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A Failure Mode Effect Analysis on Extracorporeal Circuits for Cardiopulmonary Bypass

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Abstract: Although many refinements in perfusion methodology and devices have been made, extracorporeal circulation remains a contributor to neurological complications, bleeding coagulopathies, use of blood products, as well as systemic inflammatory response. With the exposure of these adverse effects of cardiopulmonary bypass, the necessity to re-examine the safety of extracorporeal circuits is vital. A failure mode effect analysis (FMEA) is a proven proactive technique developed to evaluate system effect or equipment failure. FMEA was used to evaluate the six different types of extracorporeal circuits based on feedback from five clinical experts. Cardiovascular device manufacturers, the Veteran's Administration National Center for Patient Safety, and the Joint Commission on Accreditation of Healthcare Organizations recommend the use of FMEA to assess and manage risks in current and developing technologies and therapies. This analysis investigates the safety of six types of extracorporeal circuits used in coronary revascularization, including the newer miniaturized extracorporeal circuits. The FMEA lists and ranks the hazards associated with the use of each cardiopulmonary bypass extracorporeal circuit type. To increase the safety of extracorporeal circuits and minimize the effects associated with cardiopulmonary bypass, perfusionists must incorporate FMEA into their clinical practice. **Keywords:** extracorporeal circuit, failure mode effect analysis, miniaturized extracorporeal circuit, safety. *JECT. 2004;36:351–357*

Surgical intervention of coronary artery disease (CAD) using cardiopulmonary bypass (CPB) has historically been used during revascularization of the myocardium. Despite the many refinements in perfusion methodology and devices, extracorporeal circulation remains as a major contributor to bleeding coagulopathies, use of blood products, and the systemic inflammatory response syndrome (1–4). Much early advancement in CPB was based on trial and error experimentation in animals (5). As cardiovascular surgery continues to advance, the current extracorporeal technology has not changed significantly since 1985, when membrane oxygenators replaced bubble oxygenators (4). The recent increased awareness of the adverse effects of CPB to the professional community has provoked an interest in using alternative methods for mechanical cardiac assist during coronary revascularization. One developing alternative to CPB is off-pump coronary artery bypass (OPCAB). The long-term effects and benefits of OPCAB are still considered controversial, although some postulate it has the same revascularization results as conventional procedures (6). A new alternative to traditional CPB used in beating heart surgery is the use of miniaturized circuits. Two examples of the miniaturized circuits is the MECC® System (Jostra Corp., The Woodlands, TX) and the CORx™ (CardioVention, Inc., Santa Clara, CA) The new miniaturized circuits were developed to improve circuit biocompatibility by decreasing the amount of blood contact with foreign surface and complement activation as well as preserving platelet function and reducing hemodilution (4,7,8).

The United States Military originally developed the failure mode effect analysis (FMEA) process in 1949 to determine the effect of system and equipment failures (9). In the mid-1960s FMEA was used in the aerospace industry, and during the 1970s and 1980s, FMEA gained widespread use in the nuclear, chemical, electronics, and food industries (10). FMEA also has been adopted by the auto industry, where it has gained increasing popularity in recent decades for safety and quality improvement (11). In 1994, the Institute for Safe Medication Practices recommended the use of FMEA in medication use process design (10). The application of FMEA has reduced or eliminated the need for after-the-fact corrective action when processes fail.

The objective of FMEA is to gather a group of experts to identify all the ways a product or process could fail or possibly be improved, including potential mistakes of the operator. The list of potential failures is referred to as the failure modes. Each effect affiliated with its failure mode has a relative associated risk. Each failure mode is then

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Table 1. Type and description of circuits used in FMEA.

Type of Circuit	Description
Roller pump, open circuit	Roller pump with open venous reservoir and traditional tubing length.
Roller pump, closed circuit	Rolleer pump with closed venous reservoir and traditional tubing length.
Centrifugal pump, open circuit	Centrifugal pump with open venous reservoir and traditional tubing length.
Centrifugal pump, closed circuit	Centrifugal pump with closed venous reservoir and traditional tubing length.
Miniaturized open circuit, i.e., MAST (11)	Centrifugal pump with open venous reservoir and shortened tubing length. (Priming volume: 1110 mL)
Miniaturized Closed Circuit, i.e., COR-x™, MECC System® (12)	Centrifugal pump with no venous reservoir and shortened tubing length. (Priming volume: COR-x™ < 500 mL, MECC System® 500 mL)

prioritized, based on the severity of potential injury, from high to low and assigned a number from one to five. By multiplying the rating for these three factors (severity × occurrence × detection = risk priority number) a risk priority number (RPN) is determined for each potential failure mode (11,10). At this point, an evaluation is made of the necessary action to be taken. A recommendation to minimize consequences will then be implemented.

Fromes et al. stated, "Using the current CPB techniques, coronary artery bypass graft (CABG) operations have reached a level of excellence that sets the hallmark to which new techniques have to be compared" (4). The best way to improve patient outcome after CPB is to identify and eradicate problems and concerns associated with CPB procedures. This article addresses the issue of risk elimination by focusing on failure mode and effect analysis to compare routine CPB extracorporeal circuits to the new miniaturized circuits, and an emphasis is placed on how to perform a FMEA.

METHODS

The purpose of the FMEA team is to bring together a diverse base of perspectives and experiences to evaluate six types of extracorporeal circuit. FMEA literature recommends using a minimum number of FMEA team members to represent, without compromise, the interest of all groups that exert influence on the final quality and reliability of the design or process (9–11). The Joint Commission Resources recommends limiting the size of the team to no more than ten, with six to eight experts being ideal (10). Based on these recommendations, a FMEA team of five experts was recruited with at least one expert representing each type of miniature circuit. Each team member was selected based on their specific knowledge and expertise with one of the six types of circuitry, although all members had a sound fundamental understanding of extracorporeal design requirements and specifications.

Table 1 (12) provides details regarding the extracorporeal circuits evaluated in this FMEA. An open-ended survey was distributed to the FMEA team members to consider the safety issues of traditional roller pump and centrifugal circuits, open vs. closed ECCs, as well as miniaturized circuits. Failure modes identified by the FMEA team were then complied and organized according to the specific type of circuit.

The second survey was a spreadsheet with the previously identified failure modes where the experts were asked to rate severity, occurrence and detection using rating scales shown in Table 2. The results of the surveys

Table 2. Severity/Occurrence/Detection Rating Scales.

Severity Rating Scale		
Rating	Description	Definition
1	Slight	Failure unnoticeable to perfusionist and would have little-to-no effect on patient outcome.
2	Low	Failure creates minor nuisance to perfusionist, but the perfusionist is able to overcome it in the process without patient consequence.
3	Moderate	Failure results in a partial malfunction of system, but still able to complete case with no interruption of support.
4	High	Failure may cause interruption in support to patient but no long term consequence.
5	Critical	Failure could cause injury to patient during loss of support
Occurrence Rating Scale		
Rating	Description	Potential Failure Rate
1	Remote	In 100,000 cases pumped, this failure mode will only be observed one time (1:100,000).
2	Low	In 10,000 cases pumped, this failure mode will only be observed one time (1:10,000).
3	Moderate	In 1000 cases pumped, this failure mode will only be observed one time (1:1000).
4	Frequent	In 100 cases pumped, this failure mode will only be observed one time (1:100).
5	Very high	In 100 cases pumped, this failure mode will be observed five or more times (5:100).
Detection Rating Scale		
Rating	Description	Potential Failure Rate
1	Very High	Failure mode is manually inspected for during each set-up and would be identified with probable certainty upon setting-up and calibrating equipment
2	High	Defect is obvious and there is reasonable chance that the perfusionist would identify failure mode on inspection.
3	Moderate	Failure mode is inspected for on a case by case basis and is easily detected.
4	Low	Failure mode is inspected for on a case by case basis but is not easily detected.
5	Uncertain	The failure mode is not detectable or is not inspected for on a case-by-case basis.

Table 3. FMEA Spreadsheets for six circuit types ranked in descending order for each failure mode's median RPN.

Failure Mode	Potential Effects of Failure	Potential Cause of Failure	Median RPN
Open-circuit roller pump			
Antifoam embolization	Major organ infarction or impaired post bypass performance	Washout of antifoam from large defoamer foreign surface area.	48
Reservoir empties	Potential air embolism	Lack of attention, failure of safety systems.	36
Tubing spallation	Embolization or rupture of tubing causing stroke, organ failure, potential embolism, hypoperfusion, contamination increased transfusion.	Wrong occlusion setting, mechanical failure.	36
ECC overpressurization	Blood loss, hypoperfusion, contamination, increased transfusion	Failure to monitor ECC line pressure, safety system failure, operator(s) failure.	36
Reversed pump direction	Air embolism, hypoperfusion.	Operator failure	30
Mismatch of actual cardiac output delivered and roller pump reading	Improper supply of blood to patient and decrease in blood pressure, creating a metabolic and respiratory unbalance on patients blood chemistry	Roller-head occlusion not properly adjusted.	27
Large blood air interface	Systemic inflammatory response syndrome (SIRS) activator	Open reservoir design	27
Rupture of arterial or cardioplegia tubing line.	Lose of prime and blood; risk of massive air emboli.	Improper placement of a clamp in arterial or cardioplegia line; any obstruction or twist in the line, causing a sudden increase in line pressure.	24
Damage to blood components when passing through the roller bushings.	Increase in red blood cell destruction, leading to increased potassium, decrease in HCT and blood products may be necessary.	Excessive occlusion of rollers.	24
Reservoir implosion	Reservoir subject to excessive negative pressure implodes or cracks causing loss of volume to environment and interruption of bypass. Risk of hypoperfusion, increased transfusion and contamination.	In attention to vacuum level during VAVR or failure of vacuum control level.	24
Oxygenator Failure	Unable to oxygenate patient effectively; loss of blood/plasma out of exhalation port of oxygenator.	Crack in oxygenator, device sent back to manufacture.	20
Reservoir explosion	Loss of volume to environment causing interruption of bypass. Possible massive gaseous embolism retrograde up venous line and potentially to arterial circuit. Risk of hypoperfusion, increased transfusion and contamination	Failure to vent reservoir. Low level of vacuum during VAVR causing excessive pressure to develop.	20
Oxygenator overpressurization	Air embolism, fiber rupture, blood loss, increased transfusion risk, hypoxia.	Operator failure, obstruction of gas port.	20
Internal belt on roller pump broke.	Unable to flow effectively, need to hand crank.	Worn belt not visible on check.	18.5
Malfunction of roller pump or loss of power.	No blood being delivered to patient, decrease in blood pressure, decrease in pH, increase CO_2	Internal problem (mechanical or electrical) of the pump; power cable lose or disconnected from source.	18
Heat exchanger failure	Hypothermia, contamination, hemolysis	Heat exchanger leak, heater/cooler failure, failure to perform heat exchange integrity test.	16
Port failure	Blood loss, embolization, hypoperfusion, increased transfusion risk.	Plastic failure, exposure to traffic areas, poor engineering design.	8
Closed-circuit roller pump			
Massive air embolism introduced to patient.	Potential for infusing air into the patients systemic circulation; air locks in filters or membranes	Air coming from venous line, introduced to venous soft bag, perfusionist unfortunately not aware.	36
Inability to handle GME	Embolization of GME to organ systems, stroke.	Excessive negative pressure on bag outlet, operator error.	33.5
Tubing spallation	Embolization or rupture of tubing causing stroke, organ failure, potential embolism, hypoperfusion, contamination increased transfusion.	Wrong occlusion setting, mechanical failure.	24
Roller induced hemolysis	Organ failure, coagulopathy	Wrong occlusion. Excessive CPB time. Increased RPM.	24
Reservoir empties	Potential air embolism	Lack of attention, failure of safety systems.	24
Oxygenator overpressurization	Air embolism, fiber rupture, blood loss, increased transfusion risk, hypoxia.	Operator failure, obstruction of gas port.	20

Table 3: Continued

Failure Mode	Potential Effects of Failure	Potential Cause of Failure	Median RPN
ECC overpressurization	Blood loss, hypoperfusion, contamination, increased transfusion	Failure to monitor ECC line pressure, safety system failure, operator(s) failure.	18
Heat exchanger failure	Hypothermia, contamination, hemolysis	Heat exchanger leak, heater/cooler failure, failure to perform heat exchange integrity test.	10
Reversed pump direction	Air embolism, hypoperfusion.	Operator failure	10
Pump failure	Hypoperfusion, death.	Mechanical or electrical failure. Operator inattention to power cord.	10
Port failure	Blood loss, embolization, hypoperfusion, increased transfusion risk.	Plastic failure, exposure to traffic areas, poor engineering design.	8
Venous reservoir leaks	Blood loss, hypoperfusion, contamination, increased blood transfusion risk.	Sharp object pierces reservoir, manufacturing defect	6
Open-circuit centrifugal			
Antifoam embolization	Major organ infarction or impaired post bypass performance	Washout of antifoam from large defoamer foreign surface area.	60
Massive air introduction into circuit by emptying venous reservoir.	CPB has to be stopped. Air needs to be removed from centrifugal head and the membrane. CO is not delivered to patient for few seconds	Sudden reduction of venous drainage on the case of high flows and low reservoir level. Distracted attention of perfusionist. Lack of level sensor or level safety devices.	36
Reservoir implosion	Reservoir subject to excessive negative pressure implodes or cracks causing loss of volume to environment and interruption of bypass. Risk of hypoperfusion, increased transfusion and contamination.	Inattention to vacuum level during VAVR or failure of vacuum control level.	27
Large blood air interface	SIRS activator	Design	24
Reservoir empties	Potential air embolism	Lack of attention, failure of safety systems.	24
Retrograsde arterial flow	Embolization or hypoperfusion	Operator failure.	24
Decoupling between the biohead magnet and pump magnet.	RPMs of the centrifugal head and flow mismatch, as rpms go, up flow stays the same, the magnet can decouple and change of pump is indicated. Failure of pump-head. Crank placed but was able to realign magnets to resume flow.	Manufacturer defect on the pump-head.	24
Membrane fiber failure	Blood loss, embolization, hypoperfusion, increased transfusion risk, hypoxia.	Manufacturing failure, over pressurization.	24
Reservoir explosion	Loss of volume to environment causing interruption of bypass. Possible massive gaseous embolism retrograde up venous line and potentially to arterial circuit. Risk of hypoperfusion, increased transfusion and contamination.	Failure to vent reservoir. Low level of vacuum during VAVR causing excessive pressure to develop.	20
Heat generated hemolysis	Increased risk of organ failure or coagulopathy	Operator failure, using the pump at high RPM with limited flow. Too high of afterload	15
Flow probe failure	Failure to determine actual blood flow leading to hypoperfusion or hyperperfusion and potential aortic embolization	Manufacture failure, incorrect operator calibration.	12
Flow probe not calibrated.	Inaccurate flow reading	Pump not calibrated or electromagentic flow probe was not placed correctly.	12
Heat exchanger failure	Hypothermia, contamination, hemolysis	Heat exchanger leak, heater/cooler failure, failure to perform heat exchange integrity test.	10
Pump failure	Hypoperfusion, death.	Mechanical or electrical failure. Operator inattention to power cord.	10
Centrifugal head not turning	Not able to establish flow.	Internal or electrical problem of Centrifugal console. Pump set in internal not external mode, while using external drive.	10
Port failure	Blood loss, embolization, hypoperfusion, increased transfusion risk, hypoxia.	Plastic failure, exposure to traffice areas, poor engineering design.	8
Fluid found in magnet area of biohead.	No ill effects on system or to patient.	Crack in biohead or defect in cone.	8

Table 3: Continued

Failure Mode	Potential Effects of Failure	Potential Cause of Failure	Median RPN
Ability to handle GME	Embolization of GME to organ systems, stroke.	Reduced air handling capability especially at low reservoir volumes	33.5
While on bypass, ABG's reveal low PO_2.	Potential for decrease O_2 at tissue levels and organ damage.	Construction around hospital at time found outside O_2 lines were being pinched by bulldozer. Every time the Bulldozer ran over the O_2 lines there was a decrease in O_2 delivery to patient.	24
Flow probe failure	Failure to determine actual blood flow leading to hypoperfusion or hyperperfusion and potential aortic embolization	Manufacturing failure, incorrect operator calibration.	24
Retrograde arterial flow	Embolization or hypoperfusion	Operator failure, failure of impending retrograde flow safety systems	18
Membrane fiber failure	Blood loss, embolization, hypoperfusion, increased transfusion risk, hypoxia	Manufacturing failure, over pressurization.	17
Reservoir empties	Potential air embolism	Lack of attention, failure of safety systems.	16
Heat exchanger failure	Hypothermia, contamination, hemolysis	Heat exchanger leak, heater/cooler failure, failure to perform heat exchange integrity test.	16
Heat generated hemolysis	Increased risk of organ failure or coagulopathy	Operator failure, using the pump at high. RPM with limited flow. Too high of afterload	15
Failure of bag to re-expand	Interruption of CPB, hypoperfusion.	Excessive negative pressure on bag outlet, operator error.	12
Venous reservoir leaks	Blood loss, hypoperfusion, contamination, increased blood transfusion risk.	Sharp object pierces reservoir, manufacturing defect	12
Pump failure	Hypoperfusion, death.	Mechanical or electrical failure. Operator inattention to power cord.	10
Port failure	Blood loss, hypoperfusion, embolization, contamination, increased transfusion	Plastic failure, exposure to traffic areas, poor engineering design.	8
MAST, Open miniaturized circuit			
Antifoam embolization	Major organ infarction or impaired post bypass performance	Washout of antifoam from large defoamer foreign surface area.	48
Large blood air interface	SIRS activator	Design	34.5
Reservoir implosion	Loss of volume to environment causing interruption of bypass. Possible massive gaseous embolism retrograde up venous line and potentially to arterial circuit. Risk of hypoperfusion, increased transfusion and contamination.	Failure to vent reservoir. Low level of vacuum during VAVR causing excessive pressure to develop.	30
Retrograde arterial flow	Embolization or hypoperfusion	Operator failure.	27
Membrane fiber failure	Blood loss, embolization, hypoperfusion, increased transfusion risk, hypoxia.	Manufacturing failure, over pressurization.	20
Reservoir empties	Potential air embolism	Lack of attention, failure of safety systems.	18
Heat exchanger failure	Hypothermia, contamination, hemolysis	Heat exchanger leak, heater/cooler failure, failure to perform heat exchange integrity test.	16
Heat generated hemolysis	Increased risk of organ failure or coagulopathy	Operator failure, using the pump at high RPM with limited flow. Too high of afterload	15
Flow probe failure	Failure to determine actual blood flow leading to hypoperfusion or hyperperfusion and potential aortic embolization	Manufacturing failure, incorrect operator calibration.	12
Kink on the arterial line due to short lines.	When CPB instituted, unable to deliver blood back into the patient.	Physician assistant kinked the arterial line. Scrub nurse pulled arterial line too much, kinking line at base of arterial filter.	12
Pump failure	Hypoperfusion, death.	Mechanical or electrical failure. Operator inattention to power cord.	10
Port failure	Blood leaks leading to potential embolization, contamination or increased need for blood transfusions.	Plastic failure, exposure to traffic areas, poor engineering design.	8
Closed miniaturized circuit: COR-x™ and MECC System®			
Cannula entrapment	Reduced venous return and subsequent reduced arterial flow leads to transient hypoperfusion	Operator failure to monitor venous line negative pressure, surgical intervention	24

Table 3: Continued

Failure Mode	Potential Effects of Failure	Potential Cause of Failure	Median RPN
Oxygenator failure	Hypoxia or potential hypoperfusion potential GME	Fiber rupture, manufacturing defect.	14.5
Air embolism	Air entrainment exceeds system capability to remove air or exceeds extracorporeal volume leading to organ dysfunction or potential death	Operator inattention to system, failure of safety systems, cannula failure	14
Centrifugal pump failure	Hypoperfusion, organ dysfunction, death	Manufacturer electrical or mechanical failure	13
Flow probe failure	Either hypoperfusion or hyperperfusion due to inappropriate flow selection	Electrical failure or operator failure to properly calibrate	12
Port failure	Blood leaks leading to potential embolization, contamination or increased need for blood transfusions	Manufacture failure, operator failure to protect system from traffic.	8

were tabulated and RPN numbers were calculated for each proposed failure mode. The RPN was calculated by multiplying severity × occurrence × detection.

The severity, occurrence, and detection scores were collected onto a spreadsheet for analysis and reported as median values. Software from MINITAB Inc. (State College, PA) was used to perform statistical analysis. The median RPN scores were statically ranked using a two-sample test comparing the circuit types. These nonparametric survey data were analyzed using a Mann–Whitney test to rank the difference in median RPN scores. A type I error probability value of less than 0.10 was considered statistically significant.

RESULTS

Ten experts that included six perfusionists, two manufacturer's clinical specialists, and two physicians were invited to respond to a two-wave survey evaluating the safety and performance of extracorporal circuits. An expert was defined as someone who has performed or been directly involved with 100 or more cases using one of the six circuits selected in this FMEA. The results were compiled from those who responded. Two perfusionist, two manufacturer's clinical specialists, and two physicians participated in the FMEA.

RPN ranking results of the identified failure modes for each of the six circuit types is shown in Table 3. Table 4 summarizes the number of failure modes and median RPN values for each of the six circuits as determined by the FMEA team. Significant differences in the safety of the extracorporeal circuits were identified by experts between four circuits (Table 5). According to this group of experts, the miniaturized closed circuit is significantly safer than the open circuit roller pump with a p value of .007. The experts also found both the closed and open circuit centrifugal pumps to be significantly safer than the open circuit roller pump and the miniaturized open circuit to be safer than the centrifugal pump closed circuit.

Table 4. Rankings of RPN medians by circuit type.

Circuit Type	Number of Failure Modes Identified	Descending Median RPN for all Failure Modes
Roller pump, open circuit	17	24
Roller pump, closed circuit	12	24
Centrifugal pump, open circuit	17	20
MAST, miniaturized open circuit	13	18
Centrifugal pump, closed circuit	12	16
COR-x™ and MECC System® Miniaturized Closed Circuit	6	12

CONCLUSION

The FMEA technique demonstrated different levels of safety between evaluating six different routine and miniature circuit types. Failure modes with the highest RPN rating are considered to be of the greatest threat to patient safety. Stammers et al. reported the most common type of extracorporeal circuit used for routine CPB procedures in the United States is the roller pump in combination with an open reservoir (13). The roller pump open circuit was found by this group of experts to have the highest number of failure modes and to be significantly less safe by the RPN score.

Once identified, failure modes in any process or device can be compensated for or corrected to avoid adverse patient outcomes. Perfusionists can use FMEA results to guide their brainstorming and creativity to define solutions to minimize the risks associated with the more severe failure modes. To increase the safety of extracorporeal circuits and minimize the effects associated with CPB, perfusionists must incorporate FMEA into their clinical practice.

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Table 5. Statistical *p*-value rankings between circuit type and overall median RPN's.

Circuit Type	Roller Pump, Open	Roller Pump, Closed	Centrifugal Pump, Open Circuit	Centrifugal Pump, Closed Circuit	Miniaturized Open
Miniaturized closed circuit	0.007	0.166	0.180	0.466	0.057
Miniaturized open circuit	0.256	0.612	0.464	0.091	
Centrifugal pump, closed circuit	0.004	0.260	0.304		
Centrifugal pump, open circuit	0.045	0.762			
Roller pump, closed circuit	0.136				

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