

## Second Generation of Minimal Invasive Extracorporeal Circuit: Pilot Study Resting Heart System

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**Abstract:** Cardiopulmonary bypass (CPB) has evolved from a complex multifunctional system to the minimally invasive extracorporeal circuit (MIEC). Concerns currently exist regarding the technically demanding nature of off-pump coronary artery bypass (OPCAB) procedures, the quality of anastomosis associated with it, and the difficulty in achieving “complete revascularization.” Recognizing these issues, the so-called mini-CPB concept has evolved in an effort to offer the perceived benefits of OPCAB with the technical advantages of CPB and at the same time minimize the adverse effects of full-scale CPB. The first generation of MIEC had an inherited risk of gas embolisms. Therefore, there was the introduction of the resting heart system (RHS), the main characteristic of which is the venous air removal

device. The aim of this study was to describe our early experience, feasibility, and safety with this system to help others who are considering introducing this technique into their clinical practice. Using this system, we operated on 30 consecutive patients. Moderate hypothermia (33°C) CPB and cold intermittent antegrade cardioplegia was used. No technical incidents were encountered. One death from multiorgan failure occurred in a patient operated on for a thoraco-abdominal aneurysm. Our own short-term experience with the RHS has been very favorable, and we will continue to explore this development in CPB technology. **Keywords:** minimally invasive extracorporeal circuit  
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Over the past 50 years, cardiopulmonary bypass (CPB) has evolved from a complex multifunctional system to the minimally invasive extracorporeal circuit (MIEC). From the earliest clinical systems developed by Gibbon in the 1950s, the conventional CPB circuit has changed relatively little in terms of form and function and continues to be associated with a number of moderate and life-threatening complications. In response to this, the off-pump coronary artery bypass (OPCAB) technique has evolved in the recent past in an effort to eliminate the adverse effects of CPB. However, concerns currently exist regarding the technically demanding nature of OPCAB procedures, the quality of anastomosis associated with it, the difficulty in achieving “complete revascularization,” and the definition of true clinical benefit associated with its use.

Recognizing these issues, the so called mini-CPB concept has evolved in an effort to offer the perceived benefits of OPCAB with the technical advantages of CPB and

at the same time minimize the adverse effects of full-scale CPB. This halfway-house technique, it has been suggested, may reduce the inflammatory response often encountered with conventional CPB. This is achieved by reducing the surface area of the circuitry, minimizing the priming volume, and eliminating both venous reservoir and suction blood from the main circuit. Venous input is achieved and controlled using active means, and suction blood is diverted to a cell saver apparatus during the period of CPB for reinfusion later in the procedure.

The aim of this paper was to describe our early experience with this system and to help others who are considering introducing this technique into their clinical practice.

### MATERIALS AND METHODS

Mini-extracorporeal systems are in themselves not entirely new, but experience with pre-existing systems has been mixed, with many users expressing reservations relating to air handling and the risk of air embolism. The resting heart system (RHS; Medtronic, Minneapolis, MN) differs from these early systems because it incorporates a venous air removal device (VARD), which has been de-

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signed to eliminate venous air without resorting to additional reservoir technology (Figure 1). The VARD system incorporates two pairs of ultrasonic air detectors that detect air at the inlet of the system; once detected, the air is removed. The RHS comes in one complete package, which enhances ease of use, set-up, and priming (Figure 2).

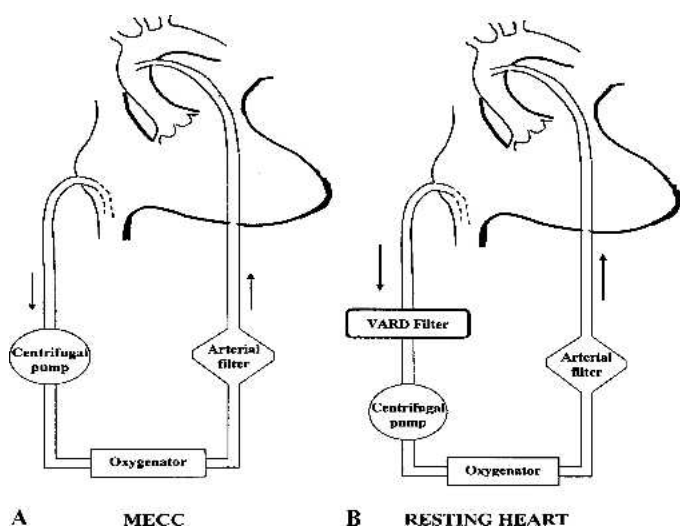
The primary advantages offered by the RHS are as follows:

- Closed-to-air system with the elimination of air-blood interface that can activate blood and therefore reduce systemic inflammatory response syndrome (SIRS) (1–3).
- Carmeda BioActive Surface: a heparin coating circuit that attenuates the inflammatory response and decreases thrombogenicity (4–7).
- The Biomedicus centrifugal pump: better flow management (laminar flow) and protection against embolic events offered by pumps of this nature (8,9).
- Minimized surface area and lower contact with foreign surfaces reduce complement activation (10).
- Minimized hemodilution: low priming with higher post-operative hematocrits and possible reduction in the inflammatory response (11,12).

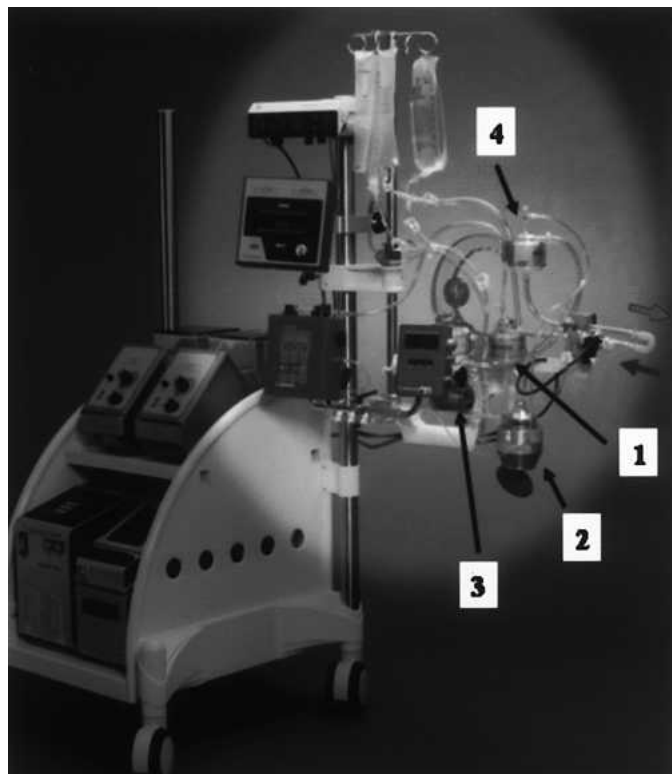
Using this system, we operated on 30 consecutive patients. Only patients undergoing mitral valve surgery were excluded from the study. The main aim of this study was to establish the safety and feasibility of using this second-generation system under routine operating conditions.

## RESULTS

We studied 30 patients undergoing CPB with the RHS



**Figure 1.** MIEC specificity over the mini extracorporeal circuit (MECC) concept. (A) MECC system. (B) MIEC system.



**Figure 2.** MIEC system. The compact presentation and easy-to-handle characteristics are obvious. (1) VARD filter. (2) Centrifugal pump (Biomedicus). (3) Oxygenator. (4) Arterial filter. A, arterial line; V, venous line.

system; the patient demographics and results of our observations are shown in Table 1.

All patients underwent moderate hypothermia (33°C) CPB, with intermittent antegrade cold blood cardioplegia in the cardiac cases.

Overall, the system functioned very well with absolutely no system failures or technical incidents, such as depriming or embolic events. One patient who underwent a tho-

**Table 1.** Demographic data and results.

Age	64 ± 11 years
Sex	M 22/F 8
Height	161 ± 30 cm
Weight	86 ± 27 kg
Ejection fraction	48% ± 12%
Heparin dose	3 mg/kg
CABG	23 patients
AVR	4 patients
Thoraco-abdominal aneurism	2 patients
Redo aorto bicarotid bypass	1 patient
Blood flow rate	2.2 L/min
Bypass time	88 ± 27 minutes
Cross clamping time	66 ± 29 minutes
Hemoglobin reduction rate	16% ± 14%
Platelet reduction rate	24% ± 28%
Mean chest drainage	579 ± 400 ml

CABG, coronary artery bypass grafting; AVR, aortic valve replacement; M, male; F, female.

raco-abdominal aneurysm surgery died 5 days after surgery with signs of multiorgan failure.

## DISCUSSION

Before making any formal comparison between the MIEC and conventional CPB, we carried out the current study to confirm the safety and efficacy of the MIEC system. This experience would permit us to familiarize the surgical team consisting of perfusionists, anesthesiologists, and surgeons with the system and to iron out any particular system-related problems associated with its use. Throughout this period, the MIEC system performed without fault, and the team was satisfied that it was truly a practical system for a broad range of surgical procedures. The absence of embolic events supports the effectiveness of the VARD system.

It is important to emphasize some practical considerations must be kept in mind when considering using the MIEC system in clinical practice. Such systems require a shift in thinking in the operating room toward a real team approach. In particular, clinicians must bear in mind that a strong communication between the perfusionist, surgeon, and anesthesiologist is essential for the safe application of the system, and in the absence of conventional reservoirs, tight control of the hemodynamic and vascular tone remains very important (avoid excessive filling and make use of vasopressors).

Finally, applying such a highly technical solution to the problems associated with conventional CPB is not inexpensive and may in the short term have a negative budgetary impact. However, growing application of MIEC technology and more formal studies focusing on blood transfusion, the systemic inflammatory response, and general outcome measures may ultimately justify any additional cost in terms of benefit.

Our own short-term experience with the RHS has been

very favorable, and we will continue to explore this exciting development in CPB technology.

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