

Original Article

Clinical Experience of a Vacuum-Assisted Nonroller Extra-Corporeal Circulation System

M. Hiroura, MD;* T. Furusawa, MD;* M. Amino, MD;* T. Moriya, MD;* H. Goto, MD;† Y. Fukaya, MD;† J. Amano, MD‡

*Suwa Central Hospital, SN SEIKI Co., LTD, †Shinonoi General Hospital, and ‡Shinshu University School of Medicine

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ABSTRACT

We designed a nonroller extra-corporeal circulation system (NRECC) to minimize space requirements and to improve the safety and ease of cardiopulmonary bypass. The NRECC includes a circuit, a centrifugal pump, and a vacuum regulator. The vacuum regulator has five channels, each of which can control negative pressure independently. Negative pressure is applied to suction, a vent, and a venous reservoir. Auto Vent-SV and one-way valves were placed between the suction/vent and the reservoir. The total space required for the NRECC with a heat exchanger was 0.49 m², which is much smaller than that of our current roller pump system.

The maximum volume through the suction/vent was 2.5 L/min at –100 mmHg measured in a simulated system. We used the NRECC for six CABG cases and compared results with those of five CABG cases managed by traditional roller pump extra-corporeal circulation (RECC). The two systems were compared in terms of set-up time and stability/accuracy of the suction/vent. The set-up time of the NRECC (5.3 ± 1.9 min) was significantly shorter than that of RECC (29 ± 3.4 min) ($p < .01$). Stable and accurate blood flow were achieved with the NRECC operating between –15 mmHg and –25 mmHg. In conclusion, NRECC can run a bypass easily and safely and has the benefit of reducing space requirements and shortening set-up time.

INTRODUCTION

Recent advances in the safety of extra-corporeal circulation systems have markedly improved the results of cardiac surgery. However, such disadvantages as hemolysis (1) and decreased immunity (2) have been suggested, and further improvement is necessary.

The centrifugal pump has long been used in cardiac surgery. There have been many studies of the safety and hemolysis-prevention using the centrifugal pump, and its advantages are well recognized (3). However, for the suction system, a conventional pump suction is still used, so the advantages of the centrifugal pump may be decreased.

We developed a nonroller extra-corporeal circulation system (NRECC) for clinical use that consists of a centrifugal pump and a low negative pressure controller and a conventional module. The NRECC was found to reduce hemolysis significantly in our previous experimental study (4). In this study, we evaluated the NRECC, which was developed to minimize space requirements and to improve safety and ease of cardiopulmonary bypass.

MATERIALS AND METHODS

NRECC

NRECC includes a circuit, centrifugal pump, and vacuum regulator. A centrifugal pump^a is placed below the main reservoir. An electromagnetic blood flow meter is placed between the centrifugal pump and oxygenator. Between the suction/vent and the reservoir, an aortic filter and a one-way valve were placed. Each suction line maintains a negative pressure by sucking from the aortic filter. The vacuum suction system consists of two suction lines and one vent line (Figure 1). A membrane oxygenator^b without heparin coating was used. The entire circuit has a priming volume of 1000 mL. The RECC in this study was the 8000 perfusion system.^b

VACUUM REGULATOR

The vacuum regulator has five channels that each control negative pressure from -10 mmHg to -200 mmHg independently. Negative pressure is applied to suction, a vent, and a venous reservoir using the conventional suction line or vacuum source in the operating room as the negative pressure source. Five parallel lines that can be individually placed are connected to the main valve for on/off switching of the suction source. Any of the five lines can be selected irrespective of the pressure of use. Negative pressure was controlled using a vacuum regulator with a pressure sensor for monitoring the set pressure. In addition, for constant monitoring of the suction, a flow sensor was placed, a flow control valve (needle type) was inserted to prevent acute suction, and a filter that also functions as a drain separator was placed on the connection port side to

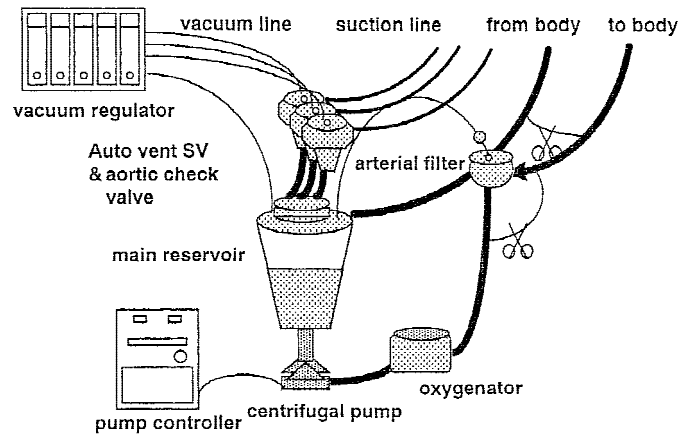


Figure 1: Schematic drawing of the nonroller extra-corporeal circulation system. A centrifugal pump is placed below the main reservoir. An electromagnetic blood flow meter is placed between the centrifugal pump and oxygenator. Each suction line, which is connected to an Auto Vent-SV and check valve for the artery on the reservoir side, maintains a low negative pressure by sucking from the Auto Vent-SV.

protect inner devices. Pressure in each chamber and the suction flow rate can be monitored by digital display. When the line is closed at the tip of the sucker during use, an alarm is set off. The pressure in the chamber can be constantly monitored, and the upper and lower limits of pressure can be set by this controller at any level between -10 and -200 mmHg (Figure 2).

Simulation Study: The performance of this vacuum suction system was investigated by simulation. Suction volume per minute was measured at each negative pressure. A pool (250 × 259 × 150 mm) was produced using stainless steel. The height

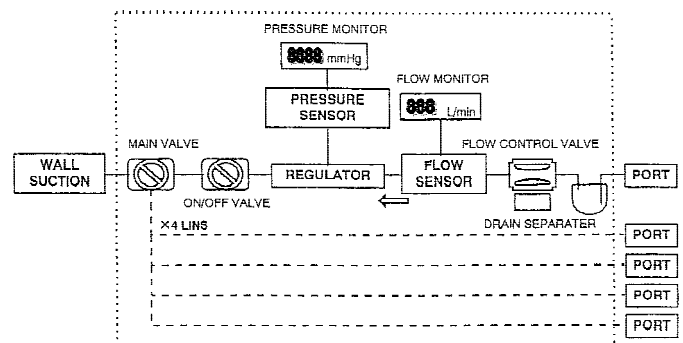


Figure 2: Schematic drawing of the low negative pressure controller. Five parallel lines that can be individually set were connected to the main valve for on/off switching of the suction source. Negative pressure was controlled using a special vacuum regulator with a pressure sensor for monitoring of the set pressure. In addition, for constant monitoring of the suction state, a flow volume sensor was placed, a flow control valve was inserted to prevent acute suction, and a filter that also functioned as a drain separator was placed on the connection port side to protect inner devices. Pressure in each chamber and the suction flow rate can be monitored by digital display.

a Medtronic Biomedicus, Eden Prairie, MN 55344
 b Terumo Medical Corporation, Somerset, NJ 08873

between the NRECC and the pool for the simulation study could be adjusted in the range of 100–500 mm. Two types of tubes (1/4" tubes, 6.35 mm in width and 120 cm or 150 cm in length) were connected to the sucker. The pool for the simulation experiment was filled with physiological saline. The saline was suctioned using each suction line, and the suction volume at each negative pressure was measured (Figure 3). Considering blood viscosity, the estimated suction volume of blood was calculated as 77% of the suction volume of saline.

Clinical Study: We used NRECC for six CABG cases, which were compared with five CABG cases run by RECC. Also, the floor area occupied by the NRECC was compared with that of the RECC.

RESULTS

SIMULATION STUDY

When the 1/4" tube, 120-cm in length, was used with the height of 10 cm, the suction volume was 0.98 L/min at a

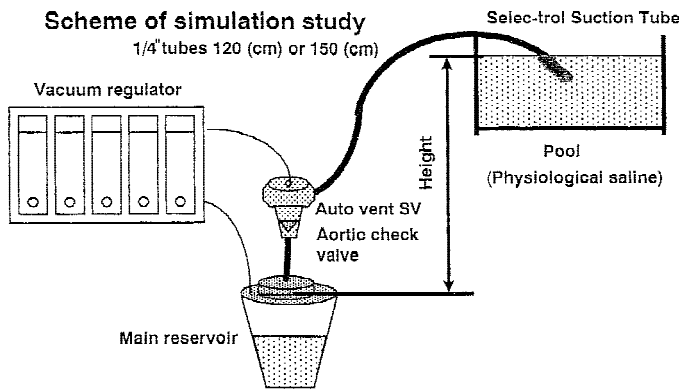


Figure 3: Schematic drawing of the mock experimental study. The pool for the mock experiment was filled with physiological saline. The saline was sucked using the each suction line, and the suction volume at each negative pressure was measured.

pressure of -10 mmHg and 1.93 L/min at -50 mmHg. With an increase in the height to 20 and 30 cm, the suction volume increased. With a height of 30 cm, the suction volume was 1.38 L/min at a pressure of -10 mmHg and 2.15 L/min at -50 mmHg. Using the tube with a length of 150 cm, the suction volume slightly decreased as compared with the 120-cm tube (Figure 4). The maximal volume of the suction/vent was 2.5 L/min on -100 mmH.

CLINICAL STUDY

Size of the System: Total space of NRECC and a heat exchanger was 0.49 m², which is much smaller than that of our roller pump system (Table 1).

Stability and Accuracy: Coronary bypass surgery could be performed with the NRECC as safely as with the RECC. Suction could be readily performed by negative pressure (-15 mmHg), and blood in the operative field could be rapidly aspirated by increasing the negative pressure to -25 mmHg.

Set-up Time: The set-up time of the NRECC (15.3 ± 1.9 min) was significantly shorter than that of the RECC (29.0 ± 3.4 min) (p < .01).

DISCUSSION

We developed the nonroller extra-corporeal circulation system with our original vacuum regulator and previously reported the results of simulated and animal experiments using this system (4). The initial optimal suction pressure was -15 mmHg, and the maximal pressure required during general surgery was -20--25 mmHg.

The maximal suction volume of this vacuum suction system was measured in the simulation study. Suction of 2.15 L/min was possible using the 1/4"-tube with a length of 120 cm with a height of 30 cm at a suction pressure of -50 mmHg. Therefore, if two suction lines are used, 4 L/min can be aspirated.

In this study, the NRECC and the RECC were compared in patients who underwent isolated CABG, and smooth surgery

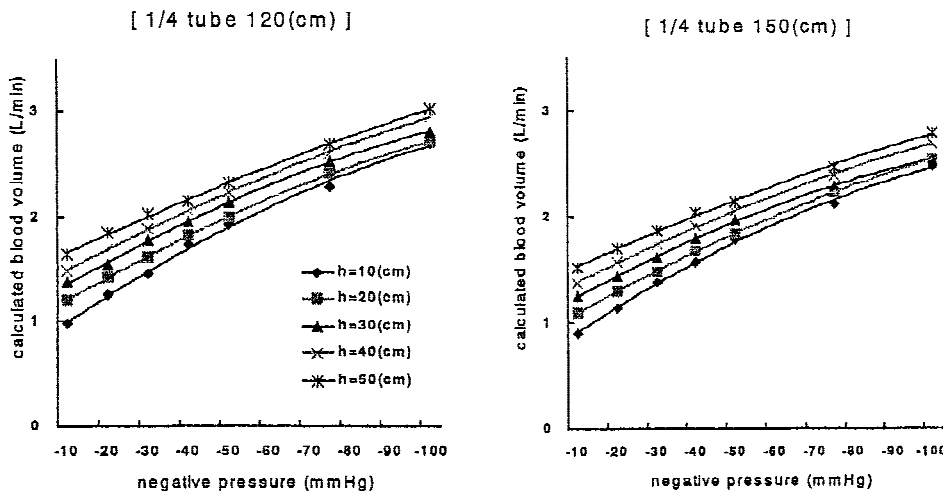


Figure 4: Estimated blood suction volume at each negative pressure with the each height. Considering blood viscosity, it was calculated as 77% of the suction volume of saline. Using the 1/4" tube with a length of 150 cm.

Table 1: Comparison of the occupancy area of the typical extracorporeal circulation system

Type	Width (cm)	Depth (cm)	Floor area (m ²)
Sarns 8000	106	67	0.71
Jostra	104	60	0.62
Shiley	102	73	0.74
NRECC (with heat exchanger)	70	70	0.49

The floor area occupied by the NRECC with a heat exchanger was 0.49 m², which was less than that of a conventional ECC (3M Sarns Perfusion System)

was possible using the NRECC. Suction at a pressure of -15 mmHg was adequate. Rapid suction of the operating field was performed easily by increasing the negative pressure to -20~-25 mmHg.

The footprint of the NRECC was much smaller than that of the RECC. The total set-up time was 15.3 ± 1.9 min in NRECC. This marked shortening of the set-up time is because the NRECC only required the time to connect the tube and not for applying the tube to the roller. Of course, more time would be required if a formal tube pressure closure test were performed using each system in RECC.

In conclusion, performance of the vacuum suction system was adequate for clinical use. The NRECC manages a bypass easily and safely and has the benefit of reducing space requirements and shortening set-up time. The nonroller extracorporeal circulation system seems adequate for clinical use.

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