

Intraoperative Surgical Sealant Application during Cardiac Defect Repair

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Bleeding can occur as a sequela to cardiac surgery. Surgical products—such as conventional sutures and clips, and somewhat less conventional sealants—have been developed to prevent this event. Among these, CoSeal is a sealant used at our institution; here we report the cases of 2 patients in whom CoSeal was used successfully as either a supplement or an alternative to suture repair. This sealant was found to be useful in attaining hemostasis both in high-pressure ventricular repair and in the rupture of a friable coronary sinus adjacent to vital structures (in this instance, a left circumflex coronary artery). (Tex Heart Inst J 2014;41(4):440-2)

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Bleeding is a major sequela of cardiac surgery and is a significant cause of morbidity and death.^{1,2} Hemostasis can be challenging during complex cardiac surgery, particularly because of friable tissue, coagulopathy, poor visualization of the surgical field, and poor bleeding-site accessibility. Failure to achieve and maintain hemostasis and reinforce fragile tissue can result in additional bleeding, which can further reduce visibility in the operative field, increase blood loss, lengthen surgery, increase the use of blood products, and contribute to postoperative complications and reoperation.³

In addition to meticulous surgical technique, conventional sutures, and ligature clips, we now have a variety of therapeutic agents available to assist in hemostasis. When ligation or other conventional methods are ineffective or impractical, surgical sealants are used to prevent suture-line bleeding. During cardiac surgery, when surgeons often deal with cardiac chambers and arterial vessels that are under pressure, proper suture-line sealing is important to minimize bleeding and achieve superior clinical outcomes.

We here present 2 reports on the use of CoSeal[®] surgical sealant (Baxter Healthcare Corporation; Deerfield, Ill) for intraoperative bleeding during cardiac rupture repair. CoSeal, which contains a fibrin component of bovine origin, was developed as a hemostatic agent for use in cardiovascular anastomosis and is the combination of 2 synthetic polyethylene glycols, a hydrogen chloride solution, and a sodium phosphate/sodium carbonate solution that cross-links with collagen as well as with other innate proteins adherent to the applied tissue.⁴⁻⁶ Our studies were performed in compliance with human studies and U.S. Food and Drug Administration guidelines, and we obtained written consent from the patients after explaining the nature of the procedure.

Case Reports

Patient 1: Contained Rupture of Left Ventricle. A 51-year-old woman with a family history of early coronary artery disease and a history of smoking and drug use experienced left-sided chest pain for 10 days before seeking medical attention. On admittance to a coronary care unit at a peripheral hospital, she was diagnosed with significant ischemic cardiomyopathy and acute myocardial infarction. Echocardiography revealed severe ventricular dysfunction and a left ventricular (LV) ejection fraction of <0.20. She underwent cardiac catheterization and placement of an intracoronary stent. During that procedure, occlusion of the mid left anterior descending coronary artery was observed. She continued to develop worsening heart failure symptoms with significant systolic ventricular impairment and severe mitral regurgitation.

When admitted to our facility, the patient had pulmonary edema and was dependent upon inotropic agents. She was considered a candidate for placement of an LV

assist device (LVAD), the HeartMate II® Left Ventricular Assist System (Thoratec Corporation; Pleasanton, Calif). During the operation, substantial adhesions in the lateral wall of the pericardium were seen to be intimately associated with hematoma, wall-thinning, and pseudoaneurysm of the LV. At the outset of device implantation, we observed considerable blood in the posterior pericardium during anastomosis of the ascending aorta to the outflow graft of the LVAD. Examination of the lateral wall of the LV revealed that the LV pseudoaneurysm was a disintegrated rupture of the LV, surrounded by extensive necrotic tissue. We resected the area, leaving a 5 × 7-cm defect, which had an extremely fragile and necrotic myocardial edge (Fig. 1). The LVAD inflow cannula was sutured through the defect in a horizontal mattress fashion, with multiple pledgeted Ethibond® Ticon™ sutures. CoSeal was placed over

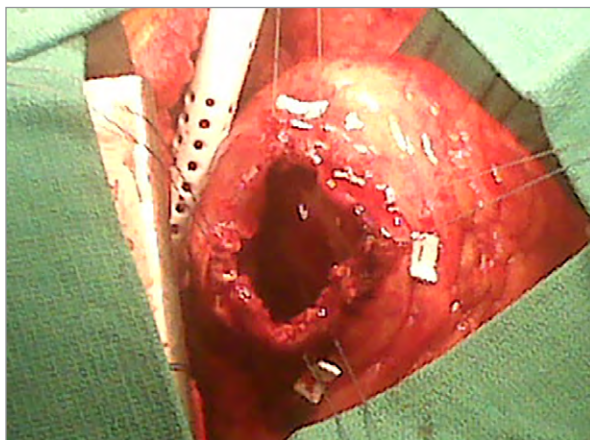


Fig. 1 Patient 1. Intraoperative photograph shows left ventricular rupture after débridement of necrotic tissue.

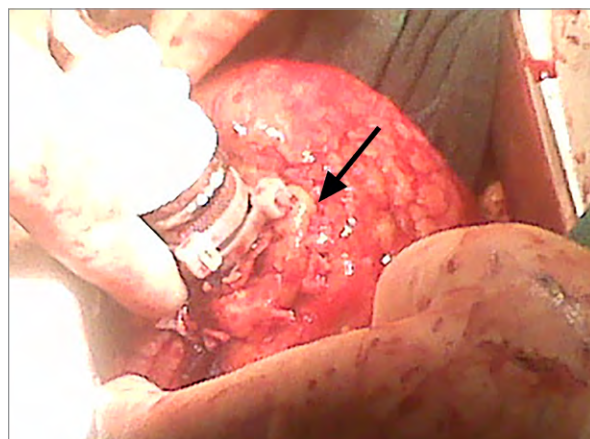


Fig. 2 Patient 1. Intraoperative photograph shows the repaired left ventricular rupture and the HeartMate II® ventricular assist device implantation. CoSeal® was applied over the anastomosis (arrow) between the cuff of the inflow cannula and the left ventricular defect.

the anastomosis between the cuff of the inflow cannula and the LV defect, to reinforce the anastomotic sealing of the fragile tissues before filling and pressurization of the LV (Fig. 2). All surgical sites were hemostatic, both at completion of the surgery and on the next day, when the chest was closed. The postoperative course was uncomplicated and the patient was discharged from the hospital a few days later, to await transplantation.

Patient 2: Coronary Sinus Rupture. A 62-year-old woman with a history of mitral valve prolapse and non-Hodgkin lymphoma was admitted for aortic valve replacement to correct severe aortic stenosis (valve area, 0.4 cm²). That surgery, however, was delayed, due to treatment of the lymphoma and of the thrombocytopenia and anemia that ensued. A valvuloplasty was next performed to improve ventricular function, after which the patient was admitted for the aortic valve replacement.

During surgery, retrograde insertion of a sinus catheter into the coronary sinus was unsuccessful and was abandoned in favor of a purely antegrade approach to cardioplegia. The aortic valve was found to be a true bicuspid valve, and severely calcified. Standard aortic valve replacement was performed. After weaning the patient from cardiopulmonary bypass, we found an accumulation of dark blood within the posterior epicardium. We diagnosed coronary sinus rupture when we found dark-blood extravasation from the sinus, with moderate bruising. The heart was lifted, but attempts to perform primary repair of the sinus with pledgeted Prolene suture were not satisfactory. CoSeal, applied as a spray to the epicardial surface, formed a thin layer that prevented further blood extravasation and achieved hemostasis. All surgical sites, upon examination a few minutes later, were hemostatic. The remainder of the patient's operation and hospital stay were uneventful. She progressed satisfactorily and was discharged from the hospital on postoperative day 6.

Discussion

These cases highlight the surgical complexity of managing either friable cardiac tissue that subsequently ruptures, or injury to a pressurized chamber. In these difficult situations, effective hemostasis can be achieved both by using meticulous surgical technique and by incorporating surgical sealants. Indeed, it can be crucial to optimize anastomotic conditions before pressurizing the cardiac chamber, in order to prevent disastrous tearing and bleeding. In both of the cases presented here, the topical hemostatic agent CoSeal was a valuable adjunct when combined with conventional suture techniques. Few studies⁶⁻⁸ have been published regarding the use of CoSeal and other surgical sealants during the implantation of an LVAD. Although these studies focus on immunologic responses from bovine fibrin and their

cross-reaction with human homologues, they also concern the use of CoSeal as a means of reducing adhesions after LVAD surgery.⁶⁻⁸ On the basis of the current medical literature and our own experience, we believe that there has been no documented reaction to the bovine origin of CoSeal's fibrin component.

Both repair and reconstruction of the aorta and the implantation of an LVAD are major cardiac surgical procedures—particularly in the setting of myocardial infarction or ventricular wall-thinning, when the tissue might be friable and its strength compromised.⁹ In addition, prosthetic graft material is often prone to bleeding at anastomotic sites,^{3,5} such as the entry points left by the large needles needed to suture thick aortic tissue.¹⁰

The introduction of high-pressure sealants, such as CoSeal, has been beneficial in helping to alleviate the intraoperative challenges described here, especially during surgery on the aorta.^{3,10} CoSeal is effective, rapid, and requires no participation of the coagulation cascade; therefore, it is effective even in patients who have severe coagulation deficiencies arising from preoperative exposure to prescribed anticoagulants, intraoperative heparinization for cardiopulmonary bypass, and intraoperative use of deep hypothermic circulatory arrest. The polymers will gel within 5 seconds and set within 60 seconds, producing a flexible, clear, degradable hydrogel that adheres to and seals tissues.^{4,11} A secure seal is maintained through a covalent tissue bond, even under high pressure in vessels such as the aorta.¹² Because CoSeal swells up to 4 times its volume within 24 hours, the surgeon should be mindful, when using it in a confined space, of its possible effect on surrounding structures. The gel is completely resorbed within 30 days.^{4,11} Clinical trials have confirmed the efficacy and safety of CoSeal. These include a multicenter randomized trial on the control of anastomotic suture-hole bleeding during aortic reconstruction procedures in which prosthetic vascular grafts were used.³

Our 2 case studies indicate that CoSeal was effective and rapid in providing hemostasis for pressurized cardiac-chamber rupture repair during major cardiac surgery. We believe that CoSeal is a useful surgical adjunct.

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