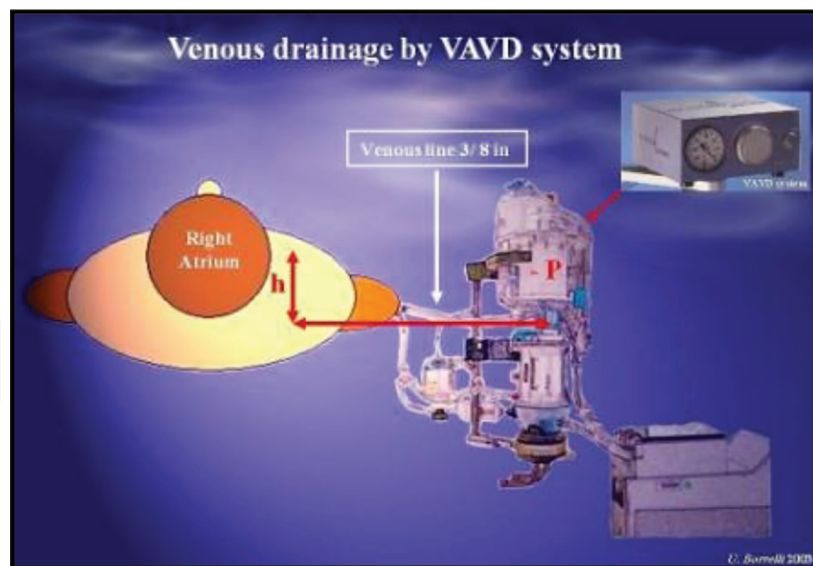


Figure 7. Group ³.

In all three groups, ECC was conducted under normothermia with warm intermittent blood cardioplegia based on potassium and magnesium. In order to verify the quality of our cardioplegia protocol, we have realised a series of studies in which one of these has been published in 2003 with the title *Comparison of the troponin i levels during coronary artery bypass graft in cardiac surgery procedures, realised with and without extracorporeal circulation* [8].

The auto transfusion system Electa (Dideco®, Mirandola, Italy) was employed for all the three groups. The volume of red blood cell concentrate re-injected for the three groups at the end of surgery did not exceed 320 ml. In order to optimise the management of the auto transfusion system, in 1998 we realised a study: *Improving the quality of red blood cells recovered with the Stat, perioperative autotransfusion system: Study of residues* [9].

2.1.1. Group ¹

- The ECC was performed with an oxygenator Compact Flow D703 (Dideco®, Mirandola, Italy)
- Membrane surface area of the oxygenator 2 m²
- Maximum blood flow rate of the oxygenator 7 l/min
- Flow index: 2.4 l/min/m²
- Mean systemic flow of ECC 4.5 l/min
- Drainage by gravity and venous line ½ in
- Arterial line 3/8 in
- Residual priming or hemodilution of the patient at the start of ECC = 900 ml
- Level detector on the venous reservoir

2.1.2. Group²

- The ECC was performed with an oxygenator Avant D903 (Dideco®, Mirandola, Italy)
- Membrane surface area of the oxygenator 1.7 m²
- Maximum blood flow rate of the oxygenator 7.5 l/min
- Flow index: 2.4 l/min/m²
- Mean systemic flow of ECC 4.4 l/min
- Drainage by gravity and venous line ½ in
- Arterial line 3/8 in
- Residual priming or hemodilution of the patient at the start of ECC = 500 ml
- Level detector on the venous reservoir
- Surface coating" Phosphorylcholine"(Dideco®, Mirandola, Italy)

2.1.3. Group³

We have positioned the set of oxygenator and compatible HSVR with VAVD as close as possible to the patient's shoulder, replacing the gravity venous drainage with a ½ in vein line through a 3/8 in vein line and routinely introduced the vacuum-assisted venous drainage, VAVD, system (Maquet® Cardiopulmonary GmbH, Germany) (**Figures 6 and 7**).

The ECC was performed with an oxygenator EOS D905 (Dideco®, Mirandola, Italy)

- Membrane surface area of the oxygenator 1.1 m²
- Maximum blood flow rate of the oxygenator 5 l/min
- Flow index: 2.4 l/min/m²
- Mean systemic flow of ECC 4.3 l/min
- VAVD system with the arterial/venous line 3/8 in and the HSVR
- Residual priming or hemodilution of the patient at the start of ECC = 250 ml
- Level detector on the HSVR
- Surface coating" Phosphorylcholine"(Dideco®, Mirandola, Italy) (**Figures 3–5**)

The result of this study shows a reduction of postoperative ventilation time from the group¹ to group³ (mean 508 ± 325 vs. 194.6 ± 39.2 min), blood loss (mean 489.2 ± 196.4 vs 236 ± 39.6 ml), duration of stay in intensive care unit (mean 3.6 vs. 1.9 days) and need for blood transfusion (mean 0.4 ± 0.7 vs. 0.1 ± 0.3 units/patient).

The study also highlights that the systems used in the first two groups were very big in relation to the patients (BSA, pathologies, physiological needs), and the postoperative impact of these systems on the patients can be compared to an artificial increase in ECC time [10–17].

3. Development of ECC with a holder system for five external pumps

In parallel with this study, we have continued to develop the McECC concept because it was not possible to set up a new CPB console.

In 2006, we decided to test an Heart Lung console: HL30 machine (Maquet® Cardiopulmonary GmbH, Germany), which was marketed only in the late 1990s. The circular base of the CPB HL30 console consists of the housing of emergency batteries, a large part of electronics and five wheels. This particular configuration has allowed to lower the centre of gravity and, therefore, it has permitted to provide a CPB console with greater stability.

The HL30 has very lightweight modular roller pumps because they consist largely of alloy.

From the initial test, it was clear that this concept console could progress into an CPB capable of housing a holder system that authorises the remote placement of oxygenator and HSVR at the height of the patient's shoulder, together with the external pumps.

Therefore, I have created a prototype that has been submitted to Maquet® Cardiopulmonary GmbH, Germany. This society has produced this prototype without making any modifications. Furthermore, the Maquet® society has made several resistance tests of the materials in order to homologate it by giving it the name of Holder System U.Borrelli (**Figures 8–10**).



Figure 8. Prototype of the holder system, top view.

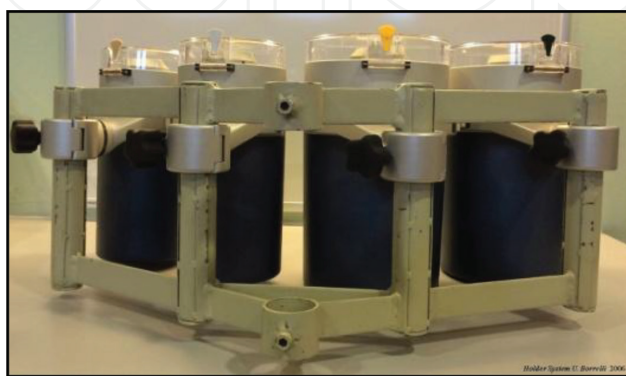


Figure 9. Prototype of the holder system, profile view.

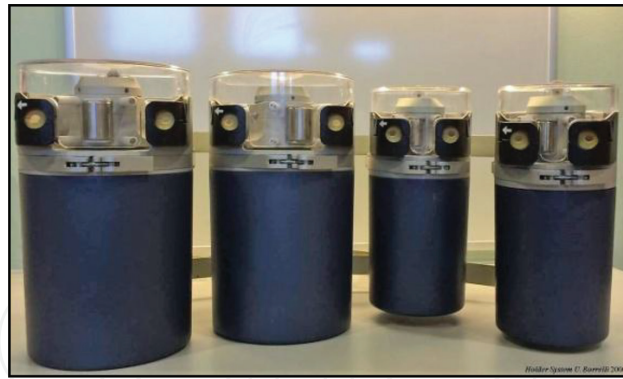


Figure 10. Prototype the holder system, front view.

In September 2007, our goal was achieved by placing on the CPB HL30 console the definitive Holder System. It was positioned using an additional mast and a four-point attachment system. The set is very stable and flexible, the weight of the overall holder system equipped with four roller pumps is 33 kg.

We placed a light at the top of the CPB console to ensure a good observation of the inner area of the heads of the roller pumps that are grey in colour. A second light at the bottom is oriented toward the oxygenator and HSVR (**Figures 11 and 12**).

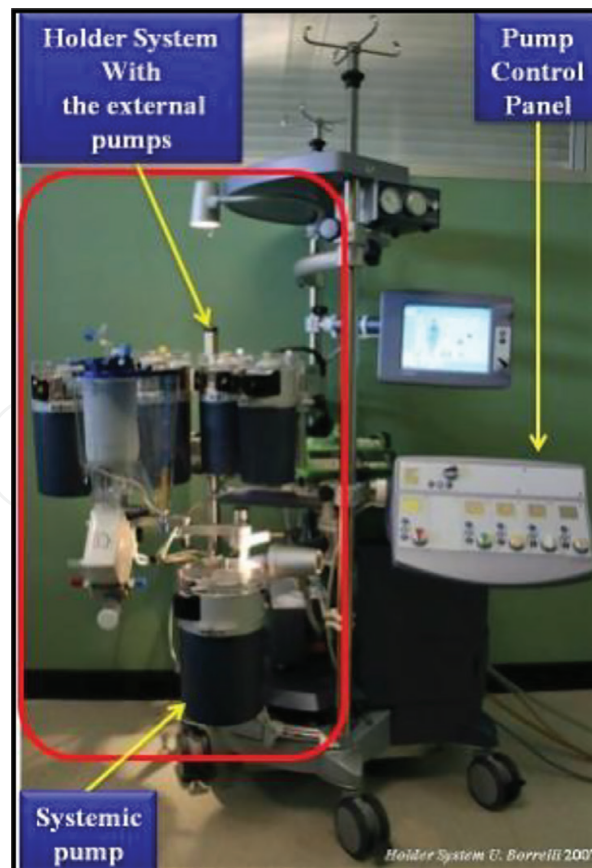


Figure 11. CPB console with the holder system, profile view.

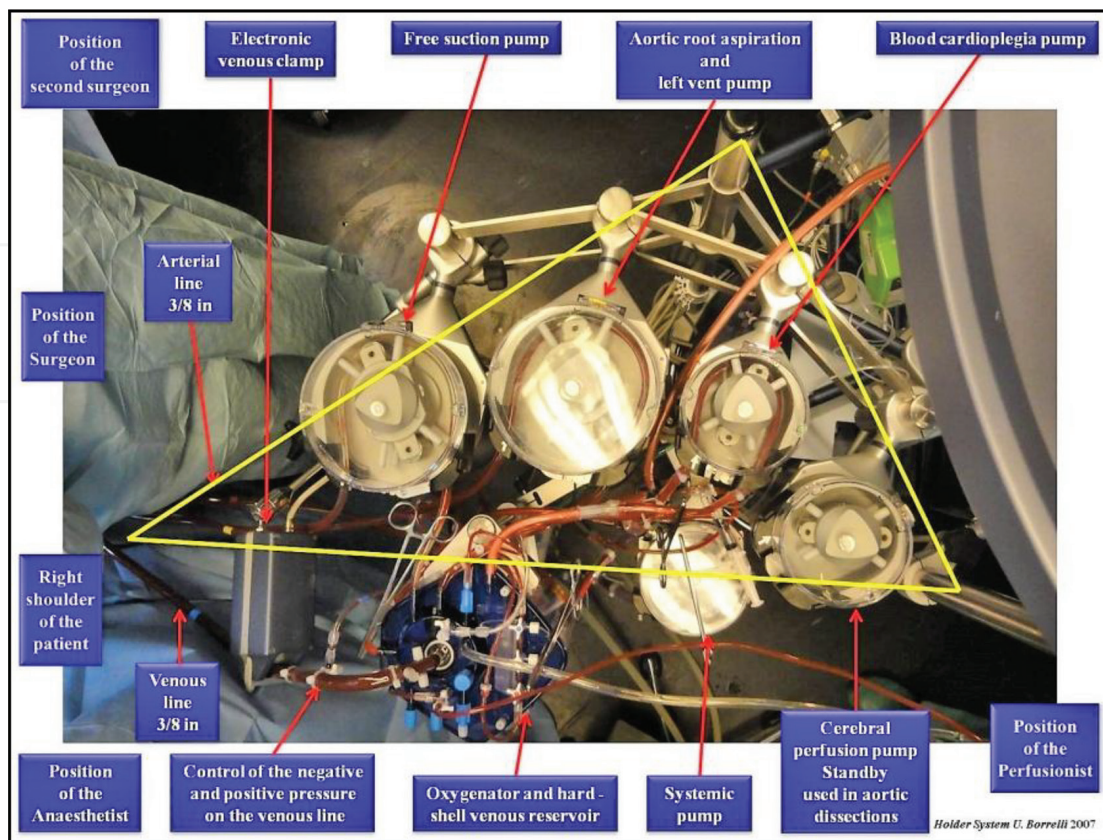


Figure 12. CPB console with the holder system, top view.

4. Optimisation of the circuit and the CPB console with a holder system

The holder system calibrates the CPB console against the ECC circuit to optimise its performance. The triangular shape of the holder system allows its remote placement of the CPB console, its distal end is near the surgeon's left hip. This has the effect of freeing up space for the different operators who are around the patient (Figures 12 and 13).

The concept of the CPB console with a holder system, has given us the possibility of reducing the lengths of lines of aspirations of $\pm 50\%$. The length of the arterial line of 3/8 in is ± 100 cm (from the output of the arterial filter of the oxygenator up to the connection of the arterial cannula). Furthermore, the length of the venous line of 3/8 in is also ± 100 cm (from the venous cannula up to the connection of the HSVR inlet). Therefore, there is a massive reduction of the air/blood surface, blood/contact materials, the dead space of the system and the priming volume (as a reminder: 100 cm of tubing 3/8 in contains 68 ml of liquid). All the dead spaces of the circuit are reduced to a minimum and it is very easy to perform an autologous priming retrograde (RAP) without any significant variation in the patient's volemia, including arterial line, arterial filter and antegrade autologous priming of the venous line (VAP) before the start of CPB [11] (Figures 12–14).



Figure 13. Position of the CPB console in the operating room.

4.1. Example of the circuit and the oxygenator and HSVR used

Alternative 1

- For a patient whose body surface is inferior or equal to 1.9 m²
- Flow index: 2.4/min/m²
- Oxygenator Quadrox—I Small Adult (Maquet® Cardiopulmonary GmbH, Germany)
- Membrane surface area of the oxygenator 1.3 m²
- Maximum blood flow rate of the oxygenator 5 l/min
- Surface coating Bioline the oxygenator of the circuit of the ECC and the compatible HSVR with VAVD (Maquet® Cardiopulmonary GmbH, Germany)

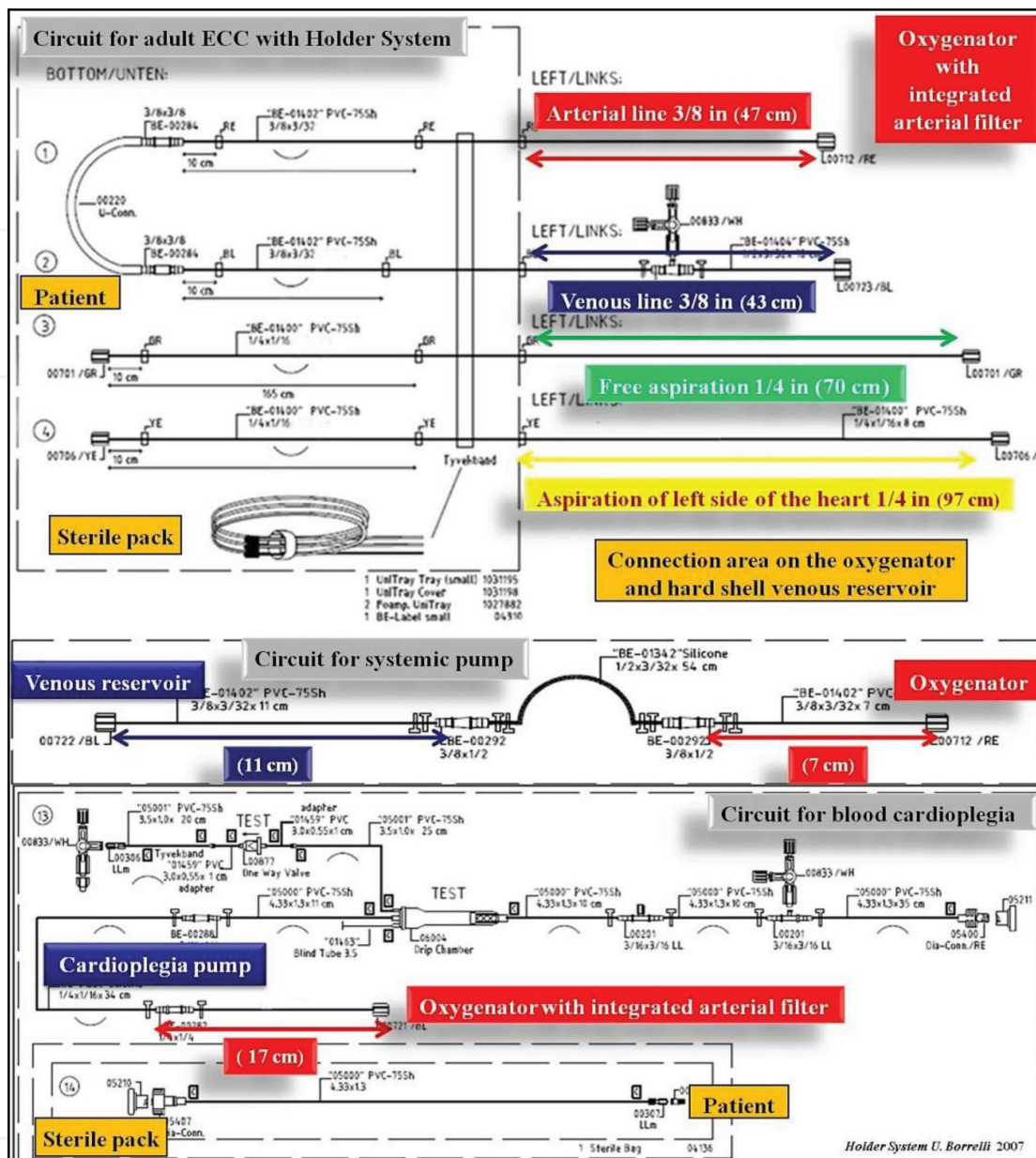


Figure 14. ECC circuit for adult patients with the holder system.

- VAVD system and arterial /venous line 3/8 in
- Level detector on the HSVR
- Retrograde autologous priming (RAP), including arterial line, arterial filter and antegrade autologous priming of the venous line (VAP)
- Residual priming or hemodilution of the patient at the start of ECC = 250 ml

Alternative 2

- For a patient whose body surface is superior to 1.9 m²

- Flow index: 2.4 l/min/m²
- Oxygenator INSPIRE 6 FM (LivaNova® Mirandola, Italy)
- Membrane surface area of the oxygenator 1.4 m²
- Maximum blood flow rate of the oxygenator 6 l/min
- Surface coating Phosphorylcholine the oxygenator of the circuit of the ECC and the compatible HSVR with VAVD (LivaNova® Mirandola, Italy)
- VAVD system and arterial/venous line 3/8 in
- Level detector on the HSVR
- Retrograde autologous priming (RAP), including arterial line, arterial filter and antegrade autologous priming of the venous line (VAP)
- Residual priming or hemodilution of the patient at the start of ECC = 300 ml

Alternative 3

- For a patient whose body surface is superior to 2.5 m²
- Flow index: 2.4 l/min/m²
- Oxygenator Quadrox—I Adult (Maquet® Cardiopulmonary GmbH, Germany)
- Membrane surface area of the oxygenator 1.8 m²
- Maximum blood flow rate of the oxygenator 7 l/min
- Surface coating Bioline the oxygenator of the circuit of the ECC and the compatible HSVR with VAVD (Maquet® Cardiopulmonary GmbH, Germany)
- VAVD system and arterial/venous line 3/8 in
- Level detector on the HSVR
- Retrograde autologous priming (RAP), including arterial line, arterial filter and antegrade autologous priming of the venous line (VAP)
- Residual priming or hemodilution of the patient at the start of ECC = 300 ml

We routinely use the VAVD system with venous cannulas that are chosen according to their hemodynamic characteristics (design, size, internal-external diameter, pressure drop, etc.). The atrio-caval venous cannulae of reduced diameter have the disadvantage of slipping into the inferior vena cava during the surgical intervention and necessitate a greater negative pressure in the HSVR by the VAVD system. It is important to choose an armed venous cannula in a diameter adapted to the right atrium and a central cage that eliminates the phenomenon of massive suction of the right atrial wall. Venous cannulae with orifices of the central cage of

sufficiently large size offset each other considerably reduce the incidence of this phenomenon of chattering (**Figure 15**).

With an appropriate venous cannula and a venous line of 3/8 in diameter, the vacuum required in the HSVR achieved by the VAVD system needs to simply replace the vacuum generated by venous drainage by gravity in a venous line of 1/2 in diameter, taking into account the internal pre-gravity of the HSVR from the right atrium of the patient to the lower part of the HSVR.

For example, for a systemic flow of 4.5–5 l/min with a venous cannula of 33–43 Fr (TF33430 Edwards®, USA) and a venous line of 3/8 in diameter, the vacuum necessary by the VAVD system is –20 to –25 mmHg (**Figure 15**).

In order to have a precise control of the VAVD system, we placed on the venous line of 3/8 in a monitoring of the negative and positive pressure. This triggers an alarm if the values reach –40 mmHg or + 3 mmHg. The VAVD system (Maquet® Cardiopulmonary GmbH, Germany) has internal safeguards that protects the HSVR from pressures above +3 mmHg and below –100 mmHg. Before each ECC intervention, we check the correct calibration of our roller pumps (**Figures 12, 13, and 15**).

The optimisation of venous return with VAVD is conditioned by the optimal choice of the venous cannula and its positioning; it improves the hemodynamics of the ECC and the

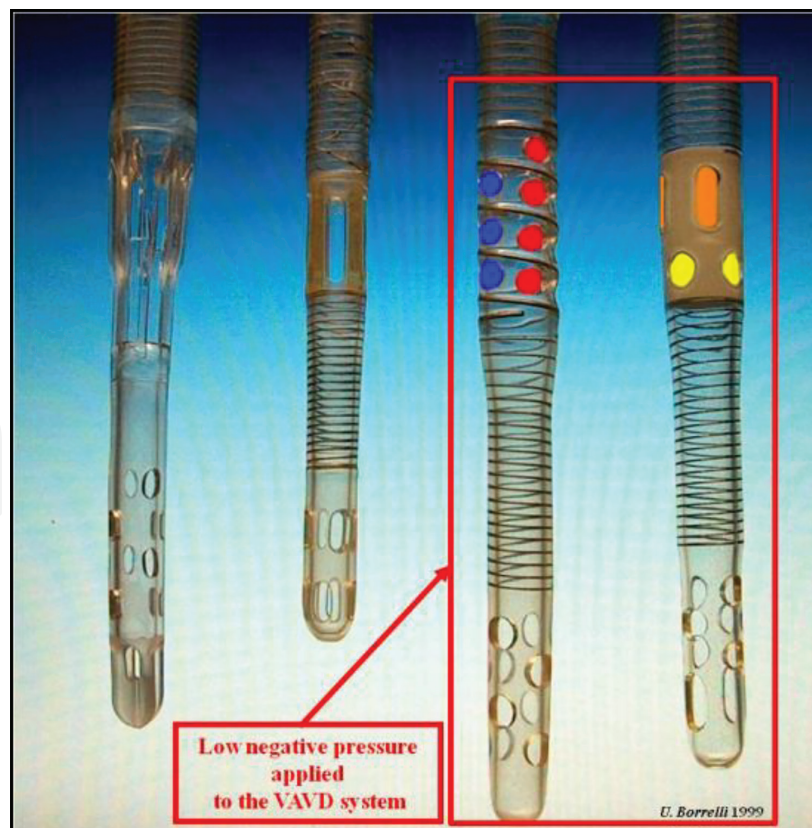


Figure 15. Venous cannulae.

patient. As the ECC becomes an arteriovenous extension of the patient's vascular network, the arterial flow and venous flow of the ECC must be in equilibrium. This constant ensures an adequate arteriovenous systemic flow capable of satisfying the patient's physiological needs during ECC [18–22].

Reducing the surface area contact of air/blood, blood/materials, the dead space of the system and the balance of arteriovenous flow results in a reduction of the risk of abdominal stasis and its repercussions on tissue perfusion. This ensures stability of the patient's blood volume that is in the HSVR. This optimisation of the hemodynamic equilibrium gives the possibility to widen the range of the strategies which are used during the management of the patients who undergo surgery under ECC (reduction of hemodilution, transfusions, etc.).

In order to limit the area contact of air/blood, blood/materials during ECC, the excess blood volume in the HSVR is isolated in biocompatible transfer bags. If necessary, it is re-infused to the patient during or at the end of the ECC. In general, the hematic volume in our HSVR during ECC is 350 to 400 ml.

The shape of the lower part of the HSVR that we use is conical or cylindrical, this has the consequence of limiting the free contact surface of the blood with the air and the biomaterials which constitute the base part of the HSVR (wall, filters, etc.) [23] (Figures 15).

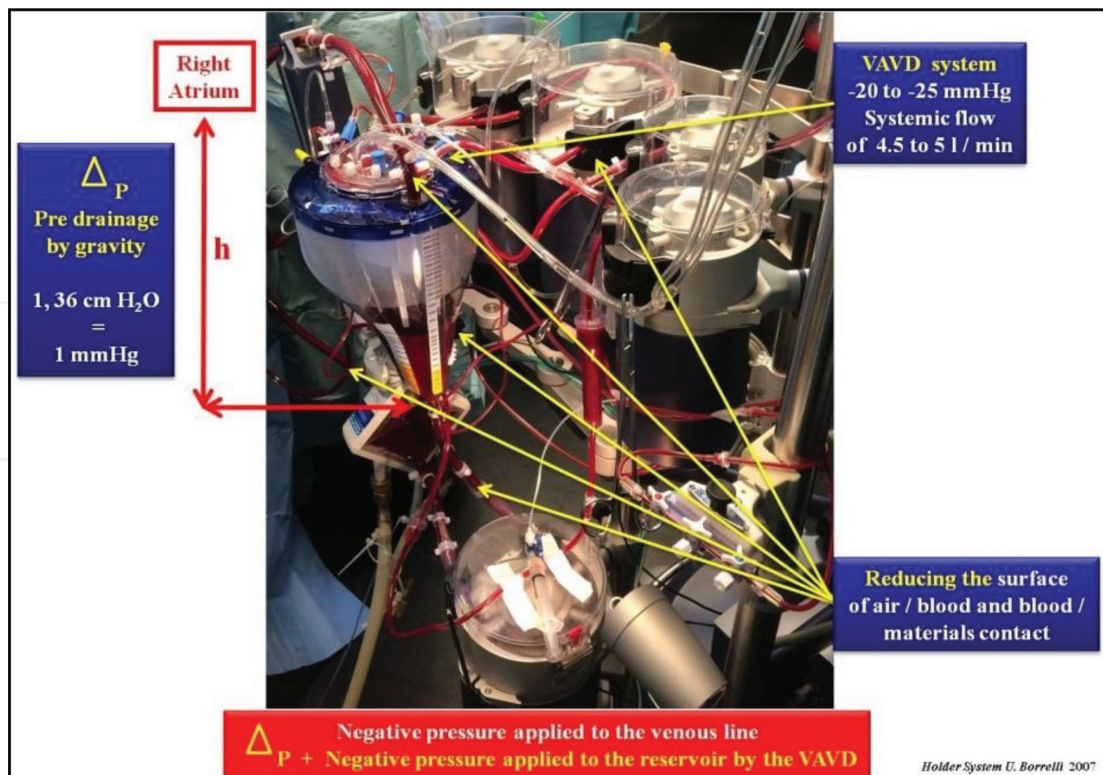


Figure 16. CPB console with the holder system, top view.

5. Conclusions

The optimisation of ECC management through:

- Used techniques (cardioplegia, autotransfusion system, etc.)
- Optimal choice of material (VAVD system, HSVR, surface coating, cannulas, design, hemodynamic, safe and accurate monitoring, security, etc.)
- The reduction of contact area surface of air/blood, blood/materials, dead space of the circuit and priming volume
- Hemodynamic equilibrium of the patient and ECC (arterial and venous flow)
- Accurate control of the patient's hemodilution

It has a direct impact on postoperative patients who have undergone surgical intervention under ECC; it could be comparable to an artificial reduction of ECC time.

For 23 years, this strategy of developing the McECC and the CPB console with the Holder System, the circuit, the various components that constitute the ECC allowed us to operate all types of patients with various pathologies with a safe and versatile system that is adapted to each patient. It gave us the possibility of a different approach for fragile patients or having to undergo paediatric, valvular or minimally invasive heart surgery.

The CPB HL30 console is very stable; thanks to its concept with its center of gravity which is low, it allowed us to place the Holder system away from the CPB console without having any technical problems. The assembly is very safe and flexible, the weight of the overall holder system provided with four roller pumps is 33 kg.

For 11 years, we have realised more than 3600 cardio-thoracic surgeries in our hospital with this concept of McECC and holder system.

This holder system was placed in 2009 on two CPB consoles at the Azienda Ospedaliera Universitaria "Ospedali Riuniti In Trieste, Italy, where more than 4300 cardio-vascular surgery were carried out with this ECC concept.

6. Future goals

Create a VAVD system with a servo controller to monitor the different pressures in HSVR (positive and negative) with respect to the hemodynamics of the patient and the ECC (arterial flow and venous flow).

Reduce the contact surface of the blood with air and biomaterials caused by HSVR, by creation of a safe and versatile VAVD HSVR that can be used as a closed or open system according to the needs of the users.

Conflict of interest

The authors declare that they have no conflicts of interest.

Notes/Thanks/Other declarations

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