During open heart surgery, access to the heart and great vessels is obtained through a longitudinal incision in the anterior pericardium. Traditionally, at the conclusion of the case, the pericardium was left open, as closing the pericardium raised concern about cardiac tamponade and early graft failure. Reoperation in patients whose pericardium was left open was often difficult and occasionally harmful, as adhesions had formed between the heart and the posterior mediastinum. These reoperative findings led to early attempts to close the pericardium primarily to minimize adhesions.

Early studies on pericardial closure and its hemodynamic and clinical effects began in the late 1970s and showed that closure of the pericardium was safe and also decreased adhesions. Since these early studies, numerous others have evaluated the effects and different types of pericardial closure. Each of these studies showed early but transient alterations to cardiac hemodynamics and preservation of distance between heart and sternum.

In cases where the pericardium cannot be closed, synthetic and biosynthetic pericardial substitutes have been described to bridge the natural pericardial closure. Several options are available; however, data related to these products and their improvement in outcomes are lacking and their use is debated. The purpose of this project was to evaluate the outcomes of using a decellularized extracellular matrix (CorMatrix ECM, Roswell, Ga, USA) for pericardial closure in patients undergoing cardiac bypass and to compare them with patients who did not undergo pericardial closure.
Methods

Following Institutional Review Board approval, we retrospectively reviewed consecutive open heart surgery cases from June 1, 2012, through December 21, 2013, performed by a single surgeon at our medical center. Data were obtained from our electronic medical records and from a prospectively collected database. Exclusion criteria included intra- and perioperative deaths and patients who left the operating room on ECMO (extracorporeal membrane oxygenation). The decision to use the extracellular matrix for closure of the pericardium was left to the discretion of the primary surgeon.

Primary endpoints were postoperative blood loss and postoperative blood transfusions in units of packed red blood cells transfused. Amount of chest tube and mediastinal tube output was used as a surrogate for postoperative blood loss. Secondary endpoints included date of mediastinal and chest tube removal and number of re-explorations. Basic demographic data included age and gender of the patients. Descriptive statistics were generated using t-test, Fisher’s exact, and $\chi^2$ test of independence, with a $P < .05$ considered significant.

Results

During the 18-month study, 316 open heart procedures were performed. Eleven patients were excluded due to 4 patient deaths and 7 patients on ECMO. Of the 305 patients remaining in the study, 143 had their pericardium closed with CorMatrix ECM, and 162 patients had their pericardium closed primarily. There was no difference in patient gender between the 2 groups, but the closed pericardium group was significantly younger than the group primarily closed (Table 1).

Fluid output was recorded until the tube was removed or through postoperative day 3, and total perioperative tube output was compared. There was no significant difference in chest tube, mediastinal tube, and total tube output between the 2 groups (Fig. 1).

There was no significant difference between groups with regard to the timing of chest tube and mediastinal tube removal (Fig. 2) or in the rate or re-exploration for bleeding between the 2 groups ($P > .05$).

We found a statistically significant difference in units of blood transfused between the patch closed and the primarily closed groups (0.4 units vs. 0.9 units, $P < .05$) (Fig. 3).

Discussion

Closure of the pericardium at the conclusion of open heart surgery has been proven to be safe and effective, causing little ill effects on hemodynamics while minimizing postoperative adhesions to the posterior sternum. The primary advantage of closing the pericardium is decreased adhesions encountered during repeat median sternotomy. Though the rate of repeat median sternotomy has increased in the past due to willingness to perform cardiac revascularization on older patients improved long-term patency of bypass grafts with vein and left internal mammary artery is extending the time between the first and subsequent cardiac revascularization procedures, causing a plateau in this rate. Subsequently, most patients who undergo a median sternotomy do not benefit from the primary advantage of a postoperative closed pericardium.

In our practice, we routinely try to close the pericardium if possible. In cases where pericardial closure may not be feasible due to pericardial contrac-
tion, cardiac enlargement, and lack of conduit in re-do operations, alternative means of closure are now available. There are several options to assist in pericardial closure, including autogenous tissue, such as a rotational pericardial flap or a pericardial fat pad, and synthetic or biosynthetic pericardial substitutes.

These substitutes include PTFE (polytetrafluoroethylene, Gore-Tex® [W. L. Gore & Associates, Inc., Flagstaff, Ariz, USA]), glutaraldehyde-treated xenografts, bioresorbable polymer films such as a barrier film containing polyactic acid and polyethylene glycol (REPEL-CV®, Sythemed Inc., Iselin, NJ, USA), and decellularized extracellular matrix such as CorMatrix ECM. CorMatrix ECM is produced from porcine small intestinal submucosa that is decellularized, leaving the complex extracellular matrix intact. CorMatrix ECM supports tissue repair, remodeling into functional pericardial tissue, and avoiding premature breakdown and calcification when used to close the pericardium. An explanted CorMatrix ECM patch used for a pericardial closure that was removed 5 years after the procedure showed that it had been almost fully recellularized, well integrated, and densely vascularized, similar to differentiated connective tissue.

Overall, there is a paucity of data examining the potential benefits of closing the pericardium with CorMatrix ECM. However, CorMatrix ECM has been shown to decrease the rate of postoperative atrial fibrillation in one retrospective study, though no randomized trial exists. Our report evaluates the use of CorMatrix ECM to close the pericardium, specifically evaluating whether we could find a secondary benefit beyond decreased reoperative adhesions to potentially offset the cost of the product used to close the pericardium. We focused our attention on blood loss and transfusion requirements, knowing that blood transfusion after cardiac surgery is a risk factor for increased length of stay if more than 3 units of blood were transfused and shorter length of stay could potentially offset the material cost of the patch.

We successfully showed a decreased transfusion need in patients who underwent patch closure of their pericardium, but likely not enough to offset the cost or affect length of stay. This decrease in transfusion requirement is difficult to explain as the blood loss and chest tube outputs were not different. One explanation is that although our cardiovascular intensive care unit and program, like many, has protocols and triggers for blood transfusion based on hemoglobin/hematocrit levels, there is also some subjectivity. In our unit, blood transfusions are based on certain triggers but also...
Abbreviations and Accronym

ECM = extracellular matrix; ECMO = extracorporeal membrane oxygenation

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11. Yau TM, Borger MA, Weisel RD, Ivanov J. Histology of cormatrix ECM pericardial closure group, although this difference is likely not clinically significant and requires further study. Future randomized studies using pericardial closure techniques are needed to determine the true benefits of this procedure. Furthermore, a thorough analysis of risk factors that places a patient at increased risk of requiring a repeat median sternotomy may allow cardiothoracic surgeons to selectively close the pericardium of these patients.

Conclusion

In conclusion, the use of a porcine-derived extracellular matrix patch to close the pericardium after open heart surgery resulted in no significant differences in chest tube output or time to removal of tubes or the operative rate for bleeding compared with primary closure. There was a significant difference in transfusion requirements in the CorMatrix ECM pericardial closure group, although this difference is likely not clinically significant and requires further study. Future randomized studies using pericardial closure techniques are needed to determine the true benefits of this procedure. Furthermore, a thorough analysis of risk factors that places a patient at increased risk of requiring a repeat median sternotomy may allow cardiothoracic surgeons to selectively close the pericardium of these patients.

There were several limitations of our study inherent in a retrospective review. There was a significant difference in the group undergoing closure using the extracellular matrix compared with the group primarily closed, which could have altered the results. This is likely from surgeon bias and using this technique preferentially in younger patients, as the likelihood for reoperation is potentially higher due to a presumed longer life span. Furthermore, the decision about how to close the pericardium was made by the surgeon at the completion of the case based on many factors, introducing another selection bias.

We also did not evaluate the long-term outcomes of these patients or whether any had undergone reoperation. Previous literature, however, has supported decreased adhesions with closure of the pericardium even with pericardial substitutes.1,3,11,14,16

There was no difference in re-exploration requirements, which can be considered a corollary finding to the studies that showed no major hemodynamic differences between groups as previously mentioned. We also found no difference in the amount of chest and mediastinal tube output, as well as the time to removal of each tube. At the onset of our study, we hypothesized that compartmentalization of the mediastinum created by closing the pericardium may lead to less blood loss, either by physiologically tolerated compression not causing tamponade, or perhaps prevention of cytokines released from the fresh operative field contacting the cardiac tissue and causing coagulopathy.


