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Case Report

Cracked Acrylic Ventricular Assist Devices after Using a Doppler Stethoscope and Ultrasound Transmission Gel to Predict Impending Pump Failure: A Case Report

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ABSTRACT

At Saint Louis University Health Sciences Center, bi-ventricular assist devices were placed in a patient after failure to wean from bypass. These acrylic devices are known to be used for post cardiotomy failure. Acrylics and other plastics are used in extracorporeal circuitry. Plastics have been known to crack when exposed to certain chemicals and conditions. This case describes the use of ultrasound transmission gel as another ingredient that causes cracking of centrifugal assist devices made of acrylic plastic.

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INTRODUCTION

The use of acrylic centrifugal assist devices after failure to wean from cardiopulmonary bypass has become an accepted temporary mode of therapy (1). Acrylic and other plastics have demonstrated structural weaknesses when exposed to certain chemicals and conditions. Polycarbonate, polysulfone and acrylic plastics have been known to fracture with the use of alcohol and acetone products (1,2,3). Liquid anesthetics are also known to damage polycarbonate plastic in oxygenators and connectors (4,5). An incident at St. Louis University Health Sciences Center in which the acrylic ventricular assist devices cracked after ultrasound transmission gel was applied on them prompted this report.

CASE REPORT

A sixty year old 104 kg male with a history of three myocardial infarctions presented to the emergency room with chest pain. The patient's past medical history was significant for hypercholesterolemia, insulin dependent diabetes mellitus, hypertension, asthma, chronic obstructive pulmonary disease, peripheral vascular disease and carotid artery disease. A cardiac catheterization was performed and revealed severe coronary artery disease with a complex left main lesion. Coronary artery bypass grafting of four vessels was performed. After several attempts at weaning from cardiopulmonary bypass (CPB), an intra-aortic balloon pump (IABP) was inserted. High dose inotropic support was also initiated. The patient was placed on bi-ventricular assist devices (BiVADs) after failure to wean from CPB. Total time for CPB was 456 minutes. Total cross clamp time was 130 minutes.

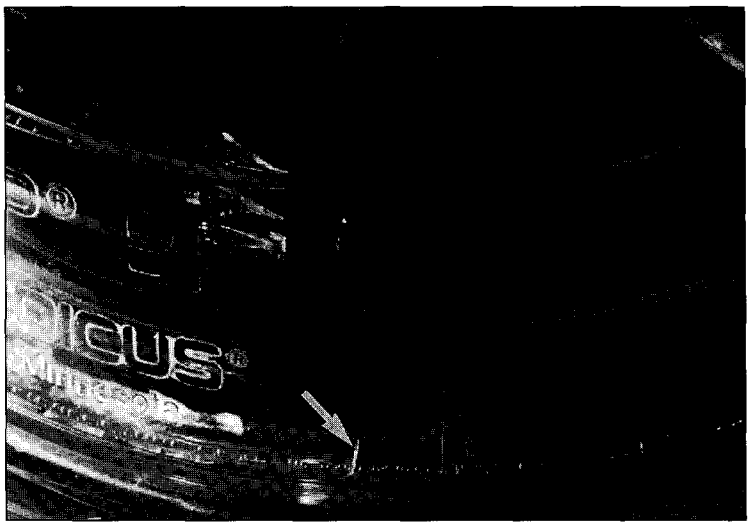
Each ventricular assist device (VAD) system consisted of Medtronic[a] Carmeda® coated cannulae, tubing and Medtronic-Biomedicus[b] centrifugal pumps. A 22 French cannula was placed in the ascending aorta and a 32 French cannula was placed in the left atrium. These were then attached to the left VAD (LVAD). A 22 French cannula was placed in the pulmonary artery and a 32 French cannula was placed in the right atrium and then attached to the right VAD (RVAD). The sternum could not be approximated and therefore a synthetic membrane was used to close the chest.

Average flows for the BiVADs were between 4.0 to 4.5 l/min. Normal VAD management guidelines include keeping the platelets above 100,000 mm^3, hemoglobin above 10 mg/dl, hematocrit above 30%, and an activated clotting time (ACT) between 150-160 seconds. Since this patient was on a Carmeda® system, the ACTs were checked every hour until stabilization after surgery and then every four hours. A heparin drip was not required on this patient.

On the first VAD day the patient required 39 units of packed red blood cells (PRBC), 16 units of fresh frozen plasma (FFP) and 6 units of single donor platelets. The patient was explored and found to have significant bleeding from the aortic and pulmonary artery cannulae. These cannulae were then repositioned and secured and the bleeding was well controlled. Also at this time the IABP was exchanged due to a malfunction. No complications occurred during the above procedures.

On the second VAD day the patient continued to bleed approximately 300 ml/hr. This bleeding did not interfere with the

Figure 1A: Right ventricular assist device. Arrow pointing to noticed initial crack.



1B: Enlarged photo of crack with areas of crazing noticed at seam of device. Crack does not extend through to the blood side of device.

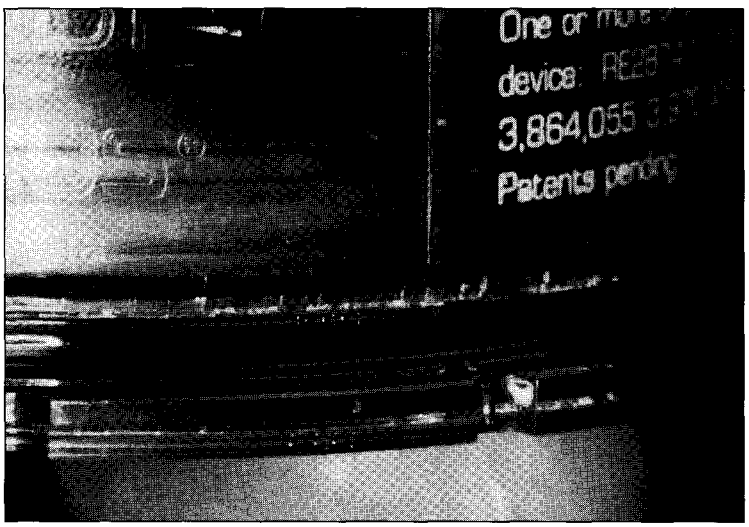
a Medtronic, Inc., Anaheim, CA 92807
b Medtronic-Biomedicus, Inc., Eden Prairie, MN 55344

ability of the BiVADs to pump 4.0 l/min. The fibrinogen returned to a normal value of 341 mcg/dl. Other significant laboratory findings include a potassium (K^+) of 6.6 mmol/L, blood urea nitrogen of 33 mg/dl and a creatinine of 2.8 mg/dl. The K^+ was treated with insulin and sodium bicarbonate and Kayexelate[c]. The patient received a total of 7 units of PRBC, 4 units of FFP and 5 units of platelets. Pharmacological agents were slowly weaned.

On the third VAD day the patient had minimal bleeding and stabilization of laboratory results and coagulation profiles. A transesophageal echocardiogram revealed poor biventricular function with the BiVADs off for one minute and the ventricles loaded. The ventricles remained severely impaired with increasing left and right atrial pressures. The impression was minimal to no recovery of postcardiotomy failure. The decision was made to maintain this patient during the evening and to remove the BiVADs in the morning. Gross hematuria was observed that evening after one unit of PRBC was given. Due to this observation and the long duration of VAD support (>72 hours), a non-invasive method for monitoring the pumphead function was instituted. Diuretics were started to clear the hematuria.

A Medasonics[d] 5MHz doppler stethoscope and Parker[e] Aquasonic® 100 ultrasound transmission gel were placed near each VAD pump backplate above the housing of the magnet and bearings. Each VAD was listened to every hour to compare for any sound change that may relate to the beginning of a pump failure. The gross hematuria cleared with the use of diuretics and no sound change was detected for the first 12 hours. At this time a small crack was found on the RVAD cone where the gel and stethoscope were used (Figures 1A and 1B). No blood leakage was noted and sterile bone wax was applied to the RVAD.

Figure 2A: Left Ventricular Assist Device. Multiple cracks seen at seam of device. Bubbles are part of normal manufacturing process of attachment of backplate to the blood pump.



2B: Enlarged cracks and crazing noticed at seam of device.

The patient was transferred to the operating room the next day and the BiVADs were removed. Massive inotropic support was instituted and the IABP remained at a 1:1 ratio. The blood pressure rapidly deteriorated to 50 mmHg systolic, and after 15 minutes the patient expired. Total BiVAD time was 94 hours.

Upon rinsing and examining the BiVADs, small splinter-like cracks, crazing and larger cracks were noticed on both devices (Figures 2A and 2B). The cracks were specifically located where the gel and stethoscope were used to listen to the devices.

DISCUSSION

Polycarbonate and acrylic plastics are materials used in extracorporeal circuitry. Polycarbonate is clear, strong and the toughest of all thermoplastics. Acrylics are easily moldable. However, both have been documented to craze and crack when exposed to certain conditions. Crazing is seen as an opaque color change in a clear plastic which is soon to crack. This crazing and cracking is known as environmental stress-cracking, defined as a failure of a plastic material in the presence of certain types of chemicals.

Stress cracking depends on three factors: tensile stress, a stress-cracking agent and inherent susceptibility of the plastic to stress cracking. (Personal communication with Nalge® Nunc, International). Alcohol, acetone, isoflurane and re-sterilization with ethylene oxide or freon have been documented to

c Sanofi Winthrop Pharmaceuticals, New York, NY 10016
d Model BF 4B Medasonics, Fremont, CA 94539
e Parker Laboratories, Inc., Orange, NJ 07050

cause structural changes in these plastics (1-9).

According to the manufacturer, the pump should be changed every 48 hours (1). In the scenerio of a critically ill patient, changing the VAD pump every 48 hours may be detrimental to the patient's well being by exposing them to possible increased blood transfusions and exposure to potential infections. Pulmonary sepsis and septic shock have been reported in patients supported by extracorporeal mechanical devices. These patients are extremely susceptible to life-threatening infections (10, 11).

To document the integrity of the pumps, we normally check the circuitry for any obvious thrombus or blood leaks and listen for irregularities of external sounds during the operation of the devices. This is common practice among institutions using VADs (1, 10-11). Because this patient was on the BiVADs longer than 72 hours and gross hematuria was associated in the same time frame, we decided to investigate the pumps further by listening for any irregularities of internal sound changes. This is a first report utilizing the technique of listening to the internal components of the pump using ultrasound gel and a Doppler stethoscope.

According to the manufacturer of the gel, it is a nonflammable, noncorrosive, temperature stable, aqueous gel that does not contain alcohol or formaldehyde. The gel is also non-injurious to transducers and nonirritating to the skin. Composition of this gel includes reverse osmosis water, humectant, polymer, preservatives to include propyl paraben and methyl paraben, water soluble fragrance and FD&C color (12). Upon further investigation into the cracking of the BiVADs, this clinical institution was able to reproduce the cracks and crazing on the VAD by using only the ultrasound gel. The manufacturer of the centrifugal pumps was able to reproduce the cracks and crazing with the gel also. A burst test was done and consisted of running the VAD at the highest revolutions per minute and placing the gel on every external part of the plastic. Actual leaking and separation of the blood component of the VAD from the pump backplate occurred. The cause of the cracking, crazing, and leaking of the VAD was due to the ultrasound gel.

In the future, manufacturers of acrylic plastics used in extracorporeal circuity should include ultrasound gel as a hazardous substance. The exact ingredient in the gel that causes this cracking is unidentified. Based on our experience, no chemical or any substance should be placed on ventricular assist devices.

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