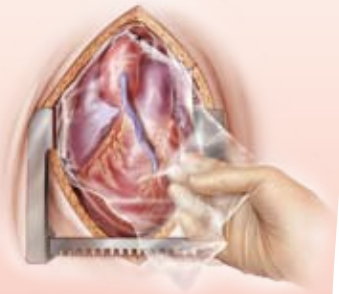
CardioWrap®

Bioresorbable Protective Sheet



Application of CardioWrap® Bioresorbable Protective Sheet in Cardiothoracic Procedures

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CLINICAL CASE REPORTS

INTRODUCTION

The Ventricular Assist Device (VAD) was developed as a heart pump to serve two medical conditions with three possible endpoints:

1) Acute Cardiogenic Shock - as a short (days to weeks) or intermediate (weeks to months) term device designed to address acute cardiogenic shock (e.g. myocardial infarction) that may have the potential for recovery. The VAD in these instances are a bridge-to-recovery (BTR) and would be placed temporarily with the hope that once the heart recovers it will be removed. Implantation of the VAD requires a sternotomy in most instances and requires a re-sternotomy for removal.

2) Chronic Heart Failure - as a long (months to years) term device designed to address chronic heart failure that no longer responds to maximal medical, interventional, or surgical therapies. The VAD in these instances would be placed as either a bridge to transplantation (BTT) or as a Destination/ Permanent Therapy (DT) in patients who are not transplant candidates. In both groups, sternotomy is generally required for implantation. In the BTT group, re-sternotomy is needed at the time of transplantation. In the DT group, re-sternotomy may never take place if the patient lives and dies on the VAD; if the heart somehow recovers in the DT group or the VAD needs to be removed for some other reason (e.g. infected, malfunction, need for exchange, upgrade, etc), then re-sternotomy would be necessary.

OBJECTIVE

Three short-term cases are presented to illustrate the implant technique and clinical observations at reoperation with re-entry at 1 day, 7 days, and 14 days. A large 130mm x 200mm, 0.05mm CardioWrap® Bioresorbable Protective Sheet was placed over the heart. The CardioWrap® sheet is a bioresorbable sheet used as a pericardium replacement device and offers an innovative option for postsurgical healing following interventional cardiothoracic surgery. It was not known at the time of VAD implantation how long the VAD would be needed.

In general, the CardioWrap® Bioresorbable Protective Sheet can be cut with sterile scissors and placed around anatomic structures of the pericardium at the time of implant. The material can be sutured where the surgeon chooses, depending on specific patient needs. The CardioWrap® sheet maintains mechanical integrity during the surgical procedure allowing the product to be easily placed and repositioned as often as necessary. How quickly the product is absorbed in the body depends upon the anatomical region, dynamic motion, and fluid exchange.

VAD Cannulae in an animal model

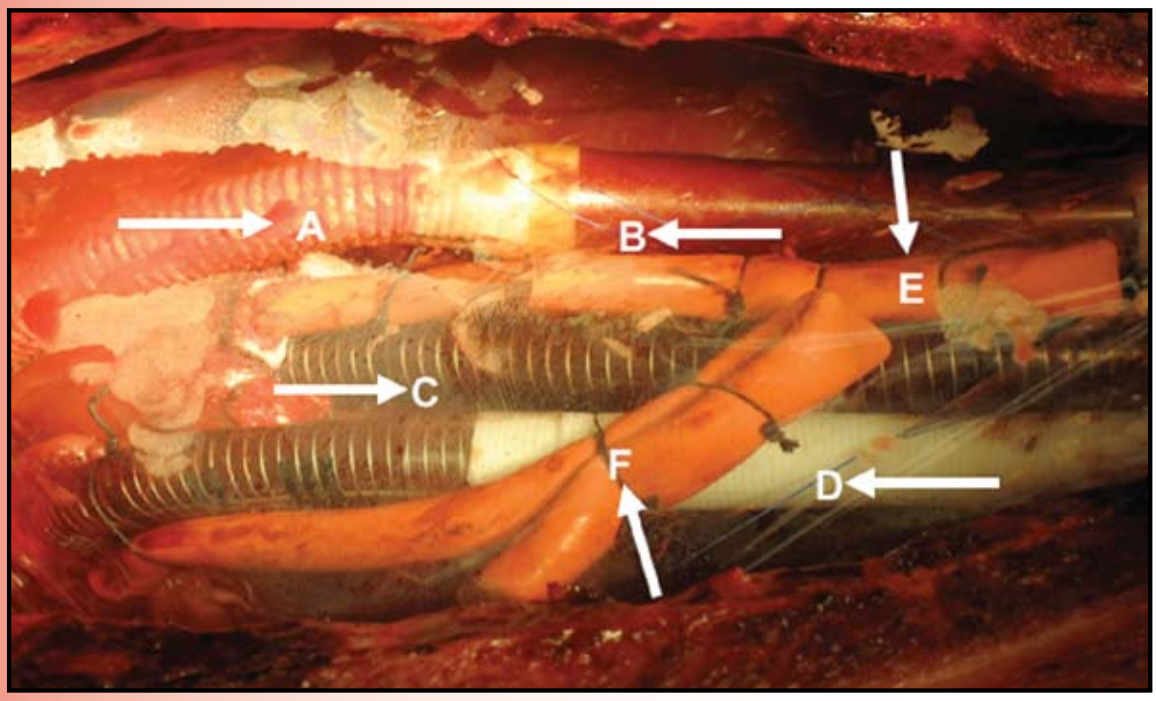

Figure 1 A) Outflow graft to aorta, **B)** Outflow cannulae to aorta, **C)** Outflow cannulae to PA, **D)** Inflow cannulae from RA, **E)** Red rubber tourniquet, **F)** Silk tie on red rubber tourniquet

VAD Cannulae following reopening of sternum in an animal model

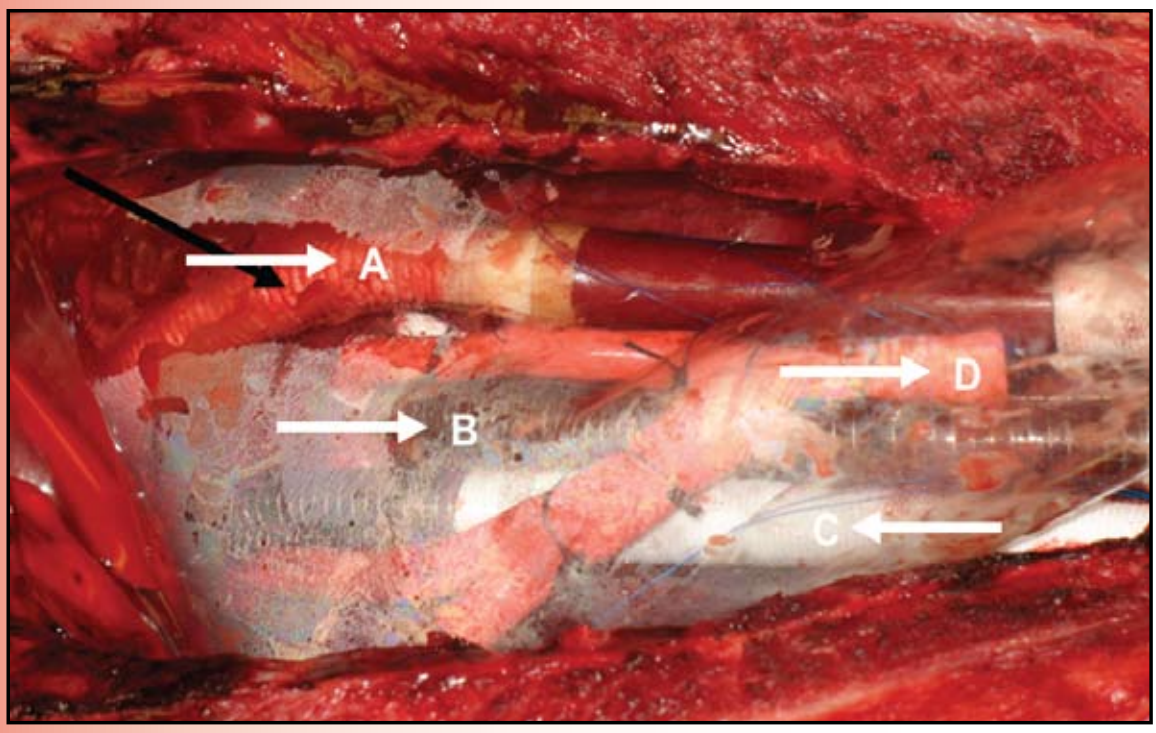

Figure 2 A) VAD outflow cannulae/graft to aorta **B)** VAD Outflow Cannulae to PA **C)** VAD inflow cannulae from RA **D)** Red rubber tourniquet

CASE DESCRIPTIONS

Case 1
A 53 year old man was undergoing elective outpatient orthopedic surgery when he suddenly went into cardiogenic shock. He was rapidly resuscitated, intubated, and transferred to the nearby hospital for further evaluation and care. Echocardiography demonstrated severe biventricular dysfunction. Cardiac catheterization showed normal coronary arteries. An intra-aortic balloon pump (IABP) was placed and inotropes started. His condition did not improve. He was rapidly transported to the OR where an Abiomed AB5000™ Left Ventricular Assist Device (LVAD) was placed. A CardioWrap® Bioresorbable Protective Sheet was placed over the heart prior to closure of the chest. The patient was transferred to a quaternary care center that evening. The next day, cardiac function normalized and the patient returned to the OR for VAD explant. The CardioWrap® sheet looked nearly pristine except for some crinkling of the product. The LVAD was successfully explanted, the sternum closed, and the patient eventually discharged in four days.

Case 2
A 70 year old man presented to an outlying hospital with an acute MI with associated congestive heart failure (CHF). He underwent cardiac catheterization which showed severe coronary artery disease with elevated filling pressures. An IABP was placed and surgical consultation obtained. Two days later, coronary artery bypass grafting was undertaken. In the midst of the operation, the inferior portion of the left ventricle (i.e. the territory of his acute MI) ruptured. The LV rupture was repaired, the bypass grafts completed, and an attempt to wean from cardiopulmonary bypass was unsuccessful. An Abiomed AB5000™ LVAD was placed. A CardioWrap® Bioresorbable Protective Sheet was placed over the heart prior to closure of the chest. The patient was transferred to a quaternary care center for further management. After 7 days, heart function improved enough to remove the LVAD. The CardioWrap® sheet remnants were visible as blood stained pieces of the original sheet. These remnants are portions of the original sheet that have gone through a process of degradation with time. These fragments are pieces of variable size, some of which are in the process of dissolving into the milieu of the surrounding tissue and fluid. The LVAD was successfully explanted, the sternum closed, and the patient eventually discharged.

Case 3
A 50 year old morbidly obese man with known heart failure presented to an outlying hospital with an acute cardiac decompensation. He was taken to the cardiac catheterization lab where he was found to have significant disease that required angioplasty and stenting of the left circumflex coronary artery. He remained unstable requiring intubation and placement of an IABP. An Abiomed AB5000™ LVAD was placed. A CardioWrap® Bioresorbable Protective Sheet was placed over the heart prior to closure of the chest. The sternum was closed, he was transferred to a quaternary care center and the patient was managed for 14 days after which heart recovery was observed. He returned to the OR for LVAD removal. There were some visible remnants of the CardioWrap® sheet, but most of it appeared to be gone or absorbed into the mixture of blood and tissue of the mediastinum. It was not difficult to identify the LVAD cannulae or the heart structures once the area was rinsed with warm saline solution and suctioned clean. The LVAD was removed, the sternum was closed, and the patient was discharged.

DISCUSSION

These three short-term cases are representative of our program's use of VADs for stabilization and myocardial recovery. As discussed in the introduction, it is not known how long the VAD will be needed or what the eventual endpoint is going to be-- either short, intermediate, or long term. However, it is known that at some point (in most cases) sternal re-entry will be needed.

One concern about any product used in this application, and particularly resorbable products, is their potential for interfering with chest tube drainage and increasing the

possibility for cardiac tamponade. While it may be quite possible for this to occur, it is our standard to place the drainage tubes away from the products. For instance, the drainage tubes—whether they are Blake drains or chest tubes—are positioned posteriorly and inferiorly so that any blood, which would drain posteriorly and inferiorly by gravity alone, would be captured by the two drainage tubes.

SUMMARY

In these three short-term cases, the CardioWrap® Bioresorbable Protective Sheet has proven to be a cost effective and an inert product for pericardium replacement in procedures which may require reoperation within six months. However, these three cases are short-term observations and should be interpreted accordingly. Further investigation is absolutely required to determine the efficacy of the CardioWrap® sheet in other cardiac surgery procedures in which re-entry is likely (e.g. congenital cases, young adults).

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