CardioWrap®

Bioresorbable Adhesion Barrier Film

Application of the CardioWrap® Bioresorbable Adhesion Barrier Film in Ventricular Assist Device Patients

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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. Any product that would facilitate the re-entry at the time of explant would be desirable.

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. As already mentioned, any product that would facilitate re-entry in the VAD patient would be desirable.

Sternal re-entry, in general, can be a hazardous undertaking, depending upon the timing of the re-entry and the extent of scar/soft tissue attachment formation (i.e. adhesions) present. As a general rule, re-entry is most challenging when the time elapsed from the original surgery is more than 1 month and less than 6 months. During this period, scarring and soft tissue attachments are still forming, and generally are not so well formed that adequate tissue planes are yet developed. Typically following cardiac surgery, scar formation occurs between the epicardial surface of the heart, the pericardium, and the surrounding mediastinum. As with other areas of the body where surgery is performed, the density of the scar evolves over time such that flimsy adhesions are usually present within the first few days to weeks followed by firmer and more fixated adhesions as time goes by. Eventually, the adhesion matures into a fairly well defined scar that sometimes can not be distinguished from the organ or structure that it is attached to. Thus, the vulnerable period is generally during that formative time when the adhesion is not well established making dissection between the organs—in this case the heart—and the surrounding structures quite hazardous. Soft tissue attachment found at re-entry can lead to higher risk of potential injury to the heart and great vessels, poor orientation and visibility, increased blood loss and operative time, and patient morbidity.

OBJECTIVE

Three short-term cases are presented to illustrate the implant technique and clinical observations at reoperation for the CardioWrap® Bioresorbable Adhesion Barrier Film with re-entry at 1 day, 7 days, and 14 days. In all three cases, the large 130mm x 200mm x 0.05mm sheet of the CardioWrap® film was placed over the heart and inflow/outflow cannulae (and therefore under the sternum). The CardioWrap® Bioresorbable Adhesion Barrier Film creates a protective barrier between opposing cardiac tissues to control the in-growth of scar tissue and subsequently control adhesions. Control of the early formation of adhesions in the area adjacent to the CardioWrap® Bioresorbable Adhesion Barrier Film may prove advantageous where clear tissue planes may result in simplified dissection and lowered risk to local anatomy. It was not known at the time of VAD implantation how long the VAD would be needed. In all three cases, the re-entries were uneventful—there was virtually no adhesion formation. It remains to be seen if these findings will be realized in longer term applications. If so, it would be of interest to VAD surgeons who are implanting devices of indeterminate duration.

VAD Cannulae with freshly placed CardioWrap® film in an animal model

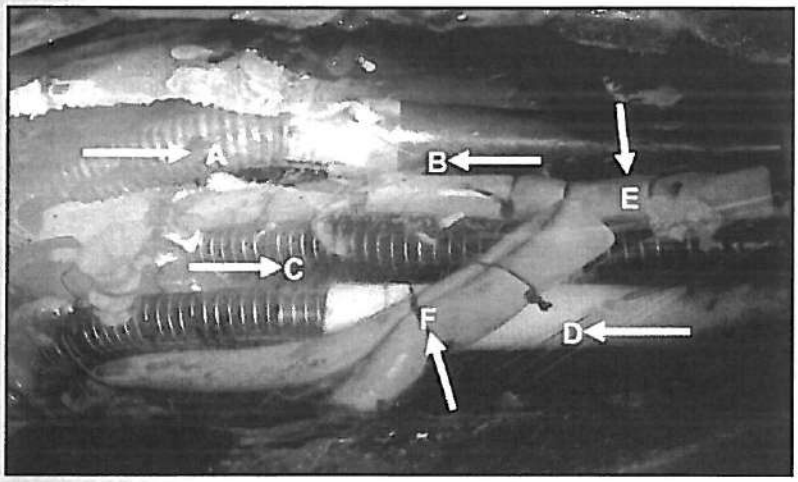

Figure 1 A) Outflow graft to aorta, **B)** Outflow cannulae to aorta, **C)** Outflow cannulae to PA, **D)** Inflow cannulae from RA, **E)** Red rubber tourniquet, **F)** Silk tie on red rubber tourniquet

VAD Cannulae with CardioWrap® following reopening of sternum in an animal model

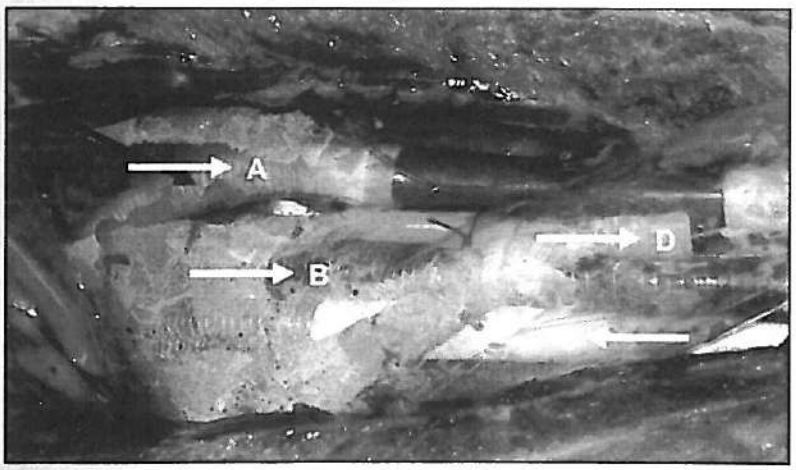

Figure 2 A) VAD outflow cannulae/graft to aorta **B)** VAD Outflow Cannulae to PA **C)** VAD inflow cannulae from RA **D)** Red rubber tourniquet

In general, CardioWrap® Bioresorbable Adhesion Barrier Film can be cut with sterile scissors and placed around anatomic structures at the time of implant. The material can be sutured or "companion fit" as a surgeon chooses depending on specific patient needs. The CardioWrap® film 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. A good example of how the CardioWrap® film is placed and looks in the actual OR during VAD placement is demonstrated in an animal model (Figures 1 & 2).

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. The CardioWrap® Bioresorbable Adhesion Barrier Film was used to cover the inflow/outflow cannulae of the LVAD where they entered and exited the heart as well as the heart itself. 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. Re-entry was simple and scar formation was non-existent. The CardioWrap® film 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. The CardioWrap® Bioresorbable Adhesion Barrier Film was used to cover the inflow/outflow cannulae of the LVAD where they entered and exited the heart as well as the heart itself. The patient was transferred to a quaternary care center for further management. After 7 days, heart function improved enough to remove the LVAD. Re-entry was uneventful with adhesion formation. The CardioWrap® film remnants were visible as blood stained pieces of the original sheet. These remnants were portions of the original sheet that had gone through a process of degradation with time. These fragments were pieces of variable size, some of which were in the process of dissolving into the milieu of the surrounding tissue and fluid. The LVAD was removed without incident, the sternum closed, and the patient eventually discharged.

Products that create a physical barrier between the sternum and the heart are desirable

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. Two large sheets of CardioWrap® Bioresorbable Adhesion Barrier Film were needed to cover the heart and cannulae. One sheet was placed closer to the aorta while the other sheet was placed closer to the skin entry of the cannulae. There was some overlap of the product but this did not contribute to any product migration or product 'bunching' at closure. 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. Sternal re-entry was simple with no adhesion formation, resulting in a modestly shorter operative time compared to using nothing at closure. There were some visible remnants of the CardioWrap® film, 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 re-closed, and the patient recovered. He was eventually 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. Our program's approach has been to utilize techniques and products that would help minimize the risk associated with sternal re-entry. Products that create a physical barrier between the sternum and the heart are desirable from the standpoint of protecting the heart from mechanical damage when re-entering, but the concerns associated with these types of products are two fold: (1) an artificial foreign body that may become infected; and (2) higher cost. Products made of inert and resorbable material, such as the CardioWrap® Bioresorbable Adhesion Barrier Film, help mitigate the concern associated with infection. It is this type of product that deserves further investigation for all types of VAD scenarios in which sternal re-entry is likely.

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. Anterior drainage tubes would introduce the possibility for clogging when using these type of products. This simple solution should alleviate any concerns associated with drainage tubes becoming clogged by using the CardioWrap® film.

SUMMARY

In these three short-term cases, the CardioWrap® Bioresorbable Adhesion Barrier Film has proven to be a cost effective and inert product that aided in the sternal re-entry procedure. In some of these cases, it was observed that there were fewer adhesion formations than compared to procedures in which nothing was used. The CardioWrap® film was easy to position during implant and effortless to remove. 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® film in VAD patients and other forms of cardiac surgery patients in which re-entry is likely (e.g. congenital cases, young adults).

The CardioWrap® Bioresorbable Adhesion Barrier Film creates a protective barrier between opposing cardiac tissues to control the in-growth of scar tissue and subsequently control adhesions. Control of the early formation of adhesions in the area adjacent to the CardioWrap® Bioresorbable Adhesion Barrier film may prove advantageous where clear tissue planes may result in simplified dissection and lowered risk to local anatomy.

The CardioWrap® Bioresorbable Adhesion Barrier Film has the following indications.

- *Separate opposing tissues and prevent the in-growth of scar tissues and the formation or reformation of adhesions immediately adjacent to the barrier film.*
- *Aid in re-operation procedures by promoting the formation of a surgical dissection plane immediately adjacent to the barrier film.*
- *Prevent the formation or reformation of adhesions and promote the formation of a surgical dissection plane in the pericardium, epicardium, and retrosternal anatomical regions.*

Note: Figure 1 (JPEG Figure 1): Placement of the CardioWrap® Bioresorbable Adhesion Barrier Film in the animal model of a VAD. Notice the cellophane-type appearance and its ability to cover the VAD cannulae as well as the epicardial surface of the heart. Figure 2 (JPEG Figure 6): Same as Figure 1 except that the sternum had been closed temporarily and then reopened to demonstrate CardioWrap's appearance with this maneuver.

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