Original Article

Evaluation of a New Generation Cardioplegia Administration System

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ABSTRACT

The delivery of cardioplegia has traditionally been constrained by the physical limitations of the mechanical devices in use, yet myocardial protective strategies may vary both according to patient condition and operative requirements. The need for a cardioplegia administration device that allows flexibility and safety is evident. The purpose of this study was to evaluate the performance of the Quest Myocardial Protection System™ (MPS) during clinically simulated conditions.

The MPS was evaluated in an in vitro setting under the following conditions: blood to crystalloid ratios (1:1, 4:1, 8:1, all blood), potassium concentrations ($[K^+]$) of 10 and 25 mmol/L, calcium concentrations ($[Ca^{++}]$) of 1.4 and 2.8 mmol/L, and at flow rates of 100 and 300 ml/min. Predicted values from the MPS were compared with measured values, with statistically significance accepted at $p<.05$ level.

Significant differences were seen between measured and MPS cardioplegia delivery volumes at the 4:1, 8:1 and all blood ratios with a flow rate of 300 ml/min. There were no significant differences seen between measured and expected $[K^+]$ and $[Ca^{++}]$ delivery values across all combination of flow rates and ratios. Differences between delivery pressures of the MPS and measured values for flow rates of 100, 250 and 500 ml/min were 0.4, 1.2 and 7.6 mmHg respectively. The mean cardioplegia cooling time from 37°C to 9°C was 37±4.5 seconds, while rewarming from 7°C to 37°C, took 53±10.4 seconds.

In conclusion, the Myocardial Protection System performance characteristics were precise in ratio delivery, concentrations of potassium agents, additive agent concentration, temperature, and pressure across all experimental conditions, with the exception of delivery volume.

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INTRODUCTION

In an attempt to preserve myocardial structural and physiological function during cardiac surgery, methods of cardioplegic protection have evolved that require the precise control of agents to the heart. In doing so, there is a lower demand for both oxygen and nutrients, which reduces the vulnerable period of injury during surgical intervention. Over the past four decades, many techniques have been developed to perform this function, including: the induction of cardiac arrest with hyperkalemic crystalloid solution in 1955 by Melrose (1), reintroduced in 1973 by Gay and Ebert (2); cold blood cardioplegia in 1978 (3,4), warm blood cardioplegic reperfusion in 1977 (5,6), warm induction in 1983 (7), alternating between antegrade and retrograde delivery in 1989 (8); normothermic cardioplegia in 1991 (9), and most recently in 1994, the techniques of simultaneous antegrade/retrograde perfusion (10) and continuous cold noncardioplegic blood perfusion (11).

Controversy continues concerning the optimum myocardial protection technique, with one significant debate centered on temperature control. In an attempt to lower myocardial oxygen consumption, decrease energy demand, and decrease the rate of enzymatic activation, cold delivery of cardioplegia (8°C to 9°C) has been widely accepted (12). Normothermic cardioplegia delivery has been proposed for the following reasons: to maintain ultrastructure stability, maintain myocardial oxygen and lactate extraction, decrease conduction disturbances, decrease cellular derangement, and shorten bypass and cross clamp time (9). Both techniques are currently in use and are practiced to meet the specific demands of the cardiac surgical procedure and patient requirements.

During cardiopulmonary bypass, the potassium concentration ($[K^+]$) of the cardioplegia solution may vary depending upon the requirements of the patient. A high $[K^+]$ solution (16 to 28 mEq/L) may be used to achieve rapid arrest, while a lower $[K^+]$ solution (8 to 16 mEq/L) is designed for multi-dose use during the course of the operation (13). Different techniques are currently being used to deliver solutions with varying $[K^+]$, with most requiring the switch to a low dose solution after the initial high dose has been infused (13). The majority of modern blood delivery cardioplegia circuits mix blood and crystalloid solutions in a fixed ratio, control thermic delivery via a heat exchanger, and deliver the solution under pressure to the coronary circulation (13,14).

Despite the significant improvements in cardioplegic delivery systems, inadequate myocardial protection is still a primary cause of cardiac mechanical failure, resulting from perioperative myocardial ischemia or reperfusion injury (15). The consequences of inappropriate myocardial protection are low output syndrome and heart failure, both of which necessitate pharmacologic and mechanical support, increased costs, and extended morbidity (16).

The increased concern with myocardial management during extracorporeal circulation has brought about a need for technology to augment the accuracy of cardioplegia delivery, assuring that myocardial protection is adequately achieved. The purpose of this study is to test the ability of the Quest Medical Myocardial Protection System™ [a] to deliver a range of ratios of blood to crystalloid, to vary arresting agent concentration, to vary additive agent concentrations, and to maintain accuracy of temperature and pressure monitoring.

MATERIALS AND METHODS

Device Description: The Myocardial Protection System™ (MPS)[a] has the ability to independently change various components of the cardioplegic solution (blood, arresting agent, additive agent), allowing modification of all delivery conditions of the cardioplegia solution. The MPS is purported to provide variable ratios of blood to crystalloid that range from 1:1 to 20:1, all blood, or all crystalloid. The system allows for variable ratio control without changing the arresting agent concentration. Also, the MPS is stated to facilitate change in arresting agent concentration without altering the ratio of blood to crystalloid solution. This is reportedly due to the system's design, which involves administration of agent from concentrated source pouches in the disposable cartridge rather than cardioplegia circuit tubing. The MPS is a device developed to control cardioplegia delivery and is not dependent upon the twin roller pump as its drive mechanism. The MPS is composed of two distinct components: a microprocessor-controlled electromechanical instrument and a disposable delivery set. The main pumping mechanism and pumping subsystem consist of four pistons driven by a stepper motor that displaces volume within a disposable pouch. The disposable circuit consist of valved pouches that alternatively fill and pump blood and crystalloid solutions, providing constant cardioplegia flow. The subsystem contains two pouches, one for the arresting agent and the other for an additive if required. When the disposable pouches or cartridge are placed into the console, the system software completes a series of self-check steps that assure the integrity of the unit.

The MPS contains an integrated heater/cooler and a stainless steel heat exchanger that controls the caloric transfer of heat. The water circulation and temperature control subsystem consists of a motor-driven water pump, a heat exchanger, a water flow control valve, a warm water reservoir with heaters, and a set of temperature sensors for monitoring and controlling the temperature. The MPS console is capable of selectively delivering cold or warm cardioplegia solution. The temperature of the cardioplegia is controlled by circulating water through the water side of the heat exchanger while the cardioplegia solution passes through the cardioplegia side. The operator can select between warm and cold solution temperatures during delivery. For warm delivery, the delivery temperature is adjustable. The warm delivery temperature range is 25°C to 39°C. When warm

a Quest Medical, Inc., Allen, TX 75002

cardioplegia delivery is selected by the operator, the water pump circulates warm water, heated within the console's internal warm water reservoir, through the heat exchanger. Temperature sensors are located throughout the system to monitor and maintain the desired cardioplegia delivery and water temperatures. These sensors communicate the temperatures to the controlling software. The software control system monitors and adjusts the water temperature to achieve the desired delivery temperature. When cold cardioplegia delivery is selected by the operator, the water pump circulates cold water from the MPS hypothermic reservoir through the heat exchanger. The cold cardioplegia delivery temperature is determined by the water temperature in the hypothermic reservoir, and therefore is not regulated by the MPS console.

The MPS contains control features that include pressure monitoring of both vascular and circuit conditions. The pressure monitoring system consists of three areas of measurement including aortic root pressure, retrograde coronary sinus pressure, and system pressure, all of which contain alarms. Integrated safety features include a bubble detector (100 uL or greater bubbles cause pump shutdown), an ultrasonic bubble trap level detector that automatically vents air when detected, and a 160 micron filter.

The MPS delivers cardioplegia up to 500 ml per minute by one of two ways: 1) direct flow control or 2) via a constant pressure mode that delivers cardioplegia under regulation of vascular pressure requirements. The system software contains default parameters that require affirmation by the user at the initial set up to ensure correct arresting agent concentration, blood to crystalloid ratio, and pressure limits. Features displayed by the device include total cardioplegia delivery volumes, blood, crystalloid, arresting agent, and additive volumes. A signal is sounded when remaining crystalloid volumes in the delivery bag fall below 150 ml. The MPS has an RS-232 port that can be used to communicate directly with an external computer.

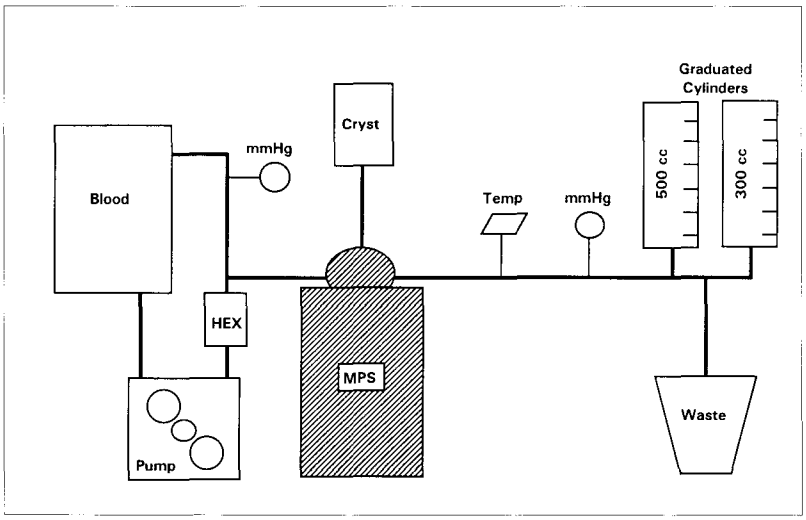
Test Circuit: A protocol for evaluating cardioplegia delivery systems has previously been investigated (17). Modifications of that protocol have been adapted to evaluate this specific device.

A test circuit was constructed allowing evaluation of the device (Figure 1). This circuit included a five gallon reservoir containing the blood source. Quarter inch polyvinylchloride (PVC) tubing was connected to the outlet of the reservoir and placed through a slightly non-occlusive twin roller pump[b]. Distal to the roller pump, a cardioplegia heat-exchanger[c] was inserted. This maintained the circulating blood temperature at 37°C, therefore eliminating viscosity changes. Circuit pressure was also monitored at this location, maintaining a line pressure greater than 100 mmHg with a flow rate of 1 L/min. Distal to the heat exchanger a 1/4in x 1/4in x1/4in connector was inserted, linking the MPS to the circulating blood source.

In order to provide the MPS with a crystalloid source (0.9% NaCl) a three liter container was elevated 60 cm above the MPS. The crystalloid line from the MPS disposable was connected directly to the outlet of the elevated reservoir. The outlet line of the MPS was modified to include six inches of 1/4 inch PVC tubing, a temperature probe, a pressure line, and a variable resistor to mimic patient resistance. The outlet line continued with a 1/4in x 1/4in x1/4in connector with one branch emptying into a waste container and the other leading to a Y connector. The branches leading from the Y connector included two inches of 1/4 inch tubing and emptied into one of two graduated cylinders used to determine the volume of cardioplegia delivered. The

b Stockert, Sorin Biomedical, Inc., Irvine, CA
c Electromedics, Inc., Englewood, CO

Figure 1: Circuit diagram



Legend: Cryst = Crystalloid; HEX = Heat exchanger; mmHg = Pressure manometer; MPS = Myocardial Protection System™; Temp = Temperature probe.

Table 1: Sequence of sampling

Flow Rates (ml/min)	100		300	
Ratios (Blood to Crystalloid)	1:1	4:1	8:1	All Blood
Potassium Concentration (mEq/L)	10		25	
Calcium Concentration (mmol/L)	1.4		2.8	
Measured Parameters	[K+]	[Ca++]	Hematocrit	Cardioplegia delivery volume

flow rates tested were 100 and 300 ml/min with volume collected for a one minute sample time.

Solutions and Blood Preparations: The MPS was primed and debubbled according to the manufacturer's directions for use. Potassium (2 mEq/ml) was used as the arresting agent while $CaCl_2$ (100 mg/ml) concentration was used as the additive solution. Expired human blood, from the American Red Cross, was washed with 1000 ml of (0.9%) NaCl using an autotransfusion device to remove preservatives and produce a packed red cell mass. Sodium chloride (0.9%) solution was added to achieve a starting hematocrit ranging between 20% to 25%. The electrolyte concentration was adjusted to achieve a starting [K^+] and calcium [Ca^{++}] concentration under 5±1 mmol/L and 1±.2 mmol/L, respectively.

System Analysis: To determine the accuracy of the MPS to deliver ratios of blood to crystalloid solutions, the end delivery hematocrit was measured. The ratios tested include: 1:1, 4:1, 8:1, and all blood at the various flow rates described in Table 1. In addition, the accuracy of the MPS to deliver cardioplegic solutions at varying concentrations was assessed by measuring the [K^+] at two levels: 10 and 25 mmol/L. The delivery accuracy of additive agent [Ca^{++}] was likewise measured at two concentrations: 1.4 and 2.8 mmol/L.

Between successive sample times, a washout was performed to prevent contamination of measured parameters. This involved setting the device to the next set of tested parameters and allowing 200 ml of solution to rinse the circuit.

The measured values were compared to computed values as determined from the baseline hematocrit and concentration of [K^+] and [Ca^{++}]. The MPS delivery volumes were compared to the measured volumes for accuracy.

Hematocrits were taken at each sample and determined in duplicate through centrifugation in a calibrated centrifuge. After four minutes of spinning at 10,200 RPM, the tubes were removed from the centrifuge and hematocrit levels were measured with a standard error of ± 2%. Prior to centrifugation, 2 ml of blood were placed into a Gem® 6 Plus[d] and analyzed for [K^+] and [Ca^{++}] with a standard error of ±16% and 4% respectively.

Table 2. 1:1 Ratio, 10 mmol/L K^+, 1.4 mmol/L Ca^{++}

	Measured	*Expected*	*Difference*	*P-Value*
100 ml/min				
Delivery	103.00 ± 2.24	102.20 ± 1.79	-1.50 ± 3.00	NS
Hematocrit	10.80 ± 1.30	10.60 ± 0.89	0.60 ± 0.89	NS
Potassium	11.70 ± 0.94	13.00 ± 2.02	-1.30 ± 1.35	NS
Calcium	1.32 ± 0.44	1.88 ± 0.47	-0.56 ± 0.32	NS
300 ml/min				
Delivery	304.40 ± 5.50	307.60 ± 4.88	3.20 ± 1.30	NS
Hematocrit	10.60 ± 0.89	10.60 ± 0.89	0.40 ± 0.55	NS
Potassium	12.16 ± 1.56	13.00 ± 2.02	-0.84 ± 0.99	NS
Calcium	1.68 ± 0.38	1.88 ± 0.47	-0.20 ± 0.46	NS

Table 3: 1:1 Ratio, 25 mmol/L K^+, 2.8 mmol/L Ca^{++}

	Measured	*Expected*	*Difference*	*P-Value*
100 ml/min				
Delivery	103.80 ± 2.39	101.60 ± 1.14	-2.20 ± 2.59	NS
Hematocrit	10.60 ± 0.89	10.60 ± 0.89	0.40 ± 0.55	NS
Potassium	26.24 ± 1.75	28.00 ± 2.02	-1.76 ± 1.50	NS
Calcium	3.04 ± 0.54	3.28 ± 0.47	-0.24 ± 0.17	NS
300 ml/min				
Delivery	303.20 ± 2.49	308.00 ± 4.00	4.80 ± 4.32	NS
Hematocrit	10.60 ± 0.89	10.60 ± 0.89	0.40 ± 0.55	NS
Potassium	27.12 ± 0.82	28.00 ± 2.02	-0.88 ± 1.85	NS
Calcium	2.92 ± 0.27	3.28 ± 0.47	-0.36 ± 0.26	NS

Table 4: 4:1 Ratio, 10 mmol/L K^+, 1.4 mmol/L Ca^{++}

	Measured	*Expected*	*Difference*	*P-Value*
100 ml/min				
Delivery	102.80 ± 2.49	102.00 ± 2.74	-0.80 ± 1.30	NS
Hematocrit	15.80 ± 1.30	16.80 ± 1.30	-1.00 ± 1.41	NS
Potassium	14.82 ± 1.99	13.00 ± 2.02	1.82 ± 0.69	NS
Calcium	2.22 ± 0.83	1.88 ± 0.47	0.34 ± 0.59	NS
300 ml/min				
Hematocrit	15.80 ± 1.30	16.80 ± 1.30	-1.00 ± 1.41	NS
Potassium	13.80 ± 2.00	13.00 ± 2.02	0.80 ± 0.88	NS
Calcium	1.64 ± 0.42	1.88 ± 0.47	-0.24 ± 0.11	NS

The flow rates, ratios, arresting agent concentration, and additive concentration were completed in a randomized fashion. The MPS was maintained according to the manufacturer's directions for use.

Temperature Accuracy: The operational characteristics of the internal heater/cooler of the MPS were evaluated. Each cardioplegia cartridge disposable was temperature tested following the previous evaluation of ratio and concentration delivery. Whole blood was circulated through the MPS until a starting blood outflow temperature of 37°C was achieved. The water temperature was then set on 4°C and rapid cooling commenced. Temperature readings were recorded every 5 seconds until a blood outflow temperature of 4°C was achieved. Once 4°C was

d Mallinckrodt Sensor Systems, Inc., Ann Arbor, MI

Table 5: 4:1 Ratio, 25 mmol/L K^+, 2.8 mmol/L Ca^{++}

	Measured	*Expected*	*Difference*	*P-Value*
100 ml/min				
Delivery	101.00 ± 1.73	102.00 ± 1.73	1.00 ± 3.39	NS
Hematocrit	15.80 ± 1.30	16.80 ± 1.30	-1.00 ± 1.41	NS
Potassium	28.32 ± 1.51	28.00 ± 2.02	0.32 ± 1.46	NS
Calcium	3.16 ± 0.78	3.28 ± 0.47	-0.12 ± 0.33	NS
300 ml/min				
Delivery	302.00 ± 2.74	309.80 ± 7.53	7.80 ± 6.57	NS
Hematocrit	16.00 ± 1.22	16.80 ± 1.30	-0.80 ± 1.48	NS
Potassium	30.84 ± 4.80	28.00 ± 2.02	2.84 ± 4.02	NS
Calcium	3.16 ± 0.43	3.28 ± 0.47	-0.12 ± 0.40	NS

Table 6: 8:1 Ratio, 10 mmol/L K^+, 1.4 mmol/L Ca^{++}

	Measured	*Expected*	*Difference*	*P-Value*
100 ml/min				
Delivery	102.60 ± 2.51	101.60 ± 0.55	-1.00 ± 2.83	NS
Hematocrit	17.60 ± 1.34	18.20 ± 1.79	-0.60 ± 0.89	NS
Potassium	15.08 ± 2.88	13.00 ± 2.02	2.08 ± 0.99	NS
Calcium	1.86 ± 0.75	1.88 ± 0.47	-0.02 ± 0.30	NS
300 ml/min				
Hematocrit	17.60 ± 1.34	18.20 ± 1.79	-0.60 ± 0.89	NS
Potassium	14.82 ± 3.19	13.00 ± 2.02	1.82 ± 1.53	NS
Calcium	1.68 ± 0.56	1.88 ± 0.47	-0.20 ± 0.10	NS

Table 7: 8:1 Ratio, 25 mmol/L K^+, 2.8 mmol/L Ca^{++}

	Measured	*Expected*	*Difference*	*P-Value*
100 ml/min				
Delivery	103.60 ± 1.52	101.80 ± 1.10	-1.80 ± 1.64	NS
Hematocrit	18.00 ± 1.58	18.20 ± 1.79	-0.20 ± 1.30	NS
Potassium	30.12 ± 2.76	28.00 ± 2.02	2.12 ± 0.98	NS
Calcium	3.12 ± 0.88	3.28 ± 0.47	-0.16 ± 0.46	NS
300 ml/min				
Hematocrit	17.80 ± 1.64	18.20 ± 1.79	-0.40 ± 1.14	NS
Potassium	28.36 ± 2.08	28.00 ± 2.02	0.36 ± 2.17	NS
Calcium	2.96 ± 0.43	3.28 ± 0.47	-0.32 ± 0.04	NS

achieved, the water temperature was reset to 37°C. Temperature readings were again recorded every 5 seconds. Blood flow rates were set at 250 ml/min for each trial.

In order to assess the MPS accuracy in recording blood outlet temperature, a YSI[e] blood outflow temperature reading was compared to the MPS console blood outlet reading. This recording of data occurred at the same 5 second intervals. Before the start of each of the trials, the YSI instrument was calibrated by placing the probe and a mercury thermometer into a water bath at a temperature of 25°C. The YSI temperature probe was calibrated to be with in ± 0.1°C of the mercury thermometer.

Pressure Accuracy: The accuracy of the pressure monitoring system of the MPS to determine system pressure was evaluated after the two previous delivery and temperature trials. A variable resistor was placed on the outlet line or patient line to reflect a cannula resistance of 100 mmHg at a flow rate of 250 ml/min. System pressure was measured by a calibrated hydraulic bedside pressure manometer. Systemic pressure was measured by splicing the manometer into the outlet line prior to the variable resistor. Trials were run at flow rates of 100, 250, and 500 ml/min. The pressure of the manometer was compared to the MPS pressure monitoring system to determine accuracy.

Statistics: Statistical analysis was performed by loading all data onto a personal computer in spreadsheet format. All data is reported as mean ± standard deviation of the mean. Differences between the predicted and the measured values were analyzed using a one way analysis of variance. When significant values were achieved, the Post-Hoc test (Fisher's PLSD) was performed. Statistical significance was accepted at the $p \leq .05$ level.

RESULTS

One MPS console was evaluated with five discrete cardioplegia disposables. Priming was completed to the manufacturer's direction for use and performed without difficulty. There were no significant differences seen between measured and expected [K^+] and [Ca^{++}] delivery values across all combination of flow rates and ratios. There also were no significant differences seen between measured and expected hematocrit delivery values at any ratio of blood to crystalloid (Tables 2-9).

Significant differences were seen between measured and MPS cardioplegia delivery volumes at the 4:1, 8:1 and all blood ratios at a flow rate of 300 ml/min (Figures 1-4).

The mean cardioplegia cooling time from 37°C to 9°C was 37 ± 4.5 seconds, while rewarming from 7°C to 37°C, took 53 ± 10.4 seconds. The mean difference between the YSI outlet temperature and the MPS recorded outlet temperature upon rewarming was 3.5°C, with the MPS recording warmer temperatures. The mean difference between the YSI outlet temperature and the MPS recorded outlet temperature upon cooling was 4.0°C, with the MPS recording cooler temperatures (Figures 5, 6).

Differences between delivery pressures of the MPS and

e YSI, Inc., Yellow Springs, OH

measured values for flow rates of 100, 250, and 500 ml/min were 0.4, 1.2, and 7.6 mmHg respectively.

DISCUSSION

The earliest methods of cardioplegia delivery consisted of infusions of concentrated solutions directly into the aortic root, or left ventricle, via hand held syringes. Unfortunately, such methods caused a heterogeneous distribution of solution and led to the need for more precise and controlled delivery techniques that assured uniform distribution. Many clinicians switched to a pressurized bag method in which a bag of crystalloid solution was placed in a pressure infusion wrap and cardioplegia infused at a semi-controlled rate, dependent upon the degree of pressure and the bore of the cardioplegic needle (18,19). Although the results were better than previous methods, it was evident that such systems suffered from a lack of safety features that included inaccurate or unknown flow delivery rates, absent pressure monitoring and control systems, perfunctory air handling capacity, dependence primarily upon asanguineous solutions, and a lack of temperature control. Vertrees and colleagues described a simple circuit that utilized a coronary perfusion reservoir, a coil submerged in ice water, and a roller pump (20). The system was a significant improvement over the pressurized bag technique in so much as it included a means to trap air and to measure pressure within the circuit. The roller pump produced faster cooling and resulted in significantly higher aortic perfusion pressures, which would provide better distribution of cardioplegia in the presence of critical coronary stenosis (21).

Despite the significant improvements in cardioplegic delivery systems, inadequate myocardial protection is still a primary causative factor influencing post cardiotomy mechanical failure resulting from perioperative myocardial ischemic, hypoxic, or reperfusion injury (15). It is clear that the need exists for a more precise control of cardioplegia to assure that adequate myocardial protection is achieved, especially since patient conditions during cardiac surgery are dynamic, and mandate rapid intervention to coincide with the changing needs of the patient.

Presently, surgeons and perfusionists must assemble

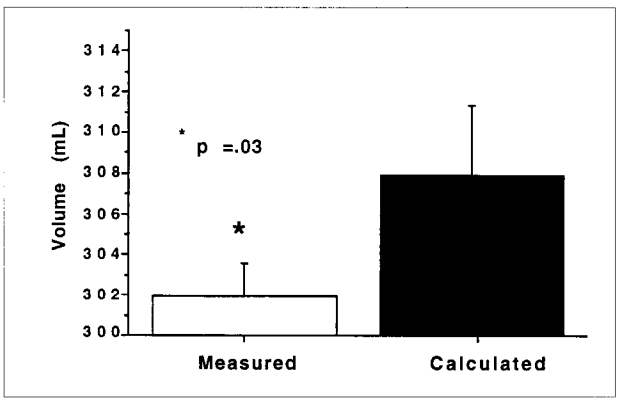
Table 8: All Blood Ratio, 10 mmol/L K^+, 1.4 mmol/L Ca^{++}

	Measured	*Expected*	*Difference*	*P-Value*
100 ml/min				
Delivery	103.20 ± 1.30	101.80 ± 0.45	-1.40 ± 1.32	NS
Hematocrit	20.20 ± 1.79	21.20 ± 1.79	-1.00 ± 0.00	NS
Potassium	16.73 ± 2.10	12.45 ± 1.86	4.28 ± 0.45	NS
Calcium	2.02 ± 0.77	1.88 ± 0.47	0.14 ± 0.31	NS
300 ml/min				
Hematocrit	20.00 ± 1.41	21.20 ± 1.79	-1.20 ± 0.45	NS
Potassium	14.83 ± 2.06	12.45 ± 0.86	2.38 ± 0.71	NS
Calcium	1.66 ± 0.61	1.88 ± 0.47	-0.22 ± 0.18	NS

Table 9: All Blood Ratio, 25 mmol/L K^+, 2.8 mmol/L Ca^{++}

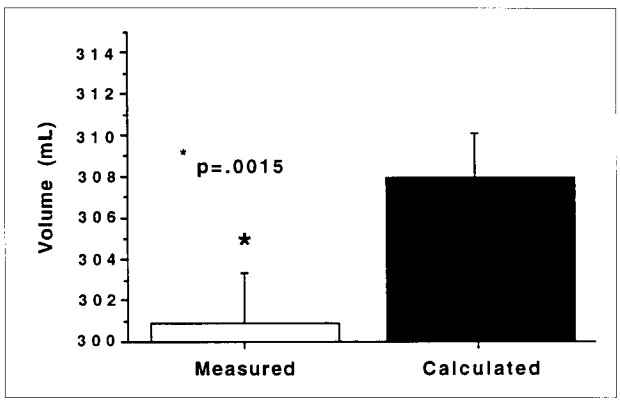
	Measured	*Expected*	*Difference*	*P-Value*
100 ml/min				
Delivery	102.00 ± 1.87	101.40 ± 0.89	-0.60 ± 1.95	NS
Hematocrit	20.20 ± 1.30	21.20 ± 1.79	-1.00 ± 0.71	NS
Potassium	31.95 ± 3.92	27.45 ± 1.86	4.50 ± 2.07	NS
Calcium	3.32 ± 0.91	3.28 ± 0.47	0.04 ± 0.46	NS
300 ml/min				
Delivery	303.00 ± 4.69	305.40 ± 3.51	2.40 ± 5.32	NS
Hematocrit	20.20 ± 1.30	21.20 ± 1.79	-1.00 ± 0.71	NS
Potassium	27.76 ± 5.70	27.45 ± 1.86	2.45 ± 0.73	NS
Calcium	3.04 ± 0.65	3.28 ± 0.47	-0.24 ± 0.19	NS

Figure 2: Delivery difference at 4:1 (ratio), 300 ml/min flow, 10 mmol/L of [K^+], 1.4 mmol/L of [Ca^{++}]



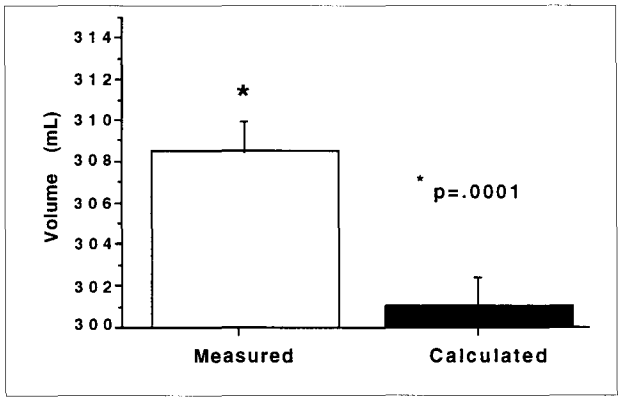
Legend: * = p = .03

Figure 3: Delivery difference at 8:1 (ratio), 300 ml/min flow, 10 mmol/L of [K^+], 1.4 mmol/L of [Ca^{++}]



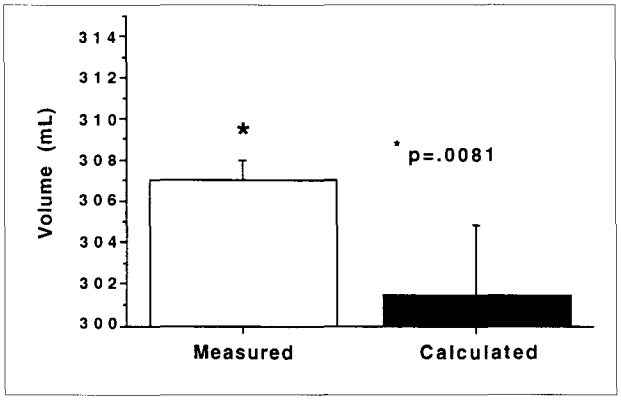
Legend: * = p = .0015

Figure 4: Delivery difference at 8:1 (ratio), 300 ml/min flow, 25 mmol/L of [K+], 2.8 mmol/L of [Ca++]



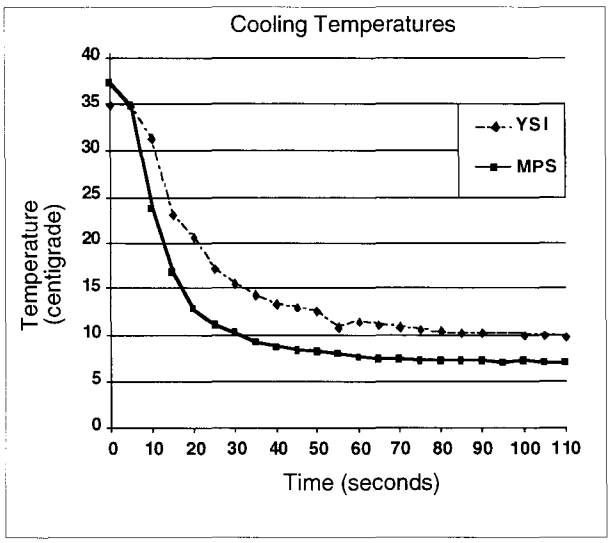
Legend: * = p = .0001

Figure 5: Delivery difference at all blood (ratio), 300 ml/min flow, 10 mmol/L of [K+], 1.4 mmol/L of [Ca++]



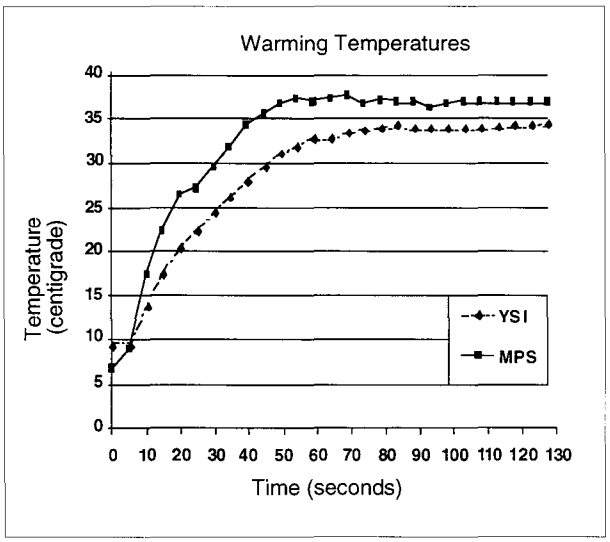
Legend: * = p = .0081

Figure 6: Blood outlet temperatures of the MPS vs. YSI outlet temperature



Legend: MPS = Myocardial Protection System™; YSI = Yellow Springs Instrument.

Figure 7: Blood outlet temperatures of the MPS vs. YSI outlet temperature



Legend: MPS = Myocardial Protection System™; YSI = Yellow Springs Instrument.

and configure several instruments and pieces of equipment to produce myocardial protection. These configurations may include a pump, a heater/cooler, one or two pressure monitoring instruments, a heat exchanger, and different crystalloid bags with appropriate arrest agent concentrations. The MPS was designed to meet the needs for increased flexibility in the delivery of cardioplegia. Even though the MPS is a single device that incorporates all of the above items, there may be some hesitancy to change from standard methods which are accepted in clinical perfusion. The technological changes within the MPS are based upon fluid movement principles that do not incorporate standard occlusion pump technology. The drive mechanism utilized by the MPS is similar to that currently used in intravenous pumps, and has been well accepted as a medical delivery system. Gaining confidence in this technology may require a change in thought process since visual observation of the working mechanism (i.e., roller pump in present systems) is lost.

As a result of the integrated nature of the MPS console, several safety features become available. When the disposable pouches or cartridge is placed into the console, the system software completes a series of self-check steps that assume the integrity of the unit. The bubble trap, located in the heat exchanger, traps air in the delivery set. An ultrasonic level detector, located in the bubble trap, signals the controlling electronics when the air in the bubble trap reaches a predetermined level. The level of air in the bubble trap is electronically monitored and auto-

matically vented as needed. The cardioplegia delivery line is routed through the ultrasonic air detector located on the top of the MPS console. The air detector monitors the delivery line and alerts the operator to prime the delivery line when bubbles are detected. If a bubble larger than 100 *ul* is detected, the pump is shut down and the operator is alerted to the condition. The console evaluates the delivery pressure against operator-set maximum and minimum pressure limits. Visual and audible alarms occur in the instance the delivery pressure reaches one of the limits. Pressure sensors, located within each pump chamber, monitor the fluid pressure within the console. The console continuously monitors the pump chamber pressures to ensure proper filling of the pump chambers, evaluate the functionality of the pump mechanism, and detect the presence of excessive back pressure.

Inadequate myocardial protection is a primary causative factor of cardiac mechanical failure (15). The consequences of inappropriate myocardial protection are low output syndrome and heart failure, necessitating pharmacologic and mechanical support, both of which result in increased cost (16). Changes in patient profile to sicker and older patients require surgeons to identify new and more effective means of intraoperative myocardial protection. In order to confirm clinical effectiveness of the MPS, outcome measures need to be quantified in a controlled prospective randomized evaluation. At the present time there are no articles on the MPS illustrating this point. Our research has shown that the delivery of end [K^+], ratios, flow rates and safety systems of the MPS would support the device's ability to meet delivery requirements.

The differences between the MPS reported delivery volumes and the measured volumes ranged from 5.60 to 7.40 ml. This small difference could have easily been caused by experimental error, such as: 1) clamping the out line prior to turning off the device, causing an additional volume of cardioplegia to be collected primarily due to compliance within the circuit; or 2) measurement error in reading the meniscus of the column of fluid in the cylinder.

In conclusion, the Myocardial Protection System performance characteristics were precise in ratio delivery, concentrations of potassium agents, additive agent concentration, temperature, and pressure across all experimental conditions, with the exception of delivery volume.

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