CPB FMEA #42 Spallation

Friends-

The recent comment that prompted this FMEA posting was a question about using silicone tubing in the pump as opposed to polyvinyl chloride (PVC) tubing. There may be a silicone tubing that the manufacturer says is safe to use in a roller pump and won’t cause spallation but I am very wary of such statements. When I first started our ECMO program in 1986 I tested the medical grade silicone pump tubing and found that it would shed like a sheep dog in a roller pump. PVC tubing shedding was not seen when I tested it. The hazards caused by silicone tubing in roller pumps were known back in 1974 according to one of the volunteer FMEA reviewers. But the first reference I found was in 1983 (Leong AS 1983). Through the years the hazards of using silicone tubing in roller pumps was well documented (Laohapand T 1983, Bourbigot B 1983, Bommer J 1985, Barron D 1986, Altmann P 1987, Hunt J 1989, Briceno JC 1992). Even as late as 1997, patients were still being harmed by spallation from silicone roller pump blood tubing (Dewan PA 1997). PVC tubing has spallation as well, but the morbidity from PVC spall has not been as acute (Kim WG 1998).

Spallation occurs when fragments (spall) of the pump boot (raceway) are shed from the inside of the tubing due to stress exerted from the pressure on the tubing between the roller and the pressure plate on a roller pump. Discussions about spallation are not very common among perfusionists anymore, because it does not seem like much of a problem nowadays. But, in my early days, spallation was a very real and dangerous problem. The roller pumps I first used were designed to use with 1 inch latex tubing. We had no tubing packs. We cut our circuits daily, connecting the pieces with stainless steel connectors and then autoclaving the entire tubing-part of the circuit. The latex tubing we used for the pump boot needed to be freshly manufactured, no more than 1 year old. If you are familiar with latex tubing you know that oxygen in the atmosphere will constantly degrade it. I am sure that at some point you have all seen crumbling latex tubing on an old blood pressure cuff or Wham-O sling shot. Well, that process begins as a microscopic degradation even in fresh tubing. So when we used latex tubing we were meticulous about not over occluding and stressing the latex. I have not even mentioned the potential for latex allergy anaphylaxis. I was very happy when we got roller pumps that could be used with PVC tubing.

Sub-micron filters can remove some particulate matter during recirculation, but those filters must be removed from the circuit prior to CPB and do not prevent spallation during CPB. Tubing spall is a strong argument for using centrifugal pumps in CPB and ECMO systems. But there are disadvantages to C-pumps as well and the threat from spallation is not entirely eliminated. CPB uses other roller pumps which can cause spallation. A high speed sucker pump can shed a lot of spall into the circuit even if an arterial C-pump is being used. If I had my druthers, I would like to see vent and sucker systems working through a secondary cardiotomy reservoir system under gentile vacuum (like a cell saver) and emptied into the circuit using a single, slow speed, totally occluded roller pump. The total occlusion would be necessary to prevent the suction from aspirating blood backwards from the CPB circuit, but this pump would normally turn slowly with little spallation. However that does not work well if rapid blood removal is needed through the vent or suckers.

I think the safest configuration in many cases is a slightly under occluded arterial roller pump to minimize the tubing stress and the use of an independent blood flow meter to assure adequate blood flow and to confirm that the under occlusion is not excessive. Under occlusion can result in excess turbulence in the tubing causing hemolysis and cavitation of gas emboli. On the other hand, if spallation is occurring, it is virtually impossible to detect during CPB.

A discussion about spallation can be quite boring. So I hope I have written this FMEA to make it interesting. If you have comments, please post them or contact me directly.

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FAILURE: Failure to prevent roller pump from causing spallation to the raceway tubing and sending foreign embolic material into the circulation and damaging cellular blood components.

EFFECT:

1. Hemolysis

2. Hyperkalemia

3. Decreased hematocrit

4. Hematuria

5. Need for transfusion

6. Spallation of the tubing raceway.

7. Infusion of tubing particulates into the patient's arterial system.

8. Embolic stroke or organ damage.

9. Splitting or jamming of the raceway and pump stoppage.

CAUSE:

1. Over occlusion of pump rollers.

2. Use of silicone raceway tubing.

PRE-EMPTIVE MANAGEMENT:

1. Occlusion is the measurement of raceway tubing cavity cross section due to the compression exerted by a roller pump on the raceway tubing.

2. Spallation is the shredding of the inner lining of the raceway tubing.

3. Over occlusion: excessive roller compression to the point that blood is damaged or spallation results.

4. Heavy duty, medical grade, plasticized polyvinyl chloride tubing of proper durometer for raceway is utilized to combat spallation or prevent rupture if the occlusion is too tight.

5. Silicone tubing should not be used for raceway tubing.

6. Wet occlusion adjustment method: The occlusion on the arterial pump is adjusted during circuit priming using the meniscus level technique and/or using system pressure drop technique. Spall from the arterial pump must pass through any arterial line filter that is used before it enters the patient’s arterial circulation. (\*The use of an arterial centrifugal pump eliminates spallation from that position and reduces the Harmfulness RPN to one, making the total RPN 1x1x3x3 = 9.)

7. Dry occlusion adjustment method: The occlusion on the vent and suckers pumps is adjusted by clamping the dry inflow line, slowly turning the pump and adjusting roller tension until the inflow side collapses. Loosen the occlusion until the tubing refills with air. Then remove the clamp. Spall from the vent and sucker pumps must pass through the cardiotomy reservoir filter before entering the patient’s circulation.

8. Over occlusion of 4:1, 1:4 or other dual tubing cardioplegia (CP) sets using a single pump: Larger 1/4” tube occlusion may need to be deliberately over tightened in order to occlude the smaller tube. Dual headed pumps or other proprietary pumps can prevent this deliberate over occlusion. Spall from the CP pump goes directly into the coronary arteries. (\*With only a single head CP pump the Harmfulness RPN should be increased to three, making the total RPN 3x1x3x3 = 27.)

9. Tubing temperature changes can alter the occlusion and make the tubing stiffer which increases the risk of spallation.

10. Excessive roller bearing pressure on the raceway tubing results in a visual 'load' alarm on some pump consoles, prompting a loosening of the occlusion.

11. An independent Doppler flow meter is used to assure adequate flow if occlusion is too loose. After going on CPB, tighten the occlusion till the flow stabilizes on the flow meter. Then loosen the occlusion just until the blood flow drops slightly. (Peek GJ, 1999). (Caution: There is a risk of finger injury while changing the occlusion as the pump turns. \*\*Without an independent flowmeter the Detectability RPN should be increased to five, making the total RPN 2x1x5x3 = 30.)

12. Initially use a submicron filter pre-bypass to catch particulates and remove it before CPB.

13. Spall may still be generated after the submicron filter is removed. Recirculate the prime through the 20-40 micron cardiotomy filter to remove generated spall and other large particulates (Knopp EA, 1982).

14. Operate ancillary pumps as slowly as possible, even when dry.

15. If circumstances allow, utilize autotransfusion system cardiotomy reservoir and suction for field suckers.

MANAGEMENT:

1. Clinical indications for over occlusion can be unexplained hyperkalemia and hematuria. (Caution: hyperkalemia and hematuria are more commonly caused by the administration of cardioplegia and hemolysis from foam generation due to excessive use of the ventricular vent and field suckers.)

2. If the raceway is damaged or split, terminate CPB and replace the raceway.

3. Alternate method: If the raceway is damaged or split, terminate CPB, remove the raceway from the roller pump and connect the remnants to a portable, battery powered centrifugal pump by cutting out the damaged portion of the raceway.

RISK PRIORITY NUMBER (RPN):

A. Severity (Harmfulness) Rating Scale: how detrimental can the failure be:

1) Slight, 2) Low, 3) Moderate, 4) High, 5) Critical

(I would give this failure a Slight RPN, 1, if a centrifugal pump is used. And a Low, 2, if an arterial roller pump is used. With only a single head CP pump the Harmfulness RPN should be increased to three.)

B. Occurrence Rating Scale: how frequently does the failure occur:

1) Remote, 2) Low, 3) Moderate, 4) Frequent, 5) Very High. (Spallation from a roller pump serious enough to injure a patient is rare. So the Occurrence is Remote. The RPN would be a 1.)

C. Detection Rating Scale: how easily the potential failure can be detected before it occurs:

1) Very High, 2) High, 3) Moderate, 4) Low, 5) Uncertain. (The Detectability RPN equals 3 on the premise that an independent flow meter is used to check over occlusion during CPB. Without an independent flowmeter the Detectability RPN should be increased to 5.)

D. Patient Frequency Scale: 1) Only a small number of patients would be susceptible to this failure, 2) Many patients but not all would be susceptible to this failure, 3) All patients would be susceptible to this failure. (All patients would be at risk. So the Frequency RPN would be 3.)

Multiply A\*B\*C\*D = RPN. The higher the RPN the more dangerous the Failure Mode.

The lowest risk would be 1\*1\*1\*1\* = 1. The highest risk would be 5\*5\*5\*3 = 375. RPNs allow the perfusionist to prioritize the risk. Resources should be used to reduce the RPNs of higher risk failures first, if possible. (The total RPN for this failure could be as low as 1\*1\*3\*3 = 9, or as high as 3\*1\*5\*3 = 30, depending on the equipment and methods used.)